Clinical study of intramedullary nailing fixation for the treatment of Danis-Weber B in lateral malleolus fracture

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Abstract
Objective: To compare the clinical effects between anatomical locking plates and interlocking intramedullary nails in patients with Danis-Weber B lateral malleolus fractures.

Methods: This retrospective study enrolled patients with Danis-Weber B fractures of the lateral malleolus. All the operations were completed by the same group of surgeons. The reduction effect, operation time, intraoperative blood loss, hospital stay, fracture healing time and ankle functional outcomes (Olerud-Molander Ankle Score [OMAS]) were compared. Postoperative complications, including incision infections, fixation discomfort and internal fixation loosening, were also compared.

Results: This study enrolled 73 patients that were treated with either an anatomical locking plate (locking plate group; n = 37) or an interlocking intramedullary nail (intramedullary nail group; n = 36). There was no significant difference between the two groups in terms of reduction effect, hospital stay and OMAS. The intramedullary nail group had significantly lower operation time, intraoperative blood loss and fracture healing time compared with the locking plate group. Postoperative complications in the intramedullary nail group were significantly lower compared with the locking plate group.

Conclusion: Using intramedullary nails resulted in more satisfactory functional outcomes compared with using locking plates in patients with Danis-Weber B fractures of the lateral malleolus.

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Introduction

Ankle fractures are among the most common lower limb fractures and account for 9% of all fractures.\(^1\) With the mechanism of injury varying from a simple fall to high-energy motor vehicle accidents, ankle fractures present a wide spectrum of fracture patterns. Ankle fractures are initially evaluated by physical examination and then by X-ray. They can be classified according to the AO Foundation (Association for the Study of Internal Fixation),\(^2\) the Weber classification or the Lauge-Hansen classification.\(^3\) Dislocated fractures need emergency treatment with immediate reduction. This is crucial for the prevention of hypoperfusion and nerve damage. Weber A or B (no injury to the medial ankle and the medial ligament is stable) fractures can usually be treated conservatively, while Weber B (with injury to the medial ankle and the medial ligament is instable) and C fractures are usually treated using surgery.\(^4\) Lateral malleolus fracture is one of the most common ankle joint injuries.\(^5,6\) The distal end of the fibula is the main part of ankle joint, which needs anatomical reduction to avoid traumatic occurrence.\(^5,6\)

Generally, lateral malleolus fractures without obvious displacement can be treated by manual reduction and plaster external fixation. Plate fixation of lateral malleolus fracture is a conventional clinical treatment method, which can ensure an anatomical position for the fracture and enable patients to exercise early, but the postoperative complications are as high as 30%, including 26% of incision infection.\(^4\) In the elderly, internal fixation loosening and internal fixation failure often occur due to fracture loosening.\(^7\) Because of the discomfort of internal fixation, it is common for patients to ask to have the internal fixation removed at a later date. Even higher complications occur in patients with early surgery,\(^7\) diabetes mellitus,\(^8\) mental illness and long-term smoking.\(^9\) For some ankle soft tissue contusion, obvious swelling, open fractures, early incision and plate fixation failure will increase the probability of incision infection.\(^10\) Surgical treatment can only be performed after the soft tissue is restored, but it increases the patient’s pain and hospitalization time, and second-stage treatment becomes more difficult.\(^10\) Fibula interlocking intramedullary nail is another fixation method for lateral malleolus fracture, which can enable early surgery in patients with poor soft tissue condition.\(^11–13\) The smaller incision is approximately 1 cm, which can protect the blood supply of the fracture end, and is conducive to fracture healing, reduces incision complications and internal fixation discomfort.\(^11–13\) In addition, it provides good mechanical stability and reduces internal fixation loosening for patients with osteoporosis.\(^11–13\)

This current study compared the clinical effects of anatomical locking plates and interlocking intramedullary nails in treating Danis-Weber B fractures of the lateral malleolus.

Patients and methods

Study population

This retrospective study reviewed data from consecutive patients with Danis-Weber type
B lateral malleolus fractures treated in the Department of Foot and Ankle Surgery, The Second Affiliated Hospital of Luohe Medical College, Luohe, Henan Province, China between January 2017 and June 2019. The inclusion criteria were as follows: (i) Danis-Weber classification was B type; (ii) lateral malleolus fracture was confirmed by X-ray; (iii) patients were informed and agreed to participate. The exclusion criteria were as follows: (i) Danis-Weber classification was A or C; (ii) patients with renal and liver dysfunction, severe cardiovascular and cerebrovascular diseases, immune diseases, acute and chronic inflammation and nausea and tumour; (iii) patients with contraindications for surgery. The patients were grouped according to the surgical method used into either the locking plate group or the intramedullary nail group. The causes of injury were recorded. The ligamentous injuries were diagnosed by magnetic resonance imaging.

