Suture Augmentation Does Not Change Biomechanical Properties and Histological Remodeling of Tendon Graft in Anterior Cruciate Ligament Reconstruction: A Study in a Porcine Model

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Purpose: To evaluate the initial safety of the combined use of ultra-high molecular weight polyethylene (UHMWPE) sutures for suture augmentation (SA) in a porcine ACL reconstruction model and examine whether the procedure can affect the anterior knee laxity and structural properties of the tendon graft itself, influence histological remodeling, and cause a foreign body-induced inflammation. **Methods:** Ten pigs were divided into SA and non-SA Groups to undergo ACL reconstruction using an autologous semitendinosus tendon with and without SA, respectively. At 12 weeks postoperatively, the tibial fixation of the grafted tendon and SA was removed, and the anterior knee laxity and structural characteristics of the grafted tendon were evaluated for mechanical testing. Histological evaluation, including the ligament tissue maturation index (LTMI) score and the presence or absence of foreign-body reaction, was evaluated. **Results:** There was no significant difference in anterior laxity between the two groups (SA Group, 1.19 ± 0.78 mm; non-SA Group, 1.08 ± 0.42 mm; $P = 1$). There were no significant differences in maximum load failure, yield strength, stiffness, elongation at failure, and the LTMI score between the two groups ($P = 0.31$, 1, 1, 1, and 0.24, respectively). All grafted tendons showed no foreign-body reactions. **Conclusion:** Suture augmentation did not have significant effect on the anterior knee laxity and the structural properties of the grafted tendon, interfere with histological remodeling, or cause foreign body-induced reactions. **Clinical Relevance:** The results of our study may lay the foundation for further clinical studies to verify the usefulness of ACL reconstruction with SA.

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Introduction

Anterior cruciate ligament (ACL) injuries often occur during sports activities in young patients.[1] ACL reconstruction with autologous tendon graft is widely performed to treat ACL injuries, since nonoperative treatment can result in a higher rate of persistent knee instability and present an increased risk for complications, such as meniscal tears, cartilage damage, and osteoarthritis.[2,3] Because a substantial amount of time is required for the nonvascularized autograft to achieve tendon/bone-to-bone healing and tendon remodeling for ensuring sufficient strength to withstand mechanical loading,[4] one drawback is the need for long-term rehabilitation before return to sports.[5,6] An effective method has not yet been established to enable safe and reliable return to sports after surgery.[7,8]

In recent years, ultra-high molecular weight polyethylene (UHMWPE) sutures/tapes have been developed and popularized for repairing damage to the extra-articular ligament of the knee, ankle, and elbow.[9-11] In addition, the new biomaterial has been used to augment the reconstructed ligament. These

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UHMWPE sutures/tapes provide high strength with a small diameter.[12] The method in which UHMWPE sutures/tapes are used in combination with the tendon graft for augmentation is called the suture augmentation (SA) technique. This new technique attempted to augment the tendon graft during the early revascularization phase[4,13] when the strength of the ligament is decreased. The SA technique has also been applied to intra-articular ligament reconstruction, including the ACL,[14-24] and the augmentation technique has been drawing attention for its potential to enable safe and early return to sports after surgery.[25-27]

Mechanical tests of ACL reconstruction using the SA technique has been shown to reduce loading and provide protection for all types of grafts.[28-32] This protective effect is also demonstrated when the diameter of the grafted tendon is small.[30] In addition, in vivo studies using various animals have also verified the efficacy of SA, providing basic data for its clinical application.[33,34] However, although these studies performed biomechanical testing with fixation devices for SA retained in situ and evaluated the extent to which SA increases the mechanical strength of the graft-tendon-thread complex,[33,34] none of them evaluated whether the combined use of UHMWPE suture affected the strength of the tendon graft itself or on early remodeling. While foreign body-induced inflammation was considered a problem in the use of artificial ligaments with autologous tendon,[35,36] it is difficult to determine whether these problems have been resolved by the SA technique.

The purpose of this study was to evaluate the initial safety of the combined use of UHMWPE sutures for SA in a porcine ACL reconstruction model and examine whether the procedure can affect the anterior knee laxity and structural properties of the tendon graft itself, influence histological remodeling, and cause a foreign body-induced inflammation. Our hypotheses were that the SA technique did not affect the structural properties and histological remodeling, nor cause a foreign body-induced inflammation.

Methods

Study Design

This study was approved by the Ethics Committee of Shinshu University School of Medicine (approval no. 020016, June 8, 2020). Ten 2-month-old male castrated pigs (Sanesu Breeding, Funabashi, Japan; mean weight, 22.3 ± 2.2 kg; range: 19-27 kg) were used in this study. The animal experimentation was carried out under the rules and regulations of our institutional Animal Care and Use Committee. The 10 pigs were randomly divided into 2 groups of 5 animals consisting of ACL reconstruction groups with and without SA (SA Group and non-SA Group, respectively). The left knees of all animals were allocated for sham surgery to obtain control data.

Anatomic ACL Reconstruction With and Without SA

All surgical procedures were performed by two experienced orthopedic surgeons (T.I., T.T.). Under intubated general anesthesia and aseptic conditions, a midline longitudinal skin incision was made at the right knee. The semitendinosus tendon was harvested through a distal part of the incision (Fig 1A). The tendon was doubled over a continuous loop of the EndoButton CL (Smith & Nephew Endoscopy, Andover, MA). The grafted tendons were harvested at a uniform width of 6 mm and trimmed to a length of 50 mm when folded over to create a uniform grafted tendon. The tibial ends of the tendon graft were stitched in a Krackow configuration with two 2-0 FiberWire sutures (Arthrex, Naples, FL). In the SA Group, a no. 5 FiberWire suture (Arthrex) with the tendon graft was passed over a continuous loop of the EndoButton CL to be used as SA, the so-called "internal brace" technique (Fig 1B). In this study, round suture was used in place of suture tape for SA.

