

A randomized comparison between lateral ligaments augmentation using suture-tape and modified Broström repair in young female patients with chronic ankle instability



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ARTICLE INFO

Article history:

Received 26 July 2017

Received in revised form 14 September 2017

Accepted 25 September 2017

Keywords:

Chronic ankle instability
Suture-tape augmentation
Modified Broström repair
Clinical outcomes
Cost-effectiveness

ABSTRACT

Background: Although various minimally invasive procedures for chronic ankle instability are increasingly being used, a question regarding whether these procedures can be a viable alternative of the modified Broström procedure remains controversial. This study was conducted to compare the intermediate-term clinical outcomes between lateral ligaments augmentation using suture-tape and modified Broström repair in a selected cohort of patients.

Methods: Sixty female patients with chronic lateral ankle instability were randomly assigned and underwent surgical treatments by one surgeon. Twenty-eight patients with suture-tape augmentation and 27 modified Broström procedures were followed ≥ 2 years and analysed in this comparative study. The clinical evaluation included the Foot and Ankle Outcome Score (FAOS), Foot and Ankle Ability Measure (FAAM), and stress radiographs. Medical expense related with operation was analysed to evaluate the cost-effectiveness.

Results: There were no statistically significant differences in the clinical outcomes between two procedures based on FAOS, FAAM, recurrence rate of instability, and stress radiographs. Total medical expense was approximately 1.3 times more in the suture-tape group ($P < 0.001$), despite shorter operation time.

Conclusions: Lateral ankle ligaments augmentation using suture-tape showed the similar clinical outcomes but low cost-effectiveness, as compared to modified Broström repair for young female patients with chronic ankle instability.

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1. Introduction

The modified Broström anatomic ligament repair is currently the most common and gold-standard primary surgical technique for chronic lateral ankle instability. There is an increasing interest in minimally invasive procedures to treat this condition [1]. Minimally invasive procedures can be divided into three major categories: arthroscopic approach including the arthroscopic ligament repair (arthroscopic Broström procedure) [2,3] and arthroscopic ligament reconstruction [4,5], non-arthroscopic reconstructive approach such as the percutaneous or mini-open

ligament reconstruction using tendon graft [6,7], non-arthroscopic augmentative approach such as the ligament augmentation using suture tape [8,9]. Although various minimally invasive procedures are increasingly being used, a conclusion regarding whether these procedures can be a viable alternative of the modified Broström procedure is still unclear.

The ligament augmentation using suture-tape as internal brace to reinforce the attenuated ligaments is a recently introduced procedure for chronic ankle instability. Although many biomechanical studies [10–12] have reported a mechanical superiority of the augmented anterior talofibular ligament reconstruction using suture-tape, clinical usefulness and appropriate indications of the suture-tape augmentation remain unclear. Routine suture-tape augmentation combined with the modified Broström procedure might have been an overtreatment in many patients with chronic ankle instability [8]. Our hypothesis was that a simple lateral ligaments augmentation using suture-tape could be a

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minimally invasive technique providing the clinical outcomes comparable to the conventional open ligament repair in well-selected patients with chronic ankle instability.

There is no clinical report with a high level of evidence evaluating the progressive relaxation and specific complications after the suture-tape augmentation for chronic ankle instability. We also could find few definitive evidence regarding a range of clinical application for this procedure. For these reasons, subjects of the current study were limited to a cohort of the young female patients who had shown a satisfactory restoration of the ankle stability in the previous study [8]. This study was performed to compare the intermediate-term clinical outcomes between lateral ligaments augmentation using suture-tape and modified Broström repair in a selected cohort of patients.