The study was approved by the Ethics Committee of The Second Affiliated Hospital of Luohe Medical College (no. SAHLMC0135). All patients provided written informed consent.

Surgical interventions

Surgery was performed under general or regional anaesthesia. Both methods were used as part of the routine clinical practice of the traumatologists involved in this study and all surgeons were familiar with these surgical techniques.

For locking plate fixation, patients were placed in the supine position. The lower limb distal to the tourniquet was routinely disinfected and draped. After inflation, an 8–10 cm longitudinal incision was made at the 1/3 of the lower fibula. The incision was made layer by layer to expose the fracture end. Then the soft tissue of the fracture end was cleaned. After the fracture was reduced with forceps, an anatomic locking plate of an appropriate length was selected and placed on the lateral side of the fibula. The hole was drilled with an electric drill and then a screw of an appropriate length was screwed into the fixation to close the incision.

The Acumed fibular intramedullary nail is the most commonly used for intramedullary nail fixation (Acumed, Hillsboro, OR, USA). The implant is available in two diameters (3 mm and 3.6 mm) and three lengths (110 mm, 145 mm and 180 mm). For intramedullary nail fixation, patients were placed in the supine position. The lower limbs were routinely disinfected after anaesthesia. A 1 cm incision was made at the tip of the lateral malleolus. Under fluoroscopic guidance, the guide wire was inserted into the tip of the ankle. The metaphysis was drilled with a hollow 6.1 mm drill. After closed reduction, a 3.1 mm or 3.7 mm reamer was selected to ream the shaft manually to determine the specific position of the fracture end and insert the intramedullary nail device. If the reduction was difficult, the reduction forceps were used to assist the reduction. The main intramedullary nail was inserted along the medullary tract and the locking screw was inserted into the distal end of the fracture. If the inferior fibular syndesmosis was not stable enough, the intramedullary nail device and the main nail were used to fix the tibiofibular syndesmosis screw. Finally, the incisions were sutured one by one.

All patients received routine anti-infection therapy after surgery. The patients were followed up for 12 months. At 3 days, 1 month, 2 months, 3 months, 6 months and 12 months after surgery, X-ray examination was undertaken to observe the healing of the fracture. The ankle function score of the last follow-up was used as the basis for ankle function evaluation.

Postoperative observations

The postoperative reduction effect, operation time, intraoperative blood loss,
hospitalization time, fracture healing time, ankle score at the last follow-up and postoperative complications were recorded and compared between the two groups.

The effect of postoperative fracture reduction was evaluated using the McLennan method as follows:14 (i) good reduction: no loss of the length of the fibula, within 2 mm of the posterior movement, an increase of 1 mm in the internal talotibial space; (ii) fair reduction: reduction of the tibia less than 2 mm, posterior displacement of 2–4 mm, external displacement of 2 mm and an increase of the internal talotibial space of 1–3 mm; (iii) poor reduction: the tibia shortened by more than 2 mm, the posterior displacement was more than 4 mm, the lateral displacement was more than 2 mm and the internal talotibial space increased by more than 3 mm.

The criteria for fracture healing were as follows: (i) there was no longitudinal percussion pain; (ii) no local tenderness; (iii) no abnormal phenomenon of local activity; (iv) the X-ray examination results showed that the fracture line had basically disappeared; (v) the patient could walk continuously on flat ground without crutches for approximately 3 min.

The assessment of the clinical condition of the ankle joint was undertaken using the Olerud-Molander Ankle Score (OMAS), which is a functional rating scale from 0 (totally impaired) to 100 (completely unimpaired) that includes activities of daily living, jumping, squatting, running, assisted walking, climbing stairs, swelling, joint stiffness and pain.15

Complications including internal fixation discomfort, incision complications, internal fixation loosening and fracture nonunion were recorded.

Statistical analyses

All statistical analyses were performed using IBM SPSS Statistics for Windows, Version 25.0 (IBM Corp., Armonk, NY, USA). Continuous data are presented as mean ± SD and compared using two-sided independent t-test. Categorical data are presented as n of patients (%) and compared using χ²-test. A P-value <0.05 was considered statistically significant.

