Original Articles

Material Properties of Suture Augmentation of Knee Medial Collateral Ligament Repair Did Not Influence Length Changes or Failure Loads in a Caged Porcine Model

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Purpose: To investigate whether the biomechanical properties of the healed superficial medial collateral ligament (sMCL) repaired by augmentation vary depending on the material properties of the suture augmentation. **Methods:** In 8 of 10 porcines (16 hindlimbs), the sMCL was detached from the femoral attachment using a scalpel under intubated general anesthesia. sMCL repair was performed using an ultra-high-molecular-weight polyethylene (UHMWPE) tape for the right hindlimbs and polyester tape (PE) for the left hindlimbs. They were sacrificed at 4 weeks postoperatively. The remaining 2 animals were assigned to the native control group (left and right hindlimb; n = 4). All connective tissues and suture augmentation, except for the repaired sMCL, were removed, and their biomechanical properties were evaluated. **Results:** No significant differences were observed in the upper yield load (PE group, 247.4 ± 116.0 N; UHMWPE group, 279.9 ± 95.7 N; and sham group, 231.6 ± 50.6 N; $P = .70$), maximum yield load (PE group, 310.1 ± 166.1 N; UHMWPE group, 334.6 ± 95.2 N; and sham group, 290.9 ± 42.3 N; $P = .84$), linear stiffness (PE group, 43.3 ± 16.5 N/mm; UHMWPE group, 52.0 ± 28.2 N/mm; and sham group, 44.7 ± 7.2 N/mm; $P = .66$), and elongation at failure (PE group, 9.4 ± 4.3 mm; UHMWPE group, 9.1 ± 2.7 mm; and sham group, 10.1 ± 2.1 mm; $P = .89$). Statistical analysis of failure modes showed no significant difference between the groups ($P = .21$). **Conclusions:** The material properties of suture augmentation used for sMCL repair did not significantly influence length changes during cyclic loading, postoperative structural properties, or failure modes. **Clinical Relevance:** The results of this study provide valuable information regarding the efficacy of suture augmentation repair regardless of the materials used.

Superficial medial collateral ligament (sMCL) injuries are common[1] and demonstrate a high degree of self-healing even in grade 3 injuries.[2] Many patients with sMCL injuries recover with nonoperative treatment.[3] However, nonoperative treatment fails in approximately 80% of grade 3 sMCL injuries,[4] with persistent valgus and rotational instability.[5] Especially in cases with concomitant anterior cruciate ligament (ACL) injuries, stabilization of the MCL by surgical treatment is expected to reduce stress on the ACL[6] and prevent failure after the reconstruction of ACL. In the acute setting, anatomic repair of sMCL injuries was reported to improve stability and functional scores with low complication rates.[7] This surgical approach combines anatomic repair with suture augmentation, providing a superior biomechanical environment that allows early rehabilitation.[6,8] On the contrary, suture anchor repair with augmentation using polyester (PE) tape did not improve the biomechanical properties of the sMCL repaired compared with the intact state in a

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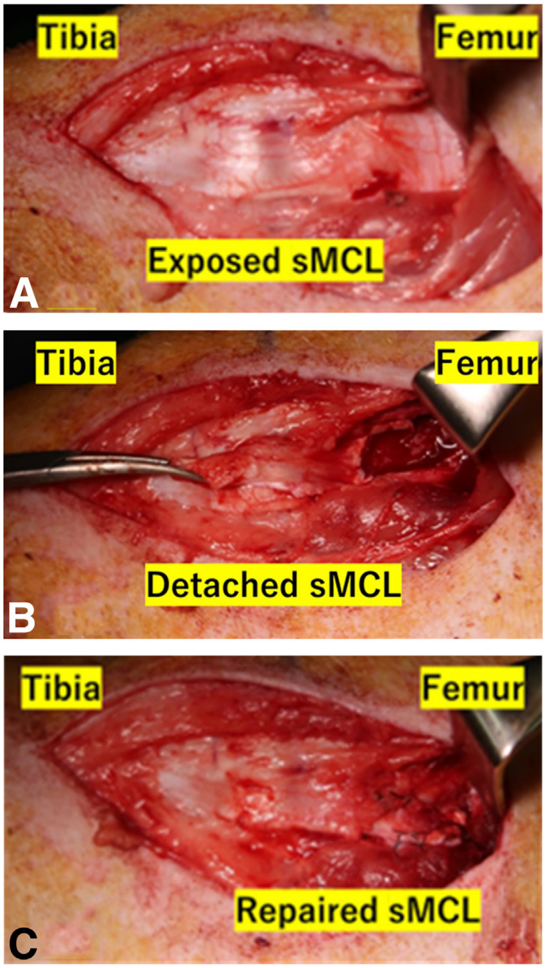

