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A New Individualized Three-Dimensional Printed Template for Lateral Ankle Ligament Reconstruction

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Data Collection B
Statistical Analysis C
Data Interpretation D
Manuscript Preparation E
Literature Search F
Funds Collection G

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Background: Anatomical reconstruction using a semitendinosus tendon autograft is one of the most widely-used techniques for chronic lateral ankle instability (CLAI), and it can result in good biomechanical recovery for patients. The purpose of this study was to investigate the outcome of a novel individualized three-dimensional printed guide template for lateral ankle ligament reconstruction compared with the traditional surgical methods.

Material/Methods: We retrospectively studied 34 patients with CLAI who required lateral ankle ligament reconstruction. Patients were randomly divided into 2 cohorts: the template group (18 patients) and the conventional group (16 patients). The average operation duration and number of radiation exposures were compared between the 2 cohorts. The displacement of anterior talar and talar tilt angle were recorded at the last follow-up, and Karlsson-Peterson score and American Orthopedic Foot and Ankle Society Score (AOFAS) were also compared.

Results: All patients had satisfactory ankle stability at the last follow-up. The average operation duration was 51.9±3.6 min and the average number of radiation exposures was 1.34±0.6 in the template group, and the average operation duration was 72.4±12.6 min and the average number of radiation exposures was 6.58±1.7 in the conventional group. Difference between the 2 cohorts was statistically significant. However, in AOFAS (95.2±2.5 *vs.* 94.9±2.2; P>0.01.) and Karlsson Score (94.7±3.6 *vs.* 93.8±4.1; P>0.01.), no significant differences were found between the 2 cohorts.

Conclusions: Both the template technique and the conventional method provided satisfactory outcomes for CLAI patients. However, the shorter operation duration and low number of radiation exposures in the template cohort suggest it is the better alternative for treatment of CLAI.

MeSH Keywords: **Individualized Medicine • Joint Instability • Lateral Ligament, Ankle**

Abbreviations: **CLAI** – chronic lateral ankle instability; **LCL** – lateral collateral ligaments; **AOFAS** – American Orthopedic Foot and Ankle Society; **ATFL** – anterior talofibular ligament; **CFL** – calcaneofibular ligament; **ES** – establishment of channels

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Background

Ankle sprain is one of the most common sports injuries. The incidence of ankle sprain can be as high as 20% out of all sports-related injuries [1]. Although most ankle sprains respond well to conservative measures with rehabilitation training and physical therapies, the incidence of chronic ankle instability after acute ankle sprains is 20–40% [2]. Although certain improvements in ankle function can be achieved using conservative methods, it is difficult to avoid lateral collateral ligament (LCL) reconstruction due to persistent ankle pain and instability [3].

The aim of surgical treatments is to provide ligament repair or reconstruction. Although the lateral ligament can be repaired in most cases, ligament reconstruction is needed in certain conditions, such as when the ligament cannot be repaired or needs to be strengthened, when the Brostrom-Gould repair fails, and when the ankle is under abnormal pressure. Ligament reconstruction consists of anatomical and non-anatomical reconstructions. Non-anatomical reconstruction, such as Chrisman-Snook [4], Evans [5], and related modified procedures, involve a certain degree of donor-area injury. For example, the valgus strength is reduced due to the loss of fibular tendon function and the effect of some surgical methods on the subtalar joint. Furthermore, long-term outcomes of non-anatomical reconstruction of the LCL show an increased risk of regression in the hindfoot; therefore, non-anatomical reconstruction should be avoided [6].

The use of semitendinosus autograft for LCL reconstruction had been demonstrated to produce satisfactory results for CLAI [7]. It is well-established that the anterior talofibular ligament (ATFL) is involved in about 80% of ankle sprains, and the calcaneofibular ligament (CFL) is involved in about 20%, while the posterior talofibular ligament is seldom involved [8]. Therefore, reconstructing the attachments of the ATFL and CFL at the fibula is vital for LCL reconstruction surgery. Anatomical reconstruction of the tendon requires precise placement and tension, and failure to do so can change the biomechanics of the joint, leading to changes in joint load. Currently available fixation methods include anchor, fibula double-channel, and fibula single-channel [9,10]. Due to the small contact area between the fibula and anchored tendon, tendon-bone healing and firm fixation are difficult to achieve, and the incidence of recurrence of ankle instability is high. In the double-channel fixation method, the operation area is limited and the operation inaccuracy is high because to the 2 parallel channels are drilled in the distal fibula. Recently, use of a digital drilling navigation template has attracted increasing interests from clinicians. A double-channel distal fibula and the more personalized and accurate operation scheme and optimization can be obtained through using a digital navigation template.

