Original Article

Combination of mini locking plate and nitinol arched shape-memory connector for purely lateral malleolus fractures: technique and clinical results

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Background: Lateral malleolus fractures occur frequently. The common techniques for fixing purely lateral malleolus fractures are often challenging, owing to the extent of soft tissue damage and fracture non-union. Herein, we report a new treatment that entails minimally invasive insertion and continuous compression of the broken ends as a novel technique, and evaluate its clinical results.

Methods: This study enrolled 21 patients (13 males and 8 females; mean age 32.06±3.45 years, range 23–69 years) with purely lateral malleolus fractures. Each patient underwent open reduction treatment with a mini locking plate for internal fixation and compression of the fracture end with an Arched Shape-Memory Connector (ASC). The clinical assessments were made using the American Orthopedic Foot and Ankle Society (AOFAS) scores, which were recorded at the final follow-up visit.

Results: The patients were followed for an average of 14.7±1.2 months (range, 12–18 months). None of the patients showed surgical failure, and all of the purely lateral malleolus fractures healed in an average of 12.6±1.5 weeks (range, 10–16 weeks). The mean AOFAS score was 88.94 (range, 83–90).

Conclusions: The new treatment had beneficial outcomes for purely lateral malleolus fractures. Mini locking plates are minimally invasive for surgical intervention, and combined with continuous concentrated compression with an ASC to accelerate osseous healing, they aid in restoration of function and enable early rehabilitation with a low incidence of postoperative complications.

Keywords: Mini locking plate; minimally invasive technique; purely lateral malleolus fractures; shape-memory alloy

Submitted May 18, 2020. Accepted for publication Oct 10, 2020.
doi: 10.21037/atm-20-4055
View this article at: http://dx.doi.org/10.21037/atm-20-4055

Introduction

Ankle fractures are among the most common skeletal injuries seen in clinical practice and constitute 3.92% of all fractures. With an annual incidence of up to 174 cases per 10,000 people, ankle fractures constitute 3.92% of all fractures (1-3). Purely lateral malleolus fractures, or isolated distal fibular fractures, account for 50.8% of ankle fractures and the incidence is increasing year by year (4).

For a long period of time, surgeons managed minimal displacement of lateral malleolus fractures using conservative treatment (5); however, based on a literature review, the majority of surgeons now prefer to use surgical treatment (6). Open reduction with internal fixation (ORIF) has become the gold standard treatment for these fractures (4,7). In recent years, according to the Biological Osteosynthesis (BO) principle, minimally invasive techniques with elastic fixation have been proposed (8,9).

Besides direct reduction of small fractures for plate insertion, stress stimulation is important for healing. By distributing, continuous, dynamic compression forces to the bone fragments through its two arms, the Nitinol (Ni-Ti) arched shape-memory connector (ASC) achieves the goal of accelerating fracture healing (10-12). Ni-Ti shape-memory alloys first appeared in the 1960s and have since been widely used in the neurosurgical (13), cardiovascular (14), and orthopedic fields (15). With its shape-memory effect, corrosion resistance, wear resistance, super-elasticity, and favorable biocompatibility, nitinol is an innovative material that has been used for internal fixation since the 1990s (12,13,15-17). Treatment that combines mini locking plates fixation with ASC meets the requirements of the BO principle, and could accelerate the healing process with minimal invasiveness. Furthermore, in view of the common skin irritation complications of lateral malleolus fractures, both mini locking plates and the ASC take up little space and can stimulate the skin to a minimum. Therefore, these combinations could represent a new advance in the orthopedic trauma field.

Because this new treatment has not been the focus of an article to date, the current study aimed to introduce the particularity of the ASC combined with mini locking plates and retrospectively evaluated the efficacy and clinical outcomes of the new treatment in purely lateral malleolus fractures. We present the following article in accordance with the STROBE reporting checklist (available at http://dx.doi.org/10.21037/atm-20-4055).

