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Application of a Ni-Ti arched shape-memory connector in unstable lateral malleolus fractures: A retrospective study

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ABSTRACT

Purpose: To compare the outcomes of the arched shape-memory connector (ASC) only fixation and the lateral one-third tubular plate fixation in managing unstable Type A or B lateral malleolus fractures according to the Weber (AO) classification, and to evaluate the feasibility and reliability of ASC only fixation in treating these fractures.

Methods: From January 2010 to January 2015, 148 patients with Type A or B (Weber (AO) classification) lateral malleolus fractures treated with the arched shape-memory connector (ASC) only fixation or lateral plate fixation were included. There were 66 patients in the ASC only fixation group and 82 patients in the lateral plate group. Intergroup differences were absent regarding patient and fracture characteristics. The incision length, complete-union time, major complications and complaints, incidence of hardware removal, and final radiographic and functional evaluations were compared.

Results: The follow-up time averaged 18.2 months in the ASC fixation group and 17.2 months in the lateral plate group. The ASC only fixation group had significantly decreased wound infection (4.55% versus 14.63%) and skin necrosis (none versus 7.32%). Of patients who underwent ASC only fixation 3.03% reported lateral ankle pain, 7.58% received palpable hardware, and 3.03% reported hardware irritation, while the corresponding observations in the lateral plate group were 19.51%, 54.88%, and 14.63%, respectively, representing a statistical difference. Furthermore, compared with the lateral plate group, the incidence of hardware removal was markedly lower in the ASC fixation group (12.12% versus 30.49%). In terms of reduction accuracy, complete-union time, and AOFAS scores, no appreciable differences were observed.

Conclusions: ASC only fixation is a reliable alternative for managing Type A or B lateral malleolus fractures, leading to fewer soft tissue complications, fewer hardware complaints, and a reduced need for hardware removal, and a reduced need for hardware removal. In addition, ASC can be used for augmented plate fixation in certain comminuted fracture patterns.

Introduction

Ankle fractures are injuries that are commonly seen in clinical practice, with a reported incidence of 71/100,000/year to 187/100,000/year; ankle fractures are primarily caused by rotation and lateral or longitudinal external forces, with the lateral malleolus representing approximately 55% of all ankle fractures [6,7,22]. For unstable lateral malleolus fractures, open anatomical reduction and stable internal fixation using a lateral plate with or without a lag screw to achieve inter-fragmentary compression is the most commonly used treatment strategy [11,25]. Nonetheless, there are several associated complications and complaints with this method, including wound infection, skin necrosis, palpable hardware, lateral pain, and hardware irritation, leading to a high incidence of remedial surgeries [9,11,21].

In an attempt to improve therapeutic effects, a less invasive surgical approach featuring lag screw only fixation has been proposed and has proven to be a favourable alternative for treating Type B fractures, leading to less soft tissue dissection, decreased hardware complaints, and a reduced need for secondary surgical removal [16,24]. However, this technique has a very narrow set of indications for specific fracture patterns and bone quality, significantly limiting its application [16,24].

Over the past several decades, Ni-Ti shape-memory alloy has been widely fabricated and applied in various clinical fields,

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including orthopaedic [29], stomatological [19], urological [12], and cardiovascular [13] due to its excellent properties of wear and corrosion resistance [2,15], good biocompatibility [14,23], and shape memory effect [4,5]. The novel arched shape-memory connector (ASC, Swan Biological Memory Medical Devices Co., Ltd., Huzhou, Zhejiang Province, China) contains 50%–53% nickel, and the rest composition is titanium, designed for different sizes with compression part, holding part, and body (Fig. 1a). It exhibits an unilateral memory effect, which is shape-plastic below 0 °C but recovers original shape at 33 ± 2 °C, providing not only stabilization but also dynamic and continuous compression forces across the healing interface [27,29]. As an alternative apparatus for internal fixation, ASC has been used to treat unstable lateral malleolus fractures for years in China. The current study aims to retrospectively compare the outcomes of the ASC only fixation technique with the lateral one-third tubular plate fixation in managing unstable Type A or B lateral malleolus fractures according to the Weber (AO) classification [18] and to further evaluate the feasibility and reliability of ASC only fixation in treating such fractures.

