



Repair of only anterior talofibular ligament resulted in similar outcomes to those of repair of both anterior talofibular and calcaneofibular ligaments

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Abstract

Purpose To compare the surgical outcomes of the two different ankle stabilization techniques.

Methods This randomized controlled trial aimed to compare the outcomes of the modified Broström procedure with [calcaneofibular ligament (CFL) group] or without CFL repair [anterior talofibular ligament (ATFL) only group]. Of the 50 patients randomly assigned to two groups, 43 were followed up prospectively for ≥ 2 years (CFL group: 22 patients, 36.6 ± 13.1 months; ATFL Only group: 21 patients, 35.3 ± 11.9 months). Functional outcomes were assessed using the Karlsson–Peterson and Tegner activity level scoring systems. Anterior talar translation (ATT), talar tilt angle (TTA), and degrees of displacement of the calcaneus against the talus on stress radiographs were measured. All parameters were compared between the two groups. Multiple regression analysis setting the postoperative Karlsson–Peterson score as the dependent variable was performed to determine the significant variable.

Results There were no significant differences between the two groups in functional (Karlsson–Peterson and Tegner activity level) scores at the last follow-up and their changes. There were no significant differences between the two groups in the ATT, TTA, their differences compared with the contralateral ankles, and degrees of displacement of the calcaneus against the talus at the last follow-up. Osteochondral lesion of the talus rather than CFL repair was the significant variable related to functional outcome.

Conclusion The modified Broström procedure with additional CFL repair did not result in a significant advantage in any measured outcome at 3 years.

Level of evidence Randomized controlled trial, Level I.

Keywords Chronic lateral ankle instability · Modified Broström procedure · Anterior talofibular ligament · Calcaneofibular ligament · Karlsson–Peterson score

Introduction

Ankle sprain is a very common injury during sports or recreational activities [9]. Although most cases can be managed successfully with conservative treatment [28], patients often

show residual dysfunction [10]. Among late dysfunctions, chronic lateral ankle instability (CLAI) is one of the most disabling condition and often requires surgery [22, 34]. The classic Broström procedure is defined as repair of the anterior talofibular ligament (ATFL) and calcaneofibular ligament (CFL) [5]. Gould et al. described the modification with augmentation of the inferior extensor retinaculum (IER) [11]. The modified Broström procedure is a standard surgery for CLAI because of its excellent clinical results with few complications [3, 22, 34].

Different from the above-mentioned traditional method, some surgeons claim not to repair the CFL [20–23], and several studies have supported such [8, 19, 24]. In other words, the need for CFL repair is controversial and tends to be performed according to surgeons' preferences [22].

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However, studies that prospectively compared the surgical results between two different techniques (the modified Broström procedure with or without CFL repair) are still rare.

On this background, a prospective randomized controlled trial was conducted to compare the surgical outcomes of the modified Broström procedure with (CFL group) or without CFL repair (ATFL Only group). The objectives of the present study were to: (1) compare the functional and radiographic outcomes between two randomly assigned groups (CFL group vs ATFL Only group); and (2) find the beneficial effect of additional CFL repair (or the effect of unrepaired CFL) using various parameters. It was hypothesized that the ATFL Only group with the augmentation of the IER would show comparable outcomes.

Materials and methods

The selection of study subjects started from May 2012 until the inclusion of 50 patients (to September 2015). Among the 140 patients considered to need repair of the lateral ligaments for CLAI during that period, 21 were excluded because of age (< 20 or > 50 years). Eight patients with generalized laxity, 10 with osteoarthritis of the ankle, 2 with talocalcaneal coalition, 3 with a history of surgery of the ankle joint, and 12 who had been planned to undergo additional procedures to correct hindfoot malalignment were excluded. Seven patients with suspected peroneal tendon pathology on physical examination or magnetic resonance imaging (MRI) findings were also excluded. Further, 2 foreign patients and 1 with schizophrenia were also excluded because periodic follow-up after surgery was expected to be difficult. Of the remaining 74 patients, 57 met the inclusion criteria of symptom duration (recurrent sprain or giving way for > 6 months), MRI findings of ATFL abnormality (appearance of an irregular or wavy contour or laxity, increased signal intensity within the substance of the ligament, discontinuity of the substance of the ligament, or non-visualization of the ligament [30]), physical examination, and stress radiograph findings. With regard to the physical examination and radiograph findings, patients with ≥ 2 of the following findings were included: (1) anterior drawer test (physical examination) finding > 10 mm; (2) anterior talar translation > 10 mm on anterior drawer stress radiograph; (3) talar tilt angle > 10° on varus stress radiograph.