After a lateral parapatellar arthrotomy was performed, the ACL was excised to identify its attachment of the femur and the tibia. The bone tunnels in the femur and the tibia were made at the centers of the ACL attachment (Fig 2, A and B). The femoral tunnel was created with a 4.5-mm cannulated drill over a guide pin from the inside-out, followed by a 6-mm cannulated drill for 20 mm. For the tibial tunnel, a 4.5-mm cannulated drill was inserted over a guide pin from the inside-out, and a 6-mm cannulated drill was inserted. The tendon graft was introduced into the joint cavity through the tibial tunnel and placed in the femoral socket. After the femoral side of the graft was fixed with an EndoButton, an initial tension of 40 N was applied to the graft, and the tibial end of the graft was fixed with a Double Spike Plate (DSP; Meira Co., Nagoya, Aichi, Japan) and cancellous bone screw at 60° of knee flexion.[13,37] In the SA Group, after fixing the tendon graft using DSP, the no. 5 FiberWire used as SA was tied over the forceps to the proximal hole of the DSP under manual maximum tension. We then confirmed that the no. 5 FiberWire was under a slightly looser independent tension than the no. 2 FiberWire that fixed the grafted tendon (Fig 2, C and D). The incision was closed in layers. In the non-SA Group, the same procedure was performed without SA.

Sham Surgery

A midline longitudinal skin incision and immediate wound closure were performed on the left knee of each animal as sham surgery.

Postoperative Management

Postoperatively, the animals were returned to their cages (2 × 3 × 2 m) and allowed full weight-bearing without restriction of motion. All animals were

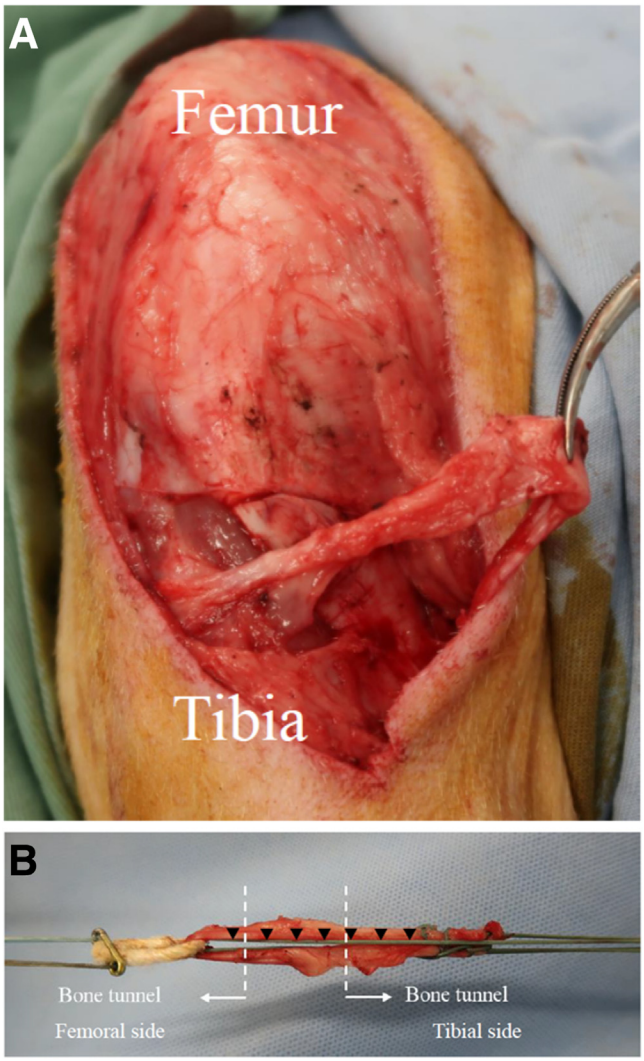

Fig 1. Harvesting and preparation of the graft with SA. (A) Semitendinosus tendon is harvested through the distal part of the incision. (B) The prepared anterior cruciate ligament graft with SA. No. 5 FiberWire suture used as SA (arrowheads) is doubled with a tendon graft over a continuous loop of EndoButton CL. SA, suture augmentation.

observed once to twice per week to monitor the occurrence of protective limping or discharge of pus. All animals exhibited normal gait within 2 weeks postoperatively. All animals were euthanized at 12 weeks postoperatively, according to the Animal Care and Use Committee regulations. We evaluated the effect of SA on autologous tendon remodeling at the 12-week postoperative timepoint, since it has been described as when the structural properties of autologous transplanted tendons are weakened in large animal ACL reconstruction models.[13] The mean weight at euthanasia was 42.9 ± 3.8 kg (range: 38-51 kg). At the time of euthanasia, a gross evaluation of the operated knee joint was performed to document the appearance of the graft and any secondary changes, such as synovitis, articular cartilage lesions, and meniscal tears. Knee specimens were retrieved immediately after euthanasia. The femur and tibia were transected 13 cm from the joint line. Using a sharp scalpel, all the surrounding muscles, patellae, and patellar tendon were removed to avoid injury to the joint capsule, ligaments, and menisci. The fibula was resected distal to the area of the lateral collateral ligament attachment site. It is important to note that the DSP and cancellous bone screw were removed from all right knees. By removing the DSP, the tendon graft was attached to the tibia only at the tendon-bone healing site in all right knees, and the fixation of the tibial side of the FiberWire used as the SA was removed, so that it could be pulled out of the tibia in the SA Group. The effect of the SA was minimized in the biomechanical testing to evaluate the anterior laxity and structural properties of the graft itself. The femur and tibia were separately potted into aluminum tubes using cement.[38,39] All right and left knees were used for biomechanical testing and histological evaluations.