Patients and methods

All closed ankle fractures compromising the lateral malleolus with a Type A or B fracture (Weber (AO) classification) treated with ASC only or lateral plate fixation at our trauma centre were identified and included using the hospital's electronic medical record system in the period between January 2010 and January 2015; this study was approved by the institutional review board of our hospital.

Medical records and images were retrieved to exclude the following patients: (1) aged younger than 18 years or older than 50 years at the time of injury, (2) fractures located within 1 cm of the distal articular surface, (3) pathologic fracture, (4) pre-existing medical condition(s) that severely limited physical or mental health before the injury, (5) severe comminuted fracture with more than 5 displaced fragments, and (6) lost to follow-up or with incomplete medical records. Ultimately, 66 and 82 patients were included in the ASC fixation group and lateral plate fixation group for this study, respectively. The demographics of the patients, including age, gender ratio, classification, and involved ankle in each group, are listed in Table 1. Intergroup differences were absent regarding patient and fracture characteristics.

All surgeries were performed by two senior orthopaedic surgeons on the same surgical team. A longitudinal, lateral incision was made at the fracture site with careful and minor dissection of the soft tissue. After the fracture was reduced anatomically with a reduction clamp or Kirschner wires, an appropriately sized ASC was immersed in ice water and flattened, as shown in Fig. 1. Then, two holes were drilled on either side of the fracture site to attach the arms of the ASC. Following the insertion, about 3 ml 40–50 °C water was injected directly and slowly at the sides of the ASC through an injection syringe, which made ASC's arms and waist revert back to their original shapes, drawing the bone fragments together. In this manner, two or three ASCs were used perpendicular to the fracture line at the appropriate positions, including the