Results

This retrospective study enrolled 73 patients (41 males and 32 females) with Danis-Weber type B lateral malleolus fractures. The mean ± SD age was 44.15 ± 15.17 years (range, 18–68 years). The patients were divided into a locking plate group (n = 37; 21 males and 16 females) and an intramedullary nail group (n = 36; 20 males and 16 females). In the locking plate group, the mean ± SD age was 43.48 ± 15.38 years. The causes of injury in the locking plate group were as follows: sprain injury in 32 patients and traffic injury in five patients. There were 10 patients with closed lateral malleolus fracture, one patient with an open lateral malleolus fracture, seven patients with deltoid ligament injury, five patients with lower tibiofibular ligament injury, eight patients with medial and lateral malleolus fracture, five patients with trimalleolar fracture and one patient with distal tibiofibular fracture. In the intramedullary nail group, the mean ± SD age was 44.83 ± 15.38 years. The causes of injury in the intramedullary nail group were as follows: 30 patients with a sprain and six patients with a traffic injury. There were 11 patients with closed lateral malleolus fracture, two patients with an open lateral malleolus fracture, eight patients with deltoid ligament injury, four patients with lower tibiofibular ligament injury, six patients with medial and lateral malleolus fracture, four patients with trimalleolar fracture and one patient with distal tibiofibular fracture.
Thirty-four patients (91.89%) in the locking plate group achieved good reduction without an increase in the internal tibial space and the shortening of the fibula (Table 1). There were three patients with fair reduction in whom the length of the fibula was not fully restored and the length of the fibula was shortened less than 2 mm. In the intramedullary nail group, 34 patients (94.44%) achieved good reduction and two patients had fair reduction. Of these two patients, one had fibula displacement less than 2 mm and in the other patient the fibula had moved back 1–4 mm. There was no poor reduction in both groups. There was no significant difference between the two groups in terms of reduction. The operation time ($P = 0.025$), intraoperative blood loss ($P < 0.001$) and fracture healing time ($P < 0.001$) of the intramedullary nail group were significantly lower than those of the locking plate group (Table 2). There were no significant differences between the two groups in terms of hospital stay and OMAS.

In the locking plate group, there were eight patients with incision infection complications as follows: superficial infection in three elderly patients with diabetes mellitus, three patients with partial skin necrosis and two patients with fat liquefaction, all of which healed after dressing change (Table 3). There was one patient with incision infection in the intramedullary nail group. Fixation discomfort occurred in eight patients in the locking plate group and two patients in the intramedullary nail group. In the locking plate group, there were three patients with screw loosening and one patient with nonunion fracture 1 year after surgery, all four of them being elderly patients with osteoporosis. Overall, the rates of incision complications, internal fixation discomfort and internal fixation loosening/fracture nonunion in the intramedullary nail group were significantly lower.

### Table 1. Reduction effect in patients ($n = 73$) with Danis-Weber B fractures of the lateral malleolus fracture treated with either an anatomical locking plate or an interlocking intramedullary nail system.

| Reduction effect | Locking plate group $n = 37$ | Intramedullary nail group $n = 36$ |
|------------------|-----------------------------|----------------------------------|
| Good             | 34                          | 34                               |
| Fair             | 3                           | 2                                |
| Poor             | 0                           | 0                                |
| Total effectiveness, % | 91.89                      | 94.44                           |

Data presented as $n$ of patients.
No significant between-group differences ($P > 0.05$); $\chi^2$-test.

### Table 2. Comparison of the operation time, intraoperative blood loss, hospitalization time, fracture healing time and Olerud-Molander Ankle Score (OMAS) in patients ($n = 73$) with Danis-Weber B fractures of the lateral malleolus fracture treated with either an anatomical locking plate or an interlocking intramedullary nail system.

| Characteristic         | Locking plate group $n = 37$ | Intramedullary nail group $n = 36$ | Statistical analyses$^a$ |
|------------------------|------------------------------|-----------------------------------|-------------------------|
| Operation time, min    | $46.1 \pm 13.9$              | $39.4 \pm 10.7$                  | $P = 0.025$             |
| Intraoperative blood loss, ml | $90.6 \pm 13.0$            | $76.5 \pm 14.2$                  | $P < 0.001$             |
| Hospital stay, days     | $8.5 \pm 1.7$               | $8.3 \pm 2.2$                    | NS                      |
| Fracture healing, weeks | $12.1 \pm 1.7$              | $10.2 \pm 1.9$                   | $P < 0.001$             |
| OMAS                   | $88.7 \pm 4.4$              | $89.5 \pm 3.8$                   | NS                      |

Data presented as mean $\pm$ SD.
$^a$Between-group comparison using two-sided independent $t$-test; NS, not significant ($P > 0.05$).
than those in the locking plate group ($P < 0.05$ for all comparisons).

