Combined dynamized nailing with partial fibulectomy for aseptic diaphyseal tibial nonunion in adults

Amr Elshahhat, Saad Abouelezz

Orthopedic Surgery, Mansoura University Hospital, Mansoura University, Mansoura, Egypt

Correspondence to Amr Elshahhat, MD, Orthopedic Surgery, Mansoura University, Algomhoria Street, Mansoura University, Postal code: 33516, Mansoura, Egypt. Tel: +201092025121; fax: +20 (50) 239733, +20 (50) 2397900; e-mail: amrelshahat@mans.edu.eg

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Background and aim of the study
Mechanical stability of hypertrophic nonunion remains the goal for treatment leading to bony bridging and remodeling. Partial fibulectomy or dynamization was reported with a wide range of clinical and radiological results. This study aims at assessment of combined dynamically locked nailing with partial fibulectomy technique to reach biological and mechanical stability with shorter healing time.
Patients and methods
This study included seventeen skeletally mature patients with aseptic diaphyseal hypertrophic tibial nonunion after nailing or external fixator. Patients with infected nonunion, atrophic nonunion, skeletally immature, and those with incomplete follow-up were excluded. Included patients were allocated into two groups, and final functional and radiological outcome regards healing time, union, limb alignment and rotation, knee and ankle rage of motions were reported.
Results
The mean follow-up period was 33.3±6.2months. All nonunions healed successfully within 11.9±1.5weeks (range: 10–16 weeks). One patient had tibial plafond injury that necessitated nail removal. The mean angle of coronal angulation was 1.4±1.4°. The rotational difference between both limbs as per the thigh-foot angle was 2.5±1.7°. The average functional outcome as per the Karlström-Olerud scale score was 30.9±3. A significant difference was evident between the external fixator group and the nailing group in terms of functional grading scale (*P*=0.03).
Conclusion
The combined dynamically locked nailing with partial fibulectomy technique is a biology-preserving technique that provides mechanical stability, allows early return to functional activity with complete bone healing and no need for further surgeries.

Keywords:
diaphyseal, dynamically locked nailing, fibulectomy, tibial nonunion

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Introduction

Tibial nonunion has been defined as the failure to achieve union by 6–9 months since the injury, with no evidence of radiological healing [1]. The hypertrophic type of nonunion has a biological potential with unstable mechanical environment [2]. A concomitant fibular fracture with tibial injury usually heals in 6 weeks [3]. The fibula carries nearly 6–15% of the lower extremity load. An intact or healed fibula in tibial nonunion acts as a strut splinting the tibial segments, and holds them apart, thus resists compression at the nonunion site, limiting the beneficial effects of weight bearing [4]. No consensus exists regarding the ideal method of management of hypertrophic tibial nonunion.

Mechanical stability remains the goal for the treatment of hypertrophic nonunion, leading to calcification of the fibrous cartilage formed at the nonunion site, subsequently, penetrated by excess new vessels, allowing final bony bridging and remodeling [2]. Partial fibulectomy (PF) was utilized as a method of management for nonunion either with or without nailing or external fixator [3,5–8]. Others reported the outcome of dynamization without PF or fibulotomy [9–12]. These studies [3,5–11,13] revealed a relatively long healing time with variable clinical and radiological results, additionally, it could necessitate another procedure as external fixator (EX-FIX) removal.

We hypothesized that combined dynamically locked nailing (DN) with PF can hold off these concerns. Biological and mechanical stability can be achieved, with a shorter healing time and no need for further interventions. This study aimed at assessment of clinical and radiological results of combined dynamically locked nailing (DN) with PF technique

(DNPF technique) in management of aseptic diaphyseal hypertrophic tibial nonunion in adults with a minimum two-year follow-up.

Patients and methods

This study has been approved by the institutional research board of the authors' affiliated institution in line with the principles of the Declaration of Helsinki. All participants completed and signed an informed consent form. This cohort study included 17 skeletally mature patients with aseptic diaphyseal hypertrophic tibial nonunion or delayed union (Fig. 1). From whom, seven patients were initially managed by uniplanar EX-FIX, and ten patients with intramedullary nailing (IMN). Patients with infected nonunion, soft tissue compromise, atrophic nonunion, skeletally immature, associated ipsilateral lower limb injuries, patients who underwent open reduction of non-correctable malalignment of tibial segments accompanying nonunion, and those with incomplete follow-up were excluded. All patients underwent DNPF and were followed at the period from January 2018 to July 2023.