Biomechanical Evaluations

Drawer Testing

Each specimen was kept moist with saline spray throughout the procedure. Anterior-posterior (AP) tibial translation of the knee was measured under an anterior drawer force using the previously reported testing system.[39] Knee specimens were mounted on a tensile tester (Tensilon RTG 1250; Orientec, Tokyo, Japan) with a set of specially designed grips. The tibia was flexed at 45° against the femur (Fig 3A).[40] Before testing, the specimen was preconditioned with a static preload of 5 N for 30 seconds, followed by 20 cycles of loading between 0 and 40 N with a cross-head speed of 100 mm/min to simulate the tibial anterior drawer setting. The anterior translations were reported from the 1st to the 20th cycle. The anterior translations were measured using the Tensilon Advanced Controller for Testing software (Orientec, Tokyo, Japan). These measurement conditions were the same as those used in a previous biomechanical study using porcine models.[39]

Structural Properties of the Femur-Graft-Tibia Complex

All connective ligaments, the joint capsule, and menisci were carefully removed except for the reconstructed graft or native ACL. The prepared femur-graft-tibia (FGT) or femur-native ACL-tibia (FAT) complex specimen was mounted on the tensile tester using a set of specially designed grips, and the tibia was flexed at 45° against the femur, so that a tensile load could be applied to the grafted tendon parallel to the long axis (Fig 3B). Before the tensile test, the specimen was preconditioned with a static preload of 5 N for 10 minutes, followed by 10 cycles of loading and unloading

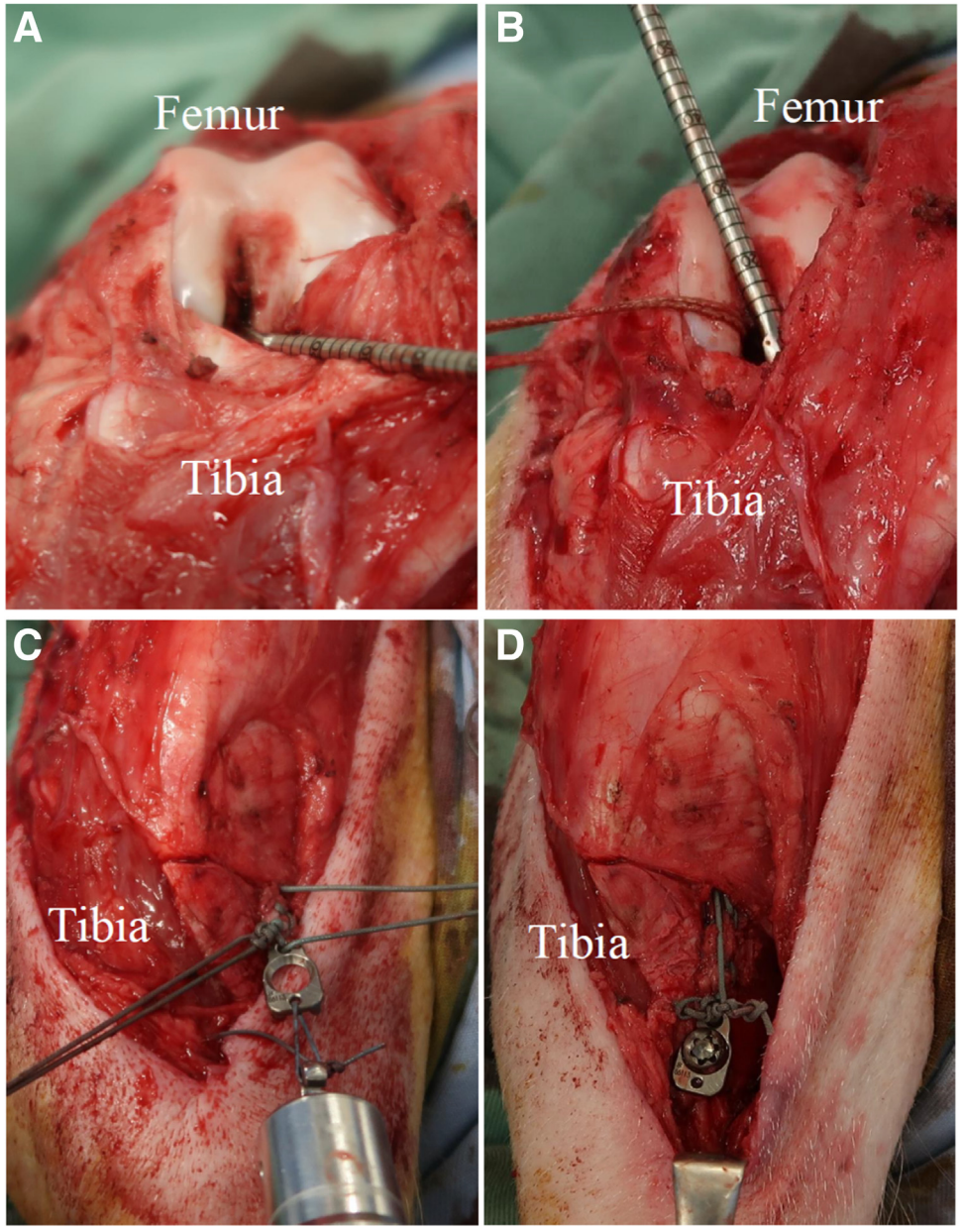

Fig 2. Bone tunnel creation and fixation of the tendon graft and SA. (A) After ACL resection, the femoral bone tunnel is created at the center of the ACL attachment. (B) The tibial bone tunnel is created at the center of the ACL attachment. (C) The tibial end of the graft is fixed with a DSP and cancellous bone screw, while applying initial tension to the graft. Stitched suture on the tibial end of the graft is tied to the DSP. SA is not yet tied to the DSP. (D) SA is tied to the DSP with independent tension, paying attention not to add more tension to the suture than the graft. ACL, anterior cruciate ligament; DSP, double spike plate; SA, suture augmentation.