Fig 1. Detachment and immediate repair of sMCL. (A) The sMCL was exposed through a longitudinal skin incision. (B) The sMCL was detached at the femoral attachment. (C) sMCL repair using 2.0 nylon thread. (sMCL, superficial medial collateral ligament.)

large animal model.[9] Recently, a new type of suture tape made of ultra-high-molecular-weight polyethylene (UHMWPE), which is biocompatible, has been developed.[10-12] The purpose of this study was to investigate whether the biomechanical properties of the healed sMCL repaired by augmentation varied depending on the material properties of the suture augmentation. We hypothesized that the biomechanical properties of the healed sMCL repaired by augmentation would vary depending on the material properties of the suture augmentation used.

Methods

Study Design

In total, ten 3-month-old female pigs (mean weight 38.3 ± 2.0 kg, range 35.1-41.4 kg) were purchased from Sun-S Breeding (Funabashi, Japan). All animal experiments were performed in accordance with the regulations of the Institution's Animal Welfare and Use Committee (approval no. 21014-01). Of the 10 pigs, 8 were assigned to the sMCL augmentation repair group: (1) anatomic repair with 2 simple nylon sutures and UHMWPE tape augmentation (right hindlimbs, n = 8) and (2) anatomic repair with 2 simple nylon sutures and PE tape augmentation (left hindlimbs, n = 8). The remaining 2 animals were assigned to the native control group (left and right hindlimbs; n = 4).

Anatomic repair followed by UHMWPE tape augmentation

Under intubated general anesthesia and aseptic conditions, a right knee medial longitudinal skin incision was made (Fig 1A), and the sMCL was completely detached at the femoral attachment using a No. 15 scalpel to create an avulsion injury (Fig 1B).[9,13] sMCL repair was performed using 2.0 nylon thread (Fig 1C) intended only to reduce the detached sMCL to its anatomic position, followed by UHMWPE tape augmentation by loading suture augmentation (ULTRATAPE; Smith & Nephew Endoscopy, Andover, MA) and 2 interference screws (Cannu-Flex SILK; Smith & Nephew Endoscopy). The initial tension of 30 N was applied to the suture augmentation, and sutures from the femoral sMCL anchor were secured to the anatomic tibial insertion of the MCL (Fig 2).[9] The incisions were closed sequentially from the deep fascia of the vastus medialis muscle. The dressing material was removed within 48 hours postoperatively.

Anatomic Repair Followed by PE Tape Augmentation

The procedure was similar to that in anatomic repair with augmentation, except for the materials of the suture augmentation used. After the anatomic repair, another PE tape (Neoligament; Xilos, Leeds, West Yorkshire, UK) and 2 interference screws were added to each anchor of the femoral sMCL footprint for PE tape augmentation (Fig 3).

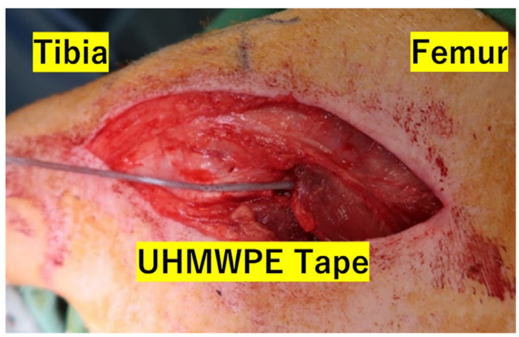

Fig 2. UHMWPE tape augmentation. UHMWPE tape augmentation was performed by loading UHMWPE tape and 2 interference screws for both femur and tibia. (UHMWPE, ultra-high-molecular-weight polyethylene.)