The purpose of this study was to investigate the outcome of a novel individualized three-dimensional printed guide template for lateral ankle ligament reconstruction compared with the traditional surgical methods.

Material and Methods

Patients

We retrospectively studied 34 patients who received LCL anatomical reconstruction for lateral ankle instability using semitendinosus tendon autograft in our hospital (Wuhan Puai Hospital). The patient information is shown in Table 1.

Establishment of channels (ES) using a 3D printed template was performed in the template group (18 cases, 11 female and 7 male, average age 26.5±7.3 years, age range 18–45 years). The traditional intraoperative fluoroscopy-guided method of ES was performed in the conventional group (16 cases, 9 female and 7 male, average 23.6±5.1 years, age range 19–42 years).

The inclusion criteria were: (1) history of recurrent ankle sprain, chronic pain or tenderness of the lateral ankle, or manifestation of "bent soft leg"; history of CLAI >6 months, conservative

Table 1. Demographic data of the patients.

	Template group (n=18)	Conventional group (n=16)	P value
Sex	Male 7, Female 11	Male 7, Female 9	0.726
Age (years)	18–45 (average 26.5)	19–42 (average 23.6)	0.728
Mean weight (SD) (kg)	70.5 (SD, 5.2)	71.2 (SD, 6.1)	0.561
Mean height (SD) (cm)	169.3 (SD, 7.4)	171.5 (SD, 9.2)	0.385
Classification of CAI	Level II 10, Level III 8	Level II 8, Level III 8	0.946

P value <0.05 considered statistically significant. Classification of CAI (American Medical Association, AMA): Level I ligament overstretching; Level II partial ligament tear; Level III complete ligament tear. SD – standard deviation. Values are presented as the mean±standard deviation, unless otherwise indicated.

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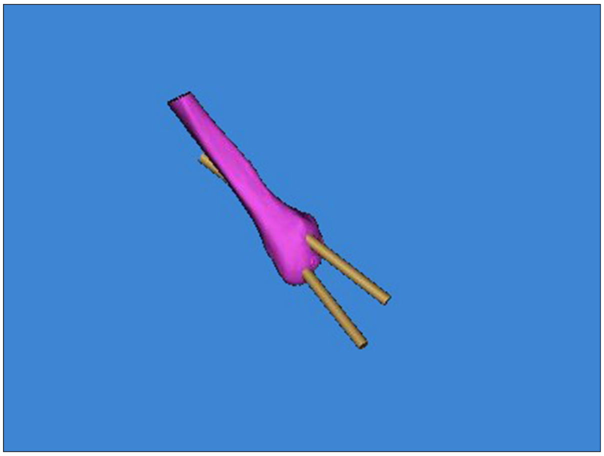

Figure 1. The design of the virtual display of the planned double-fibular channels trajectory. Purple represents the fibula. Yellow represents the guide channel.

treatment is ineffective, and positive results on MRI; (2) multiple ligamentous laxities; (3) obesity, weight >100 kg; and (4) a previous simple lateral ligament repair operation failed.

The exclusion criteria were: (1) local infection or fracture of ankle joint; (2) ankle arthritis, anterior malleolus impingement, subtalar arthritis, or medial collateral ligament injury of the ankle; (3) surgical contraindications; (4) local soft tissue condition is poor or accompanied by skin redness or sinus formation; and (5) undergoing bilateral surgery at the same time.

