Application of an arched, Ni-Ti shape-memory connector in repairing distal tibiofibular syndesmosis ligament injury

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Abstract

Objective

To investigate the clinical effect of internal fixation of a Ni-Ti arched shape-memory connector in the treatment of distal tibiofibular syndesmosis ligament injury.

Methods

From January 2013 to January 2016, 108 cases of ankle fracture with distal tibiofibular syndesmosis ligament injury in our hospital were selected, and all of them were fixed with Ni-Ti Arched shape-memory connector or screw fixation. The functional evaluation and efficacy evaluation were performed according to the Olerud Molander Ankle Score (Omas) and SF-36. At the same time, follow-ups recorded the incidence of postoperative complications: osteoarthritis, superficial infection, symptomatic hard and soft tissue irritation, early removal and poor reduction of internal fixation, and later loss of reduction.

Results

In the ASC group, the incidence of symptomatic hardware, soft tissue or superficial infection decreased to 2.77%. The early removal rate of internal fixation was also lower than that of the screw group. Compared to 2.77%, the incidence of osteoarthritis in the later follow-up was also as low as 1.38%. Loss of fracture reduction due to removal of the fixation device for the distal tibiofibular syndesmosis ligament was not observed in the ASC group. With two postoperative scoring systems (OMAS and SF-36), patients in the ASC group were also given higher scores.

Conclusion

The design of the arched, Ni-Ti d shape-memory connector can be adapted to the irregular anatomical structure of the malleolus and the ability to continue to contract through a thermostat. The use of ASCs in fixation of articular ligaments can preserve a slight range of motion, and the results suggest that ASCs can effectively reduce the incidence of fixation looseness, fracture, infection and other complications.

Introduction

Ankle injuries usually involve ligaments related to the tibia and fibula, of which the joint ligament of the inferior tibia and fibula is the more difficult to detect. These ligaments are named the anterior-distal tibiofibular syndesmosis ligament (AITF), posterior-distal tibiofibular syndesmosis ligament, inferior transverse tibiofibular syndesmosis ligament and interosseous ligament. These ligaments ensure stability and relative movement between the tibia and fibula. This group of ligaments also helps the tibia and fibula sustain the weight of the body and are key ligaments in the ankle joint.[1]

The inferior tibifibular ligament is strained during external pronation and hyperdorsiflexion of the ankle and is therefore often associated with pronation and supination ankle fractures.[2.3] Syndesmosis

injuries occur in 10% of ankle fractures and in approximately 20% of ankle fractures requiring internal fixation. Anterior tibiofibular syndesmosis ligament and interosseous membranes will fracture if ankle injury is serious enough.[4] Severe ligament injuries and tears can lead to subluxation of the distal tibiofibular joint, widening of the ankle point, and loss of normal correspondence of the tibiotalar joint. Without reduction and proper fixation, ankle instability, residual pain, and an increased incidence of traumatic arthritis can occur.

In summary, a robust and reliable internal fixation device for unstable ankle fractures is effective in reducing traumatic osteoarthritis and improving later functional outcomes.[5] Currently, there are a variety of fixation devices for the distal tibiofibular joint, and the most widely used is the distal tibiofibular screw attached to the lateral fibular plate. However, fracture of the tibiofibular screw is frequently reported in the literature [6] and forced routine removal of the screw causes wound infection and other complications in approximately 9.2% of patients [7]. Only some of the literature supports early and complete removal of distal tibiofibular fixation as being able to reduce the incidence of complications[8]. Another form of treatment is the suture button system, also known as tightrope, which repairs the tibiofibular joint while giving the joints proper mobility. Buttons, however, are located below the surface of the skin and have been reported to have a higher incidence of skin irritation and infection. Loosening of the fixation cord between the buttons, causing the joint fixation device to lose its fixation effect, is also a common complication[9]. In addition to the above two internal fixation devices, syndesmosis elastic hook and absorbable micro internal fixation methods are used for the treatment of inferior tibiofibular syndesmosis ligament injury.

Over the past several decades, arched Ni-Ti shape-memory connectors have been widely fabricated and applied in various clinical fields, including orthopaedic, stomatological, urological, and cardiovascular fields, due to their excellent properties of wear and corrosion resistance, good biocompatibility, and shape memory effects.[10–17] Therefore, by learning from the Ni-Ti arched shape-memory connector (ASC) used in other fractures[18.19], we attempted to fix the position of the distal tibiofibular bone to repair the ligament injury of the distal tibiofibular joint. To evaluate the feasibility and efficacy of this treatment, we conducted the following retrospective analysis.

