Journal of Surgical Radiology

Site: https://journalsurgrad.com/

ISSN Print 2156-213X| ISSN Online: 2156-4566 Volume: 04 Issue: 04 Open Access

Research Article

Efficacy of the Titanium Elastic Nailing System for Paediatric Femoral Diaphyseal Fractures: A Prospective Descriptive Study

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Article History
Received: 10-10-2025
Revised: 25-11-2025
Accepted: 10-12-2025
Published: 16-12-2025

Citations:
Reddy MPL, Pasha RT, Basha KM, Sharath G, Mithun GS. Efficacy of the titanium elastic nailing system for paediatric femoral diaphyseal fractures: A prospective descriptive study. J Surg Radiol, V4 (4) 50-62

Abstract: ***Introduction:*** Femoral diaphyseal fractures represent a significant source of trauma-related morbidity in the paediatric population, exhibiting a bimodal incidence peak. While conservative management strategies such as Spica casting are historically favoured for infants, the treatment of these injuries in older children and adolescents has increasingly shifted toward operative internal fixation to circumvent prolonged immobilization. This study aimed to evaluate the functional outcome, union rates, and safety profile of the Titanium Elastic Nailing System (TENS) in treating paediatric femoral shaft fractures, whilst systematically analysing associated surgical complications. **Methods:** A prospective descriptive study was conducted involving 20 children aged 5 to 15 years presenting with displaced, open (Type I/II), comminuted, or segmental diaphyseal femoral fractures. All participants underwent closed reduction and internal fixation utilizing retrograde TENS. Post-operative rehabilitation involved early mobilization and progressive weight-bearing upon evidence of bridging callus. Clinical, radiological, and functional outcomes were assessed over a follow-up period of 6 to 18 months utilizing the TENS scoring criteria established by Flynn et al. **Results:** The cohort's mean age was 9.45 years, with a male predominance (60%). High-energy road traffic accidents were the primary aetiology (65%). The mean operative duration was 70.2 minutes, and the mean duration of hospital stay was 7.2 days. Complete radiological and clinical union was achieved in 100% of cases at a mean of 8.95 weeks. Minor complications included entry-site pain (20%) and superficial infection (10%), which resolved with conservative measures. According to Flynn's criteria, 65% of patients achieved an excellent functional outcome, and 35% achieved a satisfactory outcome. No poor outcomes, major limb length discrepancies, or rotational malalignments were recorded. **Conclusion:** TENS is a physiological, minimally invasive, and highly effective operative modality for paediatric femoral diaphyseal fractures. By preserving the fracture haematoma and avoiding physeal injury, it promotes rapid bony union, permits early ambulation, and minimizes both hospital stay and major architectural complications compared to alternative conservative and rigid operative modalities.

Keywords: Femoral shaft fracture; Paediatric orthopaedics; Titanium Elastic Nailing System; Elastic Stable Intramedullary Nailing; Flynn criteria.

INTRODUCTION

The global annual incidence of femoral shaft fractures is approximately 20 per 100,000, displaying a bimodal age distribution that peaks distinctly in the second and seventeenth years of life.[1] Historically, non-operative management strategies, including Pavlik harnesses, traction, and hip Spica casting, were the preferred standard of care across all paediatric age groups.[2] While these conservative methods yield acceptable results in infants and preschoolers due to their remarkable skeletal remodelling potential, their application in older children and adolescents is frequently challenged. Prolonged conservative management in this demographic is complicated by extended hospital stays, loss of fracture alignment, joint stiffness, and a substantial psychosocial, educational, and economic burden on families.[3,4]

Conversely, the use of rigid interlocking intramedullary nailing—the gold standard for diaphyseal fractures in adults—poses severe risks in the actively growing paediatric population. The insertion of rigid, straight nails through the trochanteric apophysis can lead to disastrous architectural complications, including avascular necrosis of the femoral head and premature physeal closure culminating in coxa valga, limb length discrepancy, or profound growth arrest.[5,6] Open reduction and internal fixation with dynamic compression plates (DCP), while providing anatomical reduction, necessitates extensive periosteal stripping and evacuation of the fracture haematoma, delaying biological union.[7]