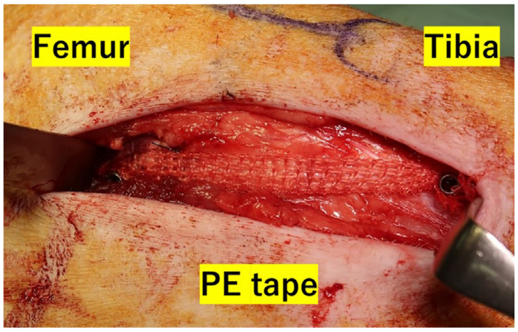

Fig 3. PE tape augmentation. PE tape augmentation was performed by loading PE tape and two interference screws for both femur and tibia. (PE, polyester tape.)

Postoperative Management

After the surgery, the animals were returned to their cages (2 × 3 × 2 m) so that they could apply sufficient weight to their limbs without limitation of limb movements. To monitor the protective limbs and pus discharge, each animal was observed once or twice a week. All animals survived during the follow-up period. They were euthanized at 4 weeks postoperatively, following reports that the sMCL had acquired mechanical characteristics equivalent to those of the original sMCL 4 weeks after repair with anchors.[9,13] Native control animals were also euthanized at the same monthly age. Knee specimens were retrieved immediately after euthanasia. All connective ligaments and capsules around the knee joint were removed, except for the repaired or native sMCL. All right and left femur—sMCL—tibia (FMT) complexes were potted in aluminum tubes.[9,13] The suture tapes were carefully removed, and no severe adhesions between the suture tapes and the repaired sMCLs were observed during the removal of either UHMWPE or PE that would damage the repaired sMCLs.[9]

Biomechanical Testing of the FMT Complex

During the experiment, the structures were kept moist with saline solution. The prepared FMT composite specimens were mounted on a tensile testing machine (Tensilon RTG 1250; Orientec Co., Tokyo, Japan) with specially designed grips. Before the testing, a static preload of 5 N was applied to the specimen for 30 seconds, followed by 20 cycles of 0 to 40 N loading at a crosshead speed of 100 mm/min. The increase in construction length was recorded. Then, each specimen was stretched to failure while preconditioning at a crosshead speed of 50 mm/min, and a tensile load was applied parallel to the long axis of the repaired or native sMCL (Fig 4). These conditions have been frequently used for measurements in previous studies using large animal models.[9,13,14] Load—extension curves were

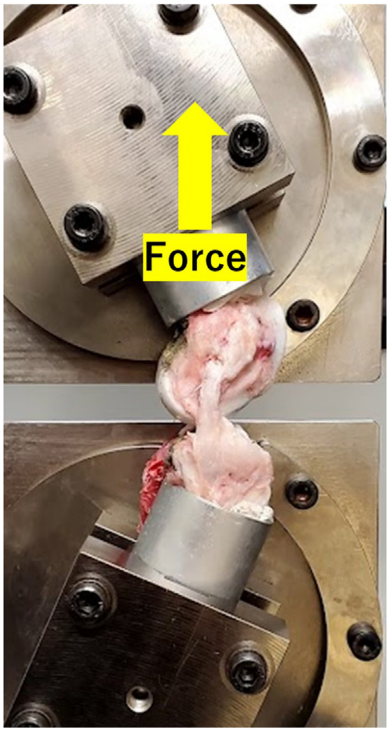

Fig 4. Biomechanical evaluation of the prepared femur—medial collateral ligament—tibia (FMT) complex. The FMT complex specimen was mounted on a tensile tester with a set of specially designed grips. A tensile load was applied to the medial collateral ligament in parallel with its long axis. Cyclic testing was performed first, followed by tensile testing.

obtained using dedicated software (Tensilon Advanced Controller for Testing; Orientec Co.). The structural properties of the FMT composites (upper yield load, maximum load, linear stiffness, and elongation at failure) were calculated using software.