Methods

Participants

The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by Ethics of Biomedicine Research of Second Military Medical University. (NO.: 112012098) and informed consent was taken from all individual participants. Between January, 2015, and February, 2017, 107 patients with lateral malleolus fractures were assessed for eligibility. The inclusion criteria included simple lateral malleolus fractures with a Type A or B fracture [Weber (AO) classification]. The exclusion criteria were: (I) stable fractures; (II) malleolus fractures involving the tibia; (III) non-traumatic fracture; (IV) aged <18 years or >70 years at the time of injury; and (V) psychological and social conditions with poor compliance. Eventually, 21 patients (13 males, 8 females) were enrolled. A flowchart of the study is shown in *Figure 1*. The mean age of the patients was 32.06±3.45 years (range, 23–69 years). The causes of fracture were sports (10/21, 47.6%), a high fall (7/21, 33.3%), and traffic accidents (4/21, 19.1%).

Structure and working principles of the ASC

The ASC device (Lanzhou Ximai Memory Alloy Co., Ltd., Lanzhou, China) was designed for the desired feature of continuous compression to promote bone healing and manufactured with 2-mm-thick Ni-Ti shape-memory alloy (with a Ni content of 50–53%). The device memorizes the original cold-forging shape and can be restored to the pre-deformation shape by heating. The shape change quantity is about 8%. The device is processed with one-way thermal treatment and a 33± 2 ℃ reversion temperature to connect the compression hooks and embracing arms with the main plate. Before implantation, the ASC is placed in 0–4 ℃ ice water for cooling to allow plastic deformation of the Ni-Ti alloy, as the ASC is malleable at lower temperatures (martensite phase). When the fixation is completed, 40–50 ℃ water is used to warm the device and stimulate its memory mechanical functions (austenite phase), which provides the continuous lateral compressive force. Simple illustrations of the mini-locking plate and ASC application process are shown in *Figure 2* and the working process of the ASC is shown in the *Video 1*.

Surgical procedure

Under lumbar anesthesia, we took the lateral position of the patient's fracture, placed an indwelling catheter, routinely disinfected it, and prepared a sterile surgical area for an anterolateral approach. A longitudinal lateral skin incision (<6 cm) was made to expose the periosteum of the fibula. After clearing necrotic bone debris and soft tissues, the damaged fibula was corrected through traction and held with bone forceps. Two Kirschner wires were crossed and implanted in the appropriate location for temporary fixation. The ASC was placed in ice water (0–4 ℃) to enable the Ni-Ti alloy ability to be shaped. We selected a correctly shaped mini locking plate, pushing the plate toward the lateral border of the fibula and centering on the fibula with good bone contact. After definitive alignment, the locked screws were inserted into holes that were drilled avoiding the fracture line. Next, two holes were drilled on both the anterior and posterior sides of the fracture site; two ASCs were required for stable fixation, with the arms embedded in the holes. After being fixed into the bone, the ASCs were heated with 40–50 ℃ water to stimulate reversion of the fibula to its original shape. *Figure 3* shows a schematic overview of all the procedures. The two arms of the ASCs generated a continuous compression force on the fracture line. The subcutaneous tissues and skin were closed in the usual manner. Active exercises with restricted weight lifting started on the first postoperative day. A gradual increase in weight and range of motion was then permitted; full weight lifting was permitted after clinical assessment of soft tissues and ankle function and X-ray evaluation. Bone healing was confirmed when the fracture area was pain-free and the

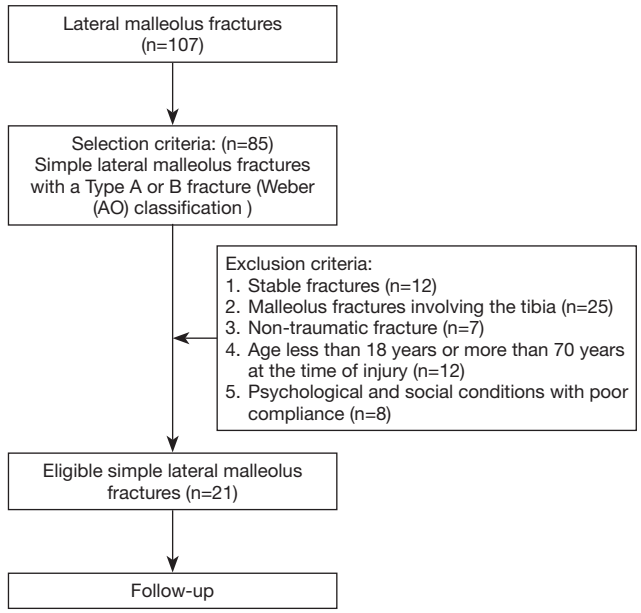

Figure 1 Flowchart of the selection and exclusion criteria for lateral malleolus fractures applicable for fixation with mini-locking plate and arched shape-memory connector (ASC).