(3% strain) at 20 mm/min. Then, each specimen was loaded to failure at 50 mm/min. These conditions have been used for measurement in the previous study with large animal models.[37] Failure modes were recorded. A load-elongation curve was created with the Tensilon Advanced Controller for Testing software. The structural properties (upper yield load, maximum load, linear stiffness, and elongation at failure) of the FGT or FAT complex were determined through software calculations.

Histological Evaluations

Immediately after biomechanical examinations, the femoral and tibial sides of the ruptured femur-graft-tibia complex was harvested from the knee and fixed using a 10% buffered formalin solution (pH = 7.4) for 24 hours at 4°C, followed by decalcification with ethylenediaminetetraacetic acid for 7 days. After embedding in paraffin, 4-μm-thick longitudinal sections were cut in the sagittal plane along the longest axis of the graft. Each section was mounted onto a glass slide coated with 0.01% poly-L-lysine. The sections were dried overnight at 37°C and dewaxed in xylene. The sections were then rehydrated with distilled water, soaked in phosphate-buffered saline (PBS; pH = 7.4), and stained with hematoxylin and eosin for histomorphological observation. The sections were evaluated using light microscopy. The ligament tissue

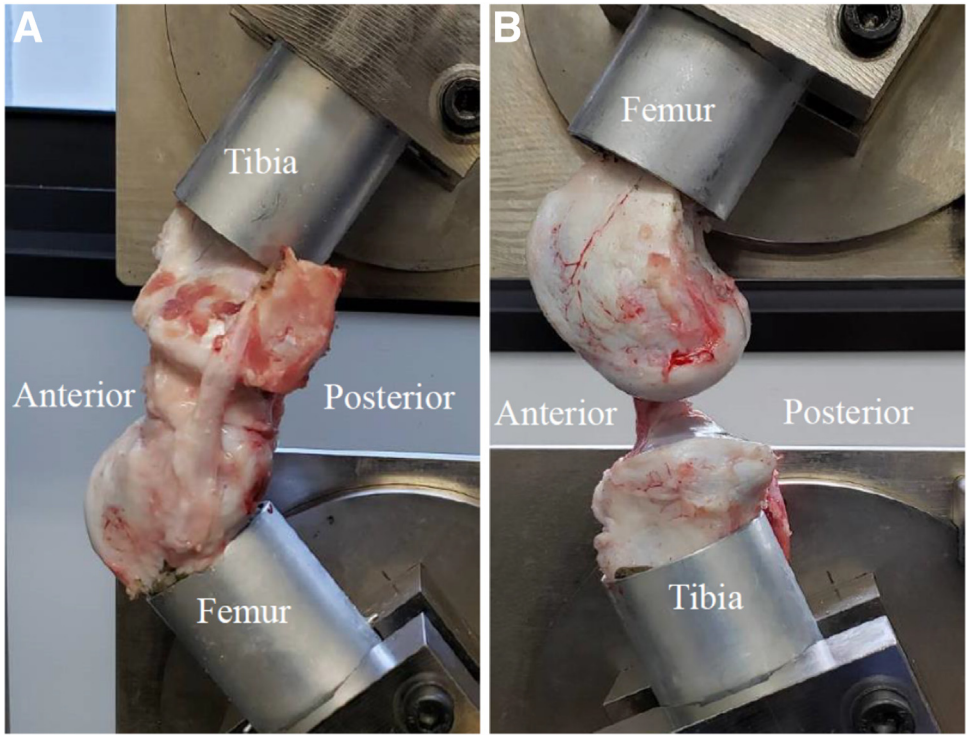

Fig 3. Prepared FGT complex of the SA Group for biomechanical evaluation. (A) Prepared FGT complex of the SA Group for anterior drawer testing. All of the surrounding muscles, patellae, and patellar tendon are removed to avoid injury to the joint capsule, ligaments, and menisci. The tibial side of the FGT complex is fixed on the upper side, and the femoral side is fixed on the lower side. (B) Prepared FGT complex of the SA Group for tensile testing. The femoral side of the FGT complex is fixed on the upper side, and the tibial side is fixed on the lower side. FGT, femur-graft-tibia; SA, suture augmentation.

maturity index (LTMI)[41] was used to evaluate the maturation of the tendon graft. This method evaluates the maturation of the tendon graft using cellularity, collagen, and vascularity. The native ACL from the contralateral knee was used as a reference. Two independent examiners who were blinded to the identification of the specimens evaluated the area 3 mm from the outlet of the tibial bone tunnel in the distal midsubstance of the tendon grafts in all animals.

