International Journal of Research in Orthopaedics
*Dinkar KS et al. Int J Res Orthop. 2025 Jan;11(1):86-92*
http://www.ijoro.org

DOI: https://dx.doi.org/10.18203/issn.2455-4510.IntJResOrthop20243891

**Original Research Article**

# A prospective study on the use of percutaneous titanium elastic nails for paediatric femoral shaft fractures

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**Received:** 22 August 2024
**Revised:** 05 October 2024
**Accepted:** 06 November 2024

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## ABSTRACT

**Background:** This study aimed to assess the efficacy and safety of using percutaneous titanium elastic nail (TEN) fixation in pediatric patients with femoral shaft fractures.
**Methods:** A prospective study was conducted on pediatric patients presenting with femoral shaft fractures between the ages of 6 to 14 years. Patients were treated with percutaneous titanium elastic nails and followed up for a minimum of 12 months. The primary outcomes assessed included fracture union time, functional outcome, and complications related to the procedure.
**Results:** A total of 28 pediatric patients with femoral shaft fractures were enrolled in the study. The patients had a mean age of 10.3 years, and the average time for fracture union was 10.5 weeks. Functional outcomes assessed using Flynn's criteria scoring systems demonstrated excellent results in 67.8% of patients. Complications such as shortening (1 patient), superficial infection (1 patient), and skin irritation at entry site (2 patients) were observed. However, these complications were managed successfully with appropriate interventions.
**Conclusions:** Percutaneous titanium elastic nail fixation is an effective and safe treatment option for pediatric femoral shaft fractures, offering early mobilization, minimal soft tissue disruption, and favorable functional outcomes. Despite some complications, the overall success rate of the procedure underscores its suitability for managing femoral shaft fractures in pediatric patients. Further studies involving larger sample sizes and follow-up periods is necessary to confirm these findings and refine treatment protocols.

**Keywords:** TENS, Shaft femur fracture, Paediatric trauma, Percutaneous fixation

## INTRODUCTION

The increased frequency of road traffic accidents and improved socioeconomic status have made fractures of the femur shaft in children one of the most common emergencies seen in hospitals.[1] The incidence of these fractures accounts for approximately 1-2% of all fractures in the pediatric population. Various treatment options are available based on factors such as age, fracture location, type, and associated injuries.[1,2] For children under 5 years old, conservative treatment using a hip spica cast is typically employed, whereas operative treatment with interlocking nailing is preferred for those over 15 years old.[3,4] However, there is ongoing debate regarding the optimal management strategy for children aged 6 to 14 years. Treatment options in this age group include traction, hip spica casting, flexible or elastic stable retrograde intramedullary nailing, and external fixation for open fractures.[5]

Conservative treatment with traction often necessitates prolonged hospital stays and uncomfortable immobilization in casts, whereas operative management allows for shorter hospitalization, easier mobilization, and weight-bearing, resulting in better patient compliance.[6,7] Various surgical techniques, such as compression plating, external fixators, rigid intramedullary nailing, and elastic stable intramedullary nailing, are utilized for shaft femur

fractures in paediatric patients. However, each method has its drawbacks, such as pin tract infections and knee stiffness with external fixation, and the need for multiple surgeries and scarring with compression plating.[8-10]

A recent trend in treatment involves intramedullary fixation using titanium elastic nails, which is gaining popularity due to its simplicity and effectiveness. This technique involves the insertion of two titanium elastic nails into the femoral canal, promoting abundant callus formation and early union at the fracture site. Despite providing less rigid fixation, the titanium elastic nail allows for early mobilization, weight-bearing, and maintains alignment without damaging the growth plate. This method offers several advantages over other surgical approaches, particularly in the 6-14 age group, including reduced risk of growth plate damage, early mobilization, minimal scarring, less soft tissue injury, improved patient compliance, ease of removal, and high patient satisfaction.[11-13] The objective of this study was to assess the efficacy and safety of percutaneous titanium elastic nail (TEN) fixation in pediatric patients with femoral shaft fractures.