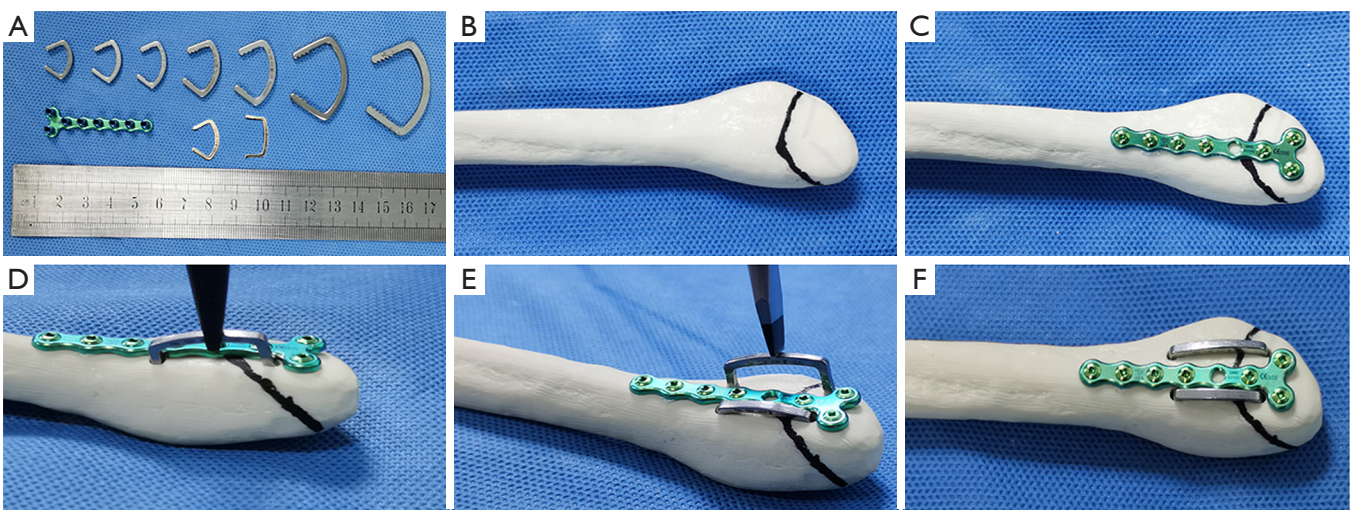

Figure 2 Simple illustrations of the mini-locking plate and arched shape-memory connector (ASC) application process. (A) Appearance and various sizes of t ASC and mini-locking plate; (B) black line shows the fibular fracture site; (C) a mini-locking plate was implanted in the fibula; (D,E) two ASCs were inserted into the bone; (F) the fracture was correctly stabilized with two ASCs and a mini-locking plate.