Histologic Evaluation

Immediately after the biomechanical examination, the femoral and tibial sides of the ruptured FMT complex were harvested from the knee, fixed in 10% buffered formalin solution (pH = 7.4) at 4°C for 24 hours, and demineralized with ethylenediaminetetraacetic acid for 7 days. After embedding in paraffin, 4 μm-thick longitudinal sections were cut in the sagittal plane along the long axis of the graft. Each section was mounted on a glass slide coated with 0.01% poly-L-lysine. The sections were then dried overnight at 37°C and degreased with xylene. The sections were rehydrated with distilled water, immersed in phosphate-buffered saline (pH = 7.4), stained with hematoxylin and eosin and toluidine blue, and observed histomorphometrically. These sections were evaluated by light microscopy (BIOREVO BZ-9000; KEYENCE, Osaka, Japan).

Table 1. Biomechanical Properties

Parameters	PE (n = 8)	UHMWPE (n = 8)	Sham (n = 4)	*P* Value
Length change, mm	1.72 (1.60)	0.86 (0.75)	0.74 (0.30)	.27
Upper yield load, N	247.4 (116.0)	279.9 (95.7)	231.6 (50.6)	.70
Maximum yield load, N	310.1 (166.1)	334.6 (95.2)	290.9 (42.3)	.84
Linear stiffness, N/mm	43.3 (16.5)	52.0 (28.2)	44.7 (7.2)	.66
Elongation at failure, mm	9.4 (4.3)	9.1 (2.7)	10.1 (2.1)	.89

NOTE. Data are expressed as mean (standard deviation).
PE, polyester tape; UHMPE, ultra-high-molecular-weight polyethylene.

Statistical Analysis

A priori power analysis was performed using G* Power 3.1 (Franz Paul, Kiel, Germany).[15] The sample size was calculated with 79% power and a Cohen's effect size of 0.8 to test the study hypothesis. Among the 3 groups, one-way analysis of variance with Bonferroni post-hoc analysis was performed to evaluate differences between the groups. All data are presented as mean ± standard deviation. A Fisher exact test was performed to evaluate the difference in failure modes between the groups. All statistical analyses were performed using EZR.[16] *P* values of <.05 were considered significant.

Results

Length Change During Cyclic Loading

No significant differences were observed in the length change during the cyclic testing (PE group, 1.72 ± 1.60 mm; UHMWPE group, 0.86 ± 0.75 mm; and sham group, 0.74 ± 0.30 mm; *P* = .27) (Table 1).

Biomechanical Evaluations of the FMT Complex

No significant differences were observed in the upper yield load (PE group, 247.4 ± 116.0 N; UHMWPE group, 279.9 ± 95.7 N; and sham group, 231.6 ± 50.6 N; *P* = .70), maximum yield load (PE group, 310.1 ± 166.1 N; UHMWPE group, 334.6 ± 95.2 N; and sham group, 290.9 ± 42.3 N; *P* = .84), linear stiffness (PE group, 43.3 ± 16.5 N/mm; UHMWPE group, 52.0 ± 28.2 N/mm; and sham group, 44.7 ± 7.2 N/mm; *P* = .66), and elongation at failure (PE group, 9.4 ± 4.3 mm; UHMWPE group, 9.1 ± 2.7 mm; and sham group, 10.1 ± 2.1 mm; *P* = .89) (Table 1).

Observation of Failure Mode at the Time of Tensile Testing

As for failure modes in tensile testing, femoral attachment avulsion was observed in 7 of 8 specimens in the PE group, 3 of 8 in the UHMWPE group, and 3 of 4 in the sham group (Fig 5A). Midsubstance tears were observed in 1 of 8 specimens in the PE group and 3 of 8 in the UHMWPE group (Fig 5B). Tibial attachment avulsions were observed in 2 of 8 specimens in the UHMWPE group and 1 of 4 in the sham group (Fig 5C). No significant difference was found between the groups (*P* = .21) (Table 2).

