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Early Weight-Bearing Using Narrow Symmetrical Distal Fibular Plate: Preliminary Results

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Abstract: Background: Ankle fractures, comprising about 10% of musculoskeletal injuries, pose a significant healthcare burden with an increasing incidence, particularly among an aging population. This study focuses on isolated Danis-Weber type B fractures. Recent trends lean towards surgical intervention for anatomical restoration and quicker recovery, albeit with associated complications. This report aims to assess the safety and efficacy of the NewClip narrow locking plate system with early weight-bearing in treating isolated fibular fractures. Methods: The study includes patients with Danis-Weber type B fractures surgically treated with the NewClip narrow locking plate system. Exclusions involved nondisplaced fractures, open fractures, or those requiring additional fixation. Results: Fifteen patients were enrolled in this study. Minor complications, including wound swelling, were observed in two cases. The Visual Analogue Scale (VAS) for pain exhibited a steady decline postoperatively, with almost complete resolution by the third month. At three months, the FAOS demonstrated excellent results, and a final follow-up at twelve months revealed complete osseous healing without complications. Conclusions: The use of this type of plate in treating isolated fibular fractures with early weight-bearing shows promising results in terms of fracture healing, pain resolution, and functional outcomes, warranting further investigation with larger cohorts.

Keywords: closed ankle fractures; distal fibular fractures; early weight-bearing

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1. Introduction

Ankle fractures are among the most common injuries affecting the lower limb [1]. The annual incidence of these fractures has been estimated at approximately 200 cases per 100,000 person-years [2,3], but international trends suggest that ankle fracture rates will continue to rise due to an aging population. Ankle fractures account for about 10% of all musculoskeletal injuries [4,5] and more than half of all foot and ankle injuries [4–6]. Within this context, isolated malleolar injuries constitute two-thirds of all ankle fractures [1,4,5]. Danis-Weber type B fractures represent the most common form of distal fibular fractures; they typically result from a supination-external rotation mechanism and are characterized by an oblique fracture line [7]. While conservative treatment has historically been recommended for isolated fibular fractures without signs of ankle instability, recent trends favor surgical intervention, offering advantages in terms of anatomic restoration and earlier recovery [8]. However, operative management of these fractures is associated with potential complications, including non-union, malunion, post-traumatic osteoarthritis, and skin-related issues, such as delayed wound healing or plate exposure [9].

Established operative management of unstable fibular fractures treated by open reduction and Internal Fixation (ORIF) or casting could require at least 6 weeks of non-weight-bearing. Protracted immobilization is both damaging to the patient and the healthcare system, due to possible postoperative complications like joint rigidity and delay for returning to daily work. However, some recent clinical studies have demonstrated that rapid

mobilization and early weight-bearing with ankle fractures significantly improved short-term outcomes [10]. In fact, it was observed that the ability to immediately weight-bear postoperatively is associated with shorter inpatient stays with no increased risk of complications and faster consolidation. However, this approach must be carefully considered based on fracture morphology, initial stability, patient age, and comorbidities.

The purpose of this brief report is to analyze whether the use of a new narrow locking plate system can be a safe treatment option for isolated fibular fractures.

2. Materials and Methods

In this study, we enrolled all patients who underwent surgery for distal fibular fractures at our level-one trauma center after January 2020. The inclusion criteria comprised Danis-Weber type B fibular fractures with displacement greater than 2 mm, shortening, or rotation. All these fractures were treated using narrow NewClip Technics distal fibula locking plates (ACTIV ANKLE). Only patients with closed growth plates (defined by a minimum age of 16 years) and a minimum follow-up of 12 months were included in the study.

We excluded cases of nondisplaced Danis-Weber type B fibular fractures that were managed with simple immobilization, as well as cases involving open fractures or medial injuries requiring additional trans-syndesmotic screw fixation or deltoid ligament repair.

Preoperative patient characteristics, including age, sex, body mass index, American Society of Anesthesiologists (ASA) score, operative time, and length of hospital stay after surgery were recorded (Table 1).

Table 1. Patient characteristic and baseline variables.

