Fibula Nail Outcomes in Soft Tissue Compromised Ankle Fractures

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Abstract
Background: To determine the clinical outcomes following fibula nail fixation and to identify the indication for the use of fibula nails in lower limb fractures.
Methods: Retrospective study of adult patients from 2 major trauma centers (MTCs) and 9 trauma units (TUs) who underwent fibula nail fixation for AO/OTA 44 fractures between January 1, 2018, and October 31, 2020. Outcome measures included infection, metalwork complications, nonunion or malunion, time to union, and length of inpatient hospital stay.
Results: Ninety-five patients were included, with a mean age of 66 years; 57.9% of patients were female. The average body mass index was 30. Sixty-nine patients (72.6%) sustained a Weber B and 24 (27.4%) sustained a Weber C fracture. In addition, 26.3% were open fractures and all patients had soft tissue compromise affecting the lateral malleolus. The calculated infection rate for fibula nail was 4.2% and metalwork complication rate was 5.2%. The nonunion and malunion rate was 8.4% and rate of removal of hardware was 2.1%. The average time to union was 12.5 weeks, and length of inpatient stay was 9.4 days (SD 10).
Conclusion: This multicenter study demonstrates that use of a fibula nail appears to be a safe approach to treating patients who have a physiologically higher risk of surgery, poor skin condition, and a complex fracture pattern.
Level of Evidence: Level III, case-control study.

Keywords: lower limb fracture, fibula nail, ankle, intramedullary, minimally invasive surgery, internal fixation, trauma

Introduction

Lower limb fractures account for a third of all orthopaedic injuries,\(^6,8\) of which 22% are ankle fractures.\(^{20,22}\) Treatment of displaced and unstable fibula fracture is predominately surgical. The primary aim of open reduction and internal fixation (ORIF) is to achieve adequate reduction for bone healing, minimize posttraumatic arthritis, and allow for early mobilization.\(^12\) Plate fixation with or without interfragmentary screw compression remains the standard mode of internal fixation for fibula fractures and allows for anatomic reduction to restore length and rotation of the fibula.\(^5\) The nonunion and metalwork complication rates are relatively low for fibula plate fixation.\(^7\) However, the potential complications of plate fixation can present significant challenges for surgeons. Fracture site exposure requires a large incision and considerable soft tissue dissection,\(^5,7\) which can be challenging in a high-risk patient with already fragile soft tissues. The reported average risk of wound infection is up to 25%, which increases to 40% in elderly and diabetic patients.\(^7,13,20\) There is considerable variation among studies in metalwork removal rates following plate fixation ranging from 10% to 27%\(^{14,16,21}\) and is more commonly due to prominent hardware interfering with daily activities and footwear.\(^14\) There has been a gradual move toward minimally invasive techniques and key-hole surgery for lower limb fracture fixation. Studies have demonstrated comparable fracture healing rates and decreased rates of nonunion in comparison to ORIFs.\(^7,10\) Intramedullary implants have evolved over the years to dedicated fixation devices for fibula fractures. Although clinical results are limited,
Biomechanically, fibula nails are load-sharing implants that result in less stress shielding, are more tolerant to repetitive axial loading, and are effective at eliminating translation but not generally rotation and shortening. Approximately 27% to 44% of operative ankle fractures are suprasyn- desmotic fibular fractures (AO 44C) and 2.5% to 17% are multifragmentary fibular fractures (AO 44C2). In such injuries, where soft tissue dissection is necessary and anatomic reduction may prove challenging with plate fixation, fibula nails can theoretically be an ideal implant in providing stability and reestablishment of the ankle mortise with minimal tissue dissection. Insertion of fibula nails via minimally invasive or percutaneous approach makes this implant a viable alternative in high-risk patients and those with compromised soft tissue owing to smaller incisions and less soft tissue disruption leading to potentially reduced symptomatic metalwork and postoperative pain. Modern fibula nails also allow reduction and fixation of the syndesmotic through the nail via distal locking screws.

Despite these advantages, fibula nails can be technically challenging and can present with difficulties intraoperatively such as reaming complications, which include fat embolism, fracture displacement, and destruction of medullary contents. Furthermore, the clinical benefits and efficacy of fibula nails are limited and require further research.

The purpose of this study was to investigate the clinical outcomes of fibula nail fixation, including wound infection and metalwork complication rates and to review the common indications for fibula nail fixation.