Histologic Evaluation

Femoral attachment avulsion occurred between the calcified fibrocartilage layer and the laminar bone (Fig 6A). Femoral attachment-site avulsion specimens showed longitudinally oriented collagen fibers, and many spindle-shaped cells were scattered in the proximal area of the repaired sMCL (Fig 6B). Spherical- rather than spindle-shaped cells were found in the core of the repaired sMCL, with small acellular areas in both the PE group and the UHMWPE group (Fig 6C). The midsubstance tear specimens showed no longitudinally oriented collagen fibers and many spherical cells were scattered (Fig 6D). In the tibial attachment site avulsion specimen, collagen fibers were longitudinally oriented, with numerous scattered spindle-shaped cells and scattered spherical cells (Fig 6E).

Discussion

In this study, we clarified that the biomechanical properties of the native sMCL repaired by augmentation did not vary depending on the material properties of the suture augmentation used. In addition, the biomechanical properties of the repaired native sMCL were comparable with those of the normal sMCL. These results indicate that suture augmentation restores the innate biomechanical properties of sMCL independent of the material used for augmentation and affirm the repair of sMCL with suture augmentation. Results of this study provide valuable information regarding the efficacy of suture augmentation repair regardless of the materials used.

Suture augmentation has been used for elbow and ankle ligament repair as a reinforcement method that allows safe and early return to sports after surgery.[17,18] In terms of suture augmentation for knee ligament injuries, suture augmentation associated with ACL reconstruction was discontinued as the result of increased foreign body reactions and rupture of the artificial ligament[19-21]; however, recently, suture augmentation using UHMWPE tape has been reported to have good results.[22,23]

The anatomic reconstruction of the sMCL using autografts may be beneficial but may cause lesions at the donor site or interfere with other grafts or drilling tunnels when combined with other ligament

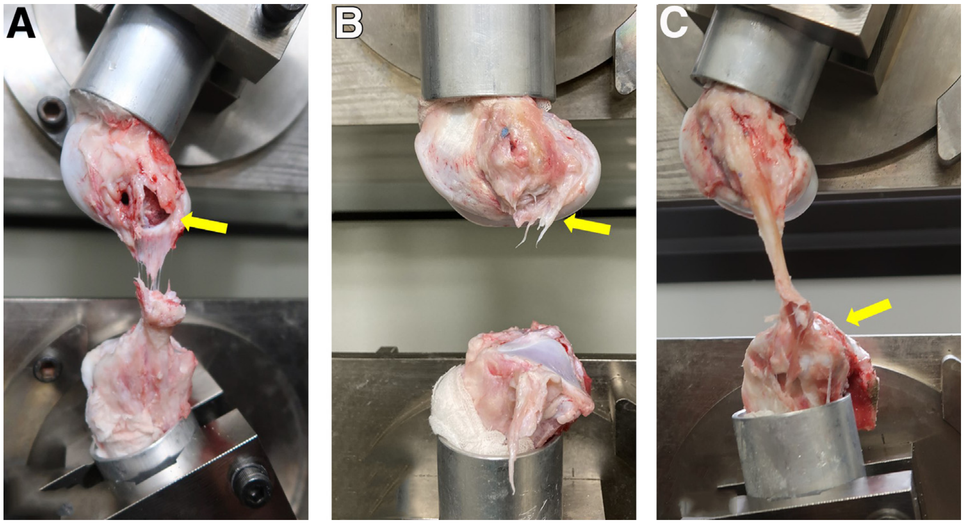

Fig 5. Failure modes at the time of tensile testing. (A) Avulsion from femoral attachment. (B) Midsubstance tear. (C) Avulsions from the tibial attachment. Yellow arrows indicate torn lesions in the superficial medial collateral ligament.

reconstructions. Therefore, the primary repair of the sMCL may be necessary for acute multiligamentous injuries. In a comparison of repair alone, repair with augmentation, and reconstruction with allograft of MCL injuries, it has been reported that repair alone has significantly inferior biomechanical properties.[8] Other studies have shown that the biomechanical properties of augmentation anatomic repair are superior to repair alone and similar to the intact state.[6,8,24] However, these studies only described the time-zero condition.