## METHODS

A prospective study was conducted at S. N. Medical College, Agra, involving 28 cases of recent femoral shaft fractures (21 males, 7 females) over a 2-year period (2019–2021). The cohort included 19 closed fractures and 9 compound fractures (6 grade I, 3 grade II), all treated using the titanium elastic nail system (TENS). Participants were aged 6–14 years, with inclusion criteria focusing on recent, minimally comminuted, short oblique, or transverse fractures. Exclusion criteria eliminated long spiral, long oblique, multi-fragmentary fractures, pathological fractures, grade III open fractures, and those outside the 6–14 age range. No control group was used, and ethical approval was obtained from the institute's ethics committee.

A sample size of 28 was chosen to assess the prevalence of vitamin D deficiency in orthopaedic trauma cases, ensuring a 95% confidence level with a type I error of $\alpha$=5% and a type II error of $\beta$=10%, providing 90% power to detect significant results. A p value below 0.05 was considered statistically significant.

The patients had an average age of 10.3 years, with a higher occurrence of fractures on the right side (15 cases, 55%) compared to the left. Road traffic accidents were the leading cause of injury, responsible for 15 cases (55%). Most fractures (20 cases, 73%) were in the middle third of the femoral shaft, with 2 cases (9%) in the proximal third and 6 cases (18%) in the distal third. Transverse fractures were the most common type, found in 18 patients (64.4%), followed by short oblique fractures in 6 patients (21.4%), and minimally comminuted fractures in 4 patients (14.2%).

Most of the patients (24 cases, 85.7%) underwent surgery within the first week after injury, while the remaining 4 cases (14.3%) had surgery within two weeks. All patients received care for any life- or limb-threatening conditions. Displaced fractures were stabilized with skin traction using a Thomas splint until the surgery. For open fractures, the treatment involved local irrigation with normal saline and povidone-iodine solution, followed by immediate administration of intravenous antibiotics after a negative skin test.

### *Surgical technique*

Two retrograde intramedullary nails (TENs) were used for all femoral fractures, with patients positioned on a traction table during surgery. Fracture reduction was guided intra-operatively with a C-arm. A 1-2 cm skin incision was made on both the lateral and medial sides of the distal femur, approximately 2 cm above the epiphyseal plate. Entry into the femur was created using a bone awl. The chosen nail size was at least 40% of the narrowest diameter of the diaphysis.[14] To achieve proper three-point contact, the TENs were pre-bent to a length about three times the diameter of the medullary canal. Using a T-handle, the nail was inserted into the femur with wrist-rotational movements. Under continuous image intensifier guidance, the nail was advanced to align the fracture anatomically or near anatomically, then further driven into the proximal fragment. Simultaneously, the second nail was inserted into the proximal fragment through another entry point, with traction released to prevent distraction. The fracture reduction was reassessed with the image intensifier, and once confirmed, the nail tip was buried, and the incision was closed.

Following surgery, an above-knee plaster of Paris slab was applied to provide rotational stability for two weeks, as we believe elastic nails alone may not offer enough rotational support. The plaster was removed after two weeks when the fracture became tacky, indicating that the TENs alone could now provide ample stability. Antibiotic prophylaxis was administered for three days. Knee mobilization commenced upon slab removal. Non-weight-bearing mobilization with a walker began on the second postoperative day or according to the patient's tolerance level. Patients were kept non-weight-bearing for four weeks, after which they could begin partial weight-bearing. Full weight-bearing was permitted once bone healing was confirmed.

The study was carried out within the orthopedics department from January 2019 to September 2022. Twenty-eight pediatric patients with femoral shaft fractures (comprising 21 boys and 7 girls) underwent fixation with TENs. Among these, 19 fractures were classified as closed, while 9 were categorized as open (grade I and II, according to Gustilo-Anderson classification).[15] Of the total cases, 15 involved left-sided fractures and 13 involved right-sided fractures. Surgical intervention was performed within three days of admission

to the hospital. The outcomes were assessed using Flynn's scoring criteria (Table 1), and radiological union was evaluated utilizing Anthony et al's scale for grading callus formation (Table 2).[16,17]