2. Patients and methods

2.1. Study design

Prior to enrollment of subjects, a power analysis was performed to determine the sufficient sample size in order to make statistically significant results. Considering the excellent results after modified Broström procedures reported by many authors and a large cohort required to prove a clinical superiority, we chose a noninferiority verification study to test the hypothesis that the simple lateral ligaments augmentation using suture-tape was not inferior to the conventional open ligament repair (modified Broström procedure) in young female patients. We calculated that allocation of the 26 patients into each group would provide 90% power to test the hypothesis regarding the validated patient-reported outcome measure (the Foot and Ankle Outcome Score, FAOS) at postoperative 2 years. The 95% confidence interval (a type-I error rate of 0.05) was used to analyse whether the difference in the FAOS at postoperative 2 years was within a margin of noninferiority. The setted margin of noninferiority was -5 points (a delta of 5 points in the FAOS) and the estimated dropout rate was 15%. The margin of noninferiority and dropout rate were determined on the basis of a pilot study. Eventually, the sample size required to make statistically significant results was 30 patients in each group.

The inclusion criteria for this study were as follows: (1) patients with subjective ankle instability including giving way, (2) patients with repeated sprain injuries for ≥ 6 months, (3) patients with marked ankle instability confirmed by the manual varus and anterior drawer stress test as compared to the contralateral ankle, (4) patients with at least 3 months of failed rehabilitation before surgery, (5) female under 40 years of age, (6) patients with body mass index (BMI) ≤ 28 kg/m², (7) patients with an amateur level of sports activity (social sports participants). The exclusion criteria were as follows: (1) patients with previous surgical history involving lateral ankle ligaments, (2) patients who underwent operation of bilateral ankle, (3) heavy laborers or high-demand athletes, (4) patients with abnormal foot alignment such as cavovarus, (5) patients with generalized ligamentous laxity (Beighton score ≥ 5 point), (6) patients with concomitant osteochondral lesion which need surgical procedures beyond simple arthroscopic synovectomy or debridement, (7) patients with neuromuscular instability (peroneal weakness). The study protocol was approved by the institutional review board in Chungbuk National University Hospital.

2.2. Study subjects

Between January 2013 and November 2014, 74 female patients consecutively underwent surgical procedures under the diagnosis of chronic lateral ankle instability. Of these, 60 patients compatible

for inclusion and exclusion criteria were enrolled in the current study. Based on a computerized random-number generator, patients were randomly assigned to a group ($n=30$) in which the suture-tape augmentation was used and a group ($n=30$) in which the modified Broström procedure was used. All patients consented to the randomization of surgical procedures, and all operations were performed by a single senior surgeon. Eventually, 28 patients with suture-tape augmentation (ST group) and 27 with modified Broström repair (MB group) could be followed for more than 2 years (Fig. 1). At the time of surgery, the mean age of the patients was 26.6 years (range 16–40 years) in ST group and 28.1 years (range 17–39 years) in MB group. The mean length of follow-up was 34.6 months (range 24–45 months) in ST group and 33.8 months (range 24–44 months) in MB group. The main sport activities practiced preoperatively by patients were jogging in 22 patients (12 in ST group and 10 in MB group), cycling in 21 patients (10 in ST group and 11 in MB group), hiking in 7 patients (4 in ST group and 3 in MB group), and aerobics in 5 patients (2 in ST group and 3 in MB group).

2.3. Surgical technique

Concomitant arthroscopic procedure was carried out as needed. In the current study, there were 31 patients (17 in ST group and 14 in MB group) with arthroscopic synovectomy for soft tissue impingement syndrome, 9 patients (5 in ST group and 4 in MB group) with arthroscopic debridement for mild chondral lesion, and 2 patients (2 in MB group) with loose body removal. In cases with suture-tape augmentation, three small incisions were made at anteroinferior border of the lateral malleolus, lateral surface of the talar neck and calcaneal body, respectively. After appropriate entry points of the suture anchors were confirmed using the temporary k-wire placement under fluoroscopic guidance, three SwiveLock[®] biocomposite suture anchors (3.5 mm in diameter, Arthrex, Naples, FL, USA) were inserted with two bundles of suture-tape (Fig. 2). In cases with modified Broström procedure, the anterior talofibular (ATF) and calcaneofibular (CF) ligaments repair was performed using two Corkscrew[®] suture anchors (3.5 mm in diameter, Arthrex). The fibular periosteum was overlapped at attachment site of the lateral ligaments, and the inferior extensor retinaculum was imbricated (Fig. 3).

