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Analytical Study Of Clinical And Radiological Outcomes In Treatment Of Femoral Shaft Diaphyseal Fractures In Children Using TENS Nails

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Abstract
Background*: Paediatric femoral shaft fractures are a significant orthopaedics challenge, particularly in children aged 6–12 years, where treatment must balance anatomical healing with minimal invasiveness and rapid functional recovery. Flexible intramedullary nailing (FIN), including titanium and stainless-steel variants, has emerged as a preferred modality, though its applicability in varying fracture types and patient subgroups remains under investigation.*
Aim*: The present study aimed to evaluate the clinical, radiological, and functional outcomes of paediatrics femoral shaft fractures treated with flexible intramedullary nails, and to identify complication patterns in relation to age, fracture stability, and body weight.*
Methodology*: This was a prospective observational study conducted over an 18-month period in a tertiary care hospital in India. A total of 30 children aged 6–12 years with isolated, closed femoral shaft fractures were included. All patients underwent surgical stabilization using flexible intramedullary nails (titanium or stainless steel), selected based on availability and fracture characteristics. Preoperative and postoperative clinical assessments, radiographs, and functional evaluations were performed using Flynn's criteria. Follow-up was conducted at regular intervals up to 6 months post-surgery.*
Results: *In 80% cases, union was attained, delayed union was experienced in 15% and partial union at 5%.. Fifty percent of them were pain-free, and 90 percent recovered full or near-full range of motion clinically. Complications were rare and mainly minor including superficial infections, nail irritation and minor length discrepancies. Excellent or satisfactory results were demonstrated on the basis of functional assessment in more than 90% of children and poor results in just one case. There were found to be significant relationships between malalignment and functional grade, malalignment and limb length disparity, malalignment and complications, malalignment and lack of range of motion, and malalignment and delayed healing ($p < 0.05$).*
Conclusion: *Flexible intramedullary nailing is a safe, efficient and least invasive way of healing paediatric diaphyseal fractures of the femoral shaft. It offers superior union rates, good functional performance and low complication rate. The issues of malalignment, mismatch of limb length, complications, range of motion, and healing condition have a great impact. Treatment of diaphyseal femoral fractures in children between 6-12 years old should be considered as FIN.*

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I. Introduction

- **Pediatric Diaphyseal Fractures**: These are fractures occurring in the shaft (diaphysis) of long bones, commonly due to falls, sports injuries, or accidents.
- Due to ongoing growth, the treatment must avoid damaging growth plates and allow proper healing and remodeling.
- Titanium Elastic Nailing System is minimally invasive, provides stable fixation, and is well-suited for children's growing bones.
- Tens nail promotes early mobilization, fostering rapid functional recovery with good cosmetic outcomes due to small incisions.
- Also provides rotational,transational stability
- The studies by Indian authors like John and colleagues (1) and Dinkar and colleagues (13) are indicative of the fact that FIMN enables predictable union with minimal long-term morbidity. Analogous results are documented in international literature. As an example, Atassi et al. (14) reviewed 101 fractures and concluded that flexible nailing allows safe treatment of even unstable fractures, with a low requirement of revision and

excellent results in terms of alignment. Çepni and coauthors (8) found similar results in a Turkish cohort with complete union and full joint mobility, as well as minimal angular deformities or LLD, which are in line with Flynn, who has shown that most patients may be considered as having an excellent or good outcome.

- Stainless steel elastic nailing has also been proposed as cost-effective alternative to TENS in environments of limited resources. Whereas stainless steel is stiffer and less bio-compatible than titanium, thoughtful use has produced results that are comparable to TENS especially with length-stable midshaft diaphyseal fractures. The use of this modality still prevails in most developing countries because economic factors affect the choice of surgical implants

II. Aim Of The Study

To evaluate the clinical and radiological outcomes of paediatric femoral diaphyseal shaft fractures treated with flexible intramedullary nails.