Among these 57 patients, 50 who agreed to undergo randomization and periodic follow-up were selected. Permuted-block randomization was used. The processes of allocation and follow-up were managed by the senior author. The study subjects were not informed about the assigned group. Finally, 43 patients were followed up prospectively for ≥ 2 years after surgery, and their outcomes were analyzed. The process of selection of study subjects is shown in Fig. 1.

Age, height, body weight, and body mass index (BMI) were assessed on the basis of the date of admission for surgery. The duration of symptoms was calculated from the time of the first injury to the operation date by reference to outpatient and hospital records. If the first injury happened too long ago to be remembered, the duration of the symptoms was asked on a yearly basis, and the median date was used. Detailed description of demographics and clinical characteristics of the two groups is shown in Table 1.

Surgical techniques and rehabilitation

All surgical procedures were performed by the senior author. All patients were placed in the supine position and a pneumatic thigh tourniquet was applied. Before repair of the ligaments, an arthroscopic examination was performed to identify and manage accompanying intra-articular pathologies. For arthroscopic procedures, a 2.9 mm/ 30° arthroscope and noninvasive ankle distractor were used. The detailed frequencies of the accompanying intra-articular pathologies are shown in Table 1. Ten patients in the CFL group and 9 in the ATFL Only group had no accompanying intra-articular pathologies. All accompanying intra-articular pathologies were managed with appropriate procedures based on the arthroscopic findings (i.e., bone marrow stimulation procedure, bony spur excision, or loose body removal). After the arthroscopic examination and procedure, the lateral ligaments were repaired according to group assignments. A slightly curvilinear incision anterior and inferior to the lateral malleolus was used. The IER was dissected and the ATFL and CFL were approached and observed. Except for 1 patient (in ATFL Only group) whose CFL was not clearly observed, all patients showed operative findings that suggested chronic injury of CFL. The ATFL with or without CFL was sutured using suture material or a suture anchor (5.0-mm Super Revo, CONMED, USA). The suture anchor was used when it was considered more advantageous considering the condition of the remnant ligaments; one suture anchor was used in both groups and inserted in the midpoint between the insertions of the ATFL and CFL. Thirteen suture anchors were used in the CFL group and 10 in the ATFL Only group (frequency was not significantly different between the two groups using the Fisher's exact test). After repair of the lateral ligaments, the dissected IER was sutured to the periosteum of the fibular tip.

After surgery, a short leg splint was applied, and tolerable weight bearing was allowed. The splint was changed to a short leg cast a few days later. Two weeks after surgery, the patients started range of motion and foot/ankle strengthening exercises with stirrup ankle braces. Full weight bearing was allowed 4 weeks after surgery, and proprioceptive training to improve balance and proprioception was started 6 weeks after surgery. The patients were followed up at 2 weeks, and