Rehabilitation protocols were equally applied to both groups. For 3 weeks postoperatively, a short leg cast and non-weight bearing ambulation with crutch were maintained. Thereafter, range of motion (ROM) exercises and partial-weight bearing ambulation with elastic ankle bandage were encouraged. From

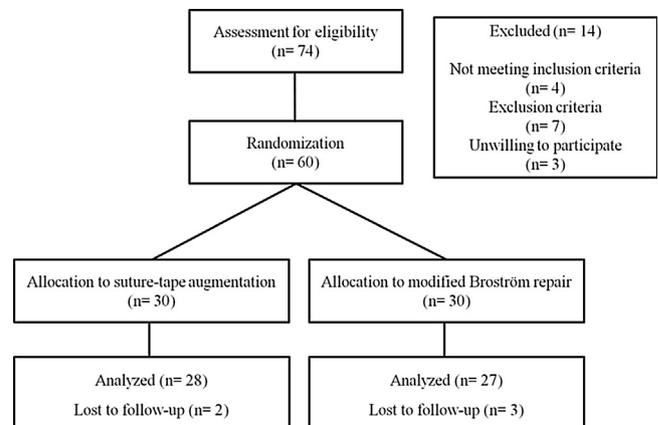


Fig. 1. Consort flow chart of the current randomized comparative study.

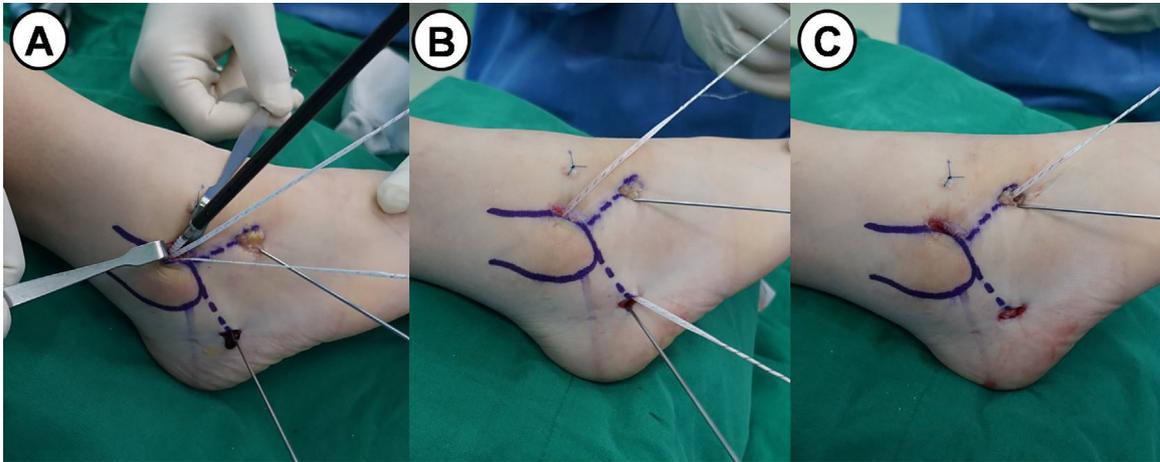


Fig. 2. ATF and CF ligaments augmentation using the suture-tape.

(A) The first Swivelock[®] anchor was inserted with 2 bundles of suture-tape at the ATF ligament origin of the lateral malleolus. (B) One bundle of suture-tape was passed through a portal over the lateral wall of the calcaneus, beneath the peroneal tendons. The second anchor was inserted into the calcaneal body. (C) The other bundle of suture-tape was subcutaneously passed through a portal at the center of the talar neck (about 1 cm anterior and superior from the sinus tarsi), over the extensor retinaculum. Then, the third anchor was inserted with suture-tape.

postoperative week 6, proprioception training and full-weight bearing gait were permitted.