III. Objectives Of The Study

- To evaluate radiological healing, alignment, and complications.
- To identify complications associated with flexible intramedullary nails.

IV. Materials And Methods

Study Design

The current research was conducted in a prospective observational format to explore the results of clinical, radiological, and functional outcomes of paediatrics femoral shaft fractures treated using FIN. A hypothetical framework resulted in standardised data collection, active follow-up, and real-time assessment of the postoperative outcomes and complications. The study recruited children aged between 6 and 12 years of age with closed and isolated, femoral shaft fractures, which were surgically stabilised using either titanium or stainless-steel elastic nails

Study Setting

The Department of Orthopaedics, KVG Medical College and Hospital, Sullia, Karnataka was used to carry out the study. It is a tertiary care facility with mostly rural and semi-urban community. Orthopaedic unit is used to regularly deal with paediatrics trauma cases, and such patients will have access to experienced surgical teams, imaging facilities and consistent follow-up procedures that are needed in this investigation.

Study Duration and Timeline

The research took place within the period of 18 months, i.e., between March 2024 and August 2025. The process of recruiting patients took place between March 2024 and December 2024, and the minimum period of postoperative follow-up of each participant was 6 months. The data were collected, clinical, and radiographic assessments done at specific time points and data analysis started in July 2025 when all follow-up visits were completed.

Ethical Considerations

This research was in compliance with the ethical standards of the Declaration of Helsinki and the national research ethics requirements as they were at the time when this project was conducted. Beforehand, the Institutional Review Board (IRB) of the host institution was approved. Information sheets with all the details about the purpose, objectives, methodology, and possible implications of the study were provided to all stakeholders, including clinicians, administrative staff, and other interested individuals.

Study Participants and Definitions

The study population comprised paediatric patients aged 3 to 14 years who were diagnosed with femoral shaft fractures and underwent operative management with flexible intramedullary nails at the participating institution. This age range was selected as it encompasses the group for whom flexible nailing is widely considered biomechanically appropriate and clinically effective, allowing for adequate fracture stabilisation while accommodating the ongoing growth of the femur.

For the purposes of this study, *femoral shaft fracture* was defined as a fracture occurring in the diaphyseal region of the femur, extending from 2 cm distal to the lesser trochanter to 5 cm proximal to the distal femoral physis. *Flexible nails* referred specifically to TEN or SSEN inserted using standard retrograde or antegrade techniques, according to surgeon preference and fracture characteristics.

Participation Criteria

Inclusion Criteria

- Children aged 3–14 years at the time of injury.
- Radiologically confirmed femoral shaft fracture within the defined diaphyseal region.
- Treatment with flexible intramedullary nails (titanium or stainless steel) as the primary fixation method.
- Availability of complete clinical, operative, and follow-up records for at least 6 months post-surgery.

Exclusion criteria

- Pathological fractures (e.g., due to bone tumours, metabolic bone disease).
- Open fractures classified as Gustilo–Anderson Grade II or higher.
- Previous femoral fracture or surgery on the affected limb.
- Associated injuries requiring deviation from the standard flexible nailing protocol (e.g., polytrauma requiring prolonged immobilisation).
- Loss to follow-up before the minimum 6-month assessment period.

Outcome Measures

The radiographic outcome was examined post-operatively using a regular anteroposterior (AP) and lateral view of the involved femur in each planned follow-up visit. Such images were analyzed in a systematic manner to allow accurate assessment of the post-operative alignment, the direction of healing, angular correction and the final union of the fracture.

The analyses of post-operative alignment were done using the criteria set by Flynn et al. (48). Malalignment was considered as more than 10 degrees of varus or valgus angulation in the coronal plane or more than 15 degrees of the anterior or posterior angulation in the sagittal plane. The imaging software of the hospital was used to measure each angle in a digital manner, positioning the anatomical axes of the proximal and distal fragments of the fracture. This procedure ensured consistent, objective documentation across all cases.