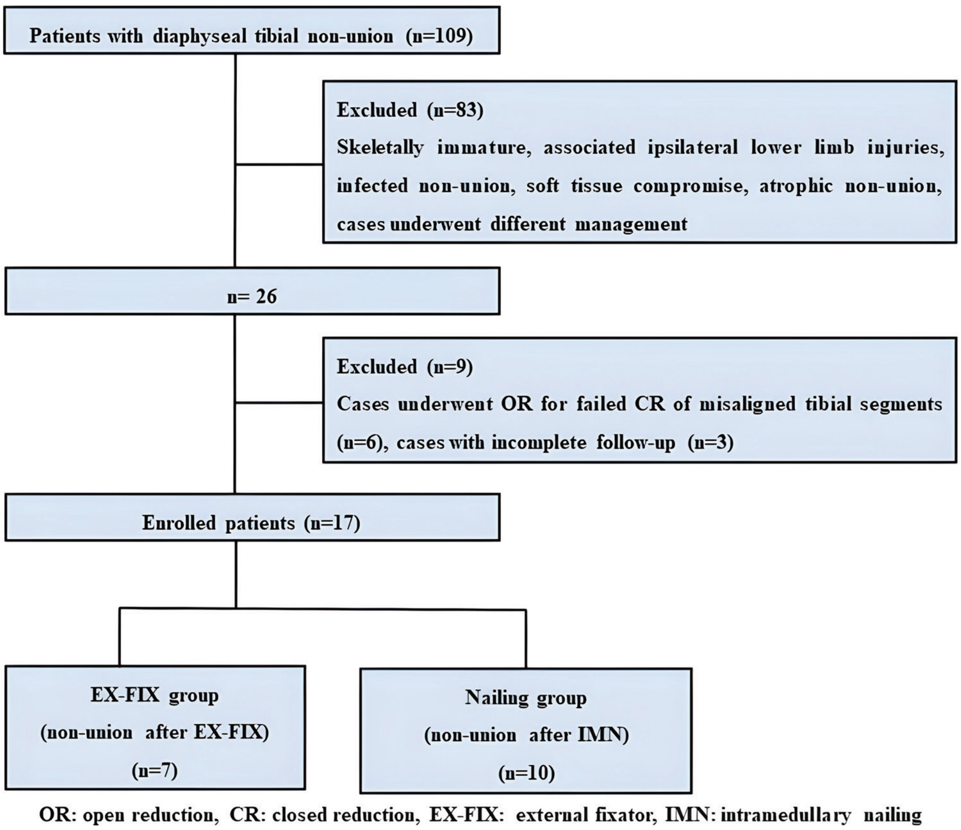
Reviewing patients' records, 13 patients (76.5%) had tibial fracture after a road traffic accident, three patients (17.6%) fell from height, and one (5.9%) after direct trauma by a heavy object. Four patients suffered an open grade 3 A injury, three with open grade 2 injury, two with open grade 1 injury, and eight patients with closed fractures. As per the revised AO/OTA classification [14], previous antero-posterior (AP) and lateral leg radiographs revealed: 42A2(b)-injury in seven patients, 42A3(b)-injury in five patients, 42B2(b)-injury in three patient, 42B3(b)-injury in one patient, and 42C2-injury in another patient. A concomitant fibular fracture was noted in twelve patients: of whom eight patients (47%) with 4F2A(a)-injury, three patients (17.6%) with 4F2B(b)-injury, and one patient (5.8%) with 4F2A(b)-injury. Fibula was intact in five patients (29.4%).

Preoperatively, infection was excluded via skin, soft tissue condition, and inflammatory markers. Recent leg radiographs were checked for healing status, implant status, and to exclude any signs of infection.

Surgical technique

All patients underwent spinal anesthesia under complete aseptic condition taking the advantage of tourniquet providing a bloodless field to facilitate dissection. EX-FIX was removed in the same setting in five patients, whilst it was removed in a separate session in two patients spaced by 6 weeks from DNPF with antibiotic coverage. Patients with history of IMN underwent nail exchange and PF in the same session.

