Randomized Controlled Trial

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Static versus dynamic intramedullary nailing for femoral and tibial shaft fractures: a double-blind, randomized clinical trial

Arvin Najafi, MD[a], Pouria Chaghamirzayi, MD[b], Dorsa Hadavi, MD[c], Monir Najafi Pirasteh, MD[d], Ali Sedighi, MD[a], Salman Azarsina, MD[a,*]

Background: The optimal fixation method for femur and tibia shaft fractures remains debated. Both static intramedullary nailing (SIMN) and dynamic intramedullary nailing (DIMN) are commonly used. This study aims to compare the efficacy of SIMN versus DIMN in promoting fracture healing.

Methods: This double-blind, randomized clinical trial was conducted from June 2022 to March 2024. Fifty-two people with single transverse or short oblique femur or tibia fractures were randomly put into two groups, SIMN and DIMN. Each group had 26 people. The primary outcome was time to union, and secondary outcomes included surgical and post-surgical complications. Statistical analysis was performed using SPSS version 28.0.

Results: The study included 52 participants (22 men and 30 women), with a mean age of 54.48 (SD 11.31). The median time to union in the DIMN group was significantly lower than in the SIMN group (20.5 (IQR 17-24) versus 24 (IQR 22-35), $P = 0.008$). No statistical significance was observed in either group regarding nonunion, malunion, delayed union, and reoperation rates.

Conclusion: Dynamic intramedullary nailing (DIMN) significantly reduces the median time to union compared to static intramedullary nailing (SIMN) for femoral and tibial shaft fractures. Despite the shorter union time with DIMN, both techniques showed similar outcomes regarding nonunion, malunion, delayed union, and reoperation rates. These findings suggest that while DIMN may offer faster fracture healing, SIMN and DIMN are viable options depending on individual patient and clinical considerations.

Keywords: dynamic intramedullary nailing, femur fractures, static intramedullary nailing, tibia fractures

Introduction

High-energy or low-energy mechanisms leading to femoral shaft fractures have been identified as common occurrences in clinical settings. These fractures are often found to be closely linked with a higher incidence of more severe and consequential injuries, making them a significant concern in the field of orthopedics and trauma care. Gunshots, ground-level falls among osteoporosis patients, vehicular accidents, and falls from heights are the most frequent causes[1,2]. The global incidence of femoral shaft fractures ranges from 10 to 21 per 100,000 individuals annually. Open fractures account for 2% of these fractures[3]. Intramedullary nailing (IMN) is widely regarded as the optimal treatment approach for femoral shaft fractures. Performing this procedure within 24 to 48 hours of the injury significantly reduces the risks of pulmonary complications, infection, and mortality in patients who are otherwise

HIGHLIGHTS

- **Faster Healing for Femoral and Tibial Fractures**: Dynamic intramedullary nailing (DIMN) significantly reduced the median time to union for both femoral and tibial shaft fractures compared to static intramedullary nailing (SIMN), with a difference of 3.5 weeks.
- **Equivalent Complication Rates**: The rates of nonunion, delayed union, and malunion were similar between DIMN and SIMN for both femoral and tibial fractures, indicating comparable safety profiles.
- **Consistent Reoperation Rates**: The need for reoperation related to union issues was not significantly different between the DIMN and SIMN groups.
- **Rigorous Methodology**: The study, a double-blind, randomized clinical trial with 52 participants, ensured a robust comparison of the two nailing techniques across femoral and tibial shaft fractures.
- **Clinical Implications**: While DIMN provides faster healing for both femoral and tibial shaft fractures, both DIMN and SIMN are effective fixation methods, with the choice of technique depending on individual patient factors and fracture characteristics.