Although suture augmentation raises concerns about tendon parenchymal deterioration due to stress shielding,[25] Iwaasa et al.[26] reported that suture augmentation of ACL reconstruction in a porcine model did not worsen the biomechanical properties of the graft or affect its initial ligament remodeling or induce adverse reaction.

In this study, UHMWPE and PE suture tapes were used for augmentation sMCL repair to determine whether the material difference affected the postoperative biomechanical properties. The use of UHMWPE showed high maximal load in the ACL avulsion fracture model.[14] Because of its high biocompatibility,[12] we hypothesized that the biomechanical properties of sMCLs repaired with UHMWPE suture tape augmentation would be superior to PE suture tape augmentation. However, the results of this study did not support this hypothesis. The material properties of the suture augmentation did not affect length changes after cyclic loading, postoperative structural properties, and failure modes and recovered without significant differences from the native control sMCL group. These results indicated that stress shielding, which may worsen the postoperative structural properties of the repair ligament,[9,25] did not occur in this model. On the contrary, the protective effect by the suture augmentation[27] might contribute to sufficient recovery. The difference between the previous study[9] and the present study appears to be in the fixation of the avulsed sMCL. The previous study used suture anchors for the fixation of the avulsed sMCL. This fixation method was reported to be noninferior to the native sMCL with respect to biomechanical properties at 4 weeks postoperatively.[13] On the contrary, in the present study, sMCL repair was performed using 2.0 nylon thread. This difference may influence the postoperative biomechanical properties after augmented sMCL repair, and the results of the present study indicated that this technique enabled sufficient recovery without additional implant costs for suture anchors. Further studies should validate the findings and further investigate the efficacy of augmented sMCL repair, including clinical trials of this surgical procedure.

Table 2. Failure Modes Among the Groups

Failure mode	PE (n = 8)	UHMWPE (n = 8)	Sham (n = 4)	*P* Value
Avulsion from the femoral attachment	7	3	4	.21
Midsubstance tear	1	3	0	
Avulsion from the tibial attachment	0	2	0	

PE, polyester tape; UHMPE, ultra-high-molecular-weight polyethylene.

