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## Original article

# Tibial graft fixation methods and bone tunnel enlargement: A comparison between the TensionLoc implant system and the double-spike plate



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## ABSTRACT

**Background/objective:** TensionLoc (Arthrex, Naples, Florida, USA), a tibial graft fixation system for anterior cruciate ligament (ACL) reconstruction, is expected to apply the preoperatively determined level of graft tension and allow setting of lower initial tension. Considering its mechanism, we hypothesised that TensionLoc would prevent postoperative bone tunnel enlargement (TE) through fixation with lower initial tension. Therefore, the present study aimed to compare TE between ACL reconstructions using the double-spike plate (DSP; Smith and Nephew, Andover, Massachusetts) and TensionLoc implant system. **Methods:** A total of 40 patients who underwent anatomical single-bundle ACL reconstruction with a hamstring tendon graft were retrospectively analysed. In the group in which DSP and screw were used, the initial graft tension was set to 40 N at 20° of knee flexion (group D). In the other group in which TensionLoc was used, the initial graft tension was set to 30 N at 20° of knee flexion (group T). Both groups included 20 patients each. Tunnel areas were measured using computed tomography images at one week and three months after surgery, and the TE ratio was calculated according to the following equation: TE ratio (%) = (tunnel area at three months after surgery – tunnel area at one week after surgery)/tunnel area at one week after surgery × 100.

**Results:** The femoral TE ratios were significantly higher in group T (80.5% ± 28.8%) than in group D (45.5% ± 34.6%) ( $p = 0.001$ ). However, the tibial TE ratios did not significantly differ between the two groups.

**Conclusion:** Compared with ACL reconstruction using DSP and screw, ACL reconstruction using TensionLoc fixed the graft with lower initial tension but showed greater femoral TE and restricted knee extension in the early postoperative period.

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## 1. Introduction

Bone tunnel enlargement (TE) is a common complication of anterior cruciate ligament (ACL) reconstruction.<sup>1,2</sup> In particular, patients who underwent ACL reconstruction using a hamstring autograft reported significantly greater TE than those who underwent ACL reconstruction using a bone-patellar tendon-bone autograft.<sup>3,4</sup> Initial graft tension is also thought to be a potential

contributor to graft-tunnel motion and widening<sup>5</sup>; Taketomi et al. reported greater femoral TE at 1 year after surgery when the autograft was manually pulled maximally, as compared to when the tension was fixed at 80 N (78.6% vs. 27.7%, respectively).<sup>6</sup> Initial graft tension is affected by the graft type and size as well as knee position at graft fixation; however, an optimal graft-tensioning protocol is yet to be established.<sup>7</sup> It is believed that too little tension can lead to residual laxity, while excessive tension can cause movement restriction.

We recently designed an original rounded rectangular dilator for the development of a novel ACL surgery method and reported favourable clinical results.<sup>8</sup> For this technique, we have been using the double-spike plate (DSP; Smith and Nephew, Andover, MA,

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### Nomenclature

TE	tunnel enlargement
ACL	anterior cruciate ligament
DSP	double-spike plate
ROM	range of motion
CT	computed tomography

USA) and screw system and fixed the graft with an initial tension of 40 N at 20° of knee flexion using a manual tensioner. Since September 2019, we have been applying the TensionLoc implant system (Arthrex, Naples, FL, USA) for graft fixation. This system involves a relatively new tibial graft fixation technique for ACL reconstruction and is a unique alternative to standard suture buttons that allows the maintenance of suture tension. In this system, a collar with a thread attached to the graft is temporarily fixed to the tibia. After pre-tensioning, the plug is inserted and fixed in the graft. Such pre-tensioning following graft fixation to the tibia is based on the same principle as the tensioning boot system devised by Mae et al., who have reported that the initial tension can be accurately loaded and that lower initial tension can be set.<sup>8</sup> Based on this report, we decided to set the initial tension in ACL reconstruction using the TensionLoc implant system at 30 N, which is lower than that with the method using the DSP. We hypothesised that the TensionLoc implant system would prevent postoperative TE and achieve good postoperative knee range of motion (ROM) through fixation with lower initial tension.

Accordingly, the primary purpose of this study was to compare TE between ACL reconstructions using the DSP and TensionLoc implant system, and its secondary purpose was to compare the knee ROM between the two groups.