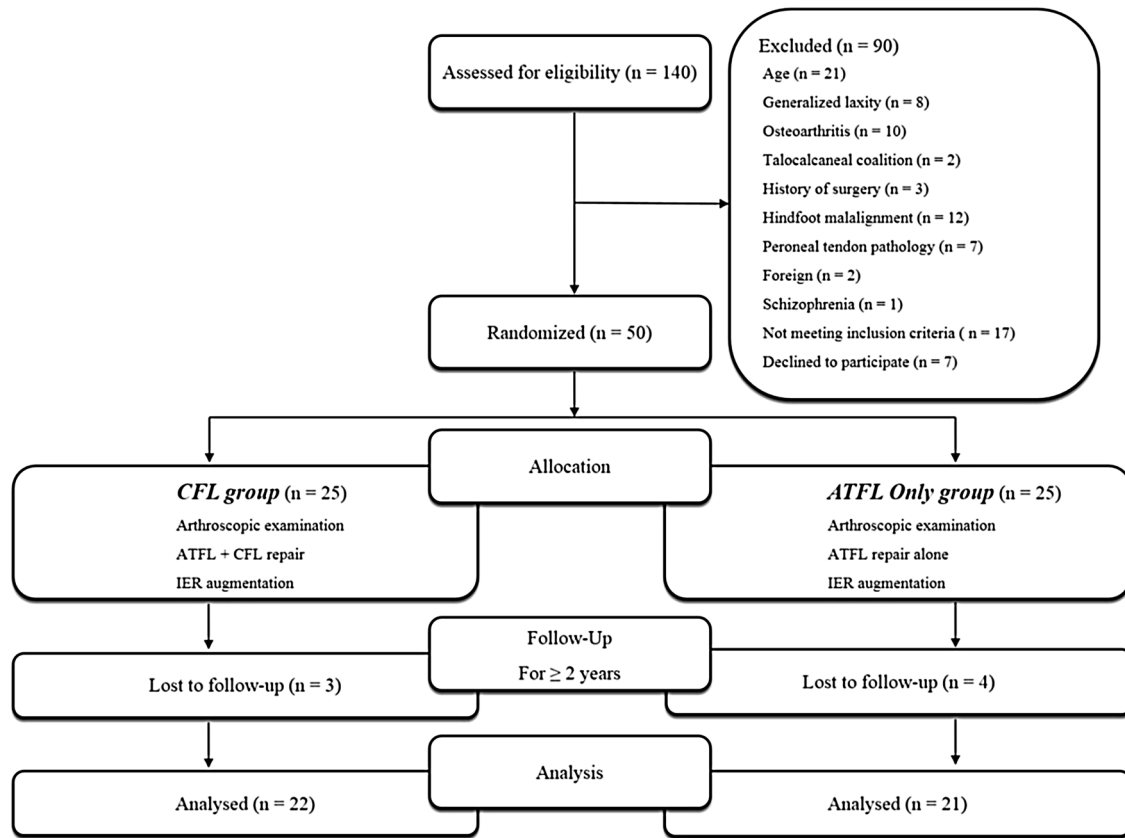


Fig. 1 Process of selection of study subjects

Table 1 Baseline characteristics of the study subjects

	CFL group (n = 22)	ATFL Only group (n = 21)	p
Demographics and clinical characteristics			
Age (years)	31.3 ± 9.8	27.6 ± 9.0	n.s.*
Male/female ratio	17/5	17/4	n.s.†
Left/right ratio	12/10	15/6	n.s.†
Height (cm)	172.6 ± 8.3	171.3 ± 6.5	n.s.*
Body weight (kg)	76.6 ± 13.7	76.5 ± 15.1	n.s.*
BMI (kg m ⁻²)	25.7 ± 4.1	26.0 ± 4.3	n.s.*
Duration of symptoms (months)	94.8 ± 92.7	83.8 ± 63.0	n.s.*
Frequencies of intra-articular pathologies			
OLT	5/22	3/21	n.s.†
Anterior bony impingement syndrome ^a	10/22	10/21	n.s.†
Loose body (intra-articular)	2/22	1/21	n.s.†
Functional scores			
Karlsson–Peterson score (preoperative)	55.6 ± 15.4	52.1 ± 9.1	n.s.*
Tegner activity level score (preinjury)	7.1 ± 1.3	7.5 ± 1.2	n.s.*
Tegner activity level score (preoperative)	3.3 ± 0.8	3.3 ± 1.0	n.s.*

CFL calcaneofibular ligament, ATFL anterior talofibular ligament, BMI body mass index, OLT osteochondral lesion of the talus, n.s. non-significant

*Obtained using the independent t test

†Obtained using Fisher’s exact test

^aGrade I with classification by van Dijk et al. [33]

at 3, 6, 12, and 24 months after surgery. Education on the rehabilitation program was conducted both at the first meeting before surgery and at the first follow-up after surgery. Patients were encouraged to perform continuous rehabilitation training through routine follow-up. The patients with a follow-up period of more than 2 years were included in the analysis.