Figure 1



A flowchart for the study enrolment process.

In supine position, a lateral skin incision, overlying fibula, was made approaching the internervous plane between both peronei, deep dissection through the plane between peronei and soleus muscles. Overlying periosteum was longitudinally excised exposing fibular surface. Subsequently, a 2 cm-fibular segment was excised using an oscillating saw and/or osteotomes. Care was taken to protect peroneal vessels. PF was performed at the level of healed fracture (middle third), or at 15 cm superior to tip of lateral malleolus (intact fibula or proximal fibular fracture), sparing 7 cm from the ankle joint to maintain ankle stability [3,15]. The fibulectomy level was confirmed intraoperatively by the image intensifier. Afterwards, the tourniquet was deflated, good hemostasis was achieved, afterwards, a suction drainage was inserted, and the wound was closed in layers. In the EX-FIX group of patients, PF was performed after EX-FIX removal and after nail exchange in nailing group. Following PF, the leg was hung vertically on the support post of the fracture table. In EX-FIX group, tibial shaft was manually corrected by means of osteoclasis correcting any coronal or sagittal malalignments.

Patellar-splitting entry was utilized in this series, and the guide wire was aimed to the center of distal tibia. Sequential balanced reaming was performed using an incremental increase of drill bits. Tibial isthmus was overreamed with 1 mm more than the final nail diameter. It was ensured that the used nails demonstrated good cortical contact, reaming was limited to a nail diameter that filled the intramedullary canal or at least 2 mm larger than initial nail diameter size. The inserted nail was only locked proximally via two screws of 5 mm-diameter. Nonunion site was neither exposed in any procedure nor graft was introduced in any of the cases.

Postoperatively, all patients were encouraged for partial weight bearing using crutches from day one. The drainage tube was removed 24 h later. Full weight bearing was allowed for all cases as pain tolerated. A 33-year-old female complained of discomfort and sense of instability with weight bearing. This may be explained by the patient's overweight, in addition to her dependence on using crutches for a long period of time that lasted for more than ten months. Accordingly, a below knee Sarmiento plaster splint was performed that was discontinued three weeks later with stitches, from then, she started unsupported weight bearing. Knee and ankle active range of motion (ROM) was encouraged from day One for all patients. Serial radiographs were followed till fracture healing.

All patients were followed for a minimum two-years. At final follow-up period, the functional outcome was assessed via the Karlström-Olerud physical function scale (Table 1) [16]. Results were evaluated as follows: poor (21–23 points), moderate (24–26points), satisfactory (27–29 points), good (30–32 points), and excellent (33–36 points). Knee and ankle active ROMs were measured bilaterally, and the difference in-between was reported. The pain grade was noted according to the numerical visual analogue scale (VAS) [17]. Tibial torsion was bilaterally assessed and compared as per the thigh-foot angle (TFA). In a prone position, the ankle was put into a neutral position and knee in 90° flexion. The angle between foot and thigh axes was measured by goniometry [18]. The torsional difference between both limbs was documented. Malrotation was considered when rotational difference was ≥10° [19,20].

Healing status at final radiographs was assessed regarding the radiographic union scale in tibial fractures (RUST) score [21]. The four tibial cortices in the leg radiographs were observed for fracture line visibility at each cortex (Table 2). Scores of 12 were the highest and 4 the lowest. Additionally, the coronal axis alignment was assessed measuring tibial mechanical axis. Also, bilateral tibial length was measured, and length discrepancy in millimeters (mm) between each tibia was documented using picture archiving and communication (PACS) system related to radiology department of authors' affiliated institution.