2.4. Clinical evaluation

All patients were evaluated clinically using the Foot and Ankle Outcome Score (FAOS) and Foot and Ankle Ability Measure (FAAM), which are the validated outcome measures for chronic ankle instability. The FAOS [13] is a patient-reported outcome measure (PROM) that consists of 42 questions and 5 subscales evaluating pain, other symptoms, activities of daily living, sports activities, quality of life. The FAAM [14] is also a PROM comprised of 2 subscales evaluating activities of daily living (21 questions) and sports activities (8 questions). The outcome score collection was performed by two orthopaedic surgeons.

Through anterior drawer and varus stress radiographs using Telos equipment with the same loading force (150 N), the talar tilt angle and degree of anterior talar translation were independently measured by two orthopedic surgeons. The talar tilt angle was defined as the angle between the distal articular surface of the tibia and the proximal articular surface the talus on varus stress view. The anterior talar translation was defined as the shortest distance

between the posterior articular border of the distal tibia and the posterior articular surface of the talus on anterior drawer stress view. This was repeated three times and the measurements were averaged.

2.5. Medical expense analysis

Based on the electronic medical records, the medical expense related with surgical procedure was analysed. Total medical expense of each patient consisted of anesthesia fee, operation fee excluding the arthroscopic procedure, surgical device fee, and nursing fee including the use of fluoroscope. In addition, operation time excluding the arthroscopic procedure, hospitalization period after operation, and frequency of outpatient follow-up (up to 6 months postoperatively) were investigated.

2.6. Statistical analysis

SPSS program (version 20.0) was used and P values < 0.05 was considered statistically significant. All datas showed a normal distribution in Kolmogorov–Smirnov test. Statistical analysis was performed to compare the differences between before and after

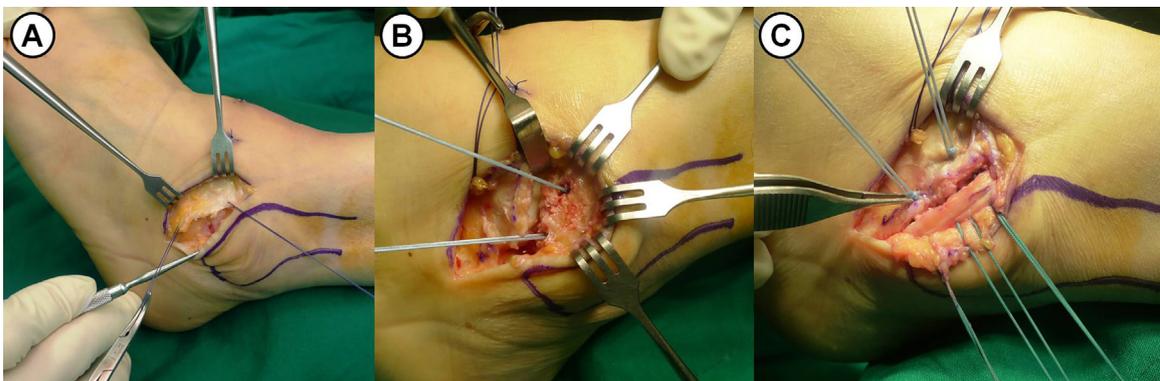


Fig. 3. Modified Broström repair using the suture anchors.

(A) Through a curved skin incision, the inferior extensor retinaculum was identified. (B) Two suture anchors were inserted at footprints of the ATF and CF ligaments in the lateral malleolus. (C) Lateral ligaments and articular capsule were reattached with suture anchors, and then residual tissue in the proximal part including fibular periosteum were imbricated to the articular capsule.

Table 1
Comparison of the clinical outcomes evaluated with the FAOS and FAAM (Mann–Whitney test).