## RESULTS

A total of 28 patients (21 boys and 7 girls) were included in the follow-up assessment. Road traffic accidents (RTAs) were the leading cause of injury, responsible for 55% of cases. Right-sided fractures were seen in 15 patients (55%) and left-sided fractures in 13 patients (45%). Most fractures (20 cases, 73%) were in the mid-diaphysis of the femur, 6 cases (18%) involved the distal third, and 2 cases (9%) were sub-trochanteric. Transverse fractures were the most common, occurring in 18 patients (55%), followed by oblique fractures in 6 patients (27%), spiral fractures in 2 patients (9%), and comminuted fractures with a butterfly fragment in 2 patients (9%). The patients were monitored for an average duration of 12 months, ranging from 6 to 18 months.

Radiological evidence indicated that all fractures had achieved union between 8 to 12 weeks post-surgery, with an average of 10.5 weeks (Tables 3 and 4). Full weight-bearing was typically resumed after 12 weeks following the surgical intervention.

**Table 1: TENS outcome score (Flynn et al).[16]**

| Variables | Poor results | Satisfac-tory results | Excell-ent results |
|---|---|---|---|
| **Limb length inequality (cm)** | >2 | <2 | <1 |
| **Mal-alignment (degrees)** | >10 | 10 | 5 |
| **Pain** | Present | None | None |
| **Complications** | Major and lasting morbidity | Minor and resolved | None |

**Table 2: Anthony et al scale for grading callus formation.[17]**

| Grades | Grading |
|---|---|
| **Grade 0** | No identifiable fracture healing |
| **Grade 1** | Primary bone healing with little or no new bone formation |
| **Grade 2** | Periosteal new bone formation on two sides of femur |
| **Grade 3** | Periosteal new bone formation on three or four sides of femur |

The average duration of surgery was 50 minutes, with an average hospital stay of 6 days. According to Flynn's scoring criteria, results were categorized as excellent in 19 patients, satisfactory in 7 patients, and poor in 2 patients. Five patients experienced post-operative knee stiffness due to non-compliance with early mobilization exercises, even after the removal of the plaster at 2 weeks. Consequently, these patients underwent regular physiotherapy, including continuous passive motion (CPM), resulting in complete restoration of knee motion within an average of 2 weeks of physiotherapy. One patient exhibited over 2 cm of shortening, attributed to early weight-bearing in the context of a spiral fracture. Another patient developed superficial infection at the insertion site, which resolved with routine dressing changes and antibiotics.

Additionally, 2 patients experienced severe irritation of skin at the insertion site, necessitating nail removal after 6 months in one case and 7 months in the other. There were no cases of septic arthritis, osteitis, pulmonary embolism, or rotational deformity were reported. Furthermore, there were no re-fractures after removal of nail, and no readmissions or secondary surgical procedures were required following discharge, except for the nail removal procedure (Table 4).

**Table 3: Patient profile.**

| Variables | Values (%) |
|---|---|
| **Gender** | |
| Male | 21 (82) |
| Female | 7 (18) |
| **Side involved** | |
| Right | 15 (55) |
| Left | 13 (45) |
| **Type of fracture (Gustilo and Anderson)** | |
| Closed fracture | 19 (73) |
| Grade I open | 6 (9) |
| Grade II open | 3 (18) |
| **Type of fracture (configuration)** | |
| Transverse | 18 (55) |
| Oblique | 6 (27) |
| Spiral | 2 (9) |
| Comminuted | 2 (9) |
| **Mean age (years)** | 10.3 |

