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Functional Outcome of Femoral Fracture in Children Treated with Titanium Elastic Nailing System: A Prospective Study in Sana'a, Yemen

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Abstract

Introduction: This study evaluated the functional outcomes of pediatric femoral shaft fractures treated with a Titanium Elastic Nailing System (TENS) in a resource-limited setting with limited access to advanced care.
Methods: This prospective observational study enrolled 20 children aged 6–13 years with closed unilateral femoral shaft fractures who were treated with TENS between May 2021 and May 2023. The surgical technique involved retrograde nail insertion under fluoroscopy, and the outcomes were assessed using Flynn's criteria (alignment, leg length, and complications) at 4, 8, 12, and 6 months. Data were analyzed descriptively using the SPSS software (version 26).
Results: Mean age was 9.06 ± 1.9 years (70% male, 30% female). Road traffic accidents caused 50% of the fractures, predominantly transverse (75%) and right-sided (70%). The mean union time was 8.2 ± 1.5 weeks (range: 6–11). Complications included pain at the nail insertion site (15%), which resolved by 24 weeks, limb length discrepancy (< 1.5 cm, 5%), and malalignment (< 10, 5%), with no infections or nonunions. At 6 months, 15 patients (75%) achieved excellent outcomes (alignment 5, discrepancy < 1 cm, no complications), and 5 (25%) were satisfactory (minor, resolved issues), with no poor outcomes. The excellent rate was higher for transverse fractures (80%) than for oblique fractures (60%).
Conclusion: TENS proved effective and safe in this resource-limited setting, with a high success rate and rapid union, comparable to those of high-resource studies. Minor complications are associated with pediatric remodeling capacity. The small sample and 6-month follow-up limit generalizability, necessitating larger, longer-term studies. TENS offers a practical alternative to casting in resource-scarce contexts, potentially improving the outcomes when traditional methods fail.

Article Info

Keywords:
Pediatric femoral fractures, TENS, resource-limited settings, Flynn's criteria

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1. INTRODUCTION

Femoral shaft fractures in children, although rare (< 2% of pediatric fractures globally), pose significant orthopedic challenges because of their impact on mobility, growth, and socioeconomic burden [1]. Representing 1%–2% of pediatric fractures annually (approximately 10–20 per 100,000 children), they often result from high-energy trauma, such as road traffic accidents, which are prevalent in resource-limited regions with poor infrastructure [2]. Treatment aims to achieve bone union, restore limb length, and minimize complications (e.g., malunion and growth plate injury), thereby leveraging pediatric bone remodeling potential [3]. Historically, con-

servative methods, such as spica casting or traction, have dominated, offering simplicity but risking prolonged immobilization (6–12 weeks), poor alignment, and delayed recovery, particularly in children over 6 years [4]. These limitations have spurred a shift to surgical options, with the Titanium Elastic Nailing System (TENS) gaining favor since the 1980s for its minimally invasive approach, early mobilization, and reduced physeal damage [5]. In high-resource settings, TENS achieves union rates of 90%–95% within 8-12 weeks, with complication rates below 10% [6]. However, evidence in resource-limited settings, where critical resources are constrained, remains scarce [7]. Such environments face specific challenges that can impede optimal surgical outcomes, including inconsistent availability of C-arm fluoroscopy, a limited inventory of TENS nail sizes, and a shortage of surgeons trained in modern pediatric orthopedic techniques [7] Furthermore, access to specialized postoperative care, such as pediatric physiotherapy, is often unavailable, making procedures that facilitate early mobilization particularly valuable. TENS offers potential advantages in this context, such as minimal equipment needs, lower costs than plating, and adaptability to resource scarcity. However, data gaps persist regarding its efficacy and safety in these contexts, with studies such as that by Bopst et al. noting logistical challenges (e.g., nail availability) [8]. This study evaluated the functional outcomes of TENS for pediatric femoral fractures in a resource-limited setting to address the evidence gap. By providing preliminary data on success rates, union times, and complications, this approach has been explored as a practical alternative to traditional methods, potentially informing clinical practice in similar environments with high fracture incidence and limited resources.