	Prior to surgery			Final follow-up		
	Suture-tape ^a	Broström ^a	P-value	Suture-tape ^a	Broström ^a	P-value
FAOS^b						
Pain	81.6 ± 10.6	82.4 ± 10.1	0.883	92.8 ± 7.1	92.5 ± 7.7	0.944
Symptoms	79.4 ± 12.5	80.5 ± 11.9	0.785	94.2 ± 4.9	95.1 ± 4.2	0.795
ADL	70.2 ± 12.8	69.8 ± 11.3	0.938	93.1 ± 5.2	94.6 ± 4.9	0.551
Sports	46.8 ± 13.8	47.6 ± 14.4	0.878	85.8 ± 10.1	89.4 ± 9.8	0.082
QOL	69.4 ± 12.2	70.8 ± 11.8	0.612	93.8 ± 5.5	94.9 ± 4.7	0.834
Total scores	69.5 ± 12.4	70.2 ± 11.9	0.818	91.9 ± 6.7	93.3 ± 6.1	0.572
FAAM^b						
Daily activity	71.1 ± 12.1	70.3 ± 11.9	0.814	94.1 ± 4.9	95.2 ± 4.1	0.722
Sports activity	45.5 ± 15.2	44.1 ± 15.3	0.675	84.6 ± 9.8	89.1 ± 8.8	0.004
Total scores	58.3 ± 13.7	57.2 ± 13.6	0.768	89.4 ± 7.4	92.2 ± 6.5	0.154

FAOS = Foot and Ankle Outcome Score, FAAM = Foot and Ankle Ability Measure, ADL = activities of daily living, QOL = quality of life.

^a Mean ± standard deviation.

^b All datas are represented as scores changed on the basis of 100 points.

Table 2
Comparison of the ankle stability evaluated with stress radiographs (Mann–Whitney test).

	Talar tilt angle (°)			Anterior talar translation (mm)		
	Suture-tape ^a	Broström ^a	P-value	Suture-tape ^a	Broström ^a	P-value
Prior to surgery	13.6 ± 5.2	14.1 ± 5.4	0.792	12.8 ± 4.4	12.6 ± 4.2	0.961
Postoperative (3 months)	3.3 ± 1.9	2.8 ± 1.6	0.885	4.2 ± 2.3	3.8 ± 1.9	0.812
Postoperative (1 year)	4.5 ± 2.6	4.3 ± 2.5	0.958	4.7 ± 2.6	4.1 ± 2.1	0.596
Final follow-up	4.6 ± 2.6	3.9 ± 2.3	0.556	4.5 ± 2.3	4.2 ± 2.1	0.872

^a Mean ± standard deviation.

surgical treatment for the same individuals in both ST and MB groups (Wilcoxon signed-rank test), to compare the clinical outcomes between 2 groups (Mann–Whitney test).

3. Results

FAOS significantly improved at the final follow-up after operation in both ST and MB groups ($P < 0.001$). Through comparison of 5 subscales, there was no statistical difference in preoperative and postoperative FAOS between 2 groups ($P > 0.05$). FAAM scores significantly improved at the final follow-up in both ST and MB groups ($P < 0.001$). There was no statistical difference in preoperative and postoperative FAAM scores between the 2 groups. However, MB group showed a significant superiority on sports activity subscale at the final follow-up ($P = 0.004$) (Table 1).

Talar tilt angle and anterior talar translation significantly improved after operation in both ST and MB groups ($P < 0.001$), and were well maintained at the final follow-up as compared to the measurements at 3 months postoperatively ($P > 0.05$). There were no significant differences in preoperative and postoperative stress

radiographs between the 2 groups (Table 2). Preoperative side to side comparison in stress radiographs was significantly different in both groups, respectively ($P < 0.001$). This returned to within non-statistical differences in both groups at the final follow-up (Table 3).