Methods
A retrospective analysis of patients who had a fibula nail fixation at 2 major trauma centers and 9 trauma units between January 1, 2018, and October 31, 2020, was performed. Inclusion criteria for the study were patients ≥18 years of age with a lower limb fracture classified as AO/OTA 44, open and closed injuries, and a minimum of 2 months' postoperative follow-up. The number of times a patient was seen followed up was up to the discretion of the surgeon. The decision to use a fibula nail was at the discretion of the operating surgeon. The exclusion criteria were patients aged <18 years, pilon fractures, and patients who were either lost to follow-up or died during the study period.

Patients were identified by reviewing on-call lists, trauma, and emergency operating lists and by liaising with respective fibula nail representatives.

All patients’ medical records were reviewed by respective centers to collect demographic data, past medical history, lifestyle choices, preoperative injuries, operative data, and postoperative complications. Any patients who used tobacco were classified as smokers independent of amount. State of patients’ soft tissues were assessed at the time of operation by the surgeon performing the procedure.

Fracture Classification
Fractures were classified based on the Weber classification and AO/OTA classification or descriptively using standard anteroposterior (AP), lateral, and mortise radiographs or computed tomography (CT) images.

Fixation Method
Operative fixation was performed or supervised by experienced orthopaedic surgeons, using the Acumed Fibula Rod (Acumed Fibula Rod System, Hillsboro, OR, USA). A minimally invasive direct approach to the lateral malleolus with radiography-guided percutaneous screw insertion was used in all patients. A maximum of 2 distal AP and 2 distal lateral to medial (LM) locking screws were available for use through the nail. In patients with syndesmotic diastasis, the distal LM screws also provided syndesmotic fixation (Figure 1). Syndesmotic reduction and decision for fixation was at the discretion of the operating surgeon; hence, no formal assessment criteria were used to assess reduction. The nail used in this study did not have a proximal locking option. Postoperative weightbearing status was at the discretion of the surgeon.

Outcome Measures
The primary outcomes of wound infection and metalwork complication rates, which included hardware removal and complications associated with the screws or fibula nail, were measured. Time to union, malunion, and nonunion rates and length of hospital stay were also measured. Union was defined as the presence of bridging callus on 3 of 4 cortices on AP and lateral radiographs. The reduction of the

**Figure 1.** Radiographs of (A) an unstable ankle fracture and (B) after fibula nail fixation.
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fibula was considered acceptable if the ankle joint was anatomical on radiograph. The secondary outcome measure was to identify common indications for fibula nail fixation.

Results

Patients

Ninety-five patients were included in this study and 7 patients were excluded due to death, lost to follow-up during the study period and alternative fracture classification. The mean age was 66 years (interquartile range [IQR] 58-77). The majority of patients were female (57.9%), and the mean body mass index was 30. Patients had multiple medical comorbidities (Table 1), with the majority having an American Society of Anaesthesiologists (ASA) of grade 2 or more (83.2%). Furthermore, 32.6% (n = 31) of patients in this study were current smokers or ex-smokers.

Injury Characteristics

All patients had soft tissue compromise affecting the lateral malleolus and ankle: 41.1% had swelling, 10.5% had ecchymosis, 8.4% had abrasions, 6.3% had swelling associated with blisters, 5.3% had abrasions, and 2.1% had friable skin. In addition, 26.3% were open fractures with significant soft tissue damage as defined by the Gustillo-Anderson classification (Table 2) with 18 patients having grade 3 open fractures. About three-fourths (72.6%) had a Weber B ankle fracture at the level of the syndesmosis (Table 2) and the remaining patients had a Weber C ankle fracture (27.4%). Close to half of patients (47.4%) had comminution (more than 2 major fragments) of the fibula of which the majority were AO 44-B2 and 44-C2 (Figure 2).

Surgical Fixation and Postoperative State

Overall, 93.7% (n = 89) and 98.9% (n = 94) of patients had at least 1 syndesmotic screw and 1 AP screw inserted through the fibula nail, respectively. A standardized assessment of syndesmotic reduction was not made and was under the discretion of the operating surgeon. Postoperative protocol for weightbearing varied by surgeon. Most patients were fully weightbearing postoperatively (n=75, 78.9%). The remainder were protected either by partial or touch weightbearing (n=3, 2.9%) or kept nonweightbearing (n=17, 16.7%). Those that were not fully weightbearing, more than 50% had an open fracture (n=10, 58.8%), were current or ex-smokers (n=15, 88.2%), and had an ASA grade 3 or 4 (n=94.1%).