Template design and printing

From February 2013 to November 2018, 18 patients' (Template group) ankle joint X-ray and CT data were collected by using the image archiving database and transmission system of our hospital, and data were output in the form of recording DVD disc. The data was imported into mimics l6.0 software in DICOM format and the 3D model was reconstructed with the best mode. The data were output and saved in STL format. The anterior inferior and posterior superior fibula bone channels were based on the ATFL and CTF footprints on the distal fibula (Figure 1). Unigraphics NX 5.0 software was used to design the STL file of the 2-pin guide channels according to the relevant measurement data and angles (Figure 2). The guide template was made by the photocurable forming method, with the photosensitive resin material cured layer-by-layer with a laser. The template was 2 mm thick, and guide holes were made in the hollow cylinder (8 mm long, 2.0 mm inner diameter; 3 mm outer diameter). The solid model of the ankle joint was printed by 3D printing technology before surgery. Drilling was conducted under the guidance of the guide plate to observe whether the guide needle was consistent with the designed insertion orientation and to verify the accuracy of the design. Plasma sterilization of the guide plate was performed before surgery.

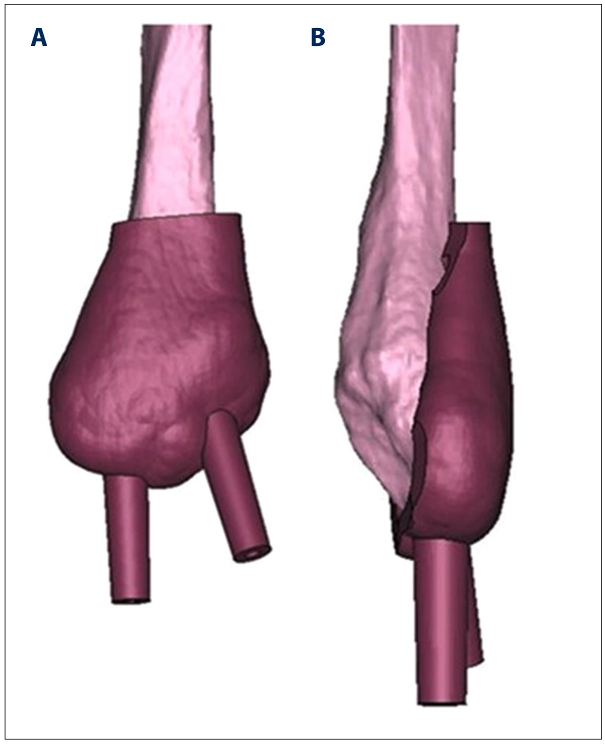

Figure 2. The design of the virtual patient-specific template fits the fibula perfectly. (**A**) Posterior view; (**B**) lateral view. Each patient had the individualized-shape template to fix on the fibula surface.

Surgical technique and postoperative management

All the patients were treated by the same 2 senior surgeons. The patient was placed in the lateral position, and the operation was performed under epidural anesthesia. After anesthesia, the anteroposterior drawer test and varus stress test were performed again on the operating table to further confirm the diagnosis. After harvesting the semitendinosus tendon, an arc incision was made at the lateral malleolus, turning forward to the sinus tarsi. First, the fibula was exposed by excising part of the fibula fascia tissue to further expose the fibula tendon and fibula rear. Then, the calcaneofibular ligament, anterior talofibular ligament, and their origin points at the calcaneus and talus were fully exposed. The positioning and navigation template were attached to the outer side of the distal fibula, and were slid forward and down to the clamping stop to make the guide plate fit the bone surface (Figure 3). According to the design, two 2.0-mm Kirschner needles were used to drill into the bone successively along the positioning hole of the positioning guide plate.

The guide plate was removed and the bone channels were enlarged with an Arthrex supporting reamer so that the diameter of bone channels basically matched with the transplanted tendon. At the ATFL talus stop point, the entire tract was drilled.