2. METHODS

2.1. Study Design

This prospective observational study, conducted from May 2021 to May 2023, evaluated the functional outcomes of pediatric femoral shaft fractures treated with a titanium elastic nail system (TENS) in a resource-limited setting. The study was conducted at the Al-Thawra Modern General Hospital (TMGH), a tertiary referral center in Sana'a, Yemen. This study adhered to the STROBE guidelines for observational research [9]. Ethical approval was obtained from the hospital's Ethics Committee (protocol number [TMGH-IRB-2021-045]), and written informed consent was obtained from the parents/guardians.

2.2. Study Population

Twenty children aged 6–13 years with closed unilateral femoral shaft fractures confirmed on anteroposterior and lateral radiographs were enrolled. The inclusion criteria were intact skin, isolated injury, and a weight $\leq$ 49 kg to ensure nail stability. The exclusion criteria were open or comminuted fractures, polytrauma (e.g., head or abdominal injuries), neuromuscular disorders (e.g., cerebral palsy), and prior femoral surgery, minimizing confounding variables. Patients were consecutively recruited from emergency admissions, reflecting typical injury patterns in the region.

2.3. Surgical Technique

TENS nails (titanium alloy, 2.0–3.5 mm diameter) were selected based on the medullary canal width ($\geq$ 40% fill), pre-bent for three-point fixation, and inserted retrogradely under fluoroscopy [6]. Incisions (1–2 cm) were made 20–40 mm proximal to the distal femoral physis to prevent damage to the growth plate. Fluoroscopy (low-dose, single-plane) confirmed reduction and nail placement based on limited imaging availability. The nails were advanced past the fracture site, anchored proximally near the trochanter, and trimmed 5–10 mm outside the cortex for ease of removal. The wounds were closed with absorbable polyglactin sutures because of their cost and availability. Postoperative care involved knee immobilization (splint or brace) for 2–4 weeks, with early hip and ankle mobilization encouraged through parental guidance because of the absence of dedicated physiotherapy services.

2.4. Outcome Measures

Functional outcomes were assessed using Flynn's criteria [10]: limb length equality (< 1.0 cm excellent, 1.0–2.0 cm satisfactory, > 2.0 cm poor), alignment ($\leq$ 5 excellent, $\leq$ 10 satisfactory, > 10 poor), pain, and complicationsat 4, 8, 12 weeks, and 6 months. Follow-ups included clinical examinations (goniometry for alignment, tape measure for length) and radiographs (anteroposterior/lateral) to verify union (bridging callus on two views). Secondary outcomes—complication rates (e.g., infection and nail irritation) and time to union (radiographic consolidation)-were recorded by blinded assessors to reduce bias.

2.5. Data Analysis

Data were collected via structured questionnaires (demographics, injury details, and outcomes) and entered into SPSS software (version 26, IBM Corporation, Armonk, NY, USA) [11]. Descriptive statistics (mean ± standard deviation, percentage) were used to summarize patient characteristics, complications, and Flynn outcomes. No inferential tests were performed because of the small sample size, which focused on exploratory analysis suitable for the study's scope and resource constraints.

3. RESULTS

3.1. Patient Characteristics

Of the 20 enrolled children, 14 (70%) were male and 6 (30%) were female, with a mean age of 9.06 ± 1.9 years (range: 6–13). Injury mechanisms included road traffic accidents (n = 10, 50%), self-falls (n = 7, 35%), and falls from heights (n = 3, 15%). The fractures were transverse (n = 15, 75%) or oblique (n = 5, 25%), with 14 (70%) right-sided fractures and 6 (30%) left-sided fractures. The age subgroups were 11 (55%) at 6-8 years, 6 (30%) at 9–11 years, and 3 (15%) at 12-13 years, with no outcome differences noted (Table 1).