[a]Shahid Madani Hospital, Alborz University of Medical Sciences, Karaj, Iran, [b]Clinical Research Development Unit of Shahid Madani Hospital, Alborz University of Medical Science, Karaj, Iran, [c]Tehran University of Medical Sciences, Tehran, Iran and [d]Joint and Related Tissues Research Center, Shahid Beheshti University of Medical Sciences, Tehran, Iran

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*Corresponding author. Address: Shahid Madani Hospital, Alborz University of Medical Sciences, Jahanshahr, Karaj 3143744693, Iran. Tel: +98 9121059727. E-mail: Dr.sazarsina@gmail.com (S. Azarsina).

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systemically stable. This timely intervention enhances patient outcomes by minimizing these critical risks. If treatment is postponed, the likelihood of pulmonary complications can rise in up to 56% of patients[1].

Tibial shaft fractures, occurring at a rate of 8.1 to 37 per 100,000 individuals annually, are a notable public health issue and the most common type of long bone fracture. The tibia's anatomical position, with limited soft tissue coverage and poor vascular supply, makes it susceptible to complications such as infection and nonunion[4,5]. The most frequent approach for managing displaced tibial shaft fractures in skeletally mature patients is IMN. This surgical method provides earlier definitive stabilization, avoids the need for extended cast or brace use, and can facilitate quicker mobilization and faster healing[6–8].

Contemporary intramedullary nails provide two fixation options: static and dynamic. In static mode, fractures are stabilized using locking screws at both the proximal and distal ends. Dynamic mode allows the shaft screw to compress the fracture site while maintaining torsional stability. Primary nail dynamization promotes bone fragment contact, promoting good periosteal callus formation[9,10]. The inability to predict the outcome of dynamic IMN for fracture fragment preservation, particularly the limited control of rotation, and the lack of consensus on whether dynamic or static methods are more effective prompted us to conduct this study to compare the two methods. The primary goal of this study was to compare the efficacy of static versus dynamic intramedullary nailing (IMN) in terms of time to union for femoral and tibial shaft fractures. Secondary objectives included assessing complication rates associated with each technique.

Methods

Study design and ethics

This research was designed as a double-blind, randomized clinical trial and was conducted from June 2022 to March 2024. This study adhered to the Consolidated Standards of Reporting Trials (CONSORT; Supplementary Digital Content, http://links.lww.com/MS9/A757) guidelines for transparent and comprehensive trial reporting. The study protocol had been approved by the Ethics Committee (Project number: IR.ABZUMS.REC.1400.234) and the Iranian Register of Clinical Trials (IRCT) by registration number: IRCT20220201053910N1.

Participants

The study population included patients with femur and tibia shaft fractures who were candidates for IMN fixation. The inclusion criteria were the age between 18 and 75, consisting of participants in the study, femur or tibia isolated transverse or short oblique closed fracture, and the occurrence of fractures in the last five days. The exclusion criteria included fractures with corroded fragments, comminuted fractures, wedge fragment that compromised fracture stability, fractures with neurovascular injuries, fractures previously treated with IMN or periprosthetic fractures, diabetes, and osteoporotic patients. Only fractures where the wedge fragment-maintained contact with the main bone fragments after reduction (i.e., stable wedge fractures) were included. A total of 168 patients were initially evaluated for eligibility in the study. Of these, 116 did not meet the criteria or were otherwise excluded from participation. Consequently, 52 patients qualified and were enrolled in the study.

Randomization

A computer-generated randomization sequence was employed to assign participants to different groups, ensuring impartiality. Allocation concealment was maintained by using sealed envelopes to prevent any prior knowledge of group assignments and to eliminate potential biases in the allocation process. Patients and analysts were unaware of the grouping criteria and study allocation. However, surgeon investigators could not be blinded to study allocation. We used a 1:1 allocation ratio and stratified randomization according to fractured bones (tibia and femur). Fifty-two patients were randomized into the static IMN (SIMN) and dynamic IMN (DIMN) groups, each including 26 patients.