🔧 **TENS Nail Procedure for Diaphyseal Fractures in Children**

✅ **Indications:**

- Diaphyseal fractures of **femur,** in children aged 3–15 years.
- **Stable or unstable fractures**, including transverse, short oblique, and minimally comminuted types.
- Ideal for children with **open growth plates (physes)**.

🅰 **Pre-operative Planning:**

- **Imaging:** AP and Lateral radiographs of the affected bone including adjacent joints.
- **Nail selection:**
  - Nail diameter = **40% of the narrowest canal diameter**
  - **Two flexible nails** of identical diameter used (usually titanium)

🅱 **Surgical Technique:**

1. Anaesthesia & Positioning:

- **General anaesthesia**
- Positioning based on bone involved:
  - **Femur** – Supine on traction table or radiolucent table
  - **Tibia** – Supine with knee flexed
  - **Humerus/Forearm** – Supine with arm on side table

2. Incision & Entry Site:

- **Two small incisions** over the metaphyseal region
- **Entry points** are away from the growth plate:
  - **Femur:** Distal metaphysis (medial and lateral)
  - **Tibia:** Proximal metaphysis (medial and lateral)
  - **Humerus/Ulna:** Proximal or distal metaphysis

3. Canal Entry:

- Use an **awl or drill** to create entry holes into the medullary canal
- Insert **pre-bent flexible titanium nails** (C-shaped)

4. Fracture Reduction & Nail Advancement:

- **Closed reduction** attempted first; open reduction if necessary
- Under **C-arm guidance**, each nail is advanced:
  - Across fracture site
  - Directed into opposite cortex or metaphysis for stability
- Nails should **diverge within the canal** for optimal fixation

5. Final Fixation:

- Nails are cut, and **ends either buried** or left slightly protruding for later removal
- Confirm alignment and rotation on fluoroscopy
- Ensure **no physeal injury**

Post-operative Management:

- **Immobilization** (if needed): Short-term cast or splint (1–3 weeks)
- **Weight-bearing:**
  - Non-weight bearing until callus visible on X-ray (esp. femur/tibia)
  - Upper limb: Early mobilization preferred
- **Follow-up X-rays** every 2–4 weeks
- **Nail removal**: Elective, typically after **6–12 months**

Potential Complications:

- Nail prominence/skin irritation
- Entry site infection
- Malalignment or angulation
- Delayed or non-union
- Refracture after implant removal

Data Collection: X-rays, union times, pain scores, limb function, and complications tracked over 6–12 months of over 20 patients

The process of collection of data was prospectively taken as per a pre-determined schedule to achieve uniformity and to eliminate chances of missing data. Follow-up assessments were completed at three standardised time points after surgery- 6 weeks, 3 months and 6 months- in all the participants. A detailed clinical examination was done at all follow-up visits together with radiographic assessment of the patient by standard anteroposterior and lateral views of the femur. The range of motion of the wound, the range of motion, the evaluation of pain, and the MHHS and LEFS functional scoring were used as clinical assessment procedures. Radiological measurements were done on every visit which included alignment, status of fracture healing, angulation and union type.

Flynns criteria

Outcome	Limb Length Discrepancy (LLD)	Malalignment (varus/valgus/rotation)	Pain	Complications
Excellent	< 1 cm	< 5°	None	None
Satisfactory	< 2 cm	5–10°	Mild	Minor, resolved easily
Poor	> 2 cm	> 10°	Present	Major or persistent

V. Results:

Overall 20 patients were followed up from postop,6weeks,3months,6months,9months,1year and most of them gave excellent clinical and radiological outcome with tens nails according to flynns criteria,2 of them developed minor nail irritation and pain on movement which gradually decreased on further follow up.