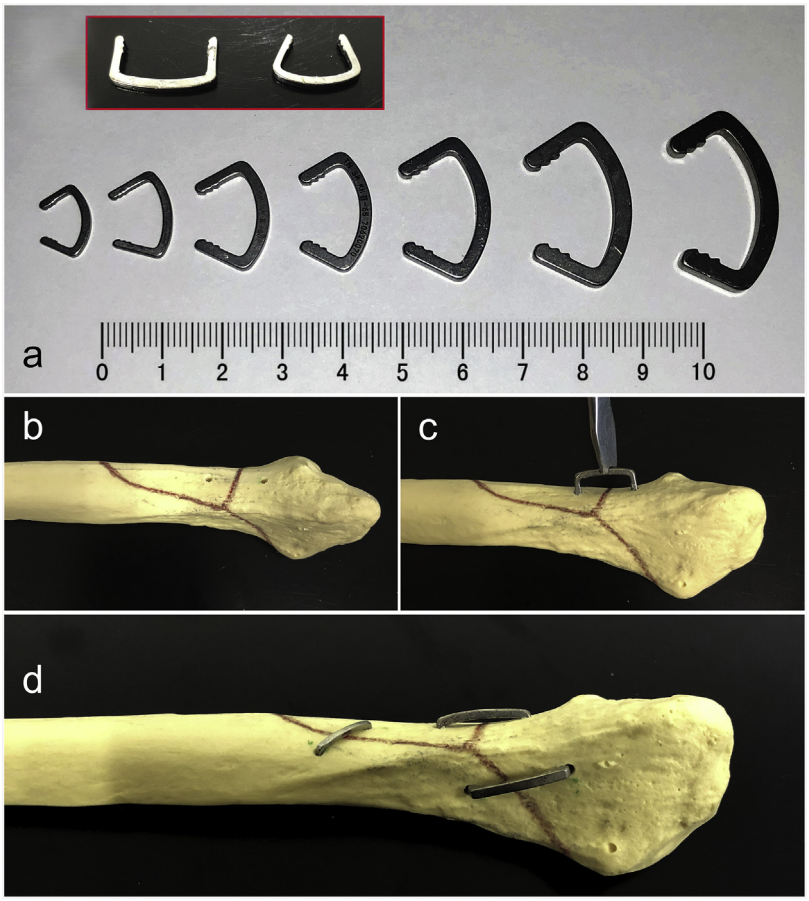

Fig. 1. Brief illustrations of the ASC application process.
a. Appearance and various sizes of the ASC. Picture in the top left corner showed different shapes of the ASC in ice water (left) and at room temperature (right) because of the shape-memory effect. **b**. Two holes were drilled on either side of the fracture site for attachment of the arms of the ASC. **c**. The ASC was inserted into bone with a special tool. **d**. The fracture was properly stabilized with three ASCs.

Table 1
Patient and fracture characteristics.

	ASC only fixation group (n = 66)	Lateral plate fixation group (n = 82)
Age(y) Mean (range)	35.68(19 to 49)	37.57(18 to 50)
Gender		
Male, n (%)	27(40.91)	36(43.90)
Female, n (%)	39(59.09)	46(56.10)
Weber (AO) classification		
A, n (%)	13(19.70)	15(18.29)
B, n (%)	53(80.30)	67(81.71)
Involved ankle		
Lateral Malleolus Only, n (%)	12(18.18)	17(20.73)
Bi-malleolar, n (%)	34(51.52)	40(48.78)
Tri-malleolar, n (%)	20(30.30)	25(30.49)

lateral aspect or anterior edge of the fibula. The application process of the ASC is briefly illustrated in Fig. 1, and a more detailed introduction of the structure and working principles can be reviewed in previous reports [29–31]. In the lateral plate group, following reduction, a 3.5 mm lag screw was inserted anteroposteriorly perpendicular to the fracture line, and a lateral one-third tubular plate was positioned. Next, ankles with an associated medial or posterior malleolar fracture were treated in a standard fashion with screw or plate fixation. A syndesmosis screw was used where lateral stress demonstrated opening of the syndemosis, and other ligament injuries, if necessary, were properly repaired for joint stability. Finally, the status of the fracture reduction and rigid fixation were checked by intra-operative radiographs and physical tests; then, the wound was sutured.

Typically, application of post-operative immobilization with a below-knee cast was not required except in cases of unsatisfactory ankle stability. Gradual, active motion in the ankle joint was allowed on the second postoperative day under the direction of the surgeons, and the exact weight-bearing time was determined by follow-up radiographs. Patients returned for both clinical and radiological assessments every 2 months until the fracture united. Complete union was defined as the presence of a bridging callous in at least three cortices based on the radiograph and no pain or tenderness over the fracture zone. Hardware removal was not routine and only undertaken for significant symptoms, patient requests, or managing complications.

Complications and complaints, including wound infection, skin necrosis, lateral ankle pain, palpable hardware, hardware irritation, and hardware removal during the follow-up, were recorded and compared as primary assessments. Hardware irritation was diagnosed when patients showed some tenderness but no pain over the hardware. The incision length and complete-union time were also compared. Finally, a radiographic assessment was conducted to evaluate the adequacy of reduction by the McLennan and Ungersma [17] method, and functional outcomes were assessed according to the American Orthopaedic Foot and Ankle Society hind foot-ankle score (AOFAS) [8,10]. All statistical analyses were performed using the Chi-squared Test and Independent Sample *T*-Test as appropriate (SPSS 19.0 statistical software). Significance tests were two-sided at the 5% significance level.

Results

The follow-up time averaged 18.2 months (range, 12–32 months) in the ASC fixation group and 17.2 months (range, 12–26 months) in the lateral plate group. The results of the main complications and complaints in the two groups are listed in Table 2. Patients treated with ASC only fixation showed significantly decreased soft tissue complications, including wound infection (4.55% versus 14.63%, p = 0.044) and skin necrosis (none versus 7.32%, p = 0.033). All patients with wound infections recovered after administration of an antibiotic with or without surgical debridement. Of 6 patients with skin necrosis, 2 underwent skin grafting and 4 did not require further management for limited and minor skin necrosis. A significantly lower incidence of lateral ankle pain was observed in the ASC only fixation group (3.03% versus 19.51%, p = 0.005). Over half of patients treated with a lateral plate exhibited palpable hardware compared to 7.58% of patients in the ASC group. Twelve patients (14.63%) in the lateral plate group complained of hardware irritation compared to only two patients (3.03%) in the ASC group. Eight patients (12.12%) in the ASC fixation group requested hardware removal compared with 25 (30.49%) patients in the lateral plate group, a statistically significant difference (p = 0.008).