Interventions

In the SIMN group, the static IMN method is used to fix the fracture, which means using three or four screws at both ends to prevent vertical and rotational instability and bending. In the DIMN group, the dynamic IMN method is used, which means using one distal or proximal screw to allow vertical compression with control over rotational and flexion instability. Antibiotics (first-generation cephalosporin) were prescribed for 72 hours in both groups. Patients in both groups followed the same postoperative rehabilitation protocol. A fast start-up (24 hours after surgery) was done for both groups. The type of IMN tool used in both groups was the same. Surgery was carried out using either general or regional anesthesia. Both methods were routinely employed by traumatologists participating in this study, and all surgeons were experienced with these surgical techniques.

Assessment and outcomes

Patients of both groups were regularly examined and visited, and radiographs of the fracture site were taken. These examinations were performed immediately after the surgery, then 4, 8, and 12 weeks later, and then at intervals of 1 week to union. The last visit and imaging were done 12 months after the surgery. Time to union was our primary outcome. Secondary outcomes included nonunion, delayed union, malunion, reoperation, and malrotation rates. Delayed union was characterized by the failure of the fracture to progress toward union within six months. Nonunion was defined as the absence of osseous healing for nine months, necessitating secondary intervention. Malunion was identified as any angular deformity greater than 5°, rotational deformity exceeding 10°, or shortening of more than 1 cm. Using anteroposterior and lateral X-ray projections, two authors checked to see if there was a bridging callus in at least three of the four cortices. This was used to determine radiological union. In cases of disagreement regarding the union status, the maximum duration for the union was used to resolve the dispute.

Sample size

The sample size was established by referencing data from a study conducted by Hernandez *et al*[11]. The average union durations were 21 weeks for the dynamic cohort and 26 weeks for the static cohort, assuming a standard deviation of 6 weeks for each group. Employing a significance level of 0.05 with a two-tailed approach and achieving 80% power, the necessary sample size was computed utilizing the following mathematical expression:

$$n = \left[2 \times (Z\_(1-\alpha/2) + Z\_(1-\beta))^2 \times \alpha^2\right] / \Delta^2$$

where Δ = 5 weeks, σ = 6, Z_(1-α/2) = 1.96, and Z_(1-β) = 0.84. Δ is the expected mean difference in union time (5 weeks), σ is the standard deviation (6 weeks), Z_{1-α/2} = 1.96 (for a two-tailed α = 0.05), and Z_{1-β} = 0.84 (for 80% power). This yielded a minimum sample size of 23 participants per group. Accounting for an estimated 10% dropout rate, we plan to enroll 26 participants in each group.

Statistical analysis

Data analysis was conducted utilizing SPSS version 28.0 (IBM Corp., 2021). When continuous variables did not follow a normal distribution, the median and interquartile range (IQR) were shown, and the Mann–Whitney U test was used to compare them. Nonparametric methods were chosen for variables where normality assumptions were not met, as determined by the Shapiro–Wilk test. For continuous variables with a normal distribution, on the other hand, the mean and standard deviation (SD) were used for reporting, and the independent t-test was used to look at the differences. Categorical variables were succinctly summarized employing frequencies and percentages, while the accuracy of assessments was determined through the application of the chi-square test. The statistical significance was ascertained with a *P*-value threshold established at below 0.05.

Results

The study comprised 52 participants (refer to Fig. 1), with a demographic breakdown of 22 men (42.3%) and 30 women (57.7%). The mean age of the participants was 54.48, with a standard deviation of 11.31. Each treatment group contained 26 patients, with 16 patients (61.5%) in each group having femoral fractures and 10 patients (38.5%) having tibial fractures. Detailed demographic and clinical data for each group are presented in Table 1. No statistically significant differences were observed between the groups concerning mean age, gender distribution, and fracture-type frequencies.