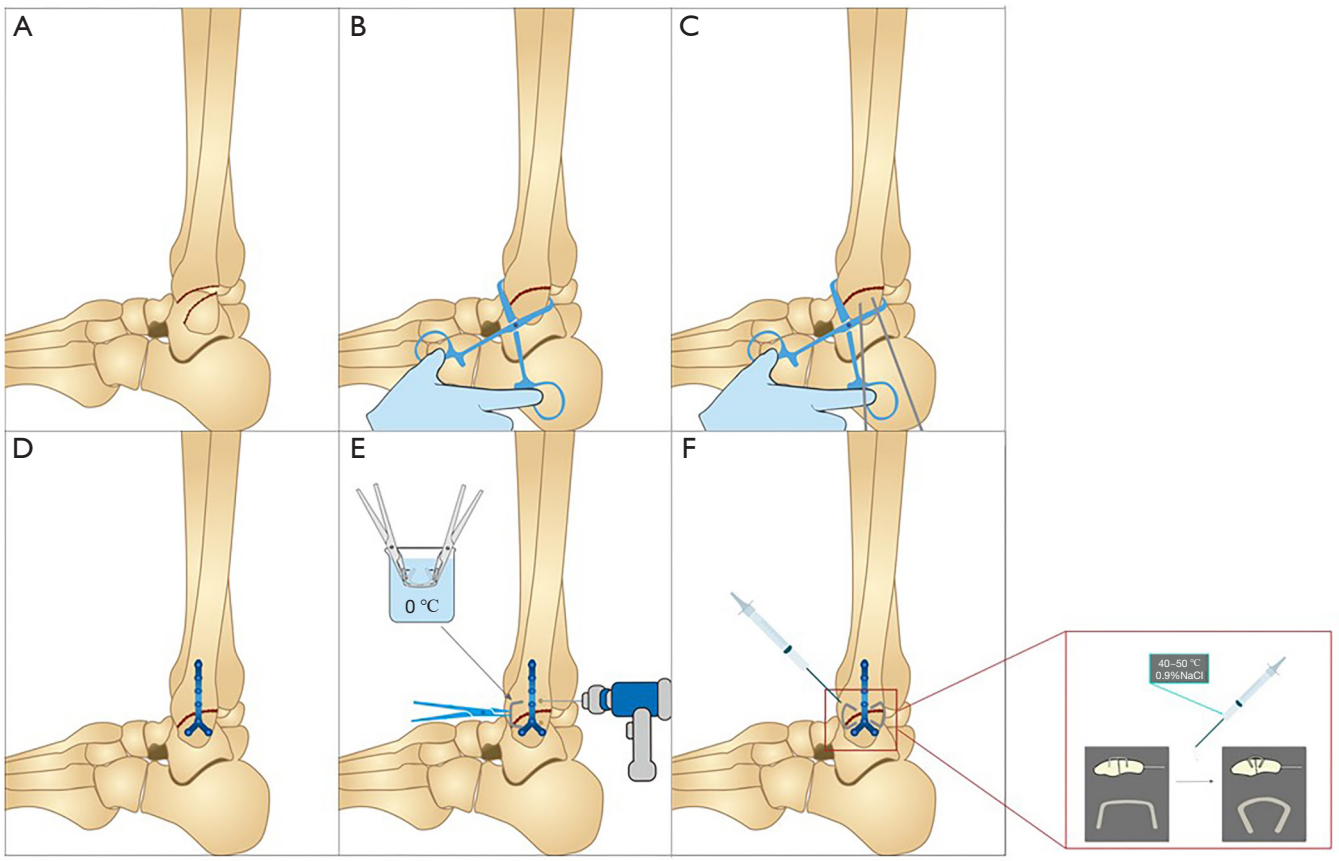

Figure 3 Schematic diagram of the surgical procedure. (A) Lateral malleolus fractures; (B,C) temporary fixation with two Kirschner wires; (D) a proper mini-locking plate was implanted as usual; (E) ASCs were cooled in ice (0 ℃) water and flattened, drill holes were placed to avoid the fracture line, and the two ASCs were inserted; (F) the ASCs were heated with hot (40–50 ℃) water to stimulate reversion of the fibula to its original shape.

cortices were bridged by visible callus in the anteroposterior and lateral views. Typical cases presented in *Figure 4* and *Figure 5*.

Clinical outcomes evaluation

Follow-up and radiographic assessments were routinely performed at 4, 8, and 12 weeks after ASC implantation. Long-term postoperative review was conducted for 12–18 months. The follow-up radiographic images of one of the patients are shown in *Figure 6*. The American Orthopedic Foot and Ankle Society (AOFAS) score was used to evaluate impairments and activity limitations, comprising four different scores for pain, activity, functional limitations, and footwear, as well as examiner-reported data about alignment, gait, and motion (17). The patients were evaluated by AOFAS score after clinical healing during follow-up. All of the clinical assessments and evaluations of postoperative complications were performed by independent observers, and the results were independently interpreted by two senior attending doctors.

Statistical analysis

This study was a cross-sectional study. All data were counted the average and standard deviation were calculated using SPSS (20.0 version) software.

Results

The mean surgical time was 44.9±6.7 min (range, 34–78 min) and the average blood loss was 42.3±2.7 mL (range, 20–75 mL). All wounds healed uneventfully without