To bridge this critical treatment gap, Elastic Stable Intramedullary Nailing (ESIN) was pioneered by the Nancy University group in the 1980s.[8] Operating on the biomechanical principle of three-point fixation, the Titanium Elastic Nailing System (TENS) functions as a

biocompatible internal splint. The symmetrical bracing action of two pre-contoured elastic nails inserted into the metaphysis provides essential flexural, axial, translational, and rotational stability while preserving the vital fracture haematoma and periosteal blood supply.[9,10] Because titanium possesses a modulus of elasticity highly suited to a child's diaphysis, it promotes controlled micromotion at the fracture site, accelerating robust external callus formation.[9]

Despite a global transition toward flexible intramedullary nailing, variations in clinical outcomes, acceptable angulations, and complication profiles necessitate rigorous evaluation across different healthcare demographics. Within the Indian orthopaedic setting, there remains a persistent need to validate the functional outcomes and comparative advantages of TENS against conservative protocols and alternative internal fixators.[11,12] Therefore, the primary objective of this prospective descriptive study was to analyse the union rates and functional outcomes of closed reduction and internal fixation utilizing TENS in paediatric diaphyseal femoral fractures. Secondary objectives included evaluating the specific technical difficulties and complications associated with the procedure, and comparing the established efficacy of TENS with current literature.

MATERIALS AND METHODS

Study Design and Setting

This prospective descriptive inpatient study was conducted at the Department of Orthopaedics, Adichunchanagiri Institute of Medical Sciences, B.G. Nagara. The study conformed to the STROBE guidelines for observational research. The sample size of 20 patients was pre-determined based on institutional admission statistics for paediatric femoral fractures managed surgically over the preceding three years (averaging 19.3 cases annually).

Participants and Eligibility Criteria

The inclusion criteria encompassed children and adolescents aged 5 to 15 years presenting with closed displaced, Type I and Type II open, closed comminuted, or segmental diaphyseal femoral fractures. Patients presenting with massive Type III open fractures, pathological fractures secondary to neoplasms or metabolic bone disease, or existing secondary/deep infections were strictly excluded from the study.

Pre-operative Protocol

Basic advanced trauma life support protocols were started on arrival. The affected limb was temporarily immobilized with a Thomas splint. Routine baseline haematological and biochemical investigations, and urinalysis, were performed. Full-length anteroposterior (AP) and lateral radiographs of the hip and knee joints were obtained for accurate morphological classification and preoperative templating (Figure 1).

Nail size selection was meticulously determined utilizing Flynn's formula, defined as 0.4 times the internal diameter of the narrowest part of the medullary canal (isthmus).[13] Two titanium nails of identical diameter were consistently selected to ensure balanced opposing bending forces. The required nail length was estimated to extend from the distal femoral physis to approximately 2 cm distal to the capital femoral physis and 1 cm distal to the greater trochanteric physis.

Surgical Technique

Patients were placed supine on a radiolucent fracture table with a traction boot under appropriate anaesthesia. Both titanium nails were pre-bent in a gentle bow shape such that the apex of the curve would fall exactly at the fracture site to provide the maximum cortical contact. Retrograde insertion was performed routinely under continuous fluoroscopic control.

Longitudinal skin incisions of 2.5 cm were made on the medial and lateral aspects of the distal thigh, approximately 2.5 cm proximal to the distal femoral physis, strictly avoiding the epiphyseal growth plate. Following incision of the fascia lata and retraction of the vastus musculature, the cortex was penetrated utilizing a bone awl to enlarge the entry hole at a 45-degree angulation. Both nails were advanced sequentially to the fracture site. Closed reduction was achieved under continuous C-arm fluoroscopy utilizing a radiolucent ‘F’ tool.

The selected nails were driven into the proximal fragment, resting appropriately distal to the capital and trochanteric physes. Varus or valgus angulation was corrected by the rotation of the nail whose concavity faced the deformation through 180 degrees. Excess nail length was trimmed, leaving 1 to 2 cm protruding from the entry cortex to facilitate future extraction, and the wounds were thoroughly irrigated and closed in layers.