Table 2 shows the results for patients over a 48-week follow-up period. It shows the time to union, the rates of nonunion and delayed union, and the number of reoperations needed because of union problems (nonunion or delayed union). The median time to union was significantly shorter in the DIMN group compared to the SIMN group (*P* = 0.008) (Figures 2–5). Nonunion occurred in five patients, with no significant difference between groups (*P* = 0.63); one patient from each group failed to achieve union by the end of the follow-up period. Delayed union was noted in seven patients, with no significant difference between groups (*P* = 0.22). Additionally, malunion was observed in one patient from the SIMN group. Union-related reoperations, due to delayed union or nonunion, were performed in ten patients, with no statistically significant difference between groups (*P* = 0.15).

Discussion

Our clinical trial evaluated the outcomes of static intramedullary nailing (SIMN) versus dynamic intramedullary nailing (DIMN) in patients with isolated transverse or short oblique femur or tibia shaft fractures. The results indicate that the DIMN group experienced a significantly shorter time to union compared to the SIMN group. Although the nonunion and delayed union rates were lower in the DIMN group than in the SIMN group, these differences were not statistically significant. These findings suggest that dynamic IMN may facilitate faster bone healing, possibly due to its allowance for controlled micro-motion, which can stimulate callus formation and remodeling.

These findings align with earlier research examining the efficacy of dynamic versus static intramedullary nailing in managing tibial or femoral shaft fractures. For instance, a meta-analysis indicated that dynamic fixation of intramedullary nails led to a significantly shorter mean time to union and fewer reoperations compared to static fixation[12]. Previous research has shown that successful fracture healing can be achieved with the use of dynamic intramedullary nails (DIMNs), even in instances where there is significant comminution present[13]. An example of this can be seen in a study by Somani *et al.*[14], who conducted a comparative analysis involving a cohort of 60 patients. Their findings indicated that DIMN proves to be both effective and safe in the treatment of closed or type 1 open tibial fractures that exhibit simple or limited comminuted patterns. In a similar vein, another research endeavor delved into femoral shaft fractures that were managed using primary dynamic interlocking nails, which resulted in the attainment of solid bony union without any accompanying complications. The series of cases presented in this study further bolsters the argument for the utilization of DIMN in intricate fracture scenarios, showcasing its ability to promote sturdy and prompt bone healing[15]. These findings are in line with our results, which emphasize the benefits of dynamic fixation in promoting early callus formation and successful healing. The significant reduction in the time to union observed in the DIMN group in our study further corroborates the advantages reported in previous research. Additionally, while the rates of nonunion and delayed union were lower in the DIMN group compared to the static intramedullary nailing (SIMN) group, the differences were not statistically significant, suggesting that dynamic fixation offers a clinically meaningful improvement in fracture management. Overall, the accumulating evidence underscores the potential of DIMN as a preferred method for managing tibial and femoral shaft fractures, particularly in enhancing the healing process and minimizing the need for reoperations. The consistent success of DIMN across various studies highlights its reliability and effectiveness in orthopedic practice.

Dynamic nailing supports bone healing by reducing tensile stresses and enabling controlled motion between fracture fragments, enhancing contact at the fracture site. Small deformation promotes callus formation, while axial loading boosts osteogenic response, leading to earlier and stronger healing. Episodic stresses improve revascularization and tissue differentiation, aiding recovery. In contrast, static fixation may lack these benefits, increasing the risk of nonunion[9,16–19].

Numerous limitations must be taken into account when analyzing the outcomes of our investigation. Despite the utilization of randomization, the study's framework failed to conceal surgeons from the intervention, thus potentially introducing bias in the delivery of treatment. Carried out in a