Table 1 The Karlström-Olerud physical function scale [16]

Outcome parameters	3 points	2 points	1 point
Pain	No	slight	Severe
Difficulty in walking	No	Moderate	Severe Limp
Difficulty in climbing stairs	No	With help	Unable
Difficulty in previous sports activity	No	Some sports	Unable
Occupational limitation	No	Moderate	Unable
Skin status	Normal	Different colour	Ulcer/Fistula
Deformity	No	Mild, up to 7°	Significant, >7°
Muscle atrophy	<1 cm	1–2 cm	>2 cm
Leg shortening	<1 cm	1–2 cm	>2 cm
Loss of motion at knee joint	<10°	10–20°	>20°
Loss of Subtalar motion	<10°	10–20°	>20°

Table 2 Radiographic union scale for tibial fractures (RUST) [21]

Cortex	Score=1 (Fracture line visible, no callus)	Score=2 (Visible fracture line and callus)	Score=3 (No fracture line, visible callus)	Total score minimum:4 maximum:12
Anterior				
Posterior				
Lateral				
Medial				

Healing time was reported as the time elapsed between the intervention and painless full weight bearing with radiological signs of progressive consolidation [22]. Successful fracture healing was defined clinically as no pain at fracture site with weight-bearing, no movement on the fracture line, radiographic solid bridging callus with sufficient cortical density connecting both segments [23]. Nonunion was clinically determined via persistent pain with weight bearing, and radiologically as a lack of radiographic bridging at three cortices on radiographs [24].

Furthermore, patients were allocated in two groups, EX-FIX and nailing groups according to previous intervention. Clinical and radiological outcomes were compared between both groups. Complications throughout the follow-up period was documented whenever found, counting for wound problems, limb shortening, pain at tibial nonunion site, anterior knee pain, ankle joint stiffness, coronal and sagittal deformities.

Data were analyzed using IBM SPSS Corp. IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp. Qualitative data were described using number and percent. Quantitative data were described using median (minimum and maximum) for non-parametric data and mean, standard deviation for parametric data. The unpaired t-test and the Man Witney U test were used to compare two independent groups with normal and abnormal distributed data. The significance of the obtained results was judged at the 0.05 level.

Results

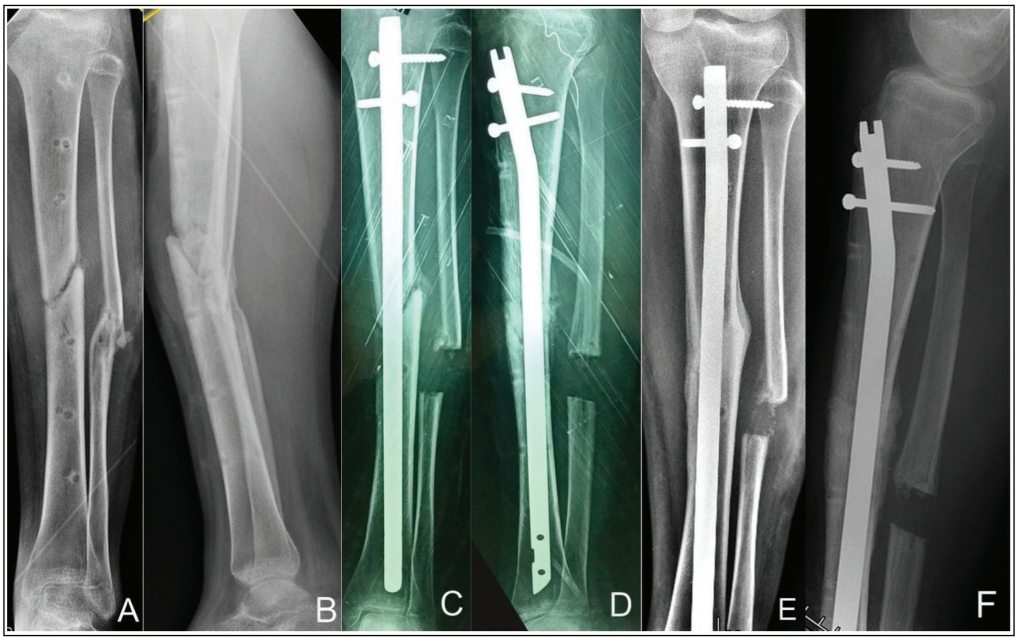
Out of seventeen patients, 16 males and one female were included in this study. The mean age was 36 ± 6.9years (range: 22–45 years). No significant difference (*P*= 0.46) was noted between the EX-FIX group (35.9 ± 8.6years) and nailing group (36.2 ± 5.9years). patients with heavy work duties accounted for 82.3% of cases, while three patients had sedentary work. Eleven patients (64.7%) were heavy smokers. No comorbidities were documented except for; three patients with hypertension and one with type 1 diabetes mellitus. All cases presented after a period of 11.6 ± 1.9 months of nonunion, with a significant difference (*P*=0.03) between EX-FIX group (10.6 ± 1.5 months) and nailing group (12.3 ± 1.9 months).