3.2. Complications

Minor complications occurred in five patients (25%). Pain at the nail insertion site occurred in 3 (15%) patients, persisted for 4–12 weeks, and resolved by 24 weeks without nail removal. Limb length discrepancy (<1.5 cm) was observed in one patient (5%, aged 7 years, transverse fracture), measured at 6 months via tape from the anterior superior iliac spine to the medial malleolus, with no functional impact. Malalignment (<10°, valgus) affected 1 patient (5%, aged 10 years, oblique fracture), evident on radiographs, but asymptomatic. In contrast to the higher rates of complex fractures, infections, nonunions, and nail breakage occurred in this study. The mean time to union was 8.2 ± 1.5 weeks (range: 6–11), faster in younger patients (6–8 years: 7.8 ± 1.2 weeks) than older (12–13 years: 9.0 ± 1.7 weeks) (Table 2).

3.3. Functional Outcomes

At 6 months, Flynn's criteria classified 15 patients (75%) as excellent and five (25%) as satisfactory, with no poor outcomes. Excellent outcomes included alignment $\leq 5°$, leg length discrepancy < 1 cm, no pain, and no complications. Satisfactory outcomes included minor issues (e.g., 1–2 cm discrepancy or $\leq 10^o$ misalignment), resolved, or were asymptomatic. Transverse fractures had 80% excellent outcomes (12/15) compared with 60% (3/5) for oblique fractures, although the sample size was limited. The outcomes were aligned with union times, with all patients weight bearing at 12 weeks (Table 3). A representative case is shown in Figure 1.

4. DISCUSSION

This study highlights the Titanium Elastic Nailing System (TENS) as an effective treatment for pediatric femoral shaft fractures in a resource-limited setting, achieving 75% excellent and 25% satisfactory outcomes according to the Flynn criteria. These findings align closely with prior research in high-resource contexts, such as Flynn et al.'s multicenter study (76% excellent outcomes) [10] and Métaizeau et al. report (80% success) [5], suggesting that TENS efficacy is robust across diverse settings. The 8.2-week mean union time compared favorably with Ligier et al. 8–10 week range [6], reinforcing the reliability of TENS for fracture healing. Minor complications—15% pain at the nail insertion site, 5% limb length discrepancy (<1.5 cm), and 5% malalignment ($< 10^o$)-resolved without intervention by 6 months, consistent with the observation of pediatric remodeling capacity by Wall et al.[12]. Notably, the absence of infections or nonunions contrasts with Sink's et al. higher complication rates (e.g., 10% infection) in various fracture types [6], possibly because this study focused on closed unilateral fractures. In resource-limited settings, TENS offers practical advantages over alternatives such as spica casting and plate fixation. Unlike casting, which requires prolonged immobilization and risks malalignment [4], TENS enables early mobilization with minimal equipment, which is crucial for advanced imaging or rehabilitation [7]. Compared with plating, TENS reduces operative complexity and cost, which is consistent with the findings of Bopst et al. regarding its feasibility in similar contexts [7]. However, the small sample size (n = 20) limits statistical power, and the 6-month follow-up may miss late complications, such as growth disturbances, as noted by Salem et al. [13]. The lack of a control group (e.g., casting) further restricted the comparative conclusions, a gap also identified in Sink et al.'s analysis [14]. Biomechanical data (e.g., nail stability under load) were not assessed, potentially underestimating the risk of mechanical failure [13]. These results suggest that TENS could improve outcomes in resource-limited regions where femoral fractures burden healthcare systems with long hospital stays and economic costs [1]. The simplicity and low resource demand make it a viable alternative; however, implementation challenges (e.g., surgeon training and fluoroscopy access) warrant further consideration. Future studies should explore the cost-effectiveness and scalability of treatment guidelines in similar settings.

5. CONCLUSIONS

TENS appears safe and effective for pediatric femoral fractures in resource-limited settings, with preliminary evidence of high success rates (75% excellent), rapid union (8.2 weeks), and minimal complications. Larger controlled studies with extended follow-up (>1 year) are needed to confirm these findings, compare TENS with casting or plating, and assess long-term outcomes, such as growth plate effects. Such research can solidify TENS as a standard option in resource-constrained environments.