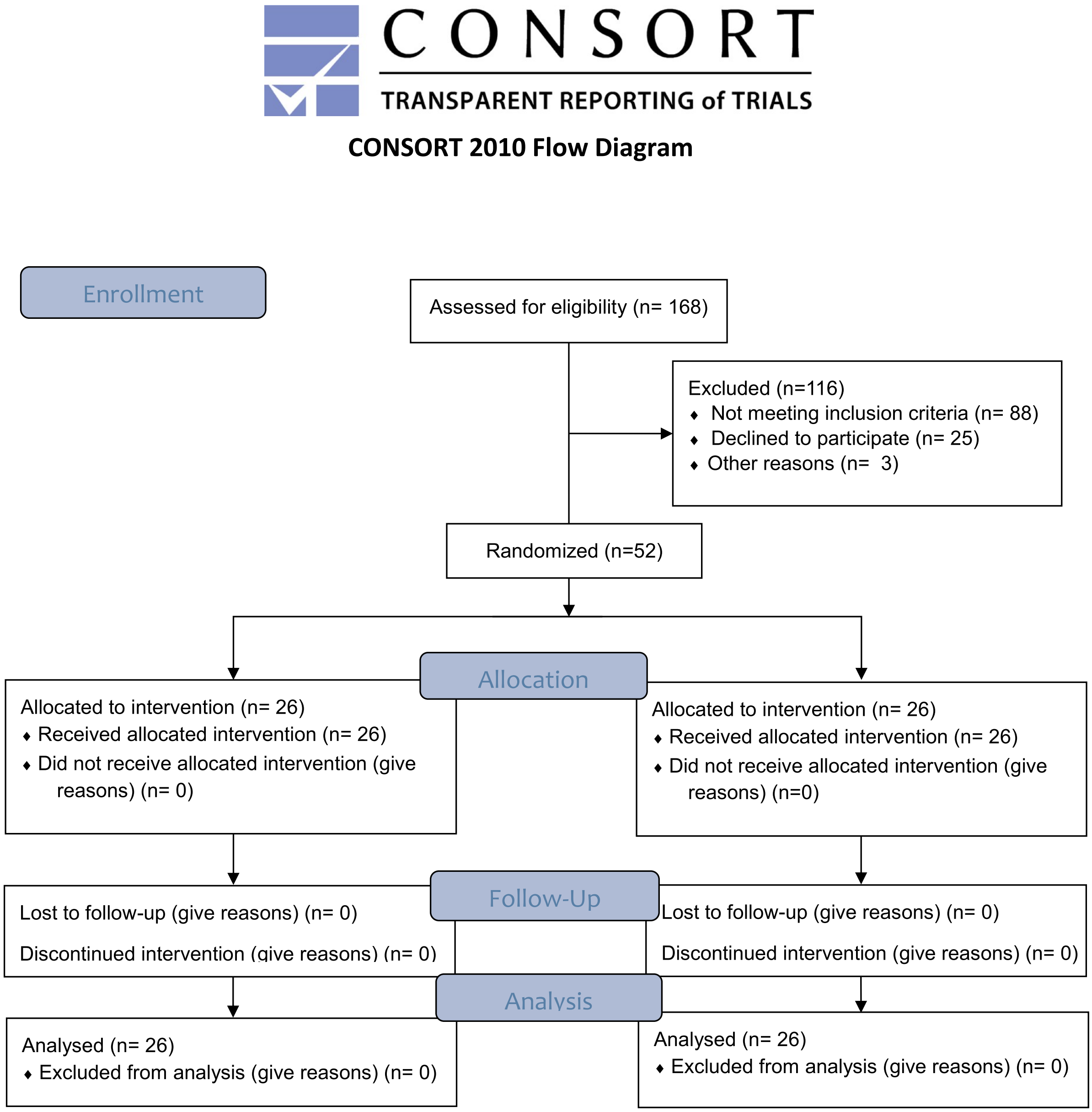

Figure 1. Flow diagram of the progress through the phases of a randomized trial (i.e. enrollment, intervention allocation, follow-up, and data analysis).

solitary facility, the research's outcomes may have limited relevance to other environments characterized by diverse surgical methodologies or patient profiles. This study's single-center design and exclusion of patients with comorbidities limit its generalizability. The lack of surgeon blinding also introduces potential bias.