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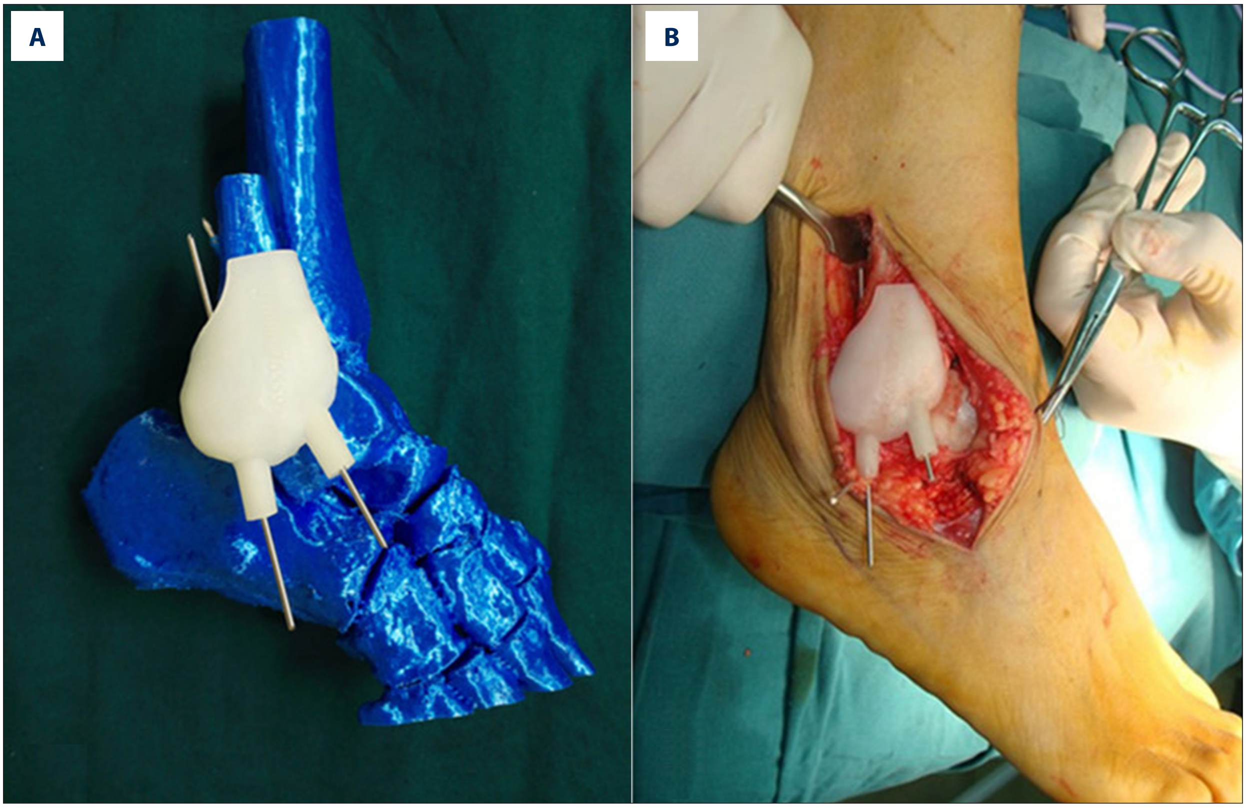

Figure 3. Images showing reconstruction of LCL using an individualized template. (**A**) Simulation operation before surgery; (**B**) practical operation during surgery. The K-wire was inserted in the guide channels.

The tendon ends were sutured with a suture line and inserted into the talus channel with the fixation of the interference screw. The other end of the bone tendon was knitted and sutured, and the tendon was inserted through the fibula channel through the ATFL origin and the posterior proximal exit of the fibula. Entering the front side of the other channel, the tendon exited from the attachment site of the CFL at the fibula. Finally, the tendon was passed through the calcaneal canal. Placing the foot in a neutral position and slightly rotated outwards, we pulled the traction line through the skin from the medial side of the calcaneus and tightened the inserted tendon. Then, a second interference screw was placed into the calcaneus. The lateral fibula tendon was sutured to the periosteum to prevent sliding. The wound was sutured layer-by-layer after rinsing. The ankle was held in place with plaster support of 90° dorsal flexion and 10° eversion (Figure 4).

For the conventional group, the operation was the same as for the template group before inserting the Kirschner wire. After the surgical area was exposed, 2 K wires were inserted and adjusted to the appropriate position at the distal fibula under the guidance of C-arm fluoroscopy. The rest of the steps were the same as above (Figure 5).