Materials And Methods

Retrospective analysis was conducted on patients with ankle fracture complicated with distal tibiofibular syndesmosis ligament injury in our hospital from 2013 to 2016. Through X-ray and CT scans, compression tests, external rotation stress tests, and intraoperative Cotton tests, the patient was diagnosed with a fracture of the ankle joint with an injury to the inferior tibiofibular syndesmosis ligament. Such patients were collected and analysed, and the sample cases that did not conform to the retrospective study were deleted according to the following exclusion criteria: ①pathological osteoporosis; ②severe infection; ③receiving long-term hormone therapy. After clean-up, 108 patients were included. There were 59 males and 49 females, aged 20-76 years old. Causes of injury included 53 cases of traffic accidents, 36 cases of sports sprain and 9 cases of fall injuries. Other detailed clinical data are listed in

Table 1. A total of 108 patients were divided into screw or ASC groups according to different surgical methods(72 patients in SCREW group while 36 patients in ACS group).According to the Lauge-Hansen classification, among the 108 patients in the whole group, there were 62 cases of pronation abduction classification, and 46 cases of supination external rotation classification. The mean follow-up time from surgery was 42 ± 11 months.

All methods were carried out in accordance with regulations or declaration of Helsinki.

Surgical procedure

A total of 108 cases of ankle joint fractures and lower tibiofibular syndesmosis ligament injuries underwent open reduction and internal fixation under the guidance of two professors in our department. The difference is that the screw group implemented traditional screw fixation of the lower tibiofibular joint, while the ASC group implemented ASC fixation. Here, we describe in detail the reduction and fixation of the distal tibiofibular syndesmosis ligament in patients with ASC. After standard methods of reduction of the fibular and tibial fractures were performed, the distal tibiofibular joint was reduced under direct visualization of the syndesmosis and held at its anatomical position by periarticular reduction forceps. The ankle joint was positioned at an angle of 90° between the tibial shaft and the foot during syndesmosis reduction and fixation. Two holes with diameters of 1.5 to 2.0 mm(According to the size of the ACS spike teeth) were drilled bilaterally on the fibula and tibia. Then, the Ni-Ti arched shape-memory connector (ASC) was placed in cold ($0-4^\circ\text{C}$) water to allow plastic deformation of the Ni-Ti alloy. The claws were unfolded. Appropriate sized ASCs were implanted in the holes. Warm water (40°C) was applied for irrigation and compression. The memory alloy creates a continuous fixation force triggered by body temperature. Then, a fluoroscopic stress test was used to confirm the syndesmotic reduction. (Figure 1)

Postoperatively, the affected limb was elevated for 3 days. For most patients, gradual full-range mobilization without weight bearing was recommended as soon as possible under the supervision of a qualified physiotherapist, and patients were encouraged to perform progressive active exercises. Partial or full weight bearing was allowed between three and four weeks after surgery, depending on patient tolerance and fracture stability. Follow-up was obtained at 1, 3, 6, and 12 months after surgery and yearly thereafter. Plain anteroposterior (AP) and lateral radiographs were obtained at each visit. All changes in the position of the implant and reduction, fixation failures and removal or complications were recorded. At the latest follow-up, functional outcomes were assessed by one of the authors using the Olerud Molander Ankle Score (OMAS) [20,21]. The Medical Outcomes Study 36-item short-form health survey (MOS SF-36) questionnaire was chosen to assess the effect of ankle fractures and lesions on health-related quality of life.

Results

No patients were lost to follow-up. The mean follow-up time from surgery was 42 ± 11 months. SPSS software was used to analyse the basic clinical information of patients in the two groups, and we confirmed that there was no statistically significant difference in the basic clinical information, such as sex, age, BMI and other indicators, between the two groups.