Total medical expense related with operation was significantly higher (approximately 1.3 times) in ST group than MB group ($P < 0.001$). Operation time excluding the arthroscopic procedure was significantly shorter in ST group ($P = 0.003$). Nursing fee was significantly higher in ST group by the additional medical costs related to a use of fluoroscope. Hospitalization period and frequency of outpatient follow-up were similar between the 2 groups (Table 4).

As postoperative complications in ST group, there were 2 cases (7.1%) of recurrence of subjective and mechanical instability and 1 case (3.6%) of damage to the sural nerve. In MB group, there were 1 case (3.7%) of local wound infection, 1 case (3.7%) of recurrence of instability, and 1 case (3.7%) of damage to the superficial peroneal nerve. There was no significant difference in recurrence rate of instability between the 2 groups ($P = 0.385$). Conservative

Table 3
Side to side comparison of the ankle stability evaluated with stress radiographs (Mann–Whitney test).

	Talar tilt angle (°) ^a		Anterior talar translation (mm) ^a	
	Prior to surgery	Final follow-up	Prior to surgery	Final follow-up
Suture-tape augmentation				
Operative side	13.6 ± 5.2	4.6 ± 2.6	12.8 ± 4.4	4.5 ± 2.3
Contralateral side	2.9 ± 1.5	3.4 ± 1.9	4.1 ± 2.1	4.3 ± 2.2
P-value	<0.001	0.116	<0.001	0.915
Modified Broström repair				
Operative side	14.1 ± 5.4	3.9 ± 2.3	12.6 ± 4.2	4.2 ± 2.1
Contralateral side	3.2 ± 1.7	3.3 ± 1.8	4.5 ± 2.3	4.4 ± 2.2
P-value	<0.001	0.455	<0.001	0.879

^a Mean ± standard deviation.

Table 4
Comparison of the medical expense related with surgical procedures (Mann–Whitney test).

	Suture-tape augmentation ^a	Modified Broström repair ^a	P-value
Medical expense ^b			
Anesthesia fee (\$)	512.6 ± 43.5	516.3 ± 45.7	0.895
Operation fee (\$)	659.8 ± 36.2	661.4 ± 35.5	0.951
Surgical device fee (\$)	763.6 ± 40.3	412.5 ± 42.8	<0.001
Nursing fee (\$)	538.5 ± 52.6	316.2 ± 44.1	<0.001
Total fee (\$)	2474.5 ± 158.2	1906.4 ± 151.6	<0.001
Operation time (min)	24.6 ± 4.4	32.5 ± 4.8	0.003
Hospitalization period (days)	3.4 ± 0.6	3.6 ± 0.8	0.936
Frequency of outpatient F/U	4.2 ± 1.1	4.3 ± 1.1	0.988

F/U = follow-up, \$ = dollar.

^a Mean ± standard deviation.

^b The won-dollar exchange rate is calculated to 1000 won per dollar.

treatment including antibiotic therapy and wound management resulted in wound healing within 1 month. Damage to the sural and superficial peroneal nerves recovered spontaneously at 4–6 months after surgery. All patients with recurrence of instability refused a reoperation in spite of limitation in sports activities.

4. Discussion

Although the concept of using nonabsorbable suture-tape to augment the modified Broström repair for ruptured or attenuated lateral ankle ligaments has recently been developed, no prospective comparative studies with other minimally invasive techniques or modified Broström procedure are reported. The most important finding of the current study was that ATF and CF ligaments augmentation using suture-tape for chronic ankle instability in young female patients provided the intermediate-term clinical outcomes comparable to the modified Broström repair. However, a cost-effectiveness of suture-tape augmentation was revealed to be low despite the advantages of a minimal invasive technique.