Functional assessment

Two scoring systems were used to evaluate the functional outcomes. The first was the Karlsson–Peterson scoring system [15, 16]. The scores immediately before surgery and at the last follow-up were used in the analysis. The second was the Tegner activity level [32]. Preinjury, preoperative and final scores were used in the analysis. The functional assessments were managed by the senior author. Preoperative functional scores of the two groups are shown in Table 1.

At baseline, the subjects' demographic and clinical characteristics, frequencies of intra-articular pathologies, and functional scores were not significantly different between the two groups (Table 1).

Radiographic measurement

Telos stress device (15daN, TELOS GmbH, Germany) was used in stress radiographs. Anterior drawer stress radiograph was taken at approximately 10° plantar flexion. Anterior talar translation (ATT) on anterior drawer stress radiographs and talar tilt angle (TTA) on varus stress radiographs were measured in the affected and contralateral ankles. The ATT was measured as the shortest distance between the posterior lip of the tibia and the talar dome. The TTA was defined as the angle between the skeletal surfaces of the tibia and talus [12]. The ATT, TTA, and their side-to-side differences (STSD) compared with the contralateral ankles were used to assess the radiographic outcomes.

The CFL has roles in stabilizing the subtalar joint as well as the ankle joint [18, 27, 35]. Therefore, an evaluation of the subtalar joint was included as a radiographic parameter to determine the effect of unrepaired CFL. The degrees of anterior and medial displacement of the calcaneus against the talus in the subtalar joint were measured using the methods described in previous studies with some modifications [13, 17]. Two studies described the radiographic measurements of calcaneal displacement at the subtalar joint that had improved after surgery in patients with subtalar instability (STI) [13, 17].

The anterior displacement of the calcaneus at the subtalar joint [anterior calcaneal translation (ACT)] was measured using the distance between two lines on anterior drawer stress radiographs. The first line was drawn through the most anterior margin of the talus, while the second was drawn

through the most anterior margin of the calcaneus. The two lines were drawn perpendicular to the line bisecting the long axis of the talus and calcaneal inclination axis. Because the talar head is anteriorly located compared with the calcaneal anterior process, smaller values indicate more anterior translation of the calcaneus (Fig. 2).

The medial displacement of the calcaneus at the subtalar joint [medial calcaneal translation (MCT)] was measured using the distance between two lines on varus stress radiographs. The first line was drawn through the most lateral margin of the talar body, and the second was drawn through the most lateral calcaneal border of the calcaneal side of the subtalar joint surface. The two lines were drawn perpendicular to ankle joint surface of the talus (Fig. 2).

The four indicators (ATT, TTA, ACT, and MCT) in the stress radiographs were measured preoperatively and at the last follow-up using the PACS system (Centricity Enterprise Web V3.0, GE Healthcare, UK). These were measured twice by two independent observers (trained in a foot and ankle fellowship course), and the calculated mean values of the four measurements were used in the analysis. Intra-class correlation coefficients were calculated to evaluate the intra- and inter-observer reliabilities and ranged 0.75–0.94 (Online Appendix). Each measurement was performed at intervals of 1 month by each observer without information about the assigned group of study subjects.

This study was approved by the institutional review board of our institution (Samsung Medical Center, IRB File No. 2012-02-046-036).

Statistical analysis

All numerical data were presented as mean \pm standard deviation. The independent *t* test was used to compare the numerical data between the two groups. Fisher's exact test was used to compare categorical data between the two groups. The paired *t* test was performed to compare the preoperative and postoperative parameters in each group. Multiple regression analysis was performed to determine the significant variable of functional outcome. All statistical analyses were performed using SPSS version 23 for Windows (IBM Corp., Armonk, NY, USA), and the significance level was set at $p < 0.05$.