Statistical Analyses

All data from statistical analyses are presented as means with standard deviations. A priori power analysis was conducted based on the results of the study by Takahashi et al.,[37] who previously reported the mean anterior tibial translation values for the remnant preserved group (9.3 ± 2.1 mm) and remnant removed group (5.4 ± 1.7 mm) in ACL reconstruction using large animals. A previous study on ligament augmentation in the same animal model was desirable but not available. It was determined that 5 specimens per group would provide a power of 80% to detect a difference ($\alpha < 0.05$) in the mean anterior tibial translation. For each parameter, one-way analysis of variance with a Bonferroni correction for multiple comparison or Student's *t*-test was performed between the groups. The inter-rater reliability of the LTMI score was assessed with Fleiss's kappa statistics. The classification of Landis and Koch was used to categorize the degree of diagnostic reliability from kappa values.[42] All statistical analyses were performed using EZR software.[43] *P* values of $<.05$ were considered statistically significant.

Results

Gross Observations in the Knee Joint

Postoperatively, there were no infectious findings, foreign body-induced inflammation, or arthrofibrosis. All tendon grafts were intact and covered with synovial tissues. No obvious degenerative changes on the articular cartilage or tears of the menisci were observed at the time of euthanasia.

Biomechanical Evaluations

Drawer Testing

The anterior translation during the cyclic testing was 1.08 ± 0.42 mm in the non-SA Group and 1.19 ± 0.78 mm in the SA Group, and 0.82 ± 0.32 mm in the native ACL. No significant difference was observed between the groups. ($P = .36$) (Table 1).

Structural Properties of the FGT Complex

During tensile testing, all tendon grafts in the non-SA and SA Groups were ruptured at the proximal midsubstance, slightly more distal to where the graft looped around the EndoButton. There were no cases in which the grafted tendon pulled out of the tibial bone tunnel. All native ACLs were avulsed from the femoral (4 knees) or tibial attachment (6 knees). The maximum load was 470.3 ± 182.6 N in the SA Group,

Table 1. Result of Biomechanical Evaluations

Parameter	Group non-SA ($n = 5$)	Group SA ($n = 5$)	Native ACL ($n = 10$)	*P* Value			
				All	non-SA vs SA	non-SA vs Native ACL	SA vs Native ACL
Displacement, mm	1.08 ± 0.42	1.19 ± 0.78	0.82 ± 0.32	.36	1	1	.56
Upper yield load, N	146.7 ± 41.6	258.8 ± 152.6	649.8 ± 270.7	<.001	1	.0013	.011
Maximum load, N	264.4 ± 91.4	470.3 ± 182.6	846.1 ± 221.6	<.001	0.31	<.001	.0060
Linear stiffness, N/mm	29.4 ± 19.8	41.2 ± 25.7	84.9 ± 43.0	.018	1	.030	.11
Elongation at failure, mm	13.3 ± 7.7	13.6 ± 4.0	13.4 ± 8.6	1	1	1	1

Data are expressed as means ± SD.
ACL, anterior cruciate ligament; SA, suture augmentation.

264.4 ± 91.4 N in the non-SA Group, and 846.1 ± 221.6 N in the native ACL. There was no significant difference between the non-SA and SA Groups ($P = .31$); however, the native ACLs were significantly greater than the SA and non-SA Groups ($P = .0060$ and $P < .001$, respectively). The upper yield load was 258.8 ± 152.6 N in SA Group, 146.7 ± 41.6 N in the non-SA Group, and 649.8 ± 270.7 N in the native ACL, with no significant difference between the non-SA and SA Groups ($P = 1$); however, the native ACL were significantly greater than the SA and non-SA groups ($P = .011$ and $P < .0013$, respectively). The linear stiffness was 41.2 ± 25.7 N in SA Group, 29.4 ± 19.8 N in non-SA Group, and 84.9 ± 43.0 N in the native ACL, and there was no significant difference between the non-SA and SA Groups and between the SA Group and native ACL ($P = 1$ and $P < .11$, respectively); however, native ACL was significantly greater than the non-SA Group ($P = .030$). There was no significant difference in elongation at failure between the SA Group, non-SA Group, and the native ACL ($P = 1$) (Table 1).

Histological Observations

Histologically, no rupture or loosening of the grafted tendon due to the mechanical test was observed in all specimens. In the distal midsubstance of the graft in the SA Group and non-SA Group, the collagen fibers were longitudinally oriented, and many spindle-shaped cells were scattered in the superficial portion of the graft. In the core portion of the graft in the non-SA and SA Groups, some cells were not spindle-shaped but spherically shaped, and there was a small acellular area (Fig 4). At the bone-tendon graft interface of the tibial bone tunnel in the non-SA and SA Groups, similar biological fixation was observed in both groups (Fig 5, A and B). Overall, the histological evaluation showed very limited signs of inflammation, similar appearance between the groups, and no adverse tissue reactions (Fig 5C). The LTMI score was 26.6 ± 0.5 in SA Group and 26.2 ± 0.4 in the non-SA Group. There was no significant difference between the groups ($P = .24$) (Table 2). Both intraobserver variability ($\kappa = 0.95$; range: 0.89-1.0) and interobserver variability ($\kappa = 0.92$; range: 0.89-1.0) of the LTMI score were near-perfect.[42]

Discussion

The main findings of our study were that SA does not have a significant effect on the initial ligament remodeling and does not induce adverse reaction. In the biomechanical evaluation, all tendon grafts in the SA Group ruptured in the midsubstance like the non-SA Group. There was no significant difference in anterior laxity and the structural properties (maximum load, upper yield load, stiffness, and elongation at failure) between the SA and non-SA Groups. Furthermore, histological results showed that the SA Group showed similar LTMI scores of the tendon graft remodeling and bone-tendon healing as the non-SA group, with no signs of inflammation due to foreign bodies in all knees. The results of this study will help fill in the gaps in the literature on the safety of the SA method and will be valuable for further clinical studies.