Other outcomes, including incision length, complete-union time, and radiographic and functional assessments, are presented in Table 3. Patients treated with the ASC showed a significantly shortened incision length in the lateral malleolus. In terms of complete-union time, no significant difference was observed between the two groups. One patient in the ASC group and two patients in the lateral plate group were confirmed as poor reduction accuracy according to our radiographic assessment criteria, representing no significant difference. The AOFAS scores in the ASC and lateral plate groups assessed at final follow-up were,

Table 2
Comparison of the major complications and complaints between the two groups.

Major complications and complaints	ASC only fixation group (n = 66)	Lateral plate fixation group (n = 82)	P value
Wound infection	3, (4.55)	12, (14.63)	0.044
Skin necrosis, n (%)	none	6, (7.32)	0.033
Lateral ankle pain, n (%)	2, (3.03)	16, (19.51)	0.005
Palpable hardware, n (%)	5, (7.58)	45, (54.88)	<0.001
Hardware irritation, n (%)	2, (3.03)	12, (14.63)	0.034
Hardware removal, n (%)	8, (12.12)	25, (30.49)	0.008

Table 3
Comparison of the general assessment indicators between the two groups.

General assessment indicators (units)	ASC only fixation group (n = 66)	Lateral plate fixation group (n = 82)	P value
Incision length (centimetres)	4.01 ± 0.78	6.14 ± 0.95	<0.001
Time of complete union (months)	4.43 ± 0.81	4.20 ± 0.99	0.092
Reduction adequacy			0.854
Good, n (%)	53(80.30)	67(81.71)	
Fair, n (%)	12(18.18)	13(15.85)	
Poor, n (%)	1(1.52)	2(2.44)	
AOFAS Scores	93.20 ± 5.93	92.81 ± 6.30	0.67

on average, 93.20 ± 5.93 and 92.81 ± 6.30 points, respectively. There was no statistically significant difference between the groups (p = 0.67). Two representative cases treated with ASC only fixation are presented in Figs. 2 and 3.

Discussion

In general, unstable lateral malleolus fractures require anatomical reduction and rigid fixation to decrease the incidence of post-