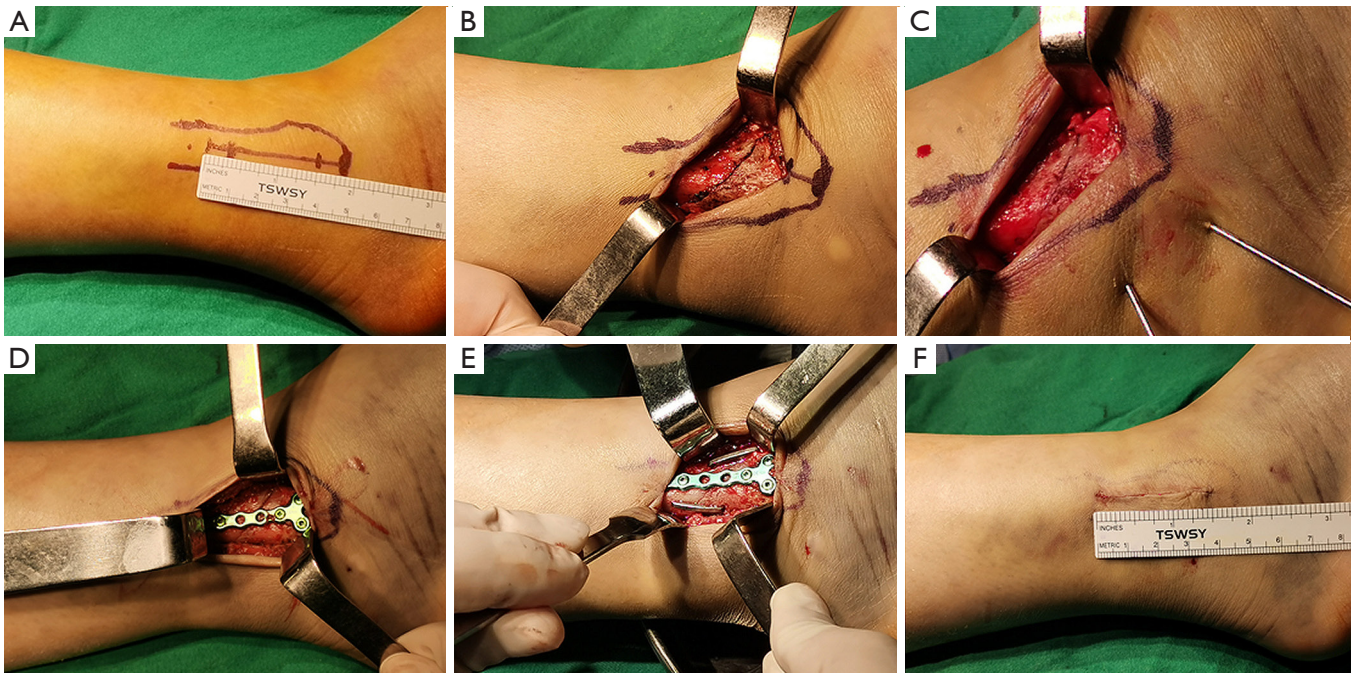

Figure 4 Case 1: Right lateral malleolus fracture. (A,B) A lateral skin incision (<5 cm long) was made to expose the periosteum of the fibula; (C) the lateral malleolus fracture was restored and temporarily fixed with two Kirschner wires; (D) a mini-locking plate was implanted in the fibula and three screws were inserted for stable fixation; (E) two ASCs were placed across the fracture at the correct location; (F) the wound was sutured with a final length <4 cm.

deep or superficial skin infection. Based on postoperative radiographic assessment, the articular reduction of the lateral malleolus fractures was classified as anatomical (17 cases), acceptable (<2 mm step, 4 cases) or poor (>2 mm, 0 cases). None of the patients showed a postoperative articular gap or step >2 mm.

The patients were followed for an average of 14.7± 1.2 months (range, 12–18 months). No patients showed loss of reduction, and all of the lateral malleolus fractures healed after an average of 12.6±1.5 weeks (range, 10–16 weeks). At the most recent follow-up, the mean AOFAS score was 88.94±1.2 (range, 83–90). The rate of complications in this study was 5/21 (23.8%); 3 patients felt numbness after the procedure, and 1 patient suffered from traumatic arthritis and hardware irritation. During follow-up, none o of the patients experienced severe complications such as comminuted osteoporotic fracture, implant failure, secondary loss of reduction, severe numbness of the dorsal malleolus, delayed union or non-union, skin necrosis, or wound infection. See *Tables 1* and *2* for details.