Previous studies have attempted the combined use of artificial ligaments and autologous tendon grafts in ACL reconstruction, but in vivo animal studies have reported decreased failure load and stiffness of the tendon graft.[35,44] Furthermore, clinical studies have reported slower remodeling of the autologous tendon,[45] more rupture of the artificial ligament, and severe synovitis due to foreign body-induced reaction.[36,46] From these results, the combined use of artificial ligaments for ACL reconstruction has fallen out of favor; however, the SA technique has been developed as a new concept for clinical applications in recent years.[14,17]

In the SA technique, UHMWPE sutures/tapes, which provides high strength with a smaller diameter compared to conventional artificial ligaments,[12] are used in combination with tendon grafts for augmentation. Unlike previous techniques that employed the combined use of artificial ligaments,[35,44,47] which assumed the strength of the artificial ligament and the ingrowth of the tissue into the artificial ligament to be permanent, the new technique attempted to augment the tendon graft during the early revascularization phase[4,13] when the strength of the ligament is

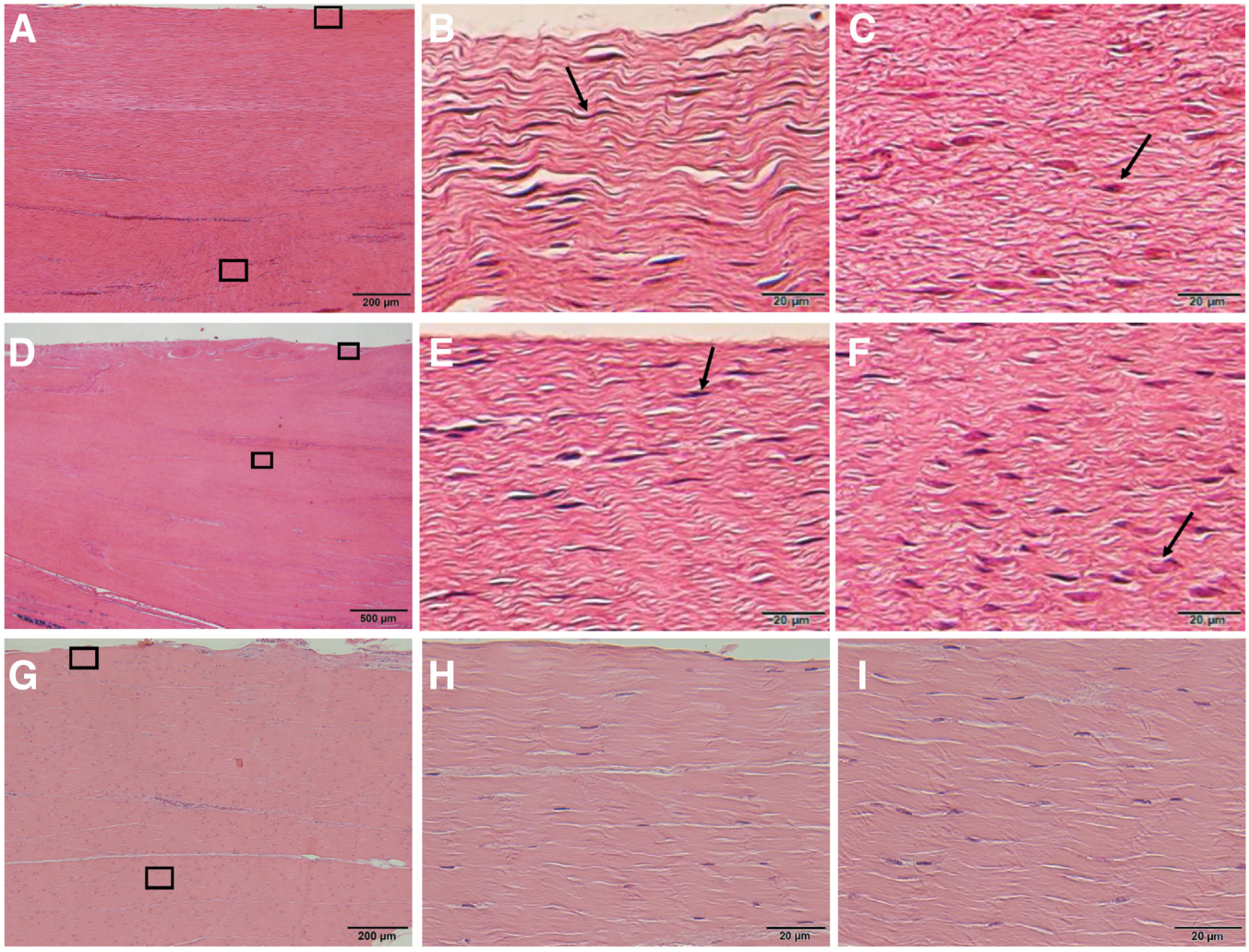

Fig 4. Histological observations of the superficial and core portions of the distal midsubstance of the grafted tendon and the native ACL. (A) Low-magnification image of the distal midsubstance portion of the grafted tendon in the non-SA group. From the boxes shown in (A), (B) shows a high-magnification image of the superficial square area, and (C) is a high-magnification image of the square area 1 mm deep from the surface layer. The right is distal, and the left is proximal. (B) In the superficial portion, the collagen fibers are longitudinally oriented, and many spindle-shaped cells, such as myofibrocytes are scattered. The cells with rod-like nuclei (black arrow) indicate good remodeling. (C) In the core portion, the collagen fibers are oriented longitudinally, and many spindle-shaped cells and some spherical cells are scattered. The cells with ovoid nuclei (black arrow) indicates insufficient remodeling. (D) Low-magnification image of the distal midsubstance portion of the grafted tendon in the SA group. From (D), (E) is a high-magnification image of the superficial square area, and (F) is a high-magnification image of the square area 1 mm deep from the surface