## 2. Materials and methods

### 2.1. Patients

This study was performed in accordance with the ethical standards as laid down in the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards. The study design was approved by the Ethics Committee of [blinded for peer review] (approval no. 1842). All patients were informed about the purpose, procedures, and known risks of the techniques, and informed consent was obtained from all patients.

We included 30 patients who underwent ACL reconstruction using the DSP and screw system between February and September 2019 (group D) and 29 patients who underwent ACL reconstruction using the TensionLoc implant system between October 2019 and March 2020 (group T). ACL tears were diagnosed based on the corresponding history of knee injury and the results of the Lachman and pivot shift tests, as well as a side-to-side difference of  $\geq 3$  mm when measured using the KT-1000 arthrometer (MEDmetric, San Diego, California, USA). All patients underwent magnetic resonance imaging for confirmation of ACL tears. Patients who underwent revision ACL reconstruction or ACL reconstruction in both knees were excluded from the analysis. Patients with multi-ligament injuries and those with inadequate follow-up information were also excluded.

### 2.2. Surgical procedures

All surgeries were performed by a single skilled surgeon using the same methods as previously reported.<sup>9</sup> Anatomical single-

bundle ACL reconstruction was performed using a hamstring tendon graft (fourfold semitendinosus graft with or without twofold gracilis tendon graft) for all patients in this study. To create a rounded rectangular femoral bone tunnel, we designed and developed an original rounded rectangular tendon diameter tester as well as a dilator for the new anatomical single-bundle ACL reconstruction method. The dilator was available in four sizes, and the appropriate size was used according to the graft size.<sup>9</sup> The tibial tunnel was drilled using a tibial guide set at a 50° angle—the tip of the aimer was positioned 3–4 mm anterior to the posterior border of the anterior horn of the lateral meniscus and directly anteromedial to the centre of the tibial attachment of the ACL; the tunnel was then drilled according to the diameter of the graft using a conventional drill.

The graft was inserted through the tibial tunnel and looped over the TightRope (Arthrex, Naples, Florida, USA) for femoral fixation. We flipped the button and manually pulled the graft backward, moving the joint several times in full ROM. The tibial end of the graft was fixed using one of the two methods. In group D, DSP and screw were used, and the initial graft tension was set to 40 N at 20° of knee flexion. In group T, the TensionLoc implant system was used, and the initial graft tension was set to 30 N at 20° of knee flexion.

### 2.3. Postoperative rehabilitation

On the first day post-surgery, physical therapists started ROM training, and full weight bearing and walking were allowed depending on the patients' pain. The patients wore an extension brace for one week after surgery and a soft brace for the next four months. In most cases, patients were able to walk with crutches for the first postoperative month and subsequently started to jog at three months, run at five months, and return to sports activities after at least six months.