Discussion

Purely lateral malleolus fractures comprise 50.8% of ankle fractures, and the incidence is rising annually (4). The bone defect of purely lateral malleolus fractures involves only the fibula, while the position of the talus (under the tibia) remains correct. Because the fibula plays an important role in maintaining the stability of the ankle joint, recovering the correct length, axis, and rotation of the distal fibula is crucial (18). Additionally, malpositioned fragments may impair blood vessels, which can lead to pseudoarthrosis. Therefore, except for cases in which no joint subluxation on radiographs or instability is found during stress examination, both of which have a low risk of displacement and can be safely treated by traditional conservative methods (19), operative treatments are now recommended for the majority of ankle fractures, including minimally displaced lateral malleolus fractures (6). In clinical practice, various operative treatments can be used to recover the anatomical structure of the fibular, though the most frequently used technique is ORIF (20).

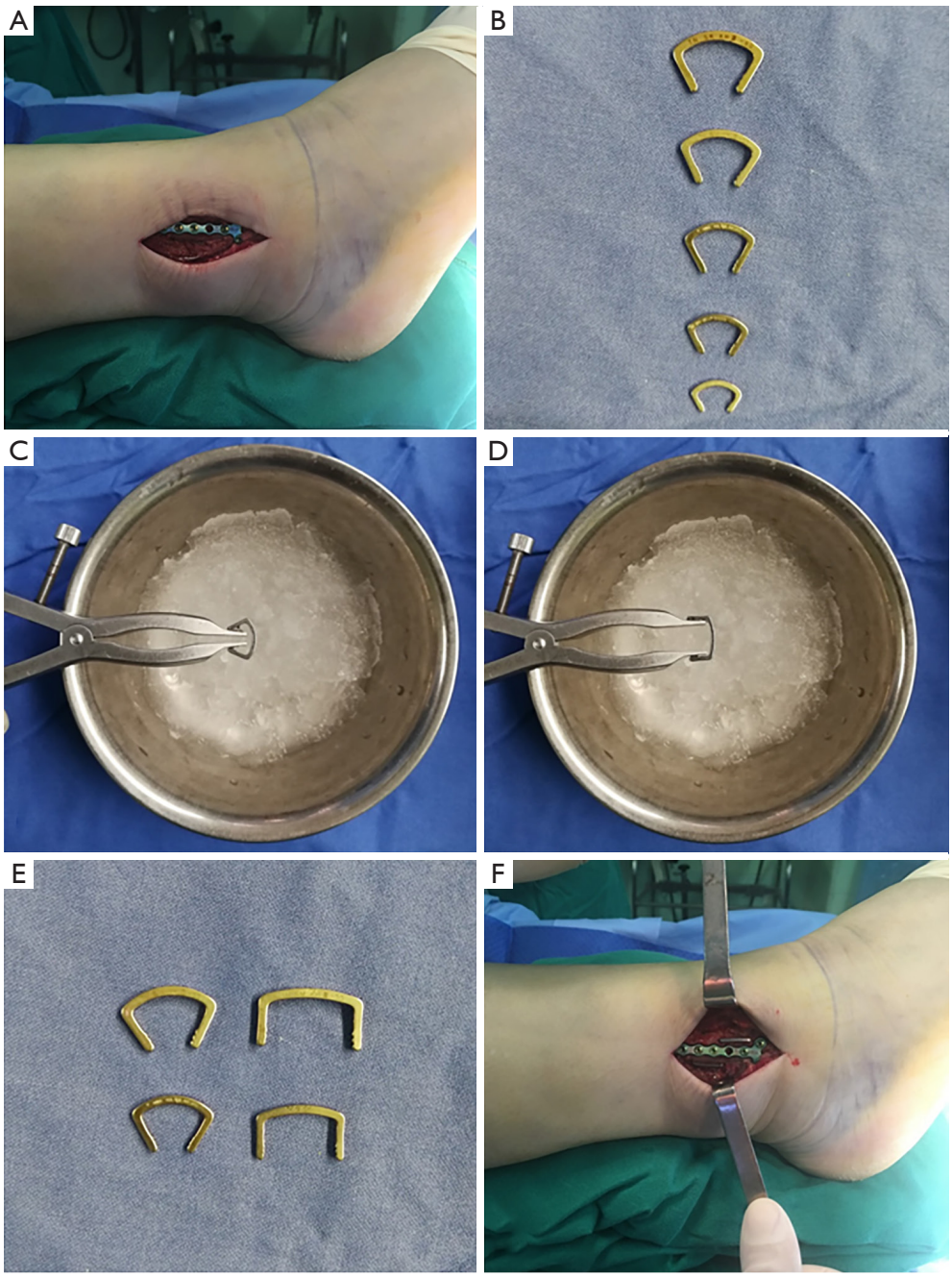

Figure 5 Case 2: Right lateral malleolus fracture. (A) A mini locking plate was fixed to the bone; (B,C,D,E) Two correctly sized arched shape-memory connectors (ASCs) were selected and flattened in iced water (0–4 ℃); (F) Drill holes were placed to avoid the fracture line, and the ASC arms were embedded for stable fixation. Next, the ASCs were warmed to active shape-memory functions and provide a continuous compressive force. ASC, arched shape-memory connector.

Traditional ORIF, which is based largely by the Arbeitsgemeinschaft für Osteosynthesefragen (AO) concept, requires rigid compression plating and results in stiffness at the fracture site (21). ORIF aims to obtain reduction of the displaced fractures, to maintain anatomical alignment of the ankle joint, and to allow

Figure 6 A 44-year-old male patient presented with right lateral malleolus fractures caused by a high fall. (A,B) Pre-operative radiographs in the anteroposterior and lateral views showed right distal fibula fracture. (C,D) Postoperative anteroposterior and lateral radiographs after 20 weeks showed successful union of the fractures; the arched shape-memory connector (ASC) is fixed in place.

patients to start functional exercise as soon as possible, which is helpful for bone union. In most cases, ORIF is performed using compression screws and neutralization plates to meet the AO principle (20). Zahn introduced pre-contoured locking plates, which improved fixation in an osteoporotic bone model (22). Despite the accumulation of clinical experience, however, the management of lateral malleolus fractures is still challenging. Besides the long operation time, mechanical failure of traditional ORIF occurs in up to 14% of cases (23,24). The hardware