layer. The right is distal, and the left is proximal. The histological findings of the superficial and core portion of the distal midsubstance of the graft in the SA Group are similar to those in the non-SA Group. (G) Low magnification image of the distal midsubstance portion of the grafted tendon in the native ACL. From (G), (H) is a high-magnification image of the superficial layer and (I) is a high-magnification image of the deep square area. The right is distal, and the left is proximal. (A) and (G) Scale bars = 200 μm. (D) Scale bars = 500 μm. (B), (C), (E), (F), (H) and (I) Scale bars = 20 μm. ACL, anterior cruciate ligament; SA, suture augmentation.

decreased. In terms of ACL reconstruction, the SA technique has been reported to improve clinical scores and the rate of return to original activity levels.[14] Mechanical studies on the SA technique have reported the successful augmentation of tendons grafts,[28,29] and an in vivo study has reported no significant difference in terms of stiffness and safety with normal ACLs at 6 months postoperatively.[34] However, few basic science studies have been conducted of biomechanical and histological evaluations on how the SA technique may affect the remodeling of the tendon graft in addition to how it may cause a foreign body-induced reaction.

Previous studies using animal ACL models have reported that moderate load reduction on the tendon graft can improve structural properties; however, excessive load reduction can cause a deterioration of

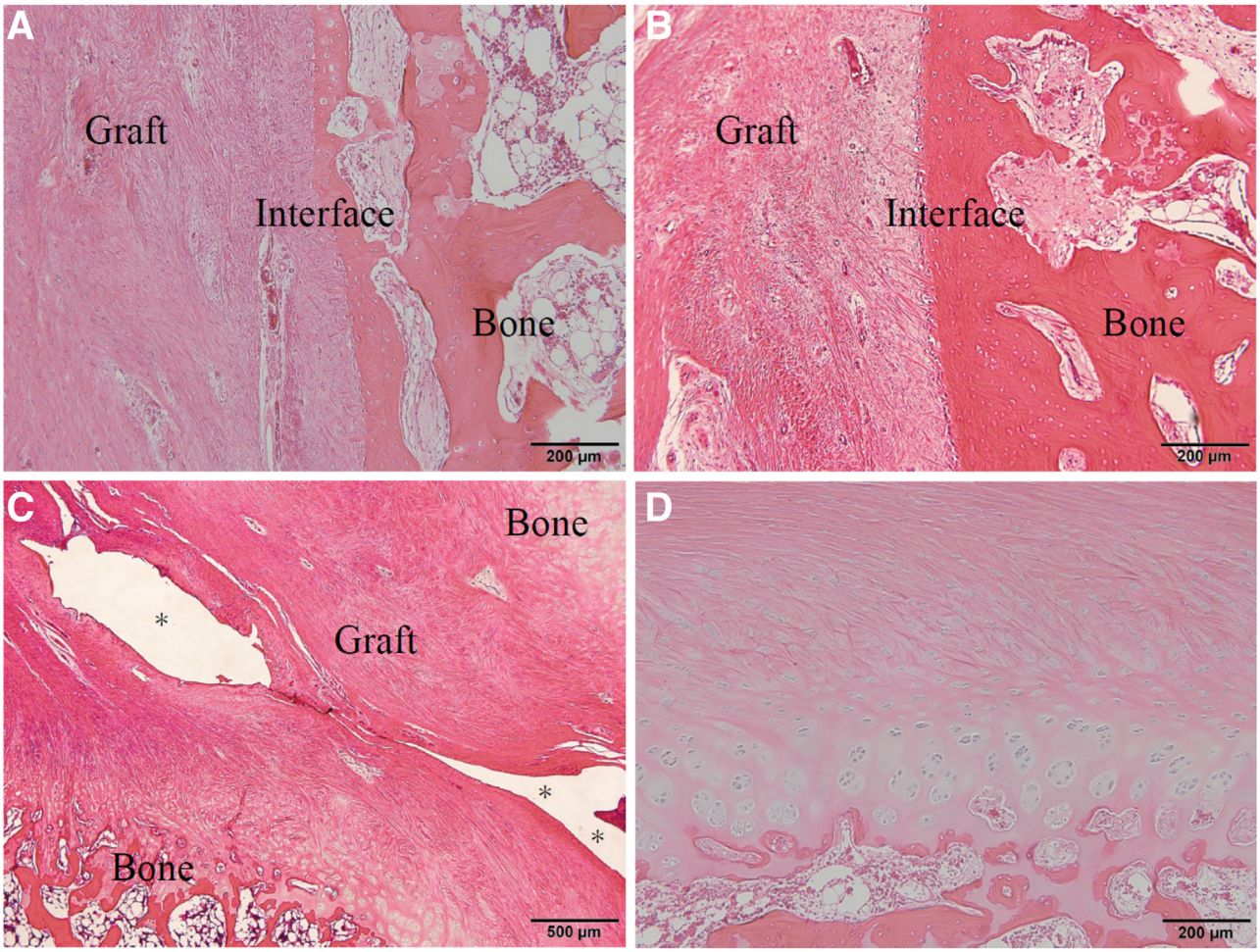

Fig 5. Histological observations of the bone-tendon graft interface of the tibial bone tunnel and the tibial attachment of the native ACL. (A) In the non-SA Group, biological fixation between the tibial bone tunnel and the graft was observed and showed collagen fiber continuities resembling Sharpey fibers. (B) Biological fixation between the tibial bone tunnel and the graft in the SA Group was similar to that of the non-SA Group. (C) The histological evaluation of the outlet of the bone tunnel around the pulled-out FiberWire used as SA. Very limited signs of inflammation are found, with no adverse tissue reactions. The asterisks indicate the hole left after the FiberWire was pulled out. (D) A histological image of the tibial attachment of the native ACL. (A), (B) and (D) Scale bars = 200 μm. (C) Scale bar = 500 μm. ACL, anterior cruciate ligament; SA, suture augmentation.