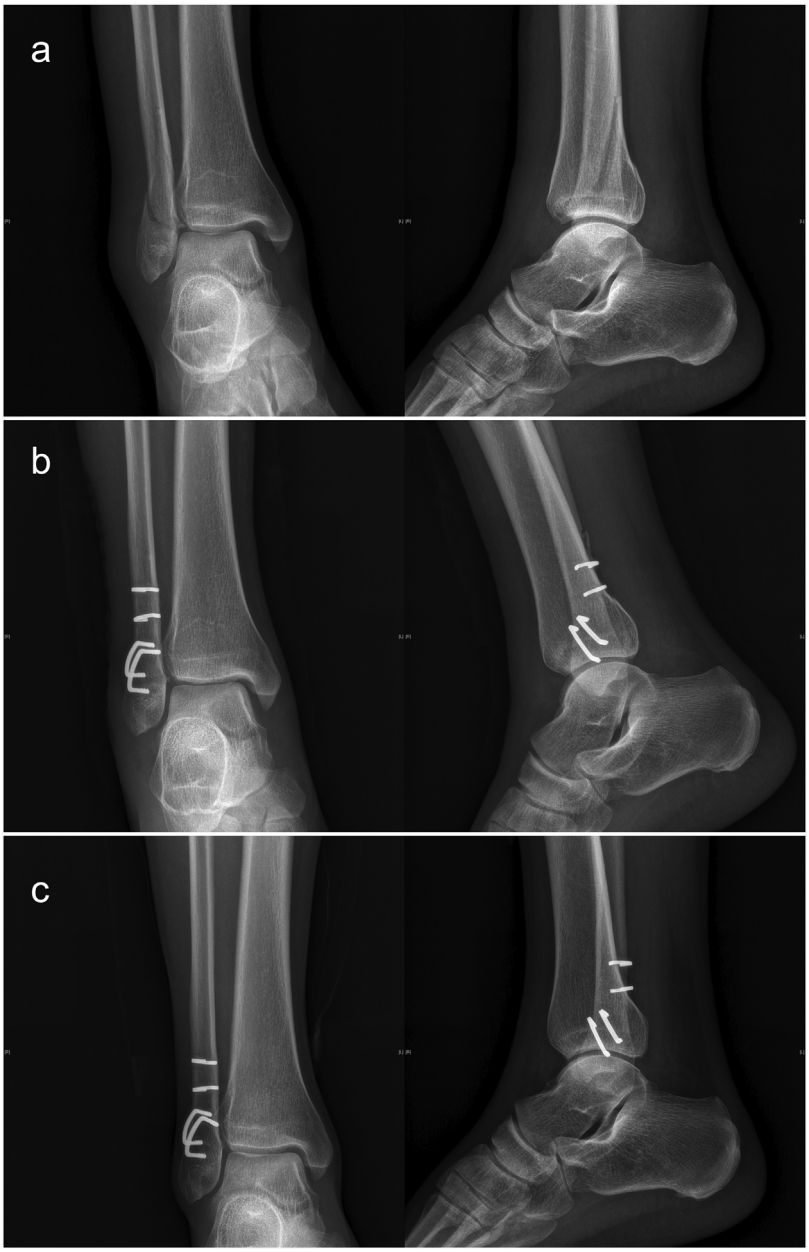

Fig. 2. Radiographs of a 37-year-old male who sustained a Type B lateral malleolus fracture and underwent ASC only fixation.
a. Pre-operation radiographs of the injured ankle. **b**. Initial post-operation radiographs following application of ASC only fixation. **c**. Radiographs at the final follow-up (14 months after the initial operation).