During our follow-up, we had only one case of osteoarthritis in the ASC group, while in the screw group, we found 5 (13.6%) patients with delayed osteoarthritis, and the data were statistically significant. Similarly, with regard to the early removal of the tibiofibular joint internal fixation device, the early removal of the tibiofibular screw was a routine operation in our surgery group, so in the screw group, the tibiofibular joint internal fixation was removed for approximately one month. The device removal rate was 100%, while in the ASC group, the early removal rate was only 2.7% (2 cases), which greatly reduced the number of operations and costs for patients. The application of ASC was small and located on the surface of the bone, so there was no need to worry about the problem that the fractured ACS cannot be removed. At the same time, in the follow-up of complications in the ASC group, we found that the incidence of symptomatic hardware and soft tissue irritation was only 2.7% and the occurrence of superficial infection was the same, and the incidence of related complications in the SCREW group was 13.8% and 11.1%, respectively. We performed AP assessment for the joint reduction of patients more than one month after the operation and half a year later. We found that the probability of poor reduction and loss of reduction in the screw group was 13.8% and 11.1%, respectively, while in the ASC group, we found only one patient with symptoms of loss of reduction. Statistical analysis of the data are included in Table 1.

Table 1
Clinical basis and prognosis-related data analysis

	ACS	Screw	P value
Age			
< 65	41	22	0.836
>=65	31	14	
gender			
Male	36	23	0.245
Female	36	13	
	25	11	
	15	8	
	12	5	
	2	2	
BMI			
Average ± Standard Deviation	22.786 ± 3.1838	22.158 ± 3.3381	0.334
lauge-hansen type			
pronation abduction	44	18	0.371
suppination external rotation	28	18	
osteoarthritis			
None	71	31	0.026
Exist	1	5	
Early removal			
None	70	0	0.000
Exist	2	36	
symptomatic hardware and soft tissue irritation			
None	70	27	0.026
Exist	1	5	
Superficial infection			
None	70	30	0.075
Exist			

	ACS	Screw	P value
	1	4	
Malreduction			
None	72	31	0.026
Exist	1	5	
Loss of reduction			
None	72	32	0.019
Exist	0	4	

To better understand the patient's prognosis and experience, we used the SF-36 and scoring rules for OMAS statistical prognosis. In both scoring systems, we found that patients in the ASC group gave a better score. (Table 2)

Table 2
Data analysis of OMAS and SF-36 scores

Parameter	Operation method	number of cases	Average	Standard Deviation	P value
OMAS	ACS	72	85.51	6.606	0.012
	Screw	36	81.97	7.229	
SF-36	ACS	72	85.21	6.068	0.000
	Screw	36	79.72	5.273	

In the group of patients divided by surgical intervention, we selected two patients, and after signing informed consent, pre- and postoperative X-ray fluoroscopy results were used to show the practical effect and prognosis of the two surgical methods (Fig. 2 for ASC and Fig. 3 for SCREW fixation).

Discussion

With our understanding of ankle joint fractures combined with lower tibiofibular syndesmosis ligament injuries, there is no doubt about the necessity of timely and effective stabilization of the lower tibiofibular joint[22]. Early fixation can effectively increase the stability of the joint and avoid the delayed occurrence of complications such as osteoarthritis. Fixtures emerging at the same time treating the tibiofibular joint are also feedback for our researchers as first-hand clinical data, including the advantages and the problems they present.

Solid and stable lag screws can effectively recover from the tibiofibular joint and syndesmosis ligament repair. According to the surgeon's habits, after resetting the tibiofibular joint, 3 or 4 layers of cortical bone can be selected to achieve the maximum fixation effect. [23.24] However, the problems exposed by this fixed method are similar to a chain reaction. Early patients reported cases of lag screw fracture (3 cases) and loose screw fracture (13 cases) [6]. While people are still studying whether penetrating several layers of the cortex, inserting a few screws, or leaving broken screws in the body affects the prognosis of patients [25.26], more scholars believe that an intact, solid screw limits the slight displacement between the tibiofibular bones, which is the culprit for many complications of the distal tibiofibular syndesmosis ligament group [27]. The routine removal of the tibiofibular lag screw in the rest of one month has become the choice of many fracture professors. This should be followed by a second heavy chain reaction born. A second operation for implant removal could lead to potential infections, an increased cost to the patient, missed work days, or other complications[28.29]. Moreover, a small prospective trial suggested that the screw fixation method resulted in malreduction and loss of reduction[30]. Beumer et al. showed that syndesmosis screw fixation did not prevent syndesmosis separation under normal weight bearing.[31] Therefore, the separation of syndesmosis is sometimes inevitable after the screw is removed. Traditional X-ray and intraoperative fluoroscopy are not accurate in assessing the reduction of tibiofibular syndesmosis ligament injury, especially in determining whether the fibula is externally rotated.