Post-operative Care and Outcome Evaluation

Post-operatively, static quadriceps exercises and passive joint movements were initiated within 24 hours, or as soon as localized pain subsided. Active range-of-motion exercises commenced at three weeks. Partial weight-bearing was permitted only after bridging callus became radiologically visible. Full independent weight-bearing was authorized upon establishing complete clinical and radiological union (typically between 6 and 8 weeks).

Patients were followed up systematically at 3, 6, and 12 weeks, and subsequently at 6 and 12 months. Functional outcomes were rigorously graded utilizing the TENS scoring system established by Flynn et al.[13] Under this system, an ‘Excellent’ outcome requires a limb length discrepancy of <1 cm, angulation of <5 degrees, absent pain, and absent complications. A ‘Satisfactory’ outcome permits <2 cm limb length discrepancy, <10 degrees

angulation, and mild complications. A 'Poor' outcome is defined by >2 cm discrepancy, >10 degrees angulation, and major unresolved complications.

Statistical Analysis

Data was aggregated utilizing MS Excel. Statistical analysis was performed employing standard descriptive statistics, including means, standard deviations, and percentages. The Pearson chi-square test was utilized to calculate P values for categorical variables, with significance established at $P < 0.05$.

RESULTS

Demographics and Injury Characteristics

The mean age at time of study was 9.45 years (range 5-15 years) in the study cohort (n=20). The highest incidence was in the 9 to 12 years age bracket (50%, n=10) followed by the 5 to 8 years group (35%, n=7). There was a clear male predominance with boys making up 60% (n=12) of the cohort. The most common mechanism of injury was road traffic accidents (RTAs) with 65% (n=13) followed by self-falls 25% (n=5) and falls from height 10% (n=2). The left femur was affected more often than the right (80%, n=16) (Table 1).

Table 1: Demographic and Injury Characteristics of the Study Cohort (n=20)

Variable	n	Percentage (%)
Age Group		
5–8 years	7	35
9–12 years	10	50
13–15 years	3	15
Sex		
Male	12	60
Female	8	40
Mechanism of Injury		
Road traffic accident	13	65
Self-fall	5	25
Fall from height	2	10
Side Affected		
Left	16	80
Right	4	20

Fracture Morphology and Operative Data

The middle third of the diaphysis was the most common fracture site and represented 65% (n=13) of the cohort. Proximal third and distal third fractures contributed 20% (n=4) and 15% (n=3) respectively. In terms of fracture patterns, transverse was the most common pattern (55%, n=11), followed by oblique (25%, n=5), spiral (15%, n=3) and comminuted (5%, n=1) patterns. Nineteen (95%) fractures were closed injuries and one (5%) was a Type I open fracture that was treated successfully with targeted intravenous antibiotics and regular dressings (Table 2).

Table 2: Fracture Morphology (n=20)

Variable	n	Percentage (%)
Fracture Location		
Proximal third	4	20
Middle third	13	65
Distal third	3	15
Fracture Pattern		
Transverse	11	55
Oblique	5	25
Spiral	3	15
Comminuted	1	5
Fracture Type		
Closed	19	95
Open (Type I)	1	5

The mean interval between trauma and surgical intervention was 4.95 days and 80% of patients were operated within 4 days. Only one patient had a delay of over 7 days due to a concomitant head injury. The average operation time was 70.2

minutes and 55% of the operations were done in between 45 and 75 minutes. The mean hospital stay was short, 7.2 days, and 95% of patients were discharged by day 10 post operation after removal of sutures.

Radiological Healing and Complications

A 100% clinical and radiological union rate was achieved within the cohort. The mean time to complete union was 8.95 weeks. Specifically, 40% of fractures united between 7 and 8 weeks, 50% between 9 and 10 weeks, and the remaining 10% between 11 and 12 weeks. The average time to initiate partial weight-bearing was 4.85 weeks (Table 3).