To calculate sample size, a previous study that retrospectively compared the outcomes of the modified Broström procedure for CLAI [31] was referenced. In that study, double suture anchors were used to repair the ATFL and CFL, while single suture anchors were used to repair the ATFL without the CFL. The Karlsson–Peterson score had improved significantly in both groups (90.5 ± 6.33 vs 89.4 ± 5.95) [31]. In the present study, the non-inferiority margin was set at six points of Karlsson–Peterson scoring system considering its contents and ranges of excellent (90–100) and good



Fig. 2 **a** Anterior drawer stress radiograph. The long axis of the talus, calcaneal inclination axis, and their bisecting line were drawn. The parallel two lines are perpendicular to the bisecting line. The marked width indicates the anterior calcaneal translation (ACT). **b** Varus

stress radiograph. The parallel two lines are perpendicular to the joint surface of the talus. The marked width indicates the medial calcaneal translation (MCT)

(80–89) results [15]. To achieve a significance level of 0.05 and power of 0.8, 21 patients were needed in each group. Assuming a dropout rate of ~20%, including a total of 50 patients was planned.

Results

Functional outcomes

During the follow-up periods (CFL group: 36.6 ± 13.1 months; ATFL Only group: 35.3 ± 11.9 months), no patients had wound problems, superficial or deep infections, nerve injuries, or other complications requiring rehospitalization or reoperation. Persistent pain and subjective instability at the last follow-up were calculated using the Karlsson–Peterson scoring system, and presented as functional outcomes with the corresponding points. The Karlsson–Peterson and Tegner activity level scores of both groups significantly improved ($p < 0.001$). There were no statistically significant differences between the two groups in the two scoring systems and their increments at the last follow-up (n.s.). In the Tegner activity level scoring system, differences between preinjury and final scores were calculated. There was no statistically significant difference (n.s.). Detailed statistical descriptions of the functional outcomes are shown in Table 2.

Table 2 Results of functional outcomes

	CFL group ($n=22$)	ATFL Only group ($n=21$)	p^*
Karlsson–Peterson score			
Increment ^a	29.5 ± 16.3 $<0.001^\dagger$	36.9 ± 13.2 $<0.001^\dagger$	n.s.
Last follow-up	85.1 ± 10.0	89.0 ± 8.7	n.s.
Tegner activity level score			
Increment ^a	1.9 ± 1.0 $<0.001^\dagger$	2.1 ± 1.0 $<0.001^\dagger$	n.s.
Last follow-up	5.2 ± 1.1	5.4 ± 0.9	n.s.
Difference ^b	1.8 ± 1.1	2.1 ± 1.1	n.s.

CFL calcaneofibular ligament, ATFL anterior talofibular ligament, n.s. non-significant

*Obtained using the independent t test (CFL group vs ATFL Only group)

[†]Obtained using the paired t test (preoperative scores vs final scores)

^aFinal scores–preoperative scores

^bPreinjury scores–final scores

Radiographic outcomes

The ATT on anterior drawer stress radiographs, TTA on varus stress radiographs, and their side-to-side differences (STSD) compared with contralateral ankles in both groups decreased significantly ($p < 0.001$). There were no

statistically significant differences between the two groups before surgery and at the last follow-up in ATT, TTA and their STSD (n.s.).

There were no statistically significant differences between the preoperative and postoperative ACT on the anterior drawer stress radiograph and MCT on the varus stress radiograph in both groups (n.s.). There were no statistically significant differences before surgery and at the last follow-up between the two groups (n.s.). Detailed statistical descriptions of the radiographic outcomes are shown in Table 3.