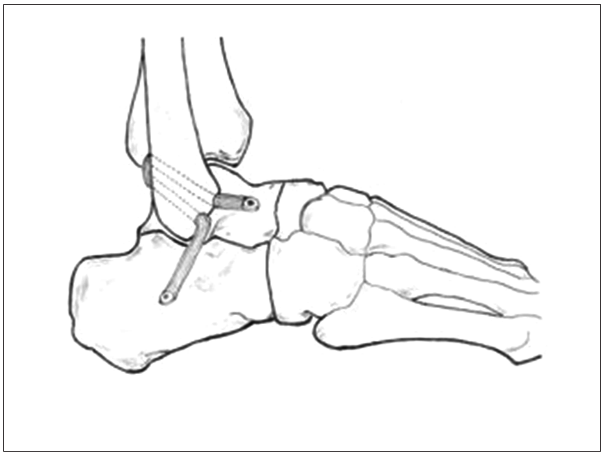

Figure 4. A diagram of reconstruction of LCL by creating double-fibula channels. The ends of the transferred tendon were fixed at the talus and calcaneus, respectively.

Routine prophylactic antibiotics were used for 3 days. After 2 weeks of non-weight-bearing gypsum, the weight-bearing was gradually increased. Protective walking boots were used for 4 weeks. Rehabilitation began 4 weeks after surgery. The ankle joint activity and the strength/varus resistance training of the tibia were gradually increased. Walking, jumping, and running started 8 weeks after surgery. The ankle brace was used

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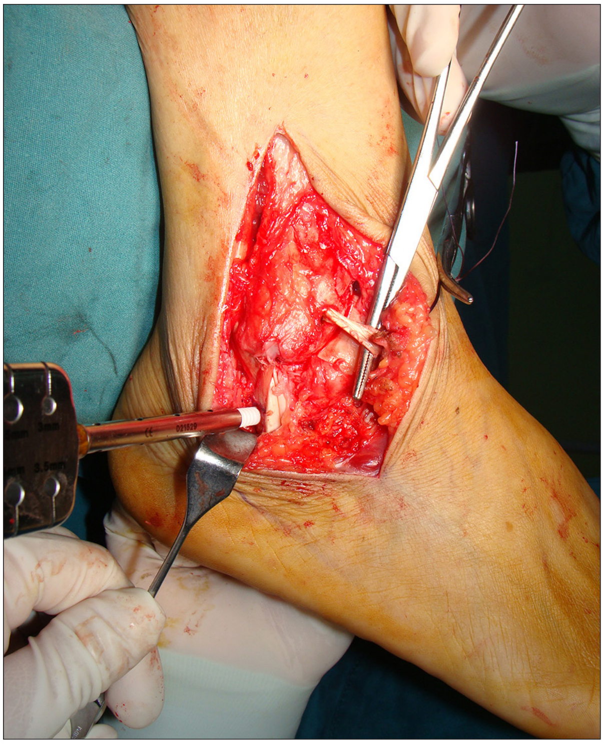

Figure 5. Image showing reconstruction of LCL using conventional methods.

intermittently to maintain daily activities until 3 months after surgery.

Statistical analysis

IBM SPSS Statistical software (version 22, IBM, Somers, NY, USA) was used for the statistical analysis. The mean±standard deviation (SD) was used for continuous variables and numbers were used for categorical measures. We performed the independent-samples *t* test to compare data between the template and conventional groups. P<0.05 was considered as a statistically significant difference.

Results

In total, 68 interference screws were implanted in 34 cases: 36 screws in the template group (18 patients) and 32 screws in the conventional group (16 patients). The average operation time was 51.9±3.6 min and the average number of radiation exposures was 1.34±0.6 in the template group. The average operation time was 72.4±12.6 min and the average number of radiation exposures was 6.58±1.7 in the conventional group (P<0.05). The average duration of follow-up was 23±3.6 months in the template group and 25±2.8 months in the conventional group. The difference was statistically significant. This study found no significant difference in AOFAS (95.2±2.5 *vs.* 94.9±2.2; P>0.05.) or Karlsson Score (94.7±3.6 *vs.* 93.8±4.1; P>0.05.) between the template group and the conventional group. There were also no significant differences of the anterior talar displacement and the talar tilt angle (Table 2).