There is still the question of whether a simple augmentation of the lateral ligaments ultimately results in biologic healing to original ligament tissue, not scar tissue. Also, few clinical report regarding the effect of biologic ligament healing on the postoperative clinical outcomes is available. Because there are limitations in histological examination through the second-look exploration or analysis based on follow-up MRI, it is difficult to conclude whether the healing to original ligament or scar tissue has any impact on the clinical outcomes. Even the modified Broström procedure known as the anatomic repair technique may result in scar tissue healing of lateral ligaments and satisfactory clinical outcomes through appropriate rehabilitation. Although there was no direct repair of ligaments in suture-tape augmentation procedure, the restoration of ankle stability might contribute to the healing process of attenuated ligaments, without iatrogenic injury to own ligament tissues.

Cost-effectiveness in comparison to conventional surgical techniques becomes a concern with the advent of new surgical devices [15]. Two surgical procedures in the current study showed statistically similar clinical outcomes measured by FAOS and FAAM score. The evaluation through stress radiographs showed also no significant differences in mechanical stability between the two procedures. The recurrence rate of postoperative ankle instability was also statistically similar. On the other hand, total medical expense related with operation was significantly higher in suture-tape augmentation group. A relatively low cost-effectiveness of this procedure in young female patients could not reflect variables such as a difference of postoperative pain in hospitalization period or esthetic satisfaction of scar, which were not assessed in the current study.

In regard of the mechanical ankle stability evaluated with stress radiographs, a mean talar tilt angle at the final follow-up was 4.6°

in ST group and 3.9° in MB group, respectively. These results were generally consistent with the radiological outcomes following other surgical techniques for lateral ligaments reconstruction. Yeo et al. [3] reported that a mean talar tilt angle was 3.9° at a minimum of 12 months follow-up after arthroscopic Broström procedure. Jung et al. [16] reported that a mean talar tilt angle was 3.8° at a mean of 22.1 months after ligament reconstruction using free tendon allograft. Solakoglu et al. [17] reported that a mean talar tilt angle was 3.5° at 6 months follow-up after anatomic tenodesis reconstruction using the peroneus tendon autograft.

Despite the discouraging complications (immunological response, debris dispersion leading to synovitis, and recurrent instability by mechanical failure) following the use of synthetic materials for ligament reconstruction, there has been a recent resurgence of interest in the artificial ligament. Many recent studies have reported successful results after anterior cruciate ligament reconstruction using an artificial ligament, with the development of new biomaterials [18,19]. In terms of suture-tape augmentation for ankle instability, one case of chronic inflammation by foreign body reaction has been reported [8]. In this study, there was no case of immunological complication associated with suture-tape at mean follow-up of 34.6 months.

The limitations of our study are as follows. First, this study has been performed in single cohort of patients. The satisfactory clinical results following suture-tape augmentation procedure can not be generalized to patients who are male, with high BMI, heavy laborers or high-demand athletes. Expansion of indications including more active and male patients will be addressed in further studies. Second, the pathway of suture-tape in our technique is not anatomical. With respect to the angle between two limbs of the suture tape, the anatomical angle between ATF and CF ligaments is well known to be approximately 120–130°. In our technique, the angle between two limbs of the suture tape was made to approximately 90–100° for technical convenience. A portal over the calcaneal body was made at close position to the peroneus tendons, because we should confirmed that the suture-tape was passed through beneath the peroneus tendons under a limited skin incision. The effect of above-mentioned difference on clinical outcomes and mechanical stability will be answered through further biomechanical studies. Third, there is a likelihood of misinterpretation in regard to cost-effectiveness results between the 2 surgical procedures. If the ST group was compared with the MB group using the bone tunnel technique (without a use of hardware), a difference in total medical expense related with operation might be greater than those of the current study.

5. Conclusions

The ATF and CF ligaments augmentation using suture-tape shows the intermediate-term clinical outcomes comparable to modified Broström repair in young female patients with chronic

ankle instability. Considering the significantly higher medical expense (approximately 1.3 times) than the modified Broström procedure, a cost-effectiveness of suture-tape augmentation appears to be low.

Conflict of interest

The authors have no conflict of interest to report and have received no financial support for the completion of this work.

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