Clinical Outcomes

There were 4 documented postoperative wound infections affecting the lateral wound in all patients, giving an infection rate of 4.2% (Table 3). Two patients were managed with intravenous antibiotics as an inpatient, and the remaining 2 patients were managed with oral antibiotics in the community, all to good effect.

The rate of metalwork complication was 5.2% (n = 5). Of these, 3 syndesmotic screws broke; 1 distal locking screw broke in a patient who had elective removal of metalwork; and 1 fibula nail bent in the proximal fragment. None of these resulted in a further unplanned procedure and were managed expectantly. The rate of removal of hardware was 2.1%: one patient had nonunion of the fibula with valgus deformity and had subsequent ankle fusion and another patient had a lateral wound infection, resulting in removal of the fibula nail.

Average time to union was 88 days (SD 70). The rate of nonunion (defined as no evidence of fracture healing for 3 months) or malunion of the fibula was 8.4% (n = 8). One elderly patient who sustained an open fracture of the fibula

Table 1. Demographics.

| Patient Characteristics | Frequency (n) | Percentage |
|-------------------------|--------------|------------|
| Total patients          | 95           |            |
| Male                    | 40           | 42.1       |
| Female                  | 55           | 57.9       |
| Age, y                  |              |            |
| Mean                    | 66           |            |
| Median                  | 68           |            |
| SD                      | 18           |            |
| Body mass index         |              |            |
| Mean                    | 30.04        |            |
| Median                  | 30           |            |
| SD                      | 6.64         |            |
| ASA classification      |              |            |
| 1                       | 19           | 20.0       |
| 2                       | 32           | 33.8       |
| 3                       | 40           | 42.1       |
| 4                       | 4            | 4.2        |
| 5                       | 0            | 0          |
| Smoking                 |              |            |
| Smokers                 | 21           | 22.1       |
| Ex-smokers              | 10           | 10.5       |
| Nonsmokers              | 64           | 67.4       |
| Comorbidities           |              |            |
| Hypertension            | 30           | 31.2       |
| Diabetes                | 19           | 20.0       |
| Cancer                  | 17           | 17.9       |
| Respiratory disease     | 15           | 15.8       |
| Cardiovascular disease  | 14           | 14.7       |
| Number of comorbidities |              |            |
| Mean                    | 1.5          |            |
| Median                  | 1            |            |
| Maximum                 | 7            |            |

Abbreviation: ASA, American Society of Anaesthesiologists.
with poor tissue quality had malunion of the fracture, resulting in removal of metalwork and hindfoot nail insertion. Seven fractures went on to nonunion: 5 were asymptomatic and did not have any further treatment, 1 had removal of metalwork and a further procedure (external fixation and ankle fusion), and 1 patient was managed expectantly owing to medical comorbidities. The mean length of inpatient stay (from date of surgery) was 9.4 days (SD 10).

Discussion

With an increasing incidence of lower limb fractures, including a notable increase incidence of lower limb fragility fractures, postoperative wound and metalwork complications in a conventional plate and screw construct are occurring more frequently in high-risk population groups. This adversely affects patients’ long-term functional outcomes and results in higher resource costs. A timely reduction and stabilization of lower limb fractures can successfully manage associated soft tissue concerns. However, “immediate definitive fixation” may not always be possible. Schepers et al reported that delaying surgery for more than a day in ankle fractures significantly increased the risk of postoperative wound infections. Similarly in another study, the timing of surgery affected bone union; a delay of 5-8 days resulted in slower bone healing at 6 weeks and prolonged immobilization. The need for reliable fixation methods has motivated surgeons to improve minimally invasive techniques. Fibula nail was first described in the 1970s and has developed over the years to an implant that allows for interlocking screw fixation and improved stability. A prospective study comparing the clinical and functional outcomes of fibula nail to ORIF in unstable ankle fractures in the elderly demonstrated a significantly reduced postoperative risk of soft tissue complications, proving to be more cost-effective than ORIF. Another study found significantly fewer postoperative complications following fibula nail fixation in comparison to ORIFs.

This is the largest multicenter study to date investigating the clinical outcomes of fibula nail fixation relative to published ankle ORIF outcomes. Our study demonstrates that the postoperative infection rate of 4.2% and metalwork complication rate of 5.2% following fibula nail fixation is lower than reported rates for ankle ORIFs. Skin incision and soft tissue dissection for fibula nail insertion is minimal at approximately 1 to 2 cm, making this an alternative implant in poor-quality skin and soft tissues. The rate of removal of hardware was 2.1%. This is less than the reported rate for plate constructs following ankle ORIFs. The nonunion and malunion rate in this study was 8.4%. Nonunion of distal fibula fractures are rarely reported. A study stated an overall incidence of fibula nonunion varying between 0.3% and 5.4%, with approximately >80% of cases being symptomatic.