	Mean	**Range**
Age (years)	41	18–64
BMI * (Kg/m^2)	23	18–29
Surgical time (minutes)	40	30–65
Hospitalization (days)	2.6	1–5
ASA	1.3	1–3
Sex	4 Female/11 Male	

* Body Mass Index.

2.1. Surgical Procedure

Patients were positioned supine on a radiolucent operating table under either general or spinal anesthesia. A pneumatic tourniquet was applied to the proximal thigh and inflated to 280 mmHg after exsanguination. All surgical procedures were performed via a lateral approach. Following manual traction for fracture reduction, we temporarily stabilized the oblique fracture by compressing the fracture site using a reduction clamp. An interfragmentary lag screw was used only once. All patients were treated with the narrow NewClip plates ACTIV ANKLE (NewClip Technics—France), which were provided as single-use sterile kits. These plates come in two sizes: size 1 with 7 holes (76 mm in length) and size 2 with 9 holes (102 mm in length). Both kits included standard 3.5 mm cortical screws and either 3.5 mm or 2.8 mm locking screws.

In all cases, at least 3 distal 2.7 mm unicortical locking screws were utilized. Proximally, a combination of cortical and locking screws was employed based on the surgeon's judgment. Closed suction drainage was placed in all cases. Subcutaneous tissue was closed using synthetic absorbable interrupted sutures, while skin closure was achieved with either surgical staples or non-absorbable monofilament sutures. After fracture fixation, ankle stability was assessed under fluoroscopic control. An external rotation force was applied to the foot, and the ankle was evaluated for "talar shift", which indicates opening of the medial clear space between the talus and the medial malleolus. Additionally, the fibula "hook-test" was performed to assess syndesmotic stability [11]. Patients exhibiting persistent instability during the intraoperative "hook-test" following distal fibular fixation

were either managed with a trans-syndesmotic screw or underwent deltoid ligament repair. Such cases were subsequently excluded from the study.

2.2. Patient Evaluation

Following surgery, the ankle joint was maintained in a neutral position using a short-leg splint. Starting from the second postoperative day, patients initiated a structured physiotherapy regimen focusing on active ankle range of motion (ROM) exercises and muscle strengthening. Progressive weight-bearing was limited to 20 kg for the first 3 weeks, during which time a bivalve ankle brace and crutches were used. After this initial period, patients transitioned to full weight-bearing as tolerated by pain, with the goal of gradually discontinuing the use of crutches. The physiotherapy program continued to emphasize muscle strengthening and achieving a complete ROM.

Patients underwent follow-up evaluations at 6 weeks, 3 months, 6 months, and 12 months postoperatively.

The follow-up assessments encompassed both clinical and radiological evaluations. To assess lower extremity and ankle function, we employed the Foot and Ankle Outcome Score (FAOS) [12], which consists of 5 subscales ranging from 0 to 100 (with higher scores indicating better function). Additionally, we utilized the Visual Analogue Scale (VAS) to evaluate pain (scores ranging from 0 to 100, with higher scores indicating more severe pain or dysfunction) [13].

Postoperative X-rays were carefully evaluated to detect bony healing, identify any secondary loss of reduction, and assess for potential mechanical failure of the implant. We considered fracture union to be achieved when the fracture line had disappeared. According to Mendelsohn [14], non-union was defined as the persistence of a fracture line at least two to three millimeters wide with sclerosing fracture surfaces, observed at least six months after the initial fracture.

2.3. Statistical Analysis

Continuous data were expressed as means, whereas categorical and ordinal data were expressed as absolute values and percentages. All analyses were performed with SPSS v. 22.0 (SPSS, Chicago, IL, USA) and Microsoft Excel v. 16.30 (Microsoft Corporation, Redmond, WA, USA).

3. Results

A total of 17 patients met the study's inclusion criteria. All successfully completed the partial weight-bearing program. However, two patients were lost to follow-up after the three-month assessment and did not participate in the twelve-month clinical and radiographic evaluations. Consequently, data from fifteen patients were available for all follow-up examinations.