Table 3: Operative Data, Healing Parameters, and Complications

Parameter	Value
Mean operative duration (minutes)	70.2
Mean hospital stay (days)	7.2
Mean time to union (weeks)	8.95
Mean time to partial weight-bearing (weeks)	4.85
Union rate	100%
Entry-site pain	4 (20%)
Superficial infection	2 (10%)
Limb length discrepancy (<1 cm)	2 (10%)
Non-union / Implant failure	0 (0%)

Minor complications were observed but resolved without secondary operative intervention. The most frequent complication was pain at the implant entry site, occurring in 4 patients (20%); this resolved universally following elective implant removal. Superficial entry-site infections occurred in 2 cases (10%) and subsided completely with oral antibiotics and local dressings. Limb length discrepancy was minimal: one patient (5%) exhibited leg lengthening of <1 cm, and one patient (5%) exhibited shortening of <1 cm, neither of which carried clinical significance. Crucially, no instances of delayed union, non-union, implant failure, deep infection, major anteroposterior angulation, or rotational malalignment were documented.

Functional Outcomes

According to Flynn's scoring criteria, the final functional outcomes were graded as Excellent in 13 patients (65%) and Satisfactory in 7 patients (35%). No patients exhibited a Poor outcome (Table 4). Sub-group analysis revealed that middle-third diaphyseal fractures yielded the highest proportion of excellent results (P = 0.059). Furthermore, transverse fracture patterns demonstrated more favourable functional recoveries compared to comminuted patterns (P = 0.09). Children within the 9 to 12 years age bracket correlated strongly with excellent outcomes (P = 0.06).

Table 4: Functional Outcomes According to Flynn's Scoring Criteria (n=20)

Outcome Grade	Criteria	N	Percentage (%)
Excellent	LLD <1 cm, Angulation <5°	13	65
Satisfactory	LLD <2 cm, Angulation <10°	7	35
Poor	LLD >2 cm, Angulation >10°	0	0

REPRESENTATIVE CASE ILLUSTRATIONS

The following representative cases illustrate the radiological and functional outcomes achieved with the Titanium Elastic Nailing System across different fracture patterns and age groups.

Case 1: 5-year-old Male, Left Femoral Shaft Fracture

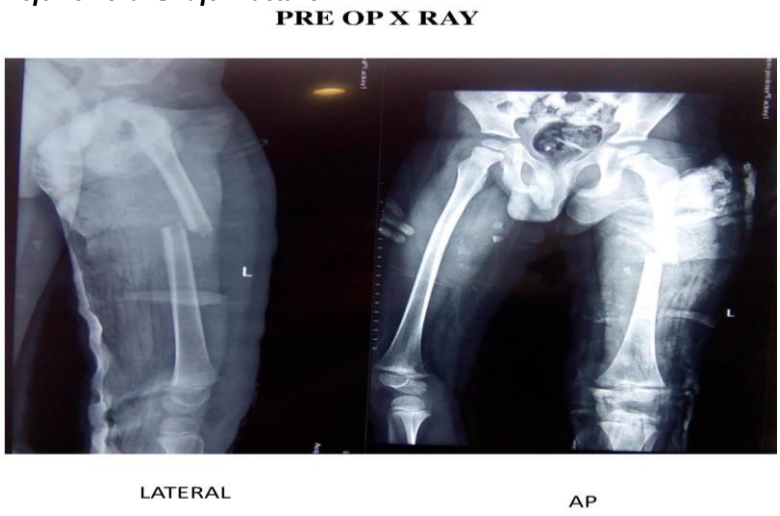

Figure 1a: Case 1 - Pre-operative anteroposterior and lateral radiographs demonstrating a displaced transverse fracture of the left femoral diaphysis.

The following representative case demonstrate the radiological healing and functional recovery achieved with TENS in children.