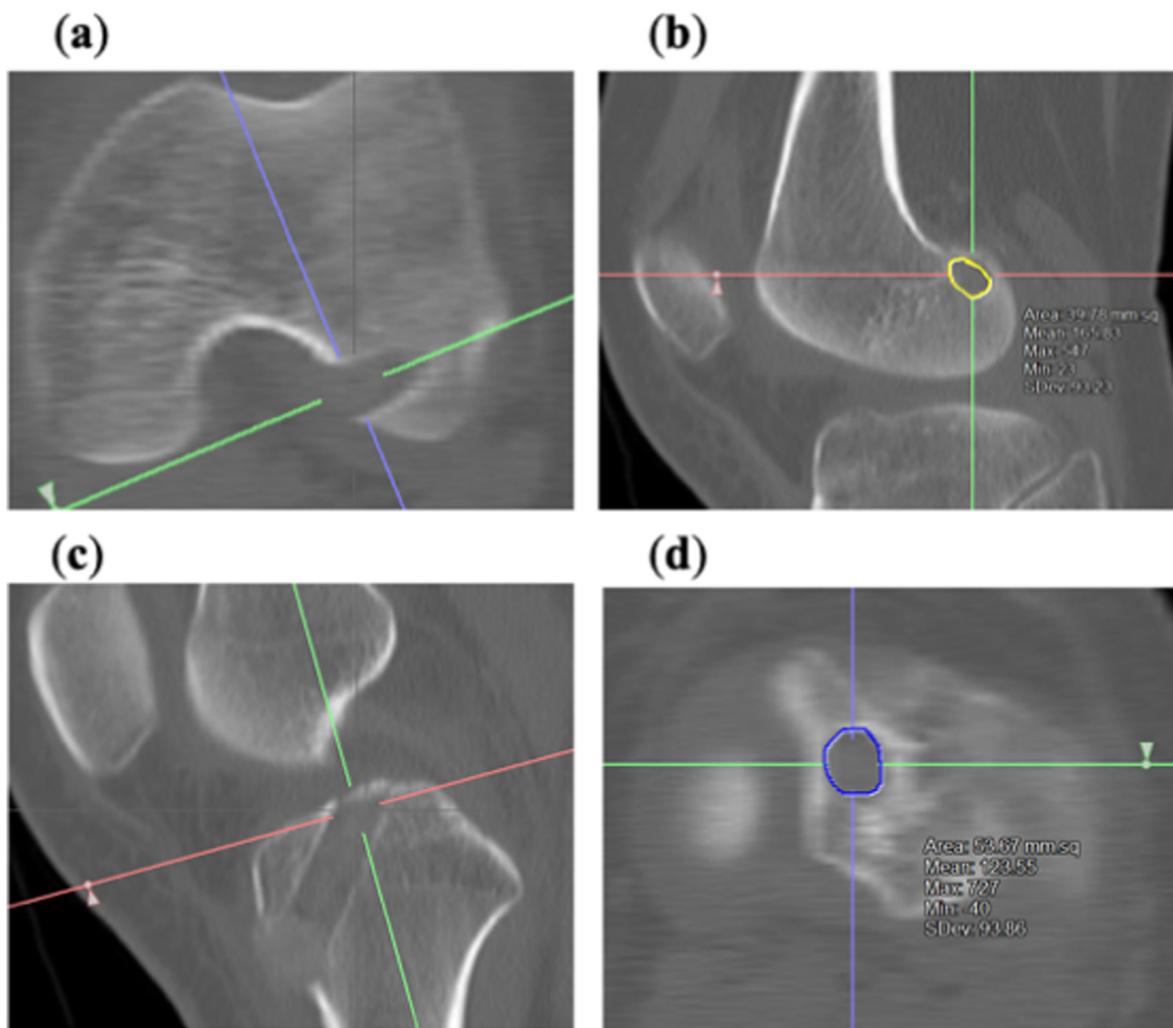
### 2.4. Postoperative evaluations

Computed tomography (CT) was used to conduct image evaluation of bone tunnels. CT images obtained at approximately one week and three months after surgery were used to calculate the TE ratio. We identified the slice of the femoral and tibial aperture using the AquarisNET software (TeraRecon Inc., Foster City, California, USA), created a 2-mm-deep cross-sectional slice near the aperture of the bone tunnel, and measured the bone tunnel area. The tunnel wall was traced within the bony margin, and the area surrounded by the trace lines was measured as the cross-sectional area (Fig. 1). The measured tunnel areas were compared within each period, and the TE ratio was calculated according to the following equation: TE ratio (%) = (tunnel area at three months after surgery – tunnel area at one week after surgery)/tunnel area at one week after surgery  $\times$  100. To increase reliability, two experienced orthopaedic surgeons who were blinded to patient information measured the bone tunnel area three times. The mean of each measurement was accepted, and the interclass correlation coefficient (ICC) was calculated.

The active knee ROM at one month and three months after surgery was measured using a goniometer and recorded in increments of 1°. The side-to-side difference in KT-1000 and IKDC score was measured at 1 year postoperatively.

### 2.5. Statistical analyses

The bone tunnel area and enlargement, knee joint ROM measurements, and IKDC score were compared using the two-sample *t*-test. Mann-Whitney *U* test was used to evaluate the side-to-side



**Fig. 1.** The bone tunnel area was measured on a 2-mm-deep slice parallel to the femoral (a) and tibial (c) bone tunnel aperture. In this representative case (group T; CT scan at one week after surgery), the femoral bone tunnel area was 39.78 mm<sup>2</sup> (b), and the tibial bone tunnel area was 53.67 mm<sup>2</sup> (d).