The mean age of the cohort was 41 years (ranging from 18 to 64). Among the participants, 4 were women and 11 were men. The average body mass index (BMI) was 23 kg/m^2 (with a range of 18–29 kg/m^2). There was 1 patient classified as ASA class 3, while 3 were ASA class 2; the remaining patients were ASA class 1. The average surgical duration was 40 min (ranging from 30 to 65 min), and the mean postoperative hospitalization time was 2.6 days (with a range of 1 to 5 days). See Table 1.

Minor complications were observed in 2 cases, characterized by swelling and redness at the wound site at the 6 week assessment.

At the final follow-up, 12 months after surgery, complete osseous healing was observed in all patients (Figures 1 and 2).

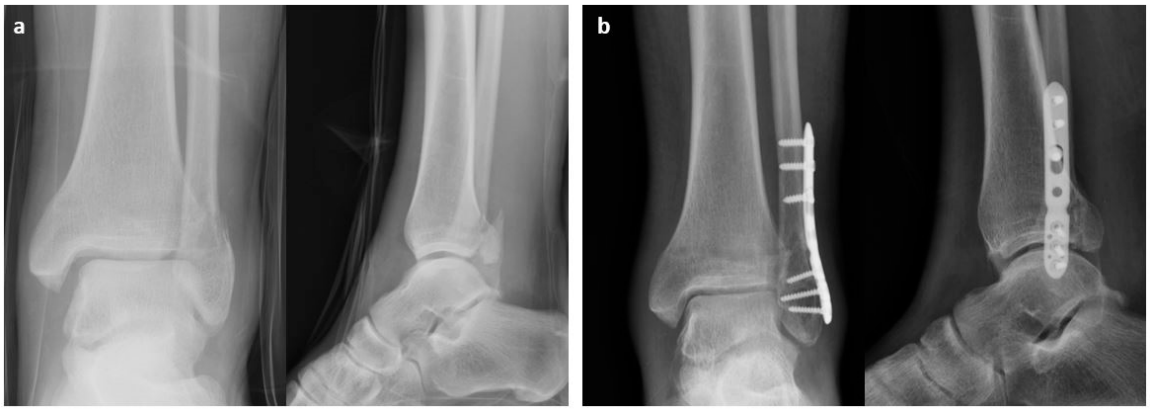


Figure 1. (**a**) Antero-posterior and lateral X-rays of a 41 year-old male patient who sustained a left lateral malleolar, Denis-Weber type-B fracture. (**b**) Antero-posterior and lateral X-rays of the same patient at the 8 month follow-up.



Figure 2. (**a**) Antero-posterior and lateral X-rays of a 64 year-old female patient who sustained a left lateral malleolar, Denis-Weber type-B fracture. She underwent an ORIF procedure with lag screw and plate fixation. (**b**) Antero-posterior and lateral X-rays of the same patient at the 12 month follow-up.

All patients but 1 reported a complete consolidation at the 3 month follow-up; the persistence of a fracture line disappeared at the next follow-up (6 months after surgery) (Figure 3). However, it was not associated with any symptoms and the patient had been free weight-bearing walking after 5 weeks post-surgery.



Figure 3. (**a**) Antero-posterior and lateral X-rays of a 32 year-old male patient who sustained a right lateral malleolar, Denis-Weber type-B fracture. (**b**) Antero-posterior and lateral X-rays of the same patient at the 3 month follow-up: the fracture line is still visible. (**c**) Antero-posterior and lateral X-rays of the same patient at the 6 month follow-up: the fracture has disappeared.

The Visual Analogue Scale (VAS) score demonstrated a progressive reduction during the initial 6 week post-treatment period, with near-complete pain resolution after 3 months. (Figure 4).