Time to union was 12.5 weeks, which is comparable to ankle ORIFs. A prospective study by Asloum et al found

| Injury Characteristics | Fracture pattern (AO Classification) | Frequency (n) | % | Post-operative infections (n) | Metalwork complications (n) | Nonunion (n) | Malunion (n) |
|------------------------|-------------------------------------|--------------|---|-----------------------------|-----------------------------|-------------|-------------|
| B1                     | 11                                  | 15.9         |    | 1                           | 2                           |             |             |
| B2                     | 32                                  | 46.4         |    | 1                           | 2                           |             |             |
| B3                     | 26                                  | 37.7         |    | 1                           | 2                           |             |             |
| C1                     | 12                                  | 41.2         |    | 2                           | 2                           | 1           |             |
| C2                     | 13                                  | 50           |    | 1                           |                             |             |             |
| C3                     | 1                                   | 3.9          |    |                             |                             |             |             |
| Closed fractures       |                                     |              |    | 3                           | 5                           |             |             |
| Swelling               | 39                                  | 41.1         |    | 1                           | 3                           |             |             |
| Abrasions              | 5                                   | 7.1          |    |                             |                             |             |             |
| Blisters               | 8                                   | 11.4         |    |                             |                             |             |             |
| Ecchymosis             | 10                                  | 14.3         |    | 1                           | 2                           |             |             |
| Swelling and blisters  | 6                                   | 8.6          |    |                             |                             |             |             |
| Poor skin quality      | 2                                   | 2.0          |    |                             |                             |             |             |
| Open fractures (Gustillo-Anderson) | | 25 | 26.3 | 2 | 2 | 2 | 1 |
| I                      | 4                                   | 16           |    | 2                           |                             |             |             |
| 2                      | 4                                   | 16           |    |                             |                             |             |             |
| 3a                     | 8                                   | 32           |    |                             |                             |             |             |
| 3b                     | 8                                   | 32           |    |                             |                             |             |             |
| 3c                     | 1                                   | 4            |    |                             |                             |             |             |
no significant difference in the rate of union between plate and nail fixation of the fibula. The average length of hospital stay in this study was 9.4 days and maximum length of stay was 42 days: there were a significant number of medically complex patients and over a quarter had open fractures, which may explain the extended length of stay. In this study, the indication for the use of the fibula nail was predominantly Weber B and C ankle fractures. This correlates with the implant design; fibula nail would be difficult to use in very distal fibula fractures owing to placement of the 2 distal AP screws.

We found the fibula nail to be a useful fixation method in patients who have compromised soft tissues. Achieving adequate reduction is possible with the modern fibula nails. Inserting 1 or 2 AP screws through the fibula nail secures the distal fragment to the rod system and allows gentle and controlled movements to anatomically reduce the ankle mortise under radiographic guidance. To maintain this reduction, another LM screw can be inserted to lock the rod system in place, stabilizing the lateral buttress of the mortise. There is a risk, however, that with reaming and drilling of the intramedullary canal, the fracture can displace.

**Limitations**

Fibula nail fixation is an evolving technique, building on conventional principles employed in current practice, but still not widely adopted. In this study, of the 33 responding centers, only the recruited 11 had performed fibula nail fixation. As with all new surgical implants, there is a period of transition and a learning curve. This study does not take into consideration the grade and subspecialty of the
surgeon performing the fibula nail. Notably, Backer et al. did not find a significant learning curve in experienced trauma surgeons adopting fibula nails in comparison to ankle plate fixations.

As this was a retrospective study, our clinical outcomes were compared to published outcomes. A randomized controlled trial is required to compare standard ORIF to nail for each fracture pattern and patient group. Furthermore, heterogeneity in radiologic interpretation for fracture union among centers may have influenced the overall rate. This study is, however, strengthened by the pragmatic design involving its multicenter nature: 11 centers including level 1 major trauma units covers a wide geographical and socially diverse population.

**Conclusion**

This study shows that use of fibula nails was a safe approach to treating high-risk patients with compromised soft tissues. The risks of wound and metalwork complications appear relatively low.

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