difference in KT-1000. All statistical analyses were performed using SPSS for Windows, version 23.0 (SPSS Inc., Chicago, Illinois, USA). The level of significance was set at  $p = 0.05$ . The sample size was calculated using G-Power 3.1 (effect size 0.8,  $\alpha$ -error 0.05, and target power 0.95); a minimum of 18 subjects per group was recommended based on a previous study.<sup>6</sup>

### 3. Results

A total of 20 patients each in group D (average age, 25.7 ± 11.8 years) and group T (average age, 24.2 ± 9.5 years) were eventually included in the current study. No significant differences in demographic characteristics such as age, height, weight, body mass index, and bone tunnel size were identified between the two groups (Table 1). At three months after surgery, the femoral bone tunnel area was significantly larger in group T than in group D (group D, 93.2 ± 19.9 mm<sup>2</sup>; group T, 112.4 ± 20.1 mm<sup>2</sup>;  $p = 0.005$ ). In addition, the femoral TE ratios were significantly higher in group T than in group D (group D, 45.5% ± 34.6%; group T, 80.5% ± 28.8%;  $p = 0.001$ ). However, the tibial TE ratios did not significantly differ between the two groups (group D, 32.8% ± 23.0%; group T, 41.5% ± 26.0%;  $p = 0.273$ ) (Table 2). As for CT assessment, the intraclass and interclass reliability ICCs were 0.958 and 0.935, respectively.

**Table 1**  
Patient demographics.

	Group D (N = 20)	Group T (N = 20)	p-value
Sex (male:female)	9:11	9:11	1
Age (mean ± SD)	25.7 ± 11.8	24.2 ± 9.5	0.66
Height (cm)	165.8 ± 6.7	164.7 ± 7.6	0.64
Weight (kg)	64.6 ± 14.9	63.5 ± 12.8	0.8
BMI	23.4 ± 4.3	23.3 ± 3.9	0.96
Graft (ST, STG)	6, 14	7, 13	
Bone tunnel size			
Femur (mm)			
6 × 9	0	1	
6 × 10	12	12	
6 × 11	7	7	
6 × 12	1	0	
mean area (SD) (mm <sup>2</sup> )	49.1 ± 2.8	48.7 ± 2.3	0.19
Tibia (mm)			
8	2	8	
8.5	11	6	
9	6	5	
9.5	1	1	
mean area (SD) (mm <sup>2</sup> )	58.8 ± 5.0	56.5 ± 6.4	0.34

\* $p < 0.05$ .

BMI body mass index; ST fourfold semitendinosus graft; STG fourfold semitendinosus and gracilis graft.

**Table 2**  
Bone tunnel area and enlargement.

		Group D	Group T	p-value
Femur	1 week after surgery (mm <sup>2</sup> )	66.3 ± 18.3	63.5 ± 14.0	0.56
	3 months after surgery (mm <sup>2</sup> )	93.2 ± 19.9	112.4 ± 20.1	<0.01*
	Bone tunnel enlargement ratio (%)	45.5 ± 34.6	80.5 ± 28.8	<0.01*
Tibia	1 week after surgery (mm <sup>2</sup> )	64.5 ± 12.6	60.6 ± 8.9	0.261
	3 months after surgery (mm <sup>2</sup> )	84.8 ± 16.9	84.5 ± 13.2	0.941
	Bone tunnel enlargement ratio (%)	32.8 ± 23.0	41.5 ± 26.0	0.273

\*p < 0.05.

Compared with the patients in group D, those in group T showed restricted knee extension at one month after surgery (group D,  $-2.21 \pm 2.23^\circ$ ; group T,  $-5.53 \pm 4.68^\circ$ ;  $p < 0.01$ ); nonetheless, this was observed to have improved at three months after surgery (group D,  $-1.05 \pm 2.29^\circ$ ; group T,  $-1.05 \pm 2.68^\circ$ ;  $p = 1$ ). There was no significant difference in flexion between the two groups at either time point ( $p = 0.863$  and  $0.482$ , respectively) (Table 3). At one month after surgery, seven patients in group T, but none in group D had restricted knee joint extension of  $10^\circ$  or more. Six of the seven patients in group T had no restricted extension at three months after surgery; however, one patient still had a residual restricted extension at 1 year after surgery and required arthroscopic manipulation.