Table 1 Patient characteristics

Characteristic	Value
Number of patients (N)	21
Gender	13M, 8F
Age (y)	
Mean	32.06±3.45
Range	23–69
Injury mechanism	
High fall	7 (33.3%)
Traffic accident	4 (19.1%)
Sports injury	10 (47.6%)
Weber (AO) classification	
A	6 (28.6%)
B	15 (71.4%)
Operation time (min)	44.9±6.7
Range	34–78
Blood loss (mL)	42.3±2.7
Range	20–75

Table 2 Follow-up clinical outcomes

Characteristic	Value
Follow-up time (months) [range]	14.7±1.2 [12–18]
Healing time (weeks) [range]	12.6±1.5 [10–16]
Articular reductions (anatomical:acceptable:poor)	(17:4:0)
Postoperative complications	
Osteonecrosis or traumatic arthritis	1
Comminuted osteoporotic fracture	0
Implant failure	0
Secondary loss of reduction	0
Numbness of dorsal malleolus (mild:moderate:severe)	3 (2:1:0)
Delayed union or non-union	0
Wound infection	0
Skin necrosis	0
Hardware irritation	1
AOFAS score [range]	88.94 [83–90]

AOFAS, American Orthopedic Foot and Ankle Society.

removal rate is approximately 33% for traditional ORIF treatment, which increases the total cost of treatment per patient (25) and increases the rate of complications to 30% (20).

These complications occur for the following reasons. First, compression produced by traditional internal fixation is discontinuous, static, and passive. The mechanical compression produced by rigid implanted plates has the consequences of weak bone, which might be associated with non-union (21). Second, lateral malleolus fractures cause local swelling because of the thinner overlying skin and lack of skeletal muscle surrounding the fibula. Extensive soft tissue dissection is needed during the traditional operation to obtain precise fracture reduction and compression (26), which can lead to damage in the limited space and the rigid traditional implants have a high risk of complications such as wound dehiscence and infection, hardware prominence, neurovascular damage, and incision disunion (27,28). Furthermore, incorrect timing of the operation and application of standard large fragment plates have been associated with treatment failure because of steel plate exposure, joint pain or malformation, and even sepsis (25,29,30). All of these reports indicate that even if traditional ORIFis performed correctly, a high risk of wound complications requiring further surgical procedures still exists.