ASC is widely used in other medical disciplines and provides inspiration [10–17]. It is a solid and reliable rigid fixation screw that can replace a fixed distal tibiofibular joint in new ways. The results of long-term follow-up and early distal tibiofibular joint fixation show that the removal rate of the device is 1.38% (100% for screws). Of the two patients in the group who had the internal fixation device removed early, one patient strongly requested early removal of the internal fixation device because of his own wishes. Another patient developed local hard object irritation, and the implant had to be removed after the patient's reduction and recovery was assessed. As mentioned above, the existence of the broken screw in the body in the report does not affect the prognosis of the patients.[8] However, broken screws cannot be easily removed, which causes inner anxiety. The investigators found that four patients had ruptured the ASC fixator during follow-up, and superficial fixation enabled the operator to completely remove the ASC device without difficulty. In addition, in the postoperative imaging examination and evaluation of the patient, no malreduction was found until the end of the follow-up. Only one patient had osteoarthritis symptoms in the late follow-up.

Currently, a suture button system as a device-fixed distal tibiofibular joint has been in use for several years by fixing the nonrigid limit under significant activity tibiofibular syndesmosis ligaments and repairing tibiofibular syndesmosis ligaments. [32]

The application of this system reduces the risk of poor joint reduction [5]. In terms of its later functional score, compared with patients in the screw group, patients in the suture button system group had a higher OMAS score, a lower VAS pain score, and a stronger VAS function [33–36]. Allowing the physiological range of movement of the lower tibiofibular joint can theoretically avoid the removal of the internal fixation device and reduce the incidence of adverse events such as damage to the fixation device and

loss of reduction after early removal. Even though the TightRope system was initially presented as a device that did not need removal, the rate of implant removal might be as high as 25%. In the current review it was 10% on average. Several authors have already made suggestions to lower the rate of implant irritation and subsequent removal[37–39]. In addition, the main material of the suture button device is an ultrahigh molecular weight polyethylene loop, which can become loose under load, even if the tension has been adjusted during surgery. Forsyth et al. found that in their model of distal tibiofibular syndesmosis ligament injury, no amount of force applied was able to maintain distal tibiofibular syndesmosis ligament reduction by a suture button device. The study found that the suture button device loosened after the patient had been fully weight-bearing for some time.[40,41]

Researchers have not stopped at the problem of avoiding early removal of internal fixation, so absorbable screws have emerged. Polyosteolytic acid degrades more slowly than other polymers and retains strength for longer periods, so it may be more suitable for the fixation of tibiofibular syndesmosis ligament. However, studies have shown that absorbable screws have failed to effectively reduce the incidence of complications compared with traditional screws. Removal rates of internal fixation are higher[42–46]. Moreover, Bostman et al. found that the reaction rate of polyglycolic acid-related foreign bodies reached 5.3% and that of polylactic acid foreign bodies reached 0.2% [47].

ASC fixtures perform well in other medical disciplines, giving us encouragement. We tried to use nitinol alloy memory ASC internal fixation to treat distal tibiofibular syndesmosis ligament injury. Medical nitinol alloy is an alloy material with a special shape memory function at a specific temperature, and its deformation temperature is 0°C- 5°C and recovery temperature is 30°C-40°C. It has the characteristics of high strength, strong bending and torsion resistance, fatigue resistance, corrosion resistance, nontoxicity and good histocompatibility. The restorative force generated by the memory alloy at a body temperature of 37°C is used to generate dynamic and continuous compressive stress to achieve the fixation effect. Nitinol alloy ASC, as one of its important applications in recent years, has been widely used in the treatment of multiple fractures. Navicular bone, shoulder blades, and collarbone non-load-bearing bone can be used independently to obtain reliable fixation. In the tibia platform, the femoral condyle position can also adapt to changeable fracture lines, such as auxiliary steel, and obtain satisfactory curative effects[10–17]. Nitinol memory ASCs were used for the first time in the treatment of tibiofibular syndesmosis ligament injury in this group. Compared with other internal fixation materials, it has the following characteristics: (1) According to the different types of ankle fractures, the anterior or posterior part of the tibiofibular joint was exposed through the lateral malleolar fracture incision. Imminent reduction under direct vision without additional incisions helps to avoid poor or excessive reduction of the tibiofibular joint (Fig. 1). (2) The ASC design medium, a variety of models, generally medium (20 mm wide) can meet most of the cases, the two claws of the ASC branch length is 12 to 15 mm, can pass through a layer of cortical bone hook into the medullary cavity. A single hook held under the fixed structure, although not able to maintain an absolutely solid fixed relationship of the lower tibiofibular joint like a screw, can limit the distance between the joints and allow micro-movement between the joints and contribute to the recovery of joint function as well as significantly reduce the broken nail; (3) The continuous compressive stress of ASC at normal body temperature may be one of the important factors