Discussion

Although conservative treatments of CLAI usually provide good outcomes for patients, the curative efficacy of these methods is incomplete, as when the ligament is not completely healed, and when the soft tissue becomes fragile due to repeated sprains. Therefore, surgical treatments provide better alternatives for this condition. In 1992, Colville et al. [11] proposed establishing bone tunnels to reconstruct the lateral collateral ligament of the ankle joint (ATFL and CFL) and performed a comparative biomechanical study with non-anatomical reconstruction methods. They found that the anatomical reconstruction can effectively resist the anteversion, entropion, and inclination of talus without affecting the subtalar joint. Similarly, numerous studies [12–15] reported that the anatomical reconstruction of CLAI is superior to non-anatomical reconstruction. Therefore, we proposed a new individualized three-dimensional printed template for anatomical reconstruction of the LCL, and satisfactory postoperative outcomes were achieved.

Table 2. Comparison between the 2 groups.

	Template group	Conventional group	P value
Operation time (min)	51.9±3.6	72.4 ± 12.6	<0.01
Exposure intraoperative (times)	1.34±0.6	6.58±1.7	<0.01
AOFAS score	95.2±2.5	94.9±2.2	NS
Karlesson-Peterson score	94.7±3.6	93.8±4.1	NS
Anterior drawer (stress radiography) (mm)	1.9±0.8	2.1±0.5	NS
Talar tilt test (stress radiography) (degrees)	3.2±0.6	3.4±0.7	NS

P value <0.05 considered statistically significant. NS – not significant, AOFAS – American Orthopedic Foot and Ankle Society.

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If there is no accurate design or method for anatomical reconstruction, the procedure can cause deviation of bone channels or iatrogenic fracture of the distal fibula, which can lead to inaccurate positioning or failure of tendon fixation, prolonging the operation time and increasing the difficulty of the operation. Since the starting point positions of the 2 channels are different, individualized measurement and design are required [16]. According to the above requirements, our novel method perfectly meets these demands and we achieved satisfactory outcomes. The functional and radiographic outcomes assessed at the final follow-up were similar between the template group and the conventional group. However, the operation time and number of radiation exposures in the template group were significantly less than in the conventional group. Guide wires were inserted and adjusted to the appropriate position at the distal fibula under the guidance of C-arm fluoroscopy. Therefore, the operation time and number of radiation exposures were longer in the conventional method. Some imaging techniques, such as multidimensional fluoroscopy and computer-assisted navigation, are used to assist in the placement of guide wires. Our method is different from these techniques in that we designed the guide plate preoperatively to reduce the operation time and the number of radiation exposures.

Radiation exposure is a significant concern in establishing the bone channel. Excessive radiation exposure can cause hair loss, muscle weakness, and even cancer [17]. Computer-assisted navigation allows the surgeon to leave the operating room during image capturing, reducing radiation exposure of the surgeon. However, our individualized template can reduce the operation time needed to implant the guide wires. As a result, compared with conventional methods, the radiation exposure of both the surgeon and the patient is much shorter.

The purpose of our study was to assess the effectiveness and feasibility of an image-based personalized template for the repair of LCL compared with the conventional method. This template design is a relatively simple solution, providing accurate, safe, and rapid implementation of the fibula drilling operation. In clinical practice, because there is no muscle attachment at the distal end of the lateral malleolus and the bone surface is irregular, placement of the guide wire is difficult. In this study, all our templates were easily and safely fixed in the appropriate position without damaging the bone surface, and facilitated the guide wire insertion very well. The initial use of ligament reconstruction is conducive to shortening the learning curve and the subsequent use of percutaneous or full microscopic ligament reconstruction [18,19]. The indications for use of this technique are: (1) history of CLAI >6 months; (2) conservative treatment was ineffective; (3) MRI images show positive results; (4) CAI Level II and level III.

Our study has certain shortcomings. Firstly, the guide plate design was based on the CT data and related skeletal reference points to design the starting point of ATFL and CFL. If the design can be based on the combination of CT and MRI, it will be more conducive to the precise positioning of the starting point of the ligament. In addition, the guide plate requires a larger incision. Last but not the least, the number of included cases was relatively small and the duration of follow-up was relatively short. Further studies with more patients and longer follow-up are needed.