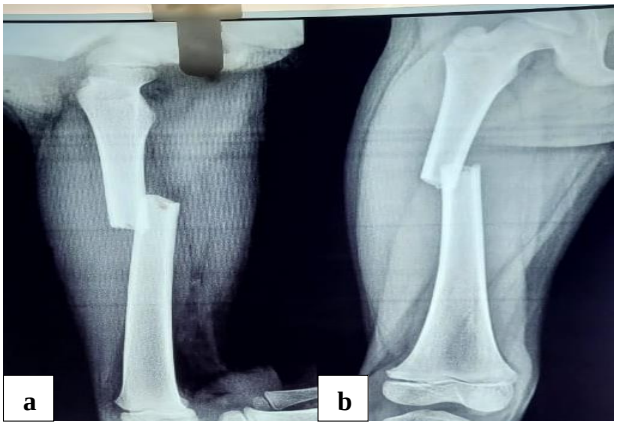


**Figure 1 (a and b): Pre-op X-ray showing fracture shaft femur (R) (proximal 1/3rd- distal 2/3rd junction) in a 6-year-old female.**

**Table 4: Results.**

| Variables | Values (%) |
|---|---|
| **Mean duration of hospital stay (days)** | 6 |
| **Mean time for radiological union (weeks)** | 10.5 |
| **Flynn's criteria result** | |
| Excellent | 19 (67.8) |
| Satisfactory | 7 (25) |
| Poor | 2 (7.2) |