There was no significant difference between the two groups in the side-to-side difference in KT-1000 (group D,  $0.65 \pm 0.81$  mm; group T,  $0.35 \pm 0.49$  mm;  $p = 0.37$ ) and in IKDC score (group D,  $87.64 \pm 7.52$ ; group T,  $88.75 \pm 5.25$ ;  $p = 0.59$ ) and at 1 year postoperatively.

#### 4. Discussion

The most important finding of this study was that, although graft fixation in group T was performed at a lower initial tension than that in group D, significant femoral TE was observed in group T. To the best of our knowledge, this is the first study to examine the TensionLoc implant system used during ACL reconstruction.

Although it is a common phenomenon, the underlying mechanism of TE after ACL reconstruction is poorly understood. TE likely occurs due to a complex interplay between biological and mechanical factors. The biological factors reportedly include graft choice, graft swelling, synovial fluid leakage, elevation of certain cytokine levels within the joint, bone quality, and cell necrosis due to drilling.<sup>1,10</sup> The mechanical factors to be considered include non-anatomic tunnel placement,<sup>10–12</sup> micromotion at the tunnel aperture when soft tissue grafts are used with suspensory fixation,<sup>3,4</sup> increased stress at the tunnel-graft interface,<sup>13</sup> and aggressive rehabilitation protocols.<sup>14</sup> Another important mechanical factor that could affect TE is excessive initial graft tension during fixation.<sup>15–17</sup>

TE occurs in both the femur and the tibia, with the amount of enlargement often being greater in the former.<sup>4,18,19</sup> This can be explained by the graft bending angle, defined as the angle between the graft and the femoral tunnel. If the intra-articular and bone

tunnel grafts are not aligned along the same straight line in the functional position of the knee joint, the repetitive bending stresses on the graft at the femoral tunnel opening are affected. This can cause TE due to the abrasive forces on the edge of the femoral tunnel aperture.<sup>20</sup> In our study, there was no significant difference in tibial TE between the two groups. In the femur, TE was significantly greater in group T than in group D. Since the surgical procedures were the same, except for the difference in tibial graft fixation methods between the two groups, it is highly possible that excessive initial tension with the TensionLoc implant system was the cause of TE.

Although previous studies have recommended high initial graft tension such that the knee joint is excessively constrained,<sup>21</sup> excessive initial graft tension can cause joint stiffness and abnormal knee kinematics, resulting in articular cartilage degeneration, knee osteoarthritis, and improper maturation of reconstructive ligaments.<sup>22–24</sup> Therefore, it is now recommended that the graft be fixed with minimum initial tension.<sup>25</sup> Hoshino et al. reported that an initial tension of less than 50 N is recommended to restore normal knee kinematics at a low flexion angle.<sup>22</sup> Based on these results, we set the initial tension at 40 N when fixing grafts using the DSP and screw system, and good postoperative results were obtained.<sup>9,26</sup>

In the current study, ACL reconstruction using the TensionLoc implant system resulted in restricted knee extension in the early postoperative period, which improved three months after surgery. This may have been due to the excessive initial graft tension compensating for the relaxation of knee contracture by producing a larger TE. Whether this TE affects clinical outcomes is debatable,<sup>27–29</sup> but TE, especially on the femoral side, is known to be correlated with increased knee laxity after ACL reconstruction and often leads to technical difficulties in creating a new bone tunnel in the event of revision surgery; hence, staged ACL reconstruction may be required after bone grafting.<sup>30</sup> In this study, there was no difference between the two groups in terms of clinical outcomes at 1 year postoperatively, such as KT-1000 and IKDC score, but considering revision surgery, it seems necessary to prevent TE with more appropriate initial graft tension.

Mae et al. have recently developed a tensioning boot system for ACL reconstruction. The tensioning boot is fixed to the calf by a bandage and has two tensioners connected to the end suture of the graft when the initial tension is applied to it. They reported that grafts could be fixed at a lower initial tension by using this system.

**Table 3**  
Range of motion of the knee after surgery (°).

		Group D	Group T	p-value
Extension	1 month after surgery	$-2.21 \pm 2.23^\circ$	$-5.53 \pm 4.68^\circ$	<0.01*
	3 months after surgery	$-1.05 \pm 2.09^\circ$	$-1.05 \pm 2.68^\circ$	1
Flexion	1 month after surgery	$109.21 \pm 16.01^\circ$	$110.26 \pm 21.05^\circ$	0.863
	3 months after surgery	$132.77 \pm 33.19^\circ$	$138.42 \pm 10.01^\circ$	0.482

\*p < 0.05.