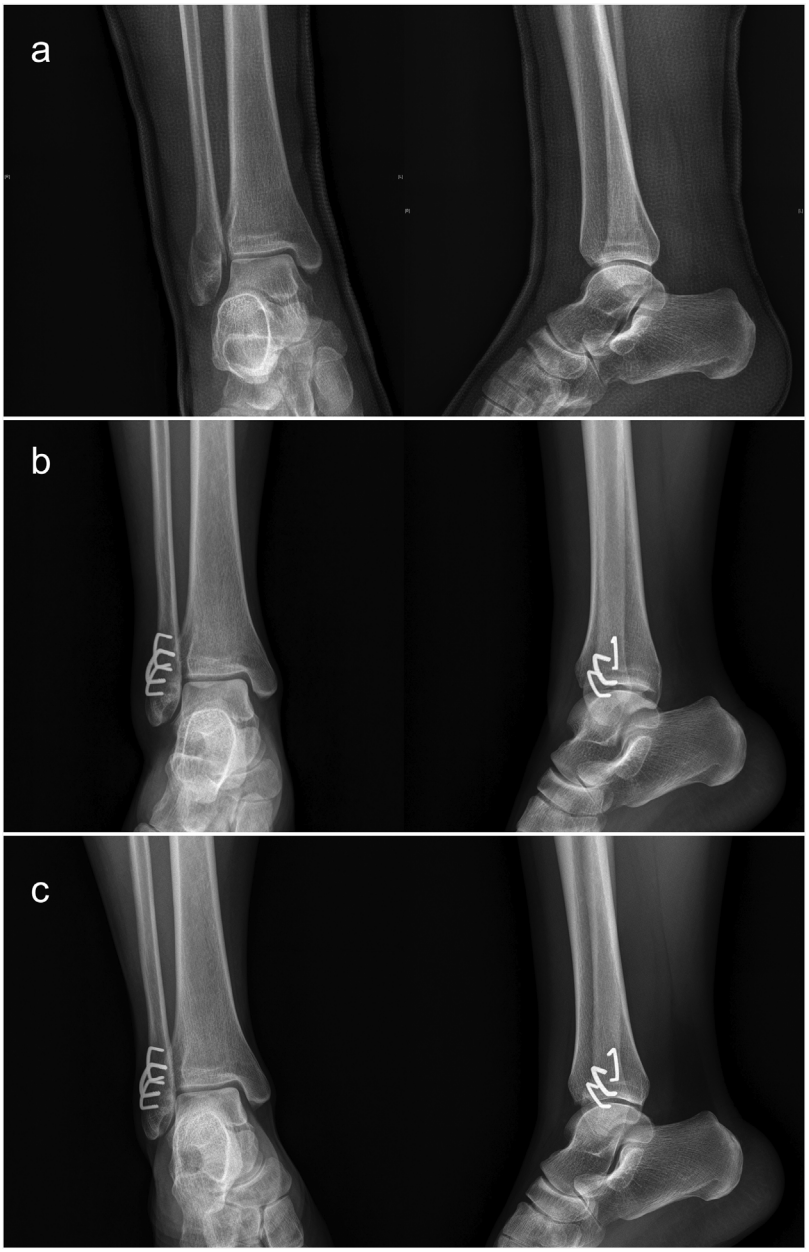

Fig. 3. Radiographs of a 39-year-old female who sustained a Type B lateral malleolus fracture and underwent ASC only fixation.
a. Pre-operation radiographs of the injured ankle. **b**. Initial post-operation radiographs following application of ASC only fixation. **c**. Radiographs at the final follow-up (17 months after the initial operation).

traumatic osteoarthritis and inferior functional results caused by displacement or shortening [28]. Lateral plate fixation with or without the use of lag screws is a well-considered strategy for operational treatment [11,25]. However, the special anatomic structure and minimal amount of soft tissue over the lateral malleolus, original and operational damage to the local blood supply, and bulk of the fibular plate may contribute to a series of complications and complaints, leading to unplanned plastic revision or hardware removal [9,11,21,24].

Kilian [9] performed lateral plate fixation in 24 patients with lateral malleolus fractures and reported 4.2% wound dehiscence, 20.9% hardware irritation, and 79.2% hardware removal. Lamontagne [11] reported 4.6% superficial infection, 3.7% wound dehiscence, 16.6% hardware removal and 12% discomfort over a lateral plate after retrospectively analysing 108 patients with an isolated, closed and unstable lateral malleolus fracture who received lateral plate fixation. Schepers [21] suggested overall 7.8% wound complications and 27.3% hardware removal after retrospectively analysing 205 patients with an isolated, closed ankle fracture who received lateral plate fixation. The reported data differed due to diverse standards and research subjects, but the limitations of lateral plate fixation for treating lateral malleolus fractures were revealed.

To minimize the “second hit” of surgery as well as decrease the complications and complaints common to lateral plate fixation, lag screw only fixation has been proposed and implemented for selected lateral malleolus fractures. Tornetta III [24] conducted a prospective study to compare the treatment outcomes of lag screw only fixation with lateral plate fixation for lateral malleolus fractures with simple oblique patterns and no comminution. In his study, high rates of lateral pain (17%), palpable hardware (56%), hardware irritation (15%), and hardware removal (31%) were

revealed in the lateral plate fixation group. By contrast, the lag screw fixation group had a relatively low rate of lateral pain (2%), and no palpable hardware, restrictions in shoe wear, loss of reduction, soft-tissue complications or hardware removal were recorded. In terms of the radiographic evaluation or range of motion, there was no significant difference between the two methods. In another retrospective comparative study by McKenna [16], compared to the lateral plate group, the lag screw-only group presented with significantly decreased wound infections (none versus 16%), palpable metal (5% versus 50%), and additional surgery (none versus 20%) while having similar AOFAS scores. Although it appears that lag screw only fixation has significant advantages over lateral plate fixation, including minor surgical damage, decreased soft tissue complications, less symptomatic and palpable hardware, and fewer additional hardware removal surgeries, the selective fracture patterns and bone quality requirements limit its application [16,24].