The mean follow-up period of our patients was 33.3 ± 6.2months. Follow-up durations were 34.7 ± 6.7 months and 32.3 ± 5.9 months in EX-FIX and nailing groups, with no significant difference in-between (*P*=0.22). Finally, all patients showed complete radiographic healing (Fig. 2), with a mean 10.5 ± 1 points as per RUST score. All nonunions healed successfully within 11.9 ± 1.5weeks (range: 10–16 weeks), there was no significant difference (*P*=0.44) in healing time between EX-FIX group (12 ± 1weeks) and nailing group (11.9 ± 1.8weeks). The mean angle of coronal angulation among patients was 1.4 ± 1.4°.

The knee flexion-extension difference was only limited by a mean of 7.6 ± 3.4° from contralateral side. The mean flexion and extension lag ROMs were limited by 4.3 ± 2.9° and 3.4 ± 1.9° from the other side. The mean differences in ankle active dorsiflexion and plantar flexion were 4.7 ± 4.7° and 2 ± 2.3° between both ankles. The mean limb shortening among patients was 0.9 ± 0.5 cm, with a complaint from three patients (17.6%), that was overcome by a shoe lift. No pain at fracture site was reported except for one patient with history of open grade 3 injury, however, radiographic healing was evident at three cortices at his radiographs. Thirteen patients (76.5%) experienced anterior knee pain. The mean VAS was 3.4 ± 1.4. The rotational difference between both limbs as per TFA was 2.5 ± 1.7°.

The functional results regard the Karlström–Olerud scale were graded excellent in eight patients (47%), good in four patients, satisfactory in three patients, and moderate in two patients. The average score was 30.9 ± 3 among patients. A significant difference was evident between EX-FIX and nailing groups in terms of functional grading scale (*P*=0.03), coronal alignment (*P*=0.002), and LLD (*P*=0.03). Anterior knee pain was evident in 71.4% and 80% of patients of the EX-FIX and nailing groups. Detailed results of each group were tabulated (Tables 3 and 4). All patients experienced a successful healing, with no complications except for one patient with tibial plafond injury (Fig. 3), that necessitated nail removal. Later, he suffered ankle stiffness.

Figure 2



Preoperative (A, B), postoperative (C, D), and final follow-up (E, F) radiographs for twenty-one year-male patient underwent DNPF technique showing complete radiological union with no malalignment in coronal and sagittal planes.

Table 3 Difference between EX-FIX and nailing groups in terms of ROMs

ROMs	EX-FIX group (*N*=7)	Nailing group (*N*=10)	*P* value
Knee flexion difference	4.1±2.8°	4.5±3.2°	0.4
Knee extension lag difference	3±2.6°	3.7±1.3°	0.24
Knee flexion-extension ROM difference	7.14±3.7°	8.2±3.2°	0.27
Ankle dorsiflexion difference	5.1±6.2°	4.5±3.8°	0.39
Ankle plantar flexion difference	2.6±3°	1.7±1.7°	0.23

*Means significant difference.

Table 4 Difference between EX-FIX and nailing groups in terms of functional and radiological outcome

Functional outcome variables	EX-FIX group (*N*=7)	Nailing group (*N*=10)	*P* value
Karlström-Olerud score	29.3±3.7	32±1.9	0.03*
LLD (cm), complaint (%)	1.2±0.6 cm, 28.6%	0.7±0.4 cm, 10%	0.03*
TFA difference	3±1.9°	2.2±1.6°	0.18
VAS	3.7±1.3	3.1±1.4	0.2
RUST score	10.6±1.1	10.4±0.9	0.37
Coronal alignment	2.5±1.5°	0.7±0.8°	0.002*