The reason for this is that the tibia moves proximally and posteriorly during tensioning, preventing load relaxation on the femur-graft-tibia complex and maintaining the balance of the component forces.<sup>8</sup> As part of our previous ACL reconstruction protocol using the DSP and screw system, we did use a manual tensioner; however, the tension was based on the surgeon’s hand and therefore inaccurate. The TensionLoc implant system is designed to maintain tension over the implant fixed to the tibia, similar to the tensioning boot system (Fig. 2). Therefore, it is expected to achieve the preoperatively determined level of graft tension.

In addition to this mechanism, attention should also be paid to the angle at which the graft is fixed. In the TensionLoc implant system, the plug is inserted at an angle close to the tensile direction of the graft, whereas with the DSP, the graft is fixed with a screw in a direction almost perpendicular to the axis of the tibial cortex (Fig. 3). These directions of implant fixation may also affect initial graft tension.

Based on this information, it was expected that the initial tension used with the DSP and screw system would be excessive when using the TensionLoc implant system. Therefore, the initial graft tension in group T was fixed at 30 N, which was lower than that of 40 N in group D; notwithstanding, the femoral TE ratio was found to be larger in group T, and knee extension was also restricted. This suggests that initial graft tension needs to be lower when using this

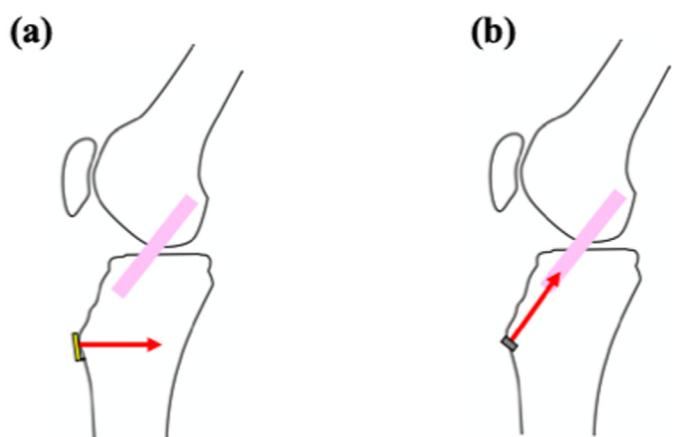


Fig. 3. The arrows indicate the direction of implant fixation. The angle of implant fixation to the graft differs between the DSP and screw system (a) and the TensionLoc implant system (b). This also results in different initial tension.

system for grafts. It should be noted that the ideal initial tension varies depending on the type of implant. In the future, it will be necessary to verify a more appropriate graft fixation method,