Over the past decade, the ASC has been gradually applied to clinical treatment of various musculoskeletal diseases, and presented favorable performance [30,31]. In the current study, the ASC was applied to treating unstable lateral malleolus fractures as the only fixation, and the clinical outcomes were compared with those of lateral plate fixation. In general, ASC only fixation exhibited significantly decreased wound infection (4.55% versus 14.63%), skin necrosis (none versus 7.32%), lateral ankle pain (3.03% versus 19.51%), palpable hardware (7.58% versus 54.88%) and hardware irritation (3.03% versus 14.63%), while presenting a similar final reduction accuracy and functional scores. The incidence of hardware removal with ASC treatment was also significantly reduced (12.12% versus 30.49%).

ASC only fixation has several advantages and meets the minimally invasive surgical trend [3,16,24,26] as the ASC has a comparatively small volume and can be flexibly and easily placed with a minor incision in a narrow space, leading to decreased complications and complaints, further avoiding an additional remedial surgery. Moreover, the sustained and dynamic compression forces provided by the ASC can be transmitted across the fracture to ensure a stable biomechanical environment that theoretically aids bone-healing process [4,5,20]. In comparison with the lag screw, the ASC is also a practical fixator in certain conditions, including transverse fractures, fragments without the enough opposite cortex or friable against twisting. In this study, ASCs were also implemented in transverse and comminuted fracture patterns, producing similar effects to plate fixation in bone union, final reduction and functional outcome. Compared with traditional lateral plating, ASC only fixation can avoid protrusion of the cortical screw tips into the joint. Moreover, although no significant difference in reduction accuracy was observed between groups, it has been shown in clinical practice of lateral plate fixation that, with the distal expansion of the fracture line, fewer screw holes in the distal part of the plate can be used, which reduces the overall stability and limits its application. By contrast, ASC only fixation has wider indications.

It has been indicated that limited fixation methods, such as lag screw only fixation, are biomechanically weaker than lateral plate fixation [1,16], which brings the concern of inadequate fixation and reduction loss. Thus, researchers commonly manage the post-operative ankle with immobilization for approximately 6 weeks. In our study, post-operative immobilization was not routine after ASC only fixation if the intra-operative radiographic and physical tests confirmed satisfactory ankle stability. The findings suggested that ASC only fixation did not result in a significant absence of reduction or function compared to lateral plate fixation, indicating that this technique, when used with proper fixed positions and connector numbers, could offer similar reduction and stability to lateral plate fixation in treating these fractures.

As with any retrospective study, there are some limitations. Surgeon-based randomization did appear to introduce some bias. Additionally, the number of patients included in this study is small. A larger sample size is required to improve the strength of the clinical evidence. Moreover, additional prospective studies and biomechanical investigations are also required.

Conclusion

ASC only fixation can serve as an effective means of managing Weber (AO) Type A or B lateral malleolus fractures with good bone quality. Compared to traditional lateral plate fixation, the benefits of ASC only fixation include: decreased wound and soft tissue complications, fewer hardware complaints, and a reduced incidence of additional surgery for revision or hardware removal. In addition, with the distal extension of the fracture line, ASC only fixation is more applicable than lateral plate fixation. For certain comminuted fracture patterns, the ASC can also be flexibly used for augmented fixation of a plate.

Conflicts of interest

On behalf of all authors, the corresponding author states that there is no conflict of interest.

Author's contribution

Author(s) initials for each category that an author contributed to. Study concepts: ZCH, YTZ, SGX.
Study design: ZCH, YX, JHW.
Data acquisition: ZCH, YTZ, JHW.
Data analysis/interpretation: ZCH, YTZ, YX, SGX.
Statistical analysis: YTZ, JHW.
Manuscript editing: ZCH, YX, JHW.
Manuscript revision/review: YTZ, SGX.

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Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:https://doi.org/10.1016/j.injury.2018.10.037.

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