Multiple regression analysis

To evaluate the effect of the CFL repair on functional outcomes with adjustments for other factors, multiple regression analysis was performed in addition to comparison between the two groups. In designing the regression model, the effects of intra-articular pathology on surgical

outcomes [6] were referenced. The effect of suture anchor use on functional outcomes was also concerned because it was not used in all study subjects. Therefore, repair of the CFL, use of suture anchor, and the presence of each intra-articular pathology were included as the independent variables. Setting the postoperative Karlsson–Peterson score as the dependent variable, the existence of osteochondral lesion of the talus (OLT) was a significant variable after adjustments for other factors ($p=0.023$). Repair of the CFL and other independent variables were not significant in this analysis (n.s.).

Discussion

The most important finding of the present study was that the modified Broström procedure with additional CFL repair did not result in a significant advantage in any measured outcome at 3 years. Different from previous studies that reported the unnecessary for the CFL procedure [8, 19–21, 23, 24], the present study was a prospective randomized controlled trial. At 3 years, there were no beneficial effects of the additional CFL repair. In addition to comparison between the two groups, the repair of the CFL was not the significant variable in the multiple regression analysis after the adjustments for other factors. These are the main strengths of our study.

Many previous biomechanical studies suggested that the CFL has roles in stabilizing the subtalar joint as well as the ankle joint [18, 27, 35]. Therefore, to determine the effect of unrepaired CFL, we believe that comparison should include evaluation of the subtalar joint. In our study, the ACT and MCT were measured using the methods in two previous studies with some modifications [13, 17]. Kato reported a method of measuring the anterior displacement of the calcaneus at the subtalar joint [17]. The distances between the most anterior margins of the talus and calcaneus in transverse plane were used [17]. The calculated anterior displacement was increased in patients with STI and decreased after surgery [17]. Anatomically, the anterior subtalar joint facet has a flat configuration that allows translation movements [29]. It is thought that the most anterior margins of the talus and the calcaneus are the appropriate points for measuring the anterior displacement of the calcaneus against the talus. In our study, anterior drawer stress radiographs were used instead of dorso-plantar radiographs. It was assumed that the line bisecting the angle between the long axis of the talus and the calcaneal inclination axis on anterior drawer stress radiograph is an appropriate standard for evaluating displacement at the subtalar joint.

Regarding the MCT, Jung et al. reported the clinical and radiographic outcomes of surgery for STI [13]. The medial translation, defined as the distance between two parallel

Table 3 Results of radiographic outcomes

	CFL group ($n=22$)	ATFL Only group ($n=21$)	p^*
ATT (mm)			
Preoperative	8.5 ± 2.5	8.3 ± 2.0	n.s.
Last follow-up	5.5 ± 1.9	5.3 ± 1.5	n.s.
	<0.001 [†]	<0.001 [†]	
STSD preoperative ^a	4.2 ± 2.2	4.1 ± 1.8	n.s.
STSD at last follow-up ^a	1.1 ± 1.3	0.9 ± 1.0	n.s.
	<0.001 [†]	<0.001 [†]	
TTA (°)			
Preoperative	12.3 ± 3.7	12.6 ± 4.1	n.s.
Last follow-up	6.1 ± 2.4	5.7 ± 3.3	n.s.
	<0.001 [†]	<0.001 [†]	
STSD preoperative ^a	7.4 ± 2.3	7.7 ± 2.3	n.s.
STSD at last follow-up ^a	2.0 ± 1.2	1.7 ± 1.7	n.s.
	<0.001 [†]	<0.001 [†]	
ACT (mm)			
Preoperative	10.1 ± 2.4	10.0 ± 2.2	n.s.
Last follow-up	10.3 ± 2.5	10.5 ± 2.8	n.s.
	n.s. [†]	n.s. [†]	
MCT (mm)			
Preoperative	7.9 ± 3.1	7.5 ± 3.2	n.s.
Last follow-up	7.6 ± 2.4	6.4 ± 3.3	n.s.
	n.s. [†]	n.s. [†]	

CFL calcaneofibular ligament, ATFL anterior talofibular ligament, ATT anterior talar translation, TTA talar tilt angle, ACT anterior calcaneal translation, MCT medial calcaneal translation, STSD side-to-side difference, n.s. non-significant

*Obtained using the independent t test

[†]Comparison using the paired t test between preoperative values and those at the last follow-up