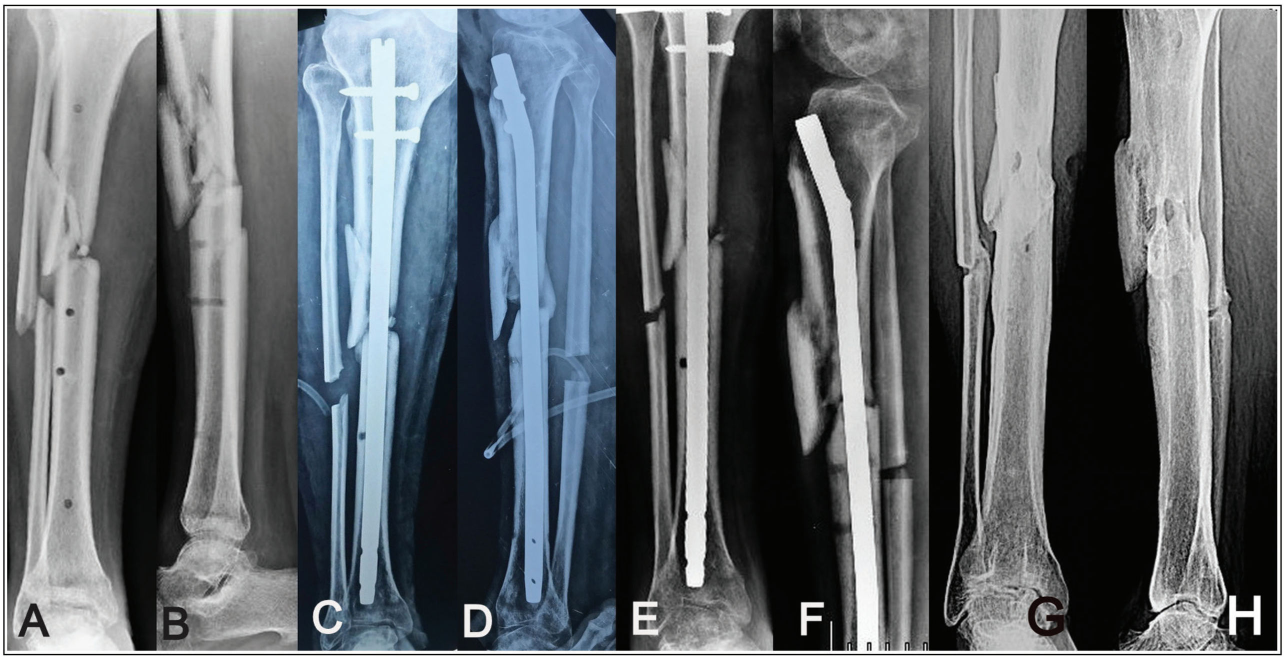
*Means significant difference.

Discussion

A hypertrophic nonunion possesses an abundant callus and viable fracture fragments. That presents a biological potential with some degree of stiffness, however, associated mechanical instability prevents maturation and consolidation [25]. Hypertrophic tibial nonunion can be managed by different surgical procedures, including dynamization of intramedullary nail, renailing, partial fibulectomy, augmentation plate over intramedullary nail with or without grafting, and Ilizarove external fixator [26].

Previous studies [3,5–11,13] reported the impact of either nail dynamization or partial fibulectomy/fibulectomy on management of tibial injuries. To the best of our knowledge, no previous study evaluated the outcome of combined DNPF procedure. Dynamization has been described in literature for nonunions initially managed with nailing. It was usually performed eight to twelve weeks postnailing to accelerate healing via contact area maximization, better distribution of weight-bearing forces, and promotion of osteogenesis at nonunion site [9,10]. Union rates after dynamization range between 54% and 95.8% [11]. However, dynamization alone may be benefit-less especially in some fracture patterns with healed or intact fibula. That might necessitate another procedure with more radiation, anesthetic exposures, and economic burden [12].

Figure 3



Preoperative (A, B), postoperative (C, D), and follow-up (E, F) AP and lateral radiographs for forty year-male patient with same technique, with last follow-up (G, H) radiographs after implant removal showing ankle arthritis.

Combined DNPF was advocated in this study. A well-vascularized environment is essential with this technique, mesenchymal progenitor cells are abundant in the tissue at nonunion site, that can differentiate into cartilage- or bone-forming cells. Also, fibrocartilaginous tissue is capable of osteogenesis with subsequently added mechanical stability [27]. A balanced reaming along with a suitable sized nail induces a periosteal vascular reaction and stimulates bone formation. Along, reaming increases the contact surface area between the nail and the medullary undulating surface providing a stable fixation [26]. Combined DNPF is supposed to reduce the strain at nonunion site without excessive rigidity. The resultant controlled compression reinforces callus formation, facilitates bone formation and remodeling. This technique can hold off the breakage of locking screws on occasion of a statistically-locked-nail.