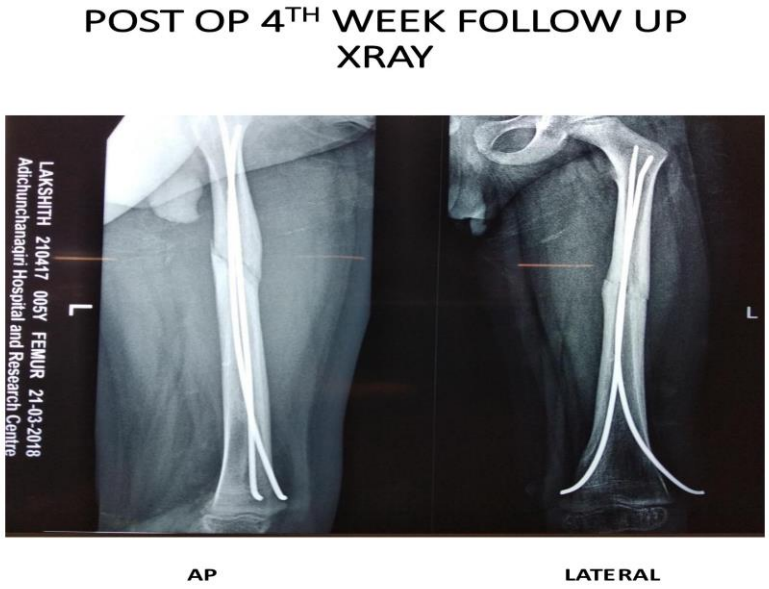

Figure 2: Case 1 - Post-operative 4th week follow-up radiographs (AP and lateral views) showing well-positioned TENS with early callus formation at the fracture site.

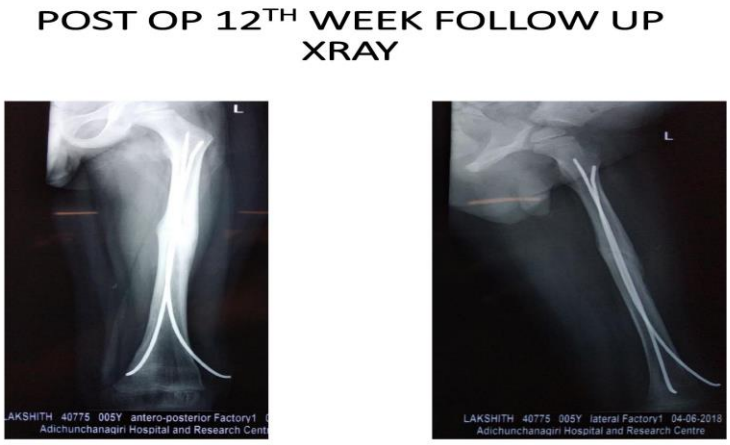

Figure 3: Case 1 - Post-operative 12th week follow-up radiographs demonstrating complete radiological union with abundant periosteal callus bridging the fracture.