Conclusions

We found that both the template technique and the conventional method can provide satisfactory outcomes for CLAI patients. However, the shorter operation duration and fewer radiation exposures in the template cohort suggest it is a better alternative for the treatment of CLAI.

Conflict of interest

None.

References:

1. Gerber JP, Williams GN, Scoville CR et al: Persistent disability associated with ankle sprains: A prospective examination of an athletic population. Foot Ankle Int, 1998; 19(10): 653–60
2. Sammarco VJ: Complications of lateral ankle ligament reconstruction. Clin Orthop Relat Res, 2001; 391: 123–32
3. Al-Mohrej OA, Al-Kenani NS: Chronic ankle instability: Current perspectives. Avicenna J Med, 2016; 6(4): 103–8
4. Chrisman OD, Snook GA: Reconstruction of lateral ligament tears of the ankle. An experimental study and clinical evaluation of seven patients treated by a new modification of the Elmslie procedure. J Bone Joint Surg Am, 1969; 51(5): 904–12
5. Evans DL: Recurrent instability of the ankle: A method of surgical treatment. Proc R Soc Med, 1953; 46(5): 343–44
6. Guillo S, Bauer T, Lee JW et al: Consensus in chronic ankle instability: Aetiology, assessment, surgical indications and place for arthroscopy. Orthop Traumatol Surg Res, 2013; 99(8 Suppl.): S411–19
7. Song B, Li C, Chen N et al: All-arthroscopic anatomical reconstruction of anterior talofibular ligament using semitendinosus autografts. Int Orthop, 2017; 41(5): 975–82
8. Brostrom L: Sprained ankles. V. Treatment and prognosis in recent ligament ruptures. Acta Chir Scand, 1966; 132(5): 537–50
9. Hua Y, Chen S, Jin Y et al: Anatomical reconstruction of the lateral ligaments of the ankle with semitendinosus allograft. Int Orthop, 2012; 36(10): 2027–31
10. Ahn JH, Choy WS, Kim HY: Reconstruction of the lateral ankle ligament with a long extensor tendon graft of the fourth toe. Am J Sports Med, 2011; 39(3): 637–44
11. Colville MR: Reconstruction of the lateral ankle ligaments. Instr Course Lect, 1995; 44: 341–48
12. Boyer DS, Younger AS: Anatomical reconstruction of the lateral ligament complex of the ankle using a gracilis autograft. Foot Ankle Clin, 2006; 11(3): 585–95

13. Krips R, van Dijk CN, Halasi T et al: Anatomical reconstruction versus tenodesis for the treatment of chronic anterolateral instability of the ankle joint: A 2- to 10-year follow-up, multicenter study. Knee Surg Sports Traumatol Arthrosc, 2000; 8(3): 173–79
14. Song B, Li C, Chen N et al: Allarthroscopic anatomical reconstruction of anterior talofibular ligament using semitendinosus autografts. Int Orthop, 2017; 41(5): 975–82
15. Vuurberg G, Pereira H, Blankevoort L et al: Anatomical stabilization techniques provide superior results in terms of functional outcome in patients suffering from chronic ankle instability compared to nonanatomical techniques. Knee Surg Sports Traumatol Arthrosc, 2018; 26(7): 2183–95
16. Sha Y, Wang H, Ding J et al: A novel patient-specific navigational template for anatomical reconstruction of the lateral ankle ligaments. Int Orthop, 2016; 40(1): 59–64
17. Mastrangelo G, Fedeli U, Fadda E et al: Increased cancer risk among surgeons in an orthopaedic hospital. Occup Med, 2005; 55(6): 498–500
18. Song B, Li C, Chen N et al: All-arthroscopic anatomical reconstruction of anterior talofibular ligament using semitendinosus autografts. Int Orthop, 2017; 41(5): 975–82
19. Glazebrook M, Eid M, Alhadhoud M et al: Percutaneous ankle reconstruction of lateral ligaments. Foot Ankle Clin, 2018; 23(4): 581–92

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