Table 1

Patients' demographic and clinical data in each group

Variables	Value	SIMN group (*n* = 26)	DIMN group (*n* = 26)	*P*-value
Age (years)	Mean (Sd)	53.8 (12.3)	55.1 (10.3)	0.69
Gender	Male, *n* (%)	10 (38.5%)	12 (46.2%)	0.57
	Female, *n* (%)	16 (61.5%)	14 (53.8%)	
Injured bone	Femur, *n* (%)	16 (61.5%)	16 (61.5%)	-
	Tibia, *n* (%)	10 (38.5%)	10 (38.5%)	
Type of fracture	Transverse, *n* (%)	17 (65.4%)	19 (73.1%)	0.54
	Short oblique, *n* (%)	9 (34.6%)	7 (26.9%)	

SIMN: static intramedullary nailing; DIMN: dynamic intramedullary nailing; Sd: standard deviation.

Table 2

Patients' outcomes in each group

Variables	Value	SIMN group (n = 26)	DIMN group (n = 26)	P-value
Time to union (weeks)	Median (IQR)	24 (22–35)	20.5 ([17–24])	0.008
Delayed union	Yes, n (%)	5 (19.2%)	2 (7.7%)	0.22
	No, n (%)	21 (80.8%)	24 (92.3%)	
Nonunion	Yes, n (%)	3 (11.5%)	2 (7.7%)	0.63
	No, n (%)	23 (88.5%)	24 (92.3%)	
Reoperation	Yes, n (%)	7 (26.9%)	3 (11.5%)	0.15
	No, n (%)	19 (73.1%)	23 (88.5%)	

SIMN: static intramedullary nailing; DIMN: dynamic intramedullary nailing; IQR: interquartile range.

Despite the study's limitations, the findings have significant implications for managing femur and tibia shaft fractures. This is the first clinical trial comparing dynamic versus static intramedullary nailing for managing femur and tibial shaft fractures. The results suggest that dynamic intramedullary nailing may be preferable for promoting fracture healing in patients with transverse or short oblique fractures without significant comorbidities. However, when choosing the fixation method, it is crucial to consider patient-specific factors, such as fracture characteristics and overall health. Future research should focus on multicenter trials with diverse populations to validate these findings.

Conclusion

In conclusion, this study demonstrates that dynamic intramedullary nailing offers superior outcomes regarding time to union for isolated transverse or short oblique femur and tibia shaft fractures compared to static intramedullary nailing. The rates of nonunion, delayed union, malunion, and reoperations were about the same for both methods. However, the DIMN group had a much shorter time to union, which suggests it may be a better way to help bones heal faster. Further research with more diverse populations is needed to validate these results and refine the indications for static and dynamic nailing techniques in fracture management.

Ethical approval

All authors and patients agreed to publish this article. All procedures complied with relevant laws and institutional guidelines (Alborz University of Medical Sciences). The study protocol had been approved by the Alborz University of Medical Science Ethics Committee (Project number: IR.ABZUMS.REC.1400.234) and the Iranian Register of Clinical Trials (IRCT) by registration number: IRCT20220201053910N1

Consent

Written informed consent was obtained from the patients to participate in this research and publish this article and any accompanying images. A copy of the written permission is available for review by the Editor-in-Chief of this journal.

Sources of funding

No funding.