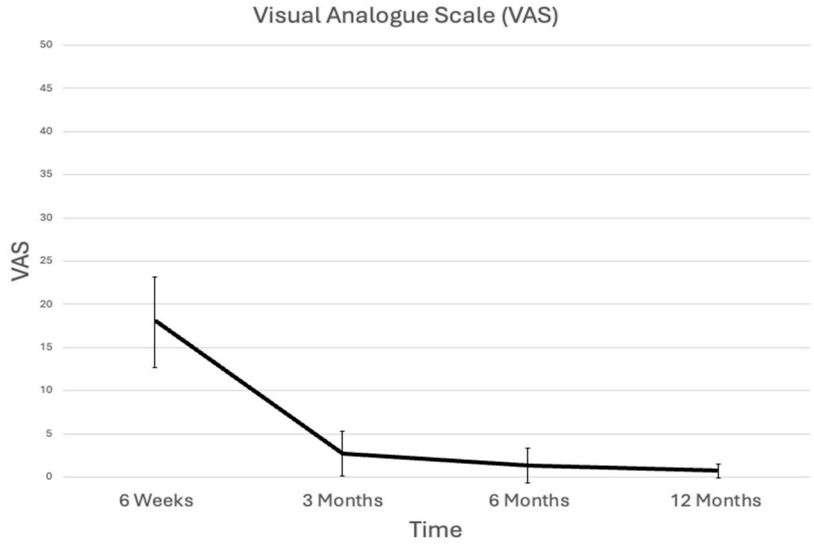


Figure 4. Patient Visual Analogue Scale (VAS) score through follow-ups.

At 3 months, the FAOS Score was 100 for 11 patients, 3 with 97, and 2 with 94 points. (Figure 5).

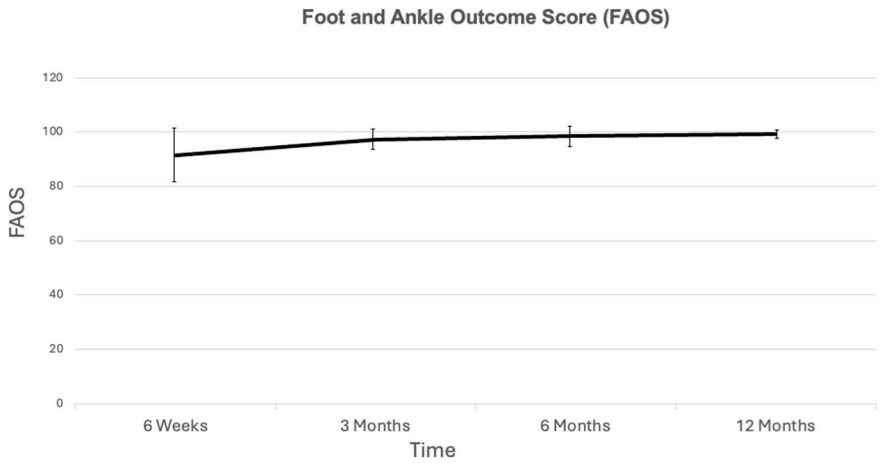


Figure 5. Patient Foot and Ankle Outcome Score (FAOS) through follow-ups.

Excellent results were reported in all cases at six months. No mechanical complications, loosening screws, or broken material were reported. No cases of deep infection have been observed. None of our patients underwent hardware removal.

4. Discussion

The key finding from this brief is that allowing early postoperative weight-bearing, associated with immediate joint function recovery, is a secure approach for managing uncomplicated unimalleolar ankle fractures classified as Danis-Weber type B. At the three-month assessment post-surgery, all patients exhibited complete consolidation, except for one patient who continued remodeling at six months. There were no mechanical complications, loosening screws, or material breakage reported. Additionally, no cases of deep infection were observed. The favorable impact of an earlier return to walking and rapid mobilization has been well-documented even for the conservative treatment of such fractures, using either a bivalve pneumatic air stirrup [15] or a hinged short-leg boot [16].

Functional treatment has also been supported by improved Visual Analogue Scale scores and total range of motion (ROM) recovery when compared with a brace rather than with a cast after six weeks [17]. Studies allowing early weight-bearing with conservative treatment have also shown good clinical outcomes, though 16% of these patients experienced fracture displacement, potentially leading to the development of secondary osteoarthritis in the long term [18].