In response to these observations, the BO principle was put forward. In contrast to the original AO concept, the BO principle implies close reduction and elastic fixation to strike a balance between fracture stability and the integrity of soft tissue (8,9). Subsequently, many surgeons began to produce and evaluate plates with reduced stiffness and minimal invasiveness to accelerate the healing process. The minimally invasive treatment concept was developed as an alternative to the direct, open treatment method, avoiding major soft tissue complications such as neurovascular injuries and skin necrosis (18). The mini locking plate introduced in this study meets the BO principle, as does the minimally invasive treatment concept, which has been reported in many cases, such as clavicular and femoral fractures (31,32). With its flexibility and ingenious construction, the mini-locking plate can maximally preserve vascularization of intermediate fragments and provides minimal invasiveness for surgical intervention. In this study, the mini locking plate not only acted as an internal fixator, but also protected the surrounding soft tissues, needing only one nterolateral incision of 6 cm.

In addition to the mini-locking plate, an arched internal fixation device made of Ni-Ti shape-memory alloy was invented for compression broken ends of bones. With the biocompatibility and corrosion resistance superiority of the Ni-Ti shape-memory alloy, the ASC has been widely used in orthopedics and has beneficially improved both intraoperative and postoperative outcomes of fracture repair (15,33). Due to its characteristic of transforming its shape with temperature changes, the force produced by two arms of the ASC sufficiently stabilizes the fracture without any further management after implantation. Moreover, the ASC has high strength and low modulus, which effectively avoids the "stress shielding effect" (34). The results of follow-ups in the present study showed that this minimally invasive operation resulted in union in 100% of cases, post-operative complications in 11.3% of cases, and satisfactory AOFAS scores. These results are comparable to those in the literature (5).

Compared with conventional techniques, this new treatment has the following advantages. The mini plating system with its simple structure occupies less space and can thus only causes only minimal skin irritation and pain when the ankle joint begins early movement. Also, neurovascular injuries are reduced, further improving fracture union and decreasing removal rates. Compression obtained with an ASC is an evenly distributed, continuous, and dynamic force that can be transmitted across the fracture terminus, contributing to healing. Additionally, this technique only requires bone holding forceps for temporary fixation and an electric drill for drilling holes, which contributes to the simplicity of the procedure and results in a small amount of damage, a short operation time, and a low risk of vascular injury and blood loss. Thus, not only are the postoperative complications reduced but there is also a decreased need for secondary operations, especially metal removal, and increased patient satisfaction.

There are some limitations to this study. First, the diagnosis of lateral malleolus fracture was mainly dependent on X-ray imaging rather than computed tomography, which made misdiagnosis of lateral malleolus fracture more likely. Second, the ASC is a novel implant and relevant biomechanical testing and evaluation are still lacking. Finally, although the ASC showed good efficacy in this preliminary study, the sample size was small and the study design was retrospective. To better validate the efficacy of this surgical approach, a rigorous prospective study with a large sample size should be performed in the future.

Conclusions

Although our study is limited by the lack of a control group, the results suggested helpful treatment outcomes for the combination of mini locking plates and ASC fixation to treat purely lateral malleolus fractures. Based on the BO concept, mini locking plates are minimally invasive and strike a balance between fracture stability and soft tissue integrity. The ASC is not only an effective rigid device for multi-fragmented and comminuted fractures with rare hardware irritation but it also provides continuous concentrated compression to accelerate osseous healing. Therefore, this new treatment aids restoration, permitting early rehabilitation with a low incidence of postoperative complications.

Acknowledgments

Funding: We acknowledge the support of the National Science Foundation for Young Scientists of China (No. 81601910), the Shanghai Rising-Star Program (No. 18QA1405400), the Military Medical Research Foundation from the Naval Military Medical University (No. 2017JS15), and the China Postdoctoral Science Foundation Grant (No. 2016M592936).

Footnote

Reporting Checklist: The authors have completed the STROBE reporting checklist. Available at http://dx.doi.org/10.21037/atm-20-4055

Data Sharing Statement: Available at http://dx.doi.org/10.21037/atm-20-4055

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at http://dx.doi.org/10.21037/atm-20-4055). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by Ethics of Biomedicine Research of Second Military Medical University (No.: 112012098) and informed consent was

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Cite this article as: Xia D, Zhang Y, Ou T, Wang Y, Hao Z, Zhou P, Xu S. Combination of mini locking plate and nitinol arched shape-memory connector for purely lateral malleolus fractures: technique and clinical results. Ann Transl Med 2020;8(23):1573. doi: 10.21037/atm-20-4055