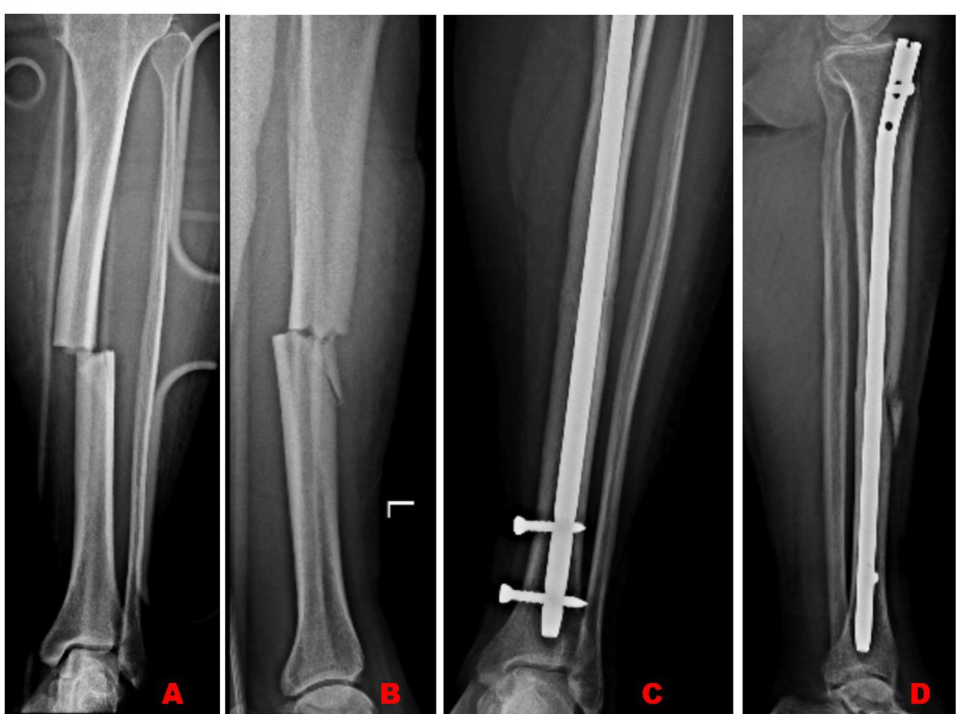

Figure 2. Radiographs of a 29-year-old man with tibial shaft fracture (A, B) managed by dynamic intramedullary nailing united at 13 weeks (C, D).

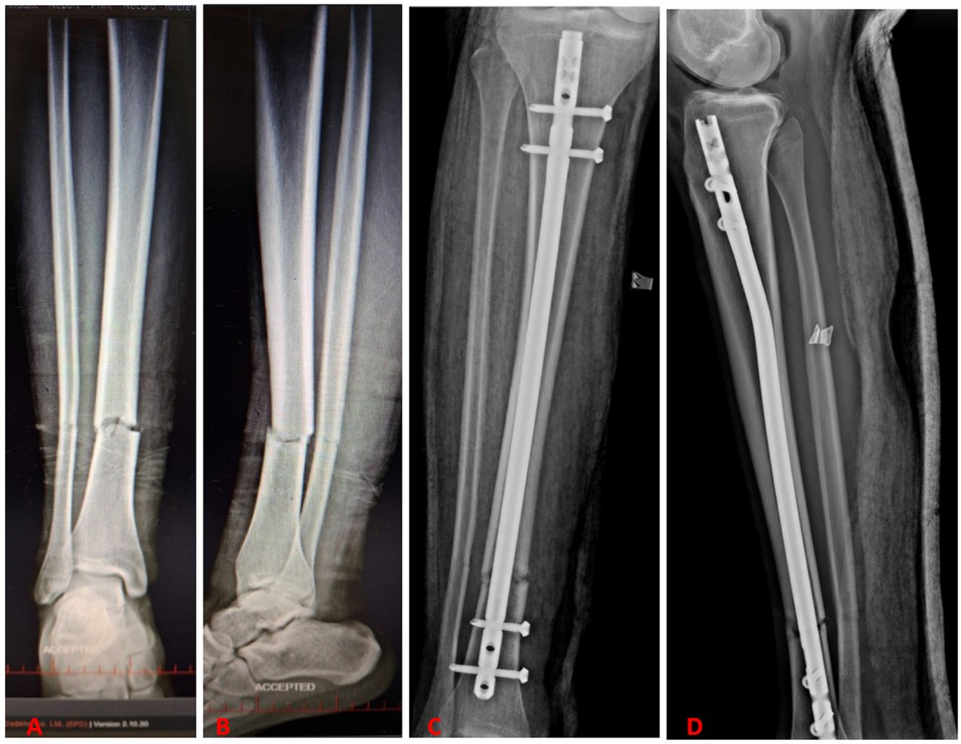

Figure 3. Radiographs of a 56-year-old man with tibia shaft fracture (A, B) managed by static intramedullary nailing at 16 weeks (B, D), united at 22 weeks.