A meta-analysis of randomized controlled trials indicated that early weight-bearing led to better outcomes in terms of returning to work and daily activities compared to late weight-bearing [19]. Another randomized controlled trial by the same author demonstrated that postoperative care involving unprotected weight-bearing and mobilization resulted in short-term functional improvements and a quicker return to work and sports, without increasing complications [20]. Our findings are consistent with these established results and support the existing body of evidence, confirming that early postoperative weight-bearing is a safe and effective strategy for improving patient outcomes in uncomplicated Danis-Weber type B ankle fractures.

Accelerating the initiation of weight-bearing has several benefits. Firstly, early weight-bearing can expedite a patient's return to independent daily activities and work. Gul et al. found that patients who began weight-bearing early returned to work significantly faster than those who did not [21].

Surgical intervention for these fractures has been associated with complications such as non-union, malunion, post-traumatic osteoarthritis, and skin issues ranging from delayed wound healing to plate exposure. Some authors have reevaluated non-operative approaches if instability is ruled out [22–24]. Recently, ankle stress radiographs have gained popularity for assessing ankle stability in cases of isolated lateral malleolar fractures [25–27].

Unfortunately, interpreting these tests is not always easy. If a perfect mortise view cannot be obtained with dorsiflexed ankles, identifying relevant landmarks becomes challenging [28]. The primary concern associated with incorrect non-operative treatment is an increased risk of ankle mortise incongruency, which can lead to secondary surgeries, early post-traumatic osteoarthritis, and compromised function.

For these reasons in the literature, there is no consensus regarding the optimal method for managing lateral malleolus fractures.

Various fixation methods have been proposed for distal fibula fractures, including the use of one-third tubular plates, dynamic compression plates, and locking plates with or without an independent lag screw. Locking malleolar plates have demonstrated improved surgical outcomes when anatomical reduction and appropriate weight-bearing capacity are achieved. Notably, the locking plate has been shown to provide higher shear and rotational stability compared to the neutralization plate in an osteoporotic bone model under physiological loading.

However, in a retrospective study, Schepers et al. [29] advised against the use of locking plates due to an increased risk of wound complications compared to conventional plates (17.5% vs. 5.5%). This discrepancy is likely related to the thickness and, consequently, the less pre-contourable nature of some of these systems.

The locking plate utilized in the study features a low-profile design, closely resembling the non-locking tubular plate. However, it incorporates polyaxial locking screws in the epiphysis, allowing for an angular range of 20 degrees. These polyaxial locking holes are strategically positioned in the epiphyseal area, accommodating 2.8 screws. This design facilitates the insertion of at least three epiphyseal screws in diverging or converging directions, optimizing the overall strength of the assembly. Additionally, the diaphyseal portion of the plates can be bent at specific areas to enhance congruence between the plate and the bone.

The primary limitation of this study lies in the small number of enrolled patients and the absence of a control group. Despite these limitations, we are confident that this study represents a crucial step in testing research protocols and providing the groundwork for future research projects.

5. Conclusions

Open reduction and internal fixation are the most common treatments for unstable ankle fractures, which can be achieved through several fixation methods. The presented study shows that early weight-bearing following osteosynthesis with a straight narrow locking plate represents a safe approach, which allows for rapid consolidation and limited complication. A well-designed prospective study is needed to confirm our findings.

Author Contributions: D.T. and C.M.L. participated in the conceptualization, development of the study design, data collection and curation, and writing of the original draft. G.M. (Giuseppe Mobilia) and C.D. performed the formal analysis and participated in writing the original draft. A.O. and S.S. participated in reviewing and editing the data and final draft. D.T., G.M. (Giuseppe Melucci), and C.M.L. provided the study materials, patients, and settings. They participated in the oversight and leadership responsibility for the research activity, planning, and execution. G.M. (Giuseppe Melucci) participated in the project administration, management, and coordination responsibility for the research activity. All authors have read and agreed to the published version of the manuscript.

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Data Availability Statement: The raw data supporting the conclusions of this article will be made available by the authors on request.

Conflicts of Interest: The authors declare no conflicts of interest.

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