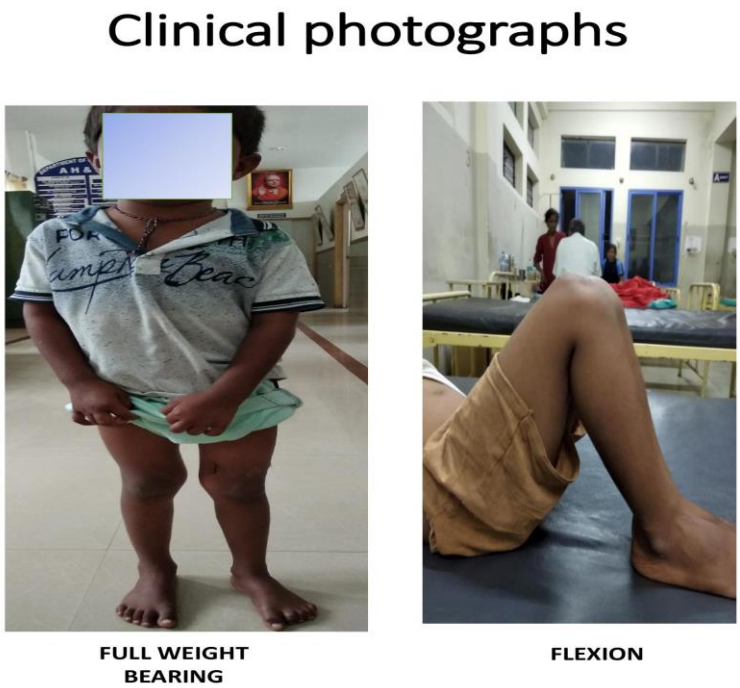

Figure 4: Case 1 - Clinical photographs at final follow-up demonstrating full independent weight-bearing (left) and complete knee flexion (right), indicating excellent functional recovery.

Case 2: 5-year-old Female, Left Femoral Shaft Fracture

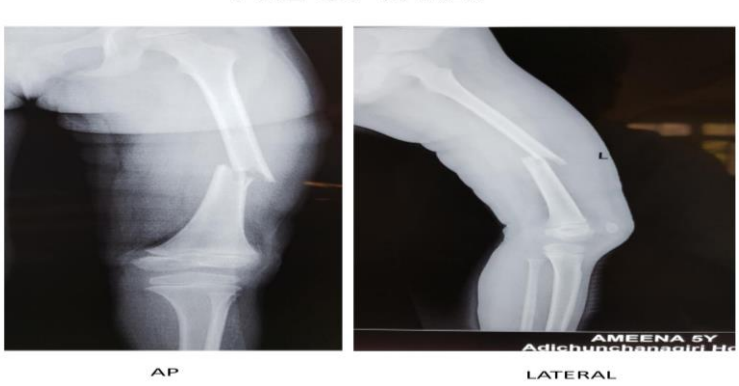

Figure 5: Case 2 - Pre-operative anteroposterior and lateral radiographs showing a displaced mid-diaphyseal fracture of the left femur.

Figure 6: Case 2 - Post-operative 4th week follow-up radiographs demonstrating satisfactory implant position with progressive callus formation.

Figure 7: Case 2 - Clinical photographs at final follow-up showing full weight-bearing and active knee flexion with satisfactory functional outcome.

Case 3: 13-year-old Female, Right Femoral Shaft Fracture

Figure 8: Case 3 - Pre-operative anteroposterior and lateral radiographs of a displaced fracture of the right femoral diaphysis.

Figure 9: Case 3 - Post-operative 4th week follow-up radiographs showing well-aligned TENS construct with early callus bridging.

Figure 10: Case 3 - Clinical photographs at follow-up demonstrating full weight-bearing capability and knee flexion, with excellent functional recovery.

Case 4: 6-year-old Male, Left Femoral Shaft Fracture

Figure 11: Case 4 - Pre-operative anteroposterior and lateral radiographs demonstrating a displaced left femoral diaphyseal fracture.

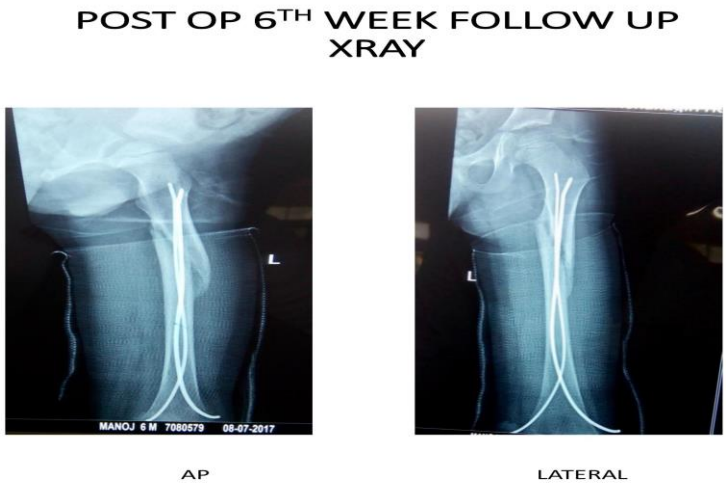

Figure 12: Case 4 - Post-operative 6th week follow-up radiographs showing satisfactory nail position and progressive callus formation.