**Discussion**

A lateral approach with open reduction and internal fixation with a plate is a very effective technique for the majority of distal fibular fractures. However, this open approach for ankle fixation may be complicated by wound dehiscence and infection, especially in high-risk patients. An alternative to plating is an intramedullary implant, which allows maintenance of length, alignment and rotation in addition to decreased soft tissue dissection.

Research shows that the operation to fix an internal plate is associated with a large incision, a greatly disturbed blood supply to the fracture, disadvantageous fracture healing and many postoperative complications. Intramedullary fixation can maintain good biomechanics, restore the coordination of the fibula height and lateral wall of ankle point, has good anti-rotation effects on the distal fracture and provides good fixation for injury of the distal tibiofibular ligament.

This current study found that the reduction effect of the two surgical methods both reached more than 90% and there was no significant difference between the two groups. The OMAS of the locking plate group was slightly lower than that of the intramedullary nail group, but there was no significant difference. These current results suggest that both the intramedullary nail and locking plate fixation surgical methods achieved satisfactory recovery results, which was in line with the results of clavicle fracture treatment.

In this current study, the operation time in the intramedullary nail group was significantly shorter than that in the locking plate group, which was consistent with the reported literature. Moreover, intraoperative blood loss and fracture healing time in the intramedullary nail group were also significantly lower than those in the locking plate group. This might be due to the locking plate technique requiring anatomical locking plate internal fixation and more soft tissue to be stripped during the procedure, which would affect the time taken and the blood supply to the fracture end. Therefore, the operation time would be expected to be longer, the blood loss greater and the fracture healing time prolonged.

A previous study reported that in the treatment of ankle fracture, fibula nails may produce similar functional outcomes

| Complication                              | Locking plate group n = 37 | Intramedullary nail group n = 36 | Statistical analyses$^a$ |
|-------------------------------------------|----------------------------|---------------------------------|--------------------------|
| Incision infection complications          | 8 (21.62)                  | 1 (2.78)                        | $P = 0.014$              |
| Discomfort of internal fixation           | 8 (21.62)                  | 2 (5.56)                        | $P = 0.046$              |
| Loose internal fixation/ fracture nonunion | 4 (10.81)                  | 0 (0.00)                        | $P = 0.042$              |

Data presented as n of patients (%).

$^a$Between-group comparison using $\chi^2$-test.
as plate fixation, but the incidence of complications was low. In addition, several articles reported that the postoperative complications of plate fixation were significantly higher than those of intramedullary nail fixation. This current study found that the rate of complications in the intramedullary nail group was significantly lower than that of the locking plate group. A previous study found that intramedullary nailing of the lateral malleolus was a reproducible technique with very few complications that provides better functional results than plate fixation. The safe and efficacious use of an intramedullary fixation device for fibula fractures with lower wound complications compared with the outcomes of lateral fibular plating has been demonstrated. The findings of both previous studies were consistent with the results of this current study. However, there were no cases of sural nerve or peroneal tendon injuries, nor any wound complications observed; and no significant difference in the rate of union between the two types of fixation, which was not consistent with the results in this current study.

This current study had several limitations. First, short-term follow-up might have resulted in an underestimation of the prevalence of long-term complications. Secondly, the small sample size was a limitation. Therefore, a large prospective randomized controlled study with long-term follow-up is required.

In conclusion, interlocking intramedullary nail fixation was associated with a significantly shorter operation time, significantly lower intraoperative blood loss and a significantly shorter fracture healing time than locking plate fixation in patients with Danis-Weber type B lateral malleolar fractures. Although there was no significant difference in the reduction effect, length of hospital stay or OMAS between the two surgical methods, the rate of postoperative complications in the intramedullary nail group was significantly lower than that of the locking plate group.

Author contributions
H.F.C., Z.L. and D.S.Y. conducted the experiments and wrote the manuscript; P.R.W., J.K.N. and X.S.H. conducted the experiments and analysed the data; G.L.W. designed the study and revised the manuscript. All authors have read and approved the manuscript.

Declaration of conflicting interest
The authors declare that there are no conflicts of interest.

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