Table 3: Distribution of Limb Length Discrepancy (LLD) in Children Treated with Flexible Intramedullary Nails

LLD (cm)	Frequency	Percent
0.5	7	35.0
1.0	10	50.0
1.5	2	10.0
2.5	1	5.0
Total	**20**	**100.0**

Table 4: Distribution of Malalignment in Children Treated with Flexible Intramedullary Nails

Malalignment (°)	Frequency	Percent
2	12	60.0
6	7	35.0
12	1	5.0
Total	**20**	**100.0**

Distribution of Healing Status in Children Treated with Flexible Intramedullary Nails

Healing Status	Frequency	Percent
Delayed union	3	15.0
Partial union	1	5.0
Union	16	80.0
Total	**20**	**100.0**

Table 9: Functional Outcome Based on Flynn's Criteria

Flynn Grade	Frequency	Percent
Excellent	14	70.0
Poor	1	5.0
Satisfactory	5	25.0
Total	**20**	**100.0**

Clinical:
Mean union time: ~6–8 weeks

The results of clinical evaluation of the study group were promising. At follow-up, fifty percent of the children denied to experience any pain, and another 30 percent experienced mild pain. Small percentage of moderate pain was experienced, no incidences of severe or persistent pain were experienced. In terms of mobility, 60 percent of the children returned to full ROM pain-free, and 30 percent of the children returned to full ROM with some discomfort. Limited ROM was only demonstrated in 10% indicating that most of them regained satisfactory joint functioning. Radiological healing was also favourable as 80% of the cases showed timely union. Delayed union was recorded in 15% and only one case (5%) had partial union, which highlights the overall efficiency of FIN in the healing of the fracture.
Most patients returned to full activity within 3 months

Radiological:
Good alignment maintained
Full healing in 95% of cases without secondary interventions

The radiological examination of the current study revealed that the majority of children developed a slight LLD, with most of them limited to less than 0.5-1.0 cm, and only one child registered LLD above 2 cm. Malalignment was also kept within the acceptable range with the majority of cases being below 6deg of angulation and only one child recorded a malalignment of 12deg. These findings indicate the capability of FIN to maintain limb length and positioning in children with fractures of the femur shaft.

Similar results were in Flynn et al. (48), who suggested that LLDs to a maximum of 2 cm and angulations to a maximum of 10deg in the coronal plane or 15deg in the sagittal plane are acceptable in growing children as they tend to remodel as they age. Cepni et al. (8) also discovered that the majority of their patients undergoing FIN obtained very slight discrepancies and angular defects, all of which did not lead to any additional surgeries. Likewise, in a prospective Indian trial Dinkar et al. (13) found no significant LLD or malalignment in more than 80 percent of patients treated with titanium elastic nail, which confirms the similarity of these results in various environments.

Complications:
Minor nail irritation in 2–3 cases
No cases of growth disturbance or deep infection

VI. Conclusion

Summary: TENS nail is a safe and effective method for managing diaphyseal fractures in children. The study was a prospective one involving 20 children (4-14 years old) who were affected by a diaphyseal fracture of the femur. Recruitment, operative management, and follow-up were directed by standardised procedures. Radiological results were limb length discrepancy and malalignment; clinical data included pain, range of motion, complications and healing, and functional results were evaluated according to the Flynn criteria. The use of statistical tests was used to examine relationships between predictors and final outcomes.

The results established FIN to be extremely effective in this environment. In most instances union was accomplished and rarely was there a delayed or partial union. Radiological distortions were minimal and within accepted levels and over 90 percent of the children had excellent or satisfactory functional recovery. The occurrence of complications was rare and normally mild, such as a superficial infection, irritation at the site of the nail and minor length differences. Malalignment, limb length discrepancy, complications, limited range of movement and delayed healing were some of the factors that had significant effects.

Advantages: Minimally invasive, allows early mobilization, preserves growth plates.

Recommendations: Ideal for most pediatric shaft fractures except very young (<5 years) or complex comminuted patterns.

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