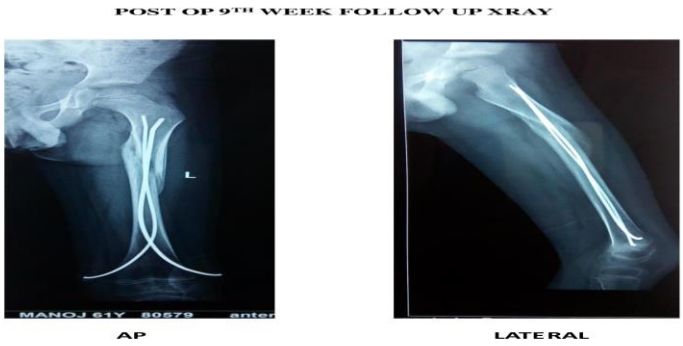

Figure 13: Case 4 - Clinical photographs at final follow-up demonstrating full weight-bearing (left) and active knee flexion (right), confirming excellent functional recovery.

DISCUSSION

The operative management of paediatric femoral shaft fractures has evolved substantially to mitigate the prolonged physical and psychosocial morbidity associated with historical Spica casting protocols. Concurrently, the severe physeal risks associated with rigid adult-style intramedullary nailing preclude its routine use in actively growing children.[6,14] This prospective descriptive study strongly corroborates that TENS successfully bridges this divide, providing essential biomechanical stability while maintaining absolute physeal protection.

Demographics and Injury Mechanisms

The demographic profile of our cohort, characterized by a mean age of 9.45 years and a 60% male predominance, aligns seamlessly with established epidemiological literature. Saikia et al. reported a comparable mean age of 10.8 years with 81.8% males, while El-Adl et al. similarly noted a 72.7% male incidence.[12,15] The predominance of high-energy road traffic accidents (65%) as the primary aetiology in our study mirrors the 58.1% RTA incidence documented in the landmark multicentre study by Flynn et al.[13] Morphologically, the high incidence of middle-third diaphyseal fractures (65%) and transverse fracture patterns (55%) corresponds precisely with the morphological distributions reported by Ramseier et al. (58% midshaft) and Ligier et al. (38.2% transverse), respectively.[16,8]

Surgical Efficiency and Hospitalization

The mean operative time of 70.2 minutes recorded in our series is virtually identical to the 70 minutes reported independently by Barlas & Beg and Saikia et al. in their respective evaluations of flexible nailing.[17,12] Caglar et al. definitively demonstrated that TENS offers a significantly shorter operative duration compared to dynamic compression plating.[18]

Because retrograde TENS is a closed, minimally invasive procedure, it inherently preserves the fracture haematoma and strictly limits periosteal stripping. This distinct physiological advantage manifested directly in our markedly short mean hospital stay of 7.2 days. This duration contrasts dramatically with the 12.9 days often required following submuscular plating, the 9 days for external fixation, and the 26 days historically required for conservative Spica casting protocols.[16,4]

Fracture Healing and Complication Profile

The 100% union rate achieved at a mean of 8.95 weeks highlights the exceptional osteogenic environment fostered by TENS. By permitting controlled micromotion at the fracture site, the elastic titanium construct promotes rapid, voluminous external callus formation.[9] Our union timeline outpaces alternative modalities reviewed in the literature; Ramseier et al. reported mean union times of 16.1 weeks for external fixation and 13.1 weeks for compression plating, while Pawan Kumar et al. noted 17.9 weeks for DCP compared to 13.8 weeks for TENS.[16,19]

Complications in our cohort were strictly minor and transient. Entry-site pain (20%), occurring secondary to prominent nail tips irritating the vastus musculature and fascia lata, was our most frequent complication. This incidence closely mirrors the 16.2% rate documented by Flynn et al.[13] Proper intraoperative trimming of the nail ends—leaving no more than 1 to 2 cm protruding—remains essential to mitigate this soft-tissue irritation.