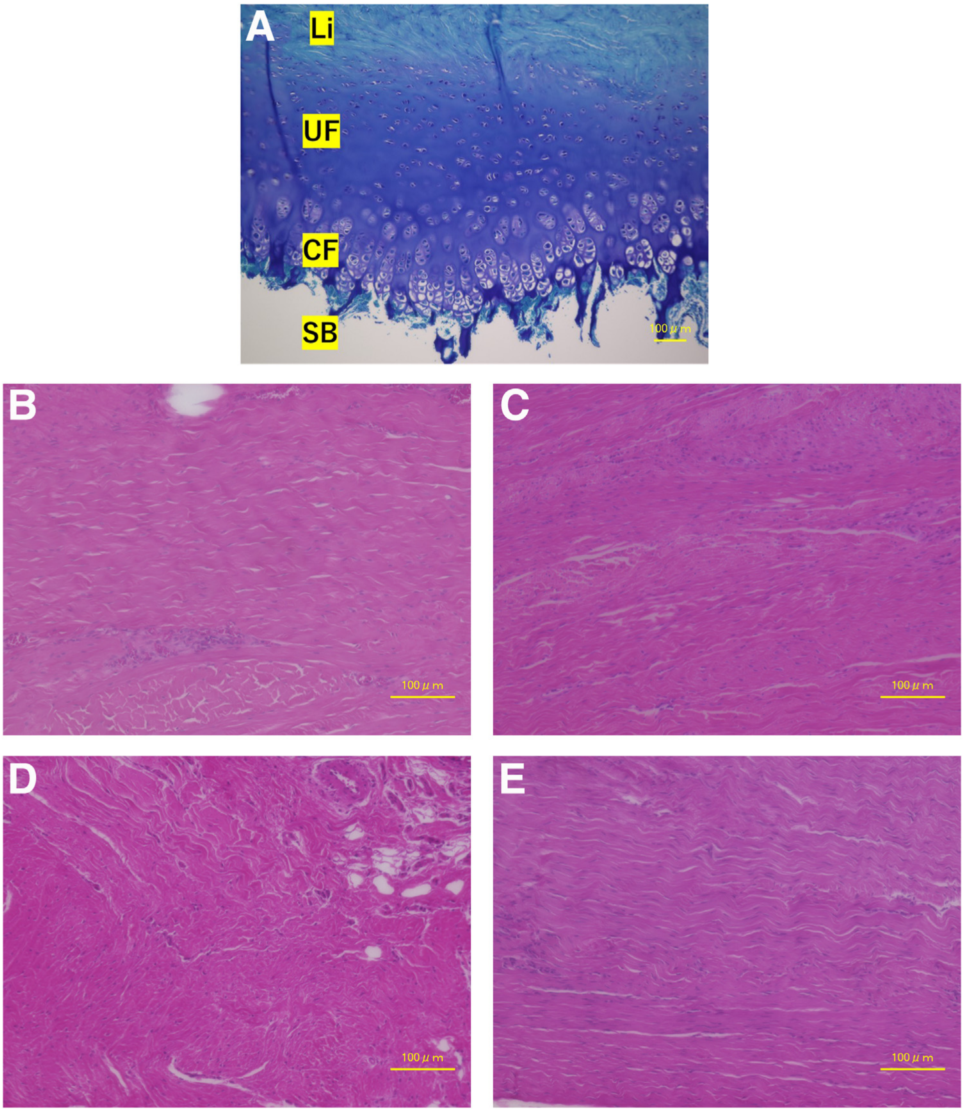

Fig 6. Histologic evaluations. (A) Toluidine blue staining ×100; histologic observations of the UHMWPE group specimen, which avulsed from the femoral attachment. This specimen showed the detachment between the SB and CF at the femoral attachment. (B) Femoral attachment site avulsion specimen. It showed longitudinally oriented collagen fibers and spindle-shaped cells in the proximal area of the repaired sMCL. (C) In the core of the repaired sMCL, spherical rather than spindle-shaped cells were observed. (D) Midsubstance tear specimens showed no longitudinally oriented collagen fibers and many scattered spherical cells. (E) In the tibial attachment site avulsion specimen, collagen fibers were longitudinally oriented, with numerous scattered spindle-shaped cells and scattered spherical cells. (CF, calcified fibrocartilage; LI, ligament; SB, subchondral bone; sMCL, superficial medial collateral ligament; UF, uncalcified fibrocartilage; UHMWE, ultra-high-molecular-weight polyethylene.)

Limitations

This study has several limitations. First, because this study used the porcine model, it could not be compared with a negative control group with conservative treatment requiring splint fixation. Second, the porcine was kept in cages of limited size, which may not have generated sufficient stress on the repaired sMCL. Third, femoral sMCL avulsion was made sharply using a scalpel at the femoral attachment, and this injury is not the same as that caused by a valgus traction force, which is frequently observed clinically. The forces involved in sMCL tearing may change the properties of the torn ligaments. Forth, the limited number of specimens and implants available reduced the number of samples available for each group. Therefore, an a priori power analysis was not performed. Fifth, although 4 weeks was a relatively short period of time, it was considered long enough to achieve adequate recovery for the reasons stated previously.

Conclusions

The material properties of suture augmentation used for sMCL repair did not significantly influence length changes during cyclic loading, postoperative structural properties, or failure modes.

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