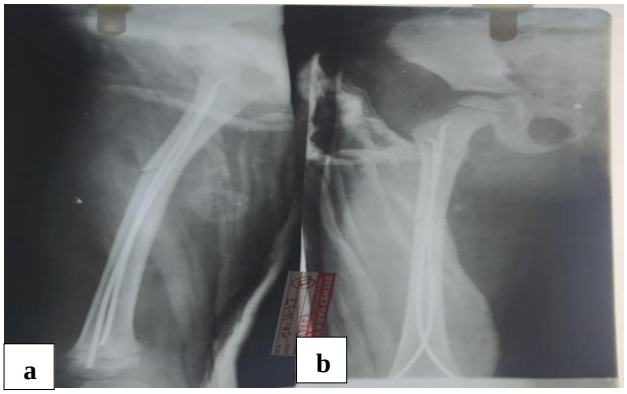


**Figure 2 (a and b): Post-op X-ray.**

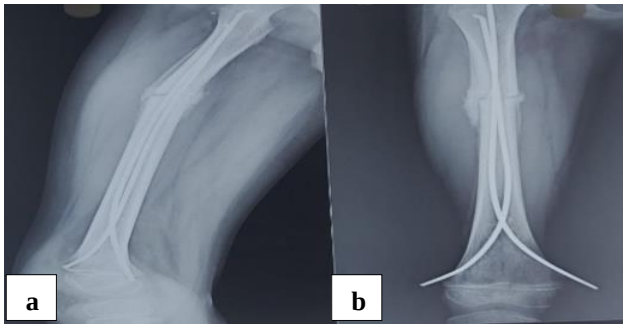


**Figure 3 (a and b): Follow up X-ray at 3 weeks.**

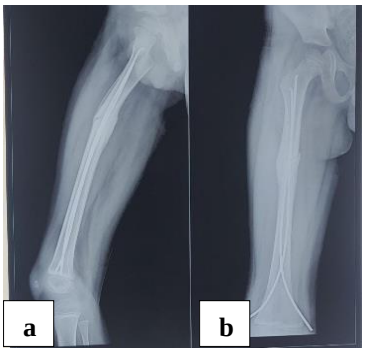


**Figure 4 (a and b): Follow up X-ray at 6 weeks.**

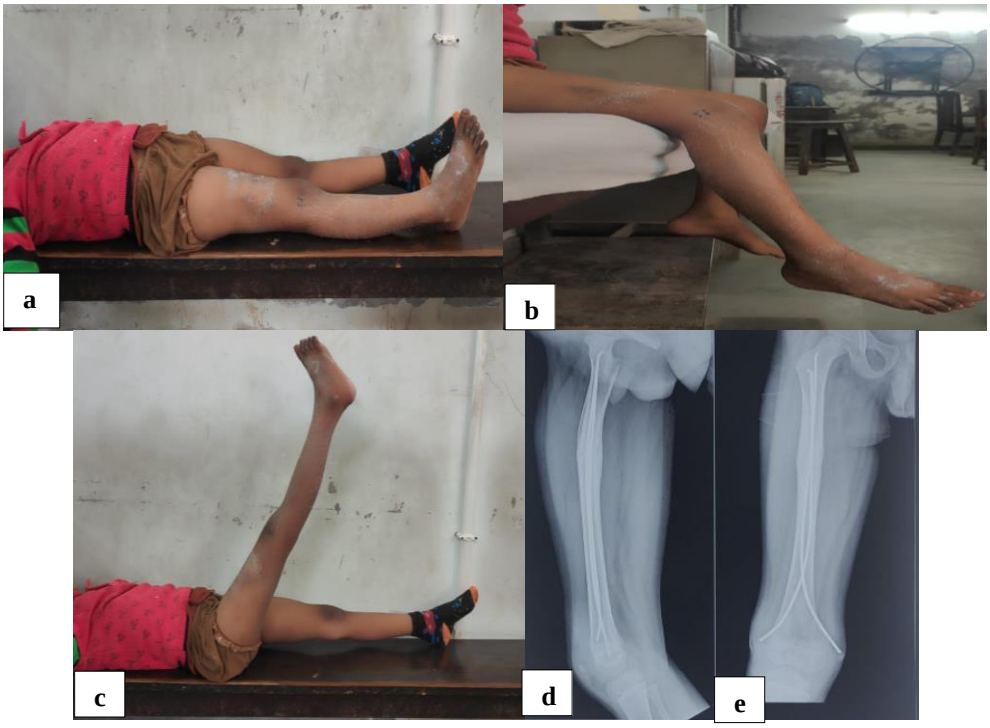


**Figure 5 (a-e): X-ray and clinical pictures at final follow up (10 weeks) showing complete union of fracture, 0-90 degrees of range of motion and patient doing active SLR suggestive of union of fracture.**

## DISCUSSION

Over the last two decades, pediatric orthopedic surgeons have experimented with various approaches to manage lower limb fractures in children, aiming to minimize prolonged immobilization and associated complications. However, each method has presented its own set of challenges: the use of spica cast immobilization either independently or following traction has led to issues such as limb-length inequality, angular deformities, rotational

malalignment, as well as psychological and economic burdens.[5] External fixation has been associated with complications including pin-tract infections, restricted knee range of motion, delayed or non-union, and the occurrence of refractures following the removal of the fixator. Antegrade intramedullary nailing has been robustly associated with trochanteric epiphysiodesis, avascular necrosis of the head of femur, and the development of coxa valga.[18,19]

The optimal implant for managing pediatric femoral fractures should be a straightforward, load-sharing internal splint. This device is designed to enable early mobilization while maintaining length and alignment over an extended period until bridging callus formation occurs, all without compromising the blood supply to the epiphysis.[20] TENs have all these desirable qualities, making them the ideal implant for treating paediatric femoral fractures. The use of TENs for fixation dates to 1982 by French surgeons, though one of the main concerns at that time was the associated treatment cost.[21]

In their research, Buechsenschuetz et al examined 71 shaft femur fractures in 68 patients, comparing the functional and clinical outcomes of 90-90 traction combined with spica casting to those of elastic stable intramedullary nail fixation.[20] Their findings revealed no discernible distinction between the two groups concerning standard clinical and functional criteria. However, the group treated with elastic nailing demonstrated a lower overall cost compared to the traction and casting group. Additionally, it yielded superior acceptance of scar and higher levels of satisfaction of parents overall.

Ligier et al and Flynn et al found in their research that when proper precautions are taken during nail insertion and in the postoperative period, particularly in cases of comminuted, spiral, and long oblique fractures, TENs can provide rotational stability.[16,22]

In their prospective clinical study evaluating the outcomes of operative treatment for pediatric femoral and tibial fractures, Gamal et al found that patients had an average hospital stay of 5.7 days, and most fractures healed within 3 months.[23] The average time to bone union was 85 days, ranging from 42 to 140 days. They concluded that titanium elastic nail fixation represents a straightforward, efficient, and dependable method for managing pediatric femoral and tibial fractures in the 5 to 16-year age group. This approach offers advantages such as reduced operative time, decreased blood loss, minimized exposure to radiation, decreased hospital stays, and reasonable timeframes for bone healing.