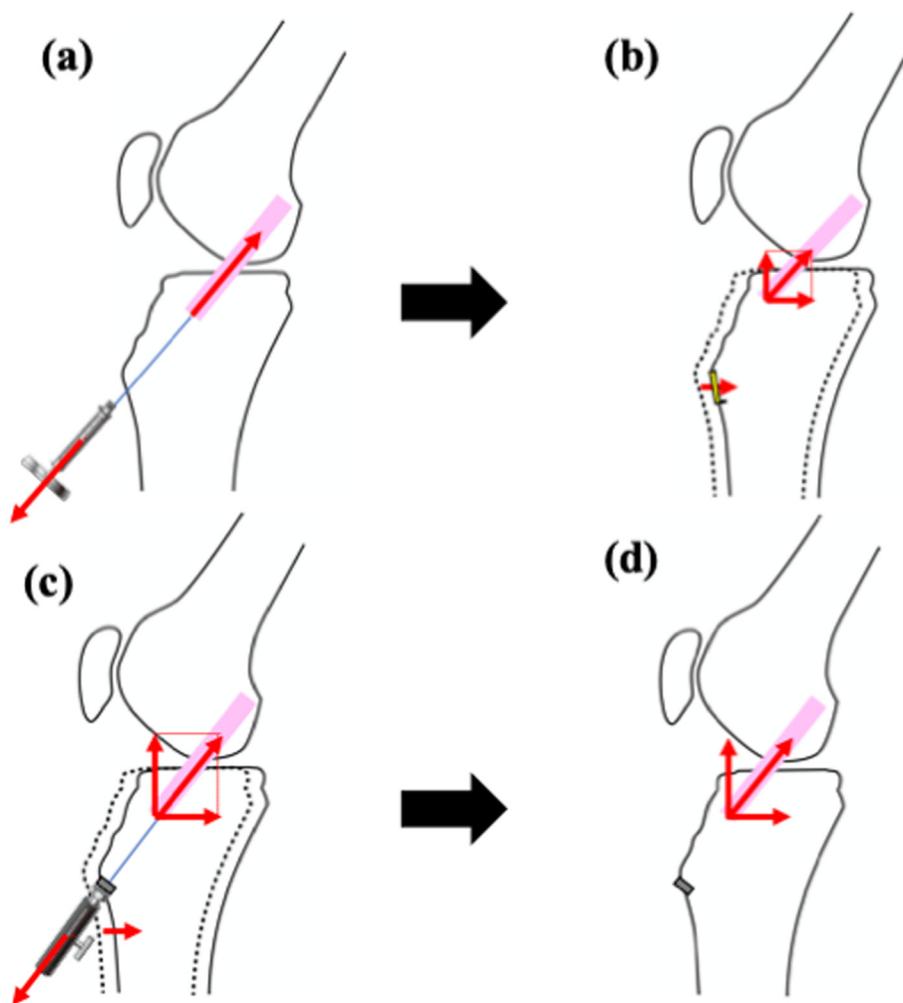


Fig. 2. Graft fixation methods DSP and screw (a, b), and the TensionLoc implant system (c, d). Even if the graft is fixed using DSP and screw after pre-tensioning, the tibia will move proximally and posteriorly, resulting in lower-than-expected tension (b). By using the TensionLoc implant system, graft tension is balanced during pre-tensioning and maintained even after graft fixation (d).

considering factors such as knee angle and tension, for ACL reconstruction using the TensionLoc implant system.

This study has certain limitations. First, this study was retrospective; surgical procedures varied across the study period and were not randomised or blinded. However, all clinical evaluations were performed by independent orthopaedic surgeons, and CT scan evaluations were performed by an orthopaedic surgeon who was blinded to the patients. Second, power analysis showed a large effect size; however, the patient population was relatively small. Based on the results of this study, we have already adopted the use of lower initial tension, making it difficult to increase the number of cases. Third, patient bone mineral density, which might have affected TE, was not assessed. Fourth, other factors that may affect TE (e.g., tunnel length, graft length, and graft bending angle) were not included in the current study. However, since the same skilled surgeons performed the procedures in the same way except for the method of fixation of the tibial graft, there was no difference in these factors between the two groups. Fifth, there was a difference in the initial tension between the two groups (40 N in group D and 30 N in group T). Finally, at only three months, the follow-up period to evaluate bone tunnel size was relatively short. Previous studies have shown that TE can occur up to 1–3 years after surgery, and most studies assess TE for up to 2 years.<sup>2,10,31</sup> Conversely, Peyrache et al. reported that tunnel widening was evident at 3 months but did not significantly change between 3 months and 2 years.<sup>10</sup> Thus, although the results may not be significantly different from those observed in the current study period, long-term follow-up may still be necessary.

## 5. Conclusion

Compared with ACL reconstruction using DSP and screw, ACL reconstruction using TensionLoc fixed the graft with lower initial tension but showed greater femoral TE and restricted knee extension in the early postoperative period. It should be noted that the ideal initial tension varies depending on the type of implant.

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No funding was received for the conduct of this study. The authors did not receive support from any organization for the submitted work.

## Ethical approval

This study was performed in accordance with the ethical standards as laid down in the 1964 Declaration of Helsinki and its later amendments. The study design was approved by the Ethics Committee of Kanazawa University Hospital (approval no. 1842).

## Informed consent

All patients were informed about the purpose, procedures, and known risks of the techniques; informed consent was obtained from all patients.

## Consent to publish

Not applicable.

## Author contributions

Study design: JN, MK, Recruitment and data collection: MK, RY, TK, Data analysis and interpretation: MK, RY, First draft of paper: MK, Revision of paper: all authors, The authors have read and approved the final manuscript.

## Declaration of competing interest

The authors have no relevant financial or non-financial interests to disclose.

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