of high healing rate and short healing time in this group of cases. (4) ASC fixation of the tibiofibular joint does not require a second operation to remove the joint in advance. In some cases, fractures occurred after ligament healing, and there was no loss of reduction. The two broken segments were located on both sides of the tibiofibular joint and did not enter the bone marrow cavity. (5) ASC is located on the surface of the anterior distal tibiofibular syndesmosis ligament or the posterior syndesmosis ligament, which is deep on the surface, without complications such as soft tissue irritation or internal fixation discomfort.

In conclusion, in this study, we adopted two surgical methods to draw conclusions after comparing prognosis and complications. We failed to set all the operation methods, and the second follow-up time was not long enough. Although there are many limitations in our research, we can still obtain guidance from them. The results of our series suggest favourable treatment outcomes of syndesmosis injuries with ASC fixation. The ACS group was used to fix the inferior tibiofibular syndesmosis ligament injury. We fixed the joint by only penetrating the single layer of cortical bone, and only one nail was screwed into the tibia and fibula. This fixation method can effectively limit the gap between the tibia and fibula (Although it shrinks after warming, the device is a monocortical fixation, and the spacing between the compressed tibia and fibula depends on the location of the drill hole in the monocortical fixation). The relative mobility of the joints, but the unicortical fixation allows slight movement between the joints, which is also consistent with the physiology of the inferior tibiofibular joint. According to the results of the initial control study, the ASC may not only serve as an effective device providing continuous concentrative compression for syndesmosis lesion healing but also retain the micromovable feature, thereby aiding the restoration of joint function permitting early rehabilitation with a low incidence of postoperative hardware complications such as breakage, irritation and looseness. Furthermore, a large, prospective, randomized controlled trial and biomechanical testing are underway for a future study.

Declarations

Ethics approval and consent to participants

The Ethics Committee of The First Affiliated Hospital of Naval Military Medical University approved the research project and analysis of the patient. written informed consent to participants was obtained from all subjects and/or their legal guardian(s) in ethical approval and consent to participants section.

Consent for publication

All subjects or legal guardians signed an informed consent form, supporting and agreeing to the publication of relevant images and table data in the research.

Availability of data and materials

The table in the article has provided the data of this study in more detail, If you need more information, please contact the newsletter and the first author of this article.

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Competing interests

The authors have no competing interests.

Authors' contributions

Jinbo Zhao and Yuntong Zhang designed and completed the project, and Yan Xia undertook the statistical analysis and conclusion summary of the project data. Xuhui Wang was responsible for the follow-up of the two groups of patients, Shuogui Xu hosted and communicated the whole topic and article writing, and Yang Xie participated in the topic discussion and conclusion summary. Jinbo Zhao and Yuntong Zhang contributed the same as co-first authors. Shuogui Xu is the corresponding author of this paper.

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Figures

Figure 1

ASCs were used to reduce and fix the distal tibiofibular ligament between the tibiofibular bones.

Figure 2

Pre- and postoperative radiographs of a patient in the ASC group

A, B. Fracture of the lateral malleolus and ligament injury of the distal tibiofibular joint were obvious. C, D: After reduction and fixation of the lateral malleolar fracture, ASC was added to reduce and fix the ligament relationship of the distal tibiofibular joint. E, F. The figure shows the patient's fracture reduction and stability more than one year after the removal of all fracture internal fixations.

Figure 3

Pre- and postoperative radiographs of a patient in the SCREW group

A, B. Fragments of the internal and external and posterior ankles and ligaments of the distal tibiofibular joint were evident. C, D: After the reduction and fixation of the fracture, a screw was added to reduce and fix the ligament relationship of the distal tibiofibular joint. E, F. The figure shows the patient's fracture reduction and stability approximately one month after the removal of all fracture internal fixations.