^aValues of affected ankle – values of contralateral ankle

lines, significantly decreased after the operation [13]. The first line was drawn through the most lateral margin of the talar body, while the second was drawn through the most lateral calcaneal border of the calcaneal side of the subtalar joint surface [13]. In our study, the MCT was measured using the distance between the two parallel lines in the same manner with the same force (15daN) applied at the hind-foot. Considering the improvements of original radiographic parameters after surgery for STI [13, 17], we believe that the ACT and MCT in our study could at least indicate relative displacements of the calcaneus against the talus to identify the effect of unrepaired CFL. Moreover, they showed excellent reliability and reproducibility (Online Appendix).

The IER starts at the lateral surface of the calcaneus, crosses the subtalar joint, and surrounds the tendons of the anterior compartment [7]. Its anatomical vector is similar to the vector sum of the ATFL and CFL. In other words, the augmentation of the IER in the modified Broström procedure can theoretically mimic the CFL repair [20]. Based on the results of our study, the isolated roles of the CFL and IER cannot be concluded. However, the augmentation of the IER that was equally performed in the two groups can explain the comparable results achieved in the ATFL Only group.

Age between 20 and 50 years was one of the inclusion criteria. Referencing a previous report of significantly worse results in those over 50 years of age after the modified Broström procedure [1], and considering consent to randomization and compliance to periodic follow-up, this criterion was set. Generalized laxity is known to be a poor prognostic factor after anatomical ligament repair [14, 26]. Therefore, such patients were excluded using the methods most commonly cited in other literature [2]. Patients with osteoarthritis, tarsal coalition, hindfoot malalignment and peroneal tendon pathology were also excluded because it was concerned that such lesions would affect the comparison.

MRI findings of the CFL were not included in the inclusion or exclusion criteria because MRI is not a proper diagnostic tool to determine CFL injury. The MRI demonstrated 58.3% of sensitivity for acute CFL injury [4]. Regarding chronic injury, the sensitivity was only 50% [25]. Considering our inclusion criteria based on physical examination and stress radiographs, we believe that all the study subjects ($n=43$) had a potential CFL injury. The absence of a significant difference in preoperative TTA between the two groups also suggests equality in CFL injury (Table 3). In fact, all subjects ($n=43$) demonstrated gross abnormalities of CFL such as fissuring, longitudinal tear, elongation and absence.

The presence of intra-articular pathologies and the use of suture anchors in some patients are the most important limitations of the present study. To minimize the effect of these pathologies on outcomes, all lesions were managed with appropriate procedures according to arthroscopic findings. Further, multiple regression analysis was performed

to find the significant factors in addition to comparison of the two groups. Repair of the CFL showed no significance. However, OLT was a significant variable after adjustments for other factors, and this finding is consistent with previous literature [6]. It is recommended that stratification according to the presence or absence of OLT should be considered in future randomized studies. The use of a suture anchor was not a significant variable in multiple regression analysis; further, suture anchors were used via a method that would be more advantageous based on the condition of the remnant ligaments. Thus, it was presumed that this would not affect the comparison between the two groups.

There are several other limitations. Despite the same rehabilitation protocol, the effect of postoperative rehabilitation and patients' compliance on rehabilitation training were unclear. To minimize the differences, in-depth education on the rehabilitation program was conducted at both the first meeting before surgery and the first follow-up after surgery. Further, a booklet with illustrations and an internet address to access the video describing the rehabilitation protocol were provided. Moreover, baseline preoperative functional deficits evaluated using the isokinetic and balance tests were not significantly different between the two groups (Online Appendix). Finally, the design based on intermediate-term follow-up and the discrepancy in the last follow-up time are additional limitations.

Conclusion

In this prospective randomized controlled trial including selected patients with CLAI, additional CFL repair did not result in functional and radiographic outcomes that were superior to those with ATFL repair alone.

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Compliance with ethical standards

Conflict of interest The authors have no conflict of interest.

Ethical approval All procedures performed in this study involving human participants were in accordance with the ethical standards of our institutional research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all participants.

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