Satisfactory clinical results were evident following our surgical procedure in line with complete radiographic healing in all patients. All nonunions healed within 11.9 ± 1.5weeks with shorter period than that reported with Partial fibulectomy alone (15 weeks to 7.5 months) [3,5] and with augmentation plating over an in-situ nail along with bone grafting (8 months) [26,28]. In the same context, Abadie *et al.* reported that Patients with fibular osteotomy proceeded to union 2.9 months faster than those without fibular osteotomy in management of tibial nonunion whatever the interlocking nail was dynamically or statistically locked [29].

Patients in this study underwent combined DNPF after a period of 11.6 ± 1.9months of nonunion and followed for 33.3 ± 6.2months. In previous studies, partial fibulectomy was performed alone or with renailing after 11–24 months from initial injury [3,5–7]. Our patients showed complete healing with an appropriate alignment, ROM, and no malrotation (Tables 3 and 4). The mean limb shortening was 0.9 ± 0.5 cm; that was tolerated with no complaint in 82% of the patients. Previous studies reported showed angulation less than 10° and no malrotation with partial fibulectomy alone [3,5–7,13]. Kim *et al.* reported an average shortening of 1.9 cm with partial fibulectomy alone [8].

Anterior knee pain was experienced by 76.5% of patients. Alike, recent reports revealed an incidence up to 70% being the most frequent complication postnailing, they attributed it to surgical approach, nail protrusion, patellar tendon itself, associated articular injuries, or multifactorial [30]. Also, prolonged disability period affects muscle mass, strength, and bone quality. This might also cause pain.

Although torsional rigidity has been linked to the use of locking screws, the fibrous callus can prevent excess mobility and rotation at the nonunion site [31]. We relied upon the resultant stiff abundant fibrous tissue at nonunion site to maintain torsional stability. Recent reports stated that tibial malrotation less than 10 degrees postnailing can be tolerated [19]. In this study, no patient experienced an abnormal gait out of malrotation. The mean malrotation difference between limbs was $2.5 \pm 1.7°$. However, this can be judged more precisely in future studies utilizing computed tomography, comparing tibial rotational profile bilaterally.

None of the patients suffered ankle pain with instability. Fibular resection was performed at the middle third (healing site), or at 15 cm superior to tip of the LM. There is no consensus on the optimal site for PF, with data shortage on the effect of different leveled-fibular osteotomies on tibial loading. Recently, Lim *et al.* reported a greater tibial axial loading with more superior fibular osteotomy [4]. Pacelli *et al.* showed that ankle stability can be maintained by retaining only 10% of distal fibular length, with osteotomy proximal to syndesmotic level [32]. Uchiyama *et al.* recommended preserving 6 cm of distal fibula [15].

The length of excised fibula was uniform (2 cm) among patients with sparing a 3 cm of nail-less segment of distal tibia. Unfortunately, one case suffered a tibial plafond injury, despite the nonunion healed properly. The interlocking nail was removed, he presented later with ankle stiffness and refused any further interventions. Hence, the length of excised fibula and the nail length should be tailored for every patient. We recommend that the nail-less part of distal tibia should correspond to the combined length of excised fibular segment and that of nonunion segment, additionally, serial radiographs can be more decisive.

Combined DNPF procedure aligned with the three main objectives of fracture care: early limb function, favorable mechanical and biological environment for healing. The strength of our study can be expressed in the uniformness of management method in all cases, besides, a reasonable period of follow-up utilizing a validated functional score and radiological parameters. The limitations of this study are represented in the limited number of involved cases, with non-comparative nature. Besides, the rotational alignment was only assessed clinically. More future prospective, comparative studies with larger number of patients can be more representative.

In conclusion, combined DNPF procedure has been effective to restore mechanical and biological environment needed for healing of patients with aseptic diaphyseal hypertrophic nonunion, providing early recovery with satisfactory clinical and radiological outcomes.

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Conflicts of interest
Both authors have no conflict of interest to disclose.

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