structural properties.[48-50] In this study, the anterior laxity was measured with the tibial fixation of the SA removed, and no significant difference was observed between the groups. Furthermore, the structural properties of the tendon graft of the SA Group were not significantly different from that of the non-SA Group. This suggests that the SA did not cause stress shielding at 12 weeks postoperatively. Past in vivo studies on artificial ligament augmentation have reported deteriorated structural properties of tendon grafts,[35,44] whereas the lack of significant difference of structural properties with and without SA in this study may be due to the lower ultimate tensile strength of FiberWire compared to artificial ligaments used in previous

Table 2. Ligament Tissue Maturity Index Score at the Distal Midsubstance of the Grafted Tendon

Parameter	Group non-SA (n = 5)	Group SA (n = 5)	P Value
Ligament tissue maturity index score	26.2 ± 0.4	26.6 ± 0.5	.24
Cellularity	8.8 ± 0.4	9.0 ± 0.0	.35
Collagen	12.0 ± 0.0	12.0 ± 0.0	>.99
Vascularity	5.4 ± 0.5	5.6 ± 0.5	.58

Data are expressed as means ± SD.
SA, suture augmentation.

studies,[12,51,52] which may have prevented stress shielding. In addition, the tibial side of the SA was fixed with independent tensioning in this study, so that the SA was not tighter than the tendon graft, and this may have made stress shielding to be less likely to occur. In a time-zero biomechanical study of the SA technique using bovine ACLs, it was reported that a strong load sharing by the SA does not occur until a certain amount of elongation occurs in the tendon graft/SA complex.[29] This was also demonstrated in this in vivo study.

We compared the group differences in parameters of previous animal studies with the results of this study. For anterior laxity, one in vivo study using large animals[37] reported a significant difference in anterior laxity of 3.9 mm between the preserved and resected groups in the area of remnant-preserved ACL, which has been reported to have some clinical benefits. Regarding structural properties, a time-zero biomechanical study[28] on suture augmentation using pig knees showed a significant difference between the suture augmentation and control groups in stiffness of 133 N/mm and maximum load of 271 N, providing evidence that the suture augmentation has a clinically protective effect. In this study, the difference between the SA and non-SA groups was 0.11 mm in anterior laxity, 11.8 N in stiffness, and 206 N in maximum load. It is very difficult to determine a clinical meaningful significance of these differences; however, the purpose of this study was to perform a noninferiority study on the safety of the SA method, and our results were sufficient to prove that SA was not inferior to non-SA techniques.

The histological remodeling of the tendon graft is also closely related to the load placed on it. In an in vivo study of rabbit patellar tendons, a histological evaluation showed that stress shielding resulted in an irregular and indistinct crimp pattern of collagen bundles in the midsubstance of the tendon graft in the early postoperative period, fewer spindle-shaped cells, and more round cells.[50] In this study, the histological evaluation of the distal midsubstance of the graft in the SA Group showed that the remodeling score was similar to that of the non-SA Group. In addition, collagen bundles showing good crimp patterns were longitudinally aligned, and spindle-shaped cells were abundant on the tibial side of the SA group, and there were no signs of stress shielding. This result suggested that the augmentation of the SA did not interfere with histological remodeling of the grafted tendon.

In the past, the use of artificial ligaments for intra-articular ligament reconstruction was problematic due to the possibility of severe synovitis with histological findings of megakaryocytes and macrophages as a result of foreign-body reactions caused by wear particles generated when the ligament is ruptured.[46,53,54] In the SA Group of this study, no signs of arthrofibrosis or foreign body-induced inflammation were observed on gross examination of the joint, and like the non-SA Group, the histological evaluation showed no adverse tissue reactions. This may suggest that the SA technique using UHMWPE sutures does not cause a foreign body-induced reaction. The absence of synovitis due to foreign-body reaction may be due to the UHMWPE suture used as augmentation in the SA Group is smaller in diameter with high strength to prevent ruptures,[12] and is less likely to produce wear particles as a result of ruptured artificial ligament due to impingements. These results indicate that SA in ACL reconstruction does not have significant effect on the anterior laxity, the structural properties of the tendon graft, its histological remodeling, nor does it induce a foreign-body reaction in the early revascularized phase. However, in this study, the impact of the SA method in the mid- to long term is unknown and needs to be verified in the future.

Limitations

There are several limitations to this study. First, this study was conducted in juvenile pigs and was evaluated at the initial 12-week period; therefore, the results of this study may not be directly applicable to adolescent humans, and the long-term effects of SA have not been evaluated. Second, the materials and methodology of the SA technique in ACL reconstruction have not yet been clearly codified. Third, histological evaluation was performed using the same specimens from the mechanical test. Fourth, the mechanical test was performed without removing the suture, which may have affected the results of the mechanical test. Fifth, the results of this study may vary depending on the performing surgeon.

Conclusions

Suture augmentation did not have significant effect on the anterior knee laxity and the structural properties of the grafted tendon, interfere with histological remodeling, or cause foreign body-induced reactions.

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