DECLERATIONS

ETHICAL APPROVAL AND PATIENTS CONSENT

This study was conducted in accordance with the ethical principles outlined in the Declaration of Helsinki. Ethical approval was obtained from the institutional review board of the Al-Thawra Modern General Hospital (TMGH) prior to the commencement of the study (approval number TMGH-IRB-2021-045 issued on May 15, 2021). Written informed consent was obtained from the parents or guardians of all the participating children. The consent process included a detailed explanation of the study's purpose, procedures, potential risks, and benefits, ensuring that the participants and their families were fully informed before agreeing to participate in the study. The confidentiality of all patient data was maintained throughout the study, and the data were anonymized to protect the identities of the participants. The study posed minimal risks to the participants, and all procedures were performed with the primary goal of ensuring patient safety and well-being.

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CONFLICT OF INTEREST

The authors declare that they have no conflicts of interest related to this study.

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DATA AVAILABILITY STATEMENT

The datasets used and analyzed during this study are available from the corresponding author upon reasonable request.

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Table 1. Patient Characteristics

Variable	Frequency (n)	Percentage (%)
Age group (years)		
6–8	11	55
9–11	6	30
12–13	3	15
Sex		
Male	14	70
Female	6	30
Mechanism of injury		
Road traffic accident	10	50
Falling from height	3	15
Self-fall	7	35
Fracture side		
Right	14	70
Left	6	30
Fracture pattern		
Transverse	15	75
Oblique	5	25

Table 2. Distribution of complications

Complication	**Frequency (n)**	**Percentage (%)**
Pain at the nail insertion site	3	15
Limb length discrepancy	1	5
Malalignment	1	5
No complications	15	75
Total	**20**	**100**

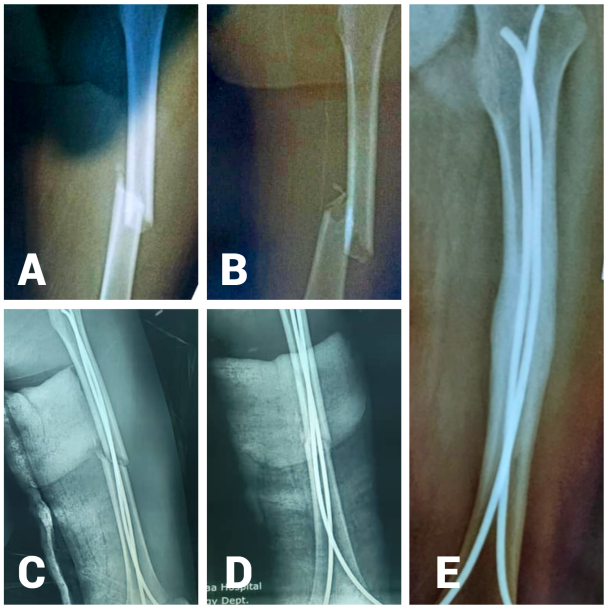

Figure 1. Radiographs of a 9-year-old male with a left femoral shaft fracture treated with TENS. (A) Anteroposterior (AP) and (B) lateral preoperative radiographs showing a transverse fracture of the femoral shaft. (C) AP and (D) lateral immediate postoperative radiographs demonstrate excellent alignment and reduction with two TENS nails. (E) Follow-up AP radiograph at 12 weeks showing bridging callus formation, indicating solid fracture union.

Table 3. Functional outcomes based on Flynn's criteria

Parameter	Excellent (n=15, 75%)	Satisfactory (n=5, 25%)	Poor (n=0, 0%)
Limb-length equality	<1.0 cm	1.0–2.0 cm	>2.0 cm
Malalignment	$\leq 5^o$	$\leq 10^o$	$>10^o$
Unresolved pain	Absent	Absent	Present
Complications	None	Minor and resolved	Major and lasting morbidity

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