Authors' contributions

N. A: conceptualization, data curation, supervision, software. A. S.: conceptualization, data curation, writing – original draft preparation. H.D.: data curation, writing – original draft preparation. C.P.: writing – reviewing and editing, software. H.S.: data curation, writing – original draft preparation.

Figure 4. Radiographs of a 55-year-old man with femur shaft fracture (A, B) managed by dynamic intramedullary nailing united at 22 weeks (C, D, E).

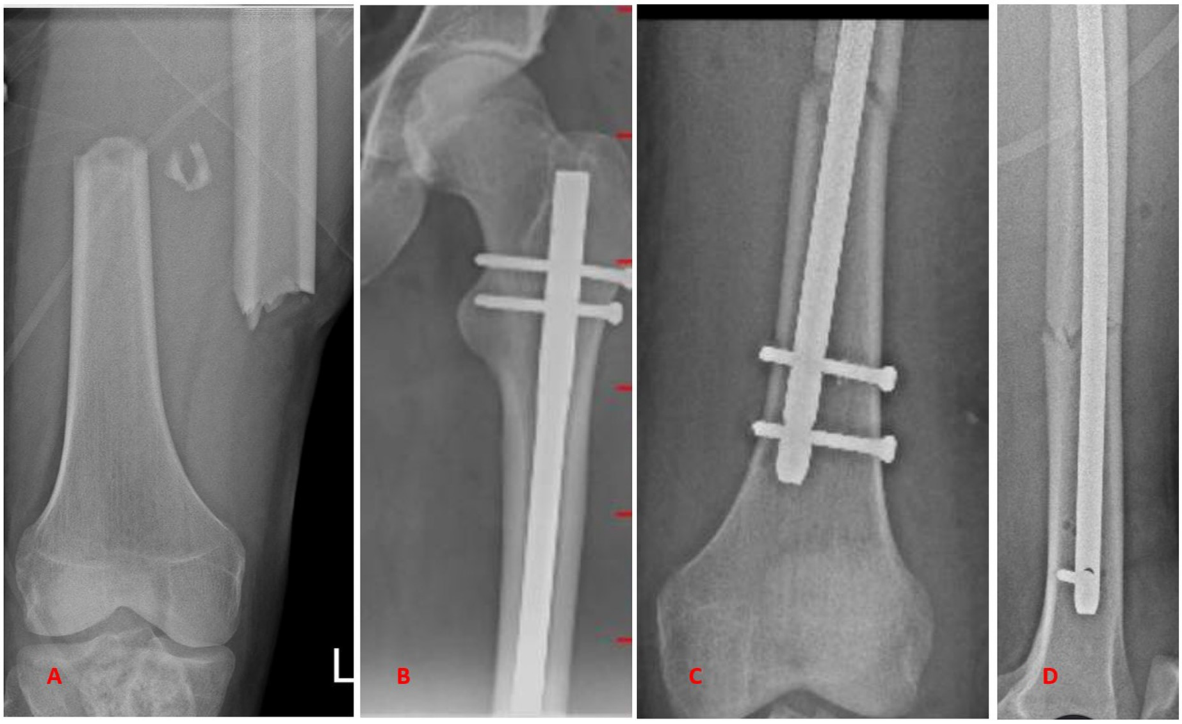

Figure 5. Radiographs of a 32-year-old man with femur shaft fracture (A) managed by static intramedullary nailing at 28 weeks (C, D, E), united at 34 weeks.

Conflicts of interest disclosure

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Guarantor

Arvin Najafi.

Research registration unique identifying number (UIN)

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Provenance and peer review

Not commissioned, externally peer-reviewed

Data availability statement

All data generated or analyzed during this study are included in this published article (available).

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