Moroz et al conducted a retrospective assessment of 229 children with 234 diaphyseal femur fractures.[24] Their clinical assessment included evaluating hip and knee range of motion, rotational alignment, duration until weight-bearing and nail removal, detection of local infection or irritation at the nail tip, as well as identifying deep infections and post-operative complications. Radiological analysis involved examining nail position, frontal and sagittal alignment, loss of reduction, callus formation, trochanteric growth disturbance, femoral head osteonecrosis, and length of femur. The anatomical axis was used to measure varus and valgus angulation. Their conclusion was that TEN is currently the preferred method for treating femoral shaft fractures in school-age children, resulting in excellent or satisfactory outcomes for the majority of patients after treatment.

The findings of this study align with those of other studies focusing on pediatric femoral shaft fracture management (Table 5). This approach presents clear advantages over alternative techniques. Noteworthy benefits include accelerated healing facilitated by micro-motion at the fracture site, early mobilization, prompt weight bearing, favorable scar formation, and high satisfaction rates among patients and parents. Additionally, the retrograde entry of TENs mitigates the risk of damage to the epiphysis or compromise of blood supply to the head of femur. The exceptional elasticity of titanium and biocompatibility further improve the effectiveness of TENs. Crucially, their elasticity enhances callus formation by reducing stress shielding, facilitating early weight bearing and accelerated healing.

**Table 5: Studies showing results of TENS in femoral shaft fractures.**

| Study | Number of patients | Hospital stay in days (mean) | LLD | Time for bony union (mean) | Flynn's score (%) | | |
|---|---|---|---|---|---|---|---|
| | | | | | Excell-ent | Satisfa-ctory | Poor |
| **Gamal et al[23]** | 66 (73 fractures) | 5.7 | None | 12 weeks (85 days) | 75.8 | 24.2 | 0 |
| **Sakia et al[5]** | 22 (22 fractures) | 9.8 | 3 (1.5 cm or less) | 8.7 weeks | 13 (59) | 6 (27.2) | 3 (13.6) |
| **Singh et al[25]** | 35 (35 fractures) | 12.3 | 3 (1 cm or more) | 9.6 weeks | 25 (71.4) | 8 (22.8) | 2 (5.8) |
| **Al-Sayed et al[26]** | 25 (25 fractures) | 12 | 5 (1.5 cm or more) | 9 weeks | – | – | – |
| **Moroz et al[24]** | 229 (234 fractures) | – | – | – | 150 (65) | 57 (25) | 23(10) |

Continued.

| Study | Number of patients | Hospital stay in days (mean) | LLD | Time for bony union (mean) | Flynn's score (%) | | |
|---|---|---|---|---|---|---|---|
| | | | | | Excell-ent | Satisfa-ctory | Poor |
| **Kumar et al[27]** | 20 (20 fractures) | – | 4 (1 cm or more) | 8 weeks | – | – | – |
| **Present study** | 28 28 (fractures) | 6 | 1 (2 cm or more) | 10.5 weeks | 19(67.8) | 7 (25) | 2 (7.2) |

***Limitations***

The limitations of this study include a small sample size, absence of a control group, short follow-up period, single-center design, potential selection bias, reliance on Flynn's criteria for outcomes, and limited exploration of complications, suggesting the need for larger, multi-center studies with longer follow-up and comparative analysis.

## CONCLUSION

In summary, we find that TEN represents a straightforward, speedy, and efficient treatment option for displaced femoral shaft fractures in children aged 6 to 14 years, with minimal complication rates. Furthermore, it diminishes hospital stays and facilitates early mobilization of pediatric patients.

*Funding: No funding sources*
*Conflict of interest: None declared*
*Ethical approval: The study was approved by the Institutional Ethics Committee*

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**Cite this article as:** Dinkar KS, Mittal V, Sharma B, Kapoor R, Goyal A, Vimal Y. A prospective study on the use of percutaneous titanium elastic nails for paediatric femoral shaft fractures. Int J Res Orthop 2025;11:86-92.