Superficial entry-site infections affected 10% of our patients. While marginally higher than Flynn's reported 1.7%, these infections were easily managed with oral antibiotics and did not compromise deep bony tissues or the implant construct. This 10% rate remains vastly superior to external fixation cohorts, where pin-tract infection rates routinely soar up to 28.5%, frequently necessitating premature frame removal.[20]

Critically, TENS entirely prevented major architectural complications. Major angular deformities and severe limb length discrepancies (>2 cm) are historically prevalent complications associated with conservative Spica casting (up to 26.6% malunion rates) and external

fixation.[21] In our study, minor limb length discrepancy (<1 cm) occurred in only two patients (10%) and carried no clinical significance, supporting the findings of Bar-On et al., who strongly recommended TENS over external fixation to avoid structural malalignment.[22]

Functional Outcomes and Comparative Analysis

Ultimately, our final functional outcome distribution—65% Excellent and 35% Satisfactory according to Flynn's strict criteria—is remarkably consistent with international benchmarks. The multicentre findings of Flynn et al. similarly reported 65% excellent outcomes, whilst Kandil documented 81.25% excellent outcomes in a comparable demographic.[13,23] The absence of any poor outcomes in our series underscores the predictable reliability of the TENS implant (Table 5).

Table 5: Comparison of Key Outcomes with Published Literature

Study	n	Union (wks)	Excellent (%)	Complications
Present study	20	8.95	65	Entry-site pain (20%)
Flynn et al.	58	10	65	Entry-site pain (16.2%)
Saikia et al.	22	8.4	72.7	Nail irritation (18%)
El-Adl et al.	22	8	81.2	Entry-site pain (13.6%)
Kandil	32	9	81.25	Nail migration (6.25%)

STRENGTHS

The primary strengths of this study include its prospective design, stringent adherence to standardized pre-operative templating (Flynn's formula), a uniform closed surgical technique avoiding periosteal disruption, and the utilization of a validated, internationally recognized scoring system (Flynn's criteria) to evaluate outcomes.

LIMITATIONS

The principal limitation is the relatively small sample size (n=20) drawn from a single institution, which limits the statistical power of subgroup analyses. Furthermore, the descriptive design inherently lacks a randomized, concurrently treated control group managed with modern alternative modalities (such as submuscular locking plates), limiting direct comparative statistical analysis.

CLINICAL RELEVANCE

The Titanium Elastic Nailing System offers a highly reliable, physeal-protective operative approach for length-stable paediatric femoral diaphyseal fractures. By avoiding the severe physical morbidity, joint stiffness, and psychosocial isolation associated with prolonged immobilization, TENS ensures children return rapidly to full ambulation and formal schooling without risking permanent skeletal architectural damage.

CONCLUSION

Based on our prospective clinical findings, the Titanium Elastic Nailing System represents an optimal, safe, and highly effective physiological treatment for paediatric femoral diaphyseal fractures in the 5 to 15-year age demographic. By promoting early controlled micromotion and preserving the fracture haematoma, TENS rapidly accelerates bony union, drastically reduces hospitalization durations, circumvents severe limb length discrepancies, and consistently achieves excellent functional outcomes relative to alternative operative and non-operative modalities.

DECLARATIONS

Funding: None.

Conflict of Interest: The authors declare no competing conflicts of interest.

Ethical Approval: The study protocol was fully approved by the Institutional Ethical Committee (IEC) of the Adichunchanagiri Institute of Medical Sciences, B.G. Nagara, Mandya District, Karnataka (IEC Certificate No. AIMS/IEC/1593/2016-17, dated 12-11-2016). The research project titled "Management of fracture shaft of femur in pediatric age group by titanium elastic nailing system" was discussed and approved by the IEC in the meeting held in November 2016.

Informed Consent: Written informed consent was obtained from the parents or legal guardians of all participating patients prior to surgical intervention.

Data Availability: The datasets generated and/or analysed during the current study are not publicly available but are available from the corresponding author on reasonable request.

Acknowledgements: The authors sincerely thank the Department of Orthopaedics at the Adichunchanagiri Institute of Medical Sciences for their institutional support.

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