ORIGINAL RESEARCH

A clinical study on Titanium elastic nail system in the treatment of diaphyseal tibial fracture in paediatric age group

¹Dr. Rajesh Kumar Ranjan, ²Dr. Rajeev Anand, ³Dr.(Prof) Bharat Singh, ⁴Dr. Ratan Kumar Gupta

^{1,4}Senior Resident, ²Associate Professor, ³Professor & HOD, Department of Orthopedic, PMCH, Patna, Bihar, India

> Corresponding author Dr. Ratan Kumar Gupta Senior Resident, Department of Orthopedic, PMCH, Patna, Bihar, India

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ABSTRACT

Aim: A clinical study on Titanium elastic nail system in the treatment of diaphyseal tibial fracture in pediatric age group. Material and methods: A total of 50 pediatric patients with diaphyseal tibial fractures were enrolled in the study. Pediatric patients aged between 5 and 16 years, patients diagnosed with diaphyseal tibial fractures confirmed by radiographic evidence, patients eligible for surgical intervention using TENS and those who provided written informed consent were included in the study. The primary outcome measure was the rate of fracture union, defined as the presence of bridging callus on radiographs and the absence of pain or tenderness at the fracture site. Secondary outcome measures such as functional outcome(PODCI scores), infection, nail migration, refracture, time to union and length of hospital stay were assessed. Results: The average scores in various categories were: Upper Extremity and Physical Function at 85.4, Transfer and Basic Mobility at 90.2, Sports and Physical Function at 82.1, Pain and Comfort at 78.5, and Happiness at 88.7. These results indicate generally positive functional outcomes post-treatment, with the highest score in Transfer and Basic Mobility and the lowest in Pain and Comfort. The study recorded several complications, including 1 case (2%) of infection, 3 cases (6%) of nail migration, and 1 case (2%) of refracture. These complications underscore the importance of careful monitoring and management during and after the use of TENS. The time to union, which was measured from the day of surgery to the confirmation of clinical and radiological union, varied among patients. Specifically, 10 patients (20%) achieved union in less than 8 weeks, 30 patients (60%) between 8-12 weeks, and 8 patients (16%) in more than 12 weeks. There were 2 cases (4%) of non-union. The majority of patients (60%) achieved union within 8 to 12 weeks, indicating a relatively quick recovery period for most. Conclusion: In conclusion, the results of this study demonstrate that TENS is an effective and safe method for managing diaphyseal tibial fractures in pediatric patients, with favorablehematological and clinical outcomes. The findings are consistent with established literature and provide further evidence supporting the use of TENS in pediatricorthopedic surgery.

Keywords: TENS, tibial fracture, paediatric, haematology

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INTRODUCTION

Diaphyseal tibial fractures are among the most common long bone fractures in the pediatric population. These fractures typically occur due to high-energy trauma such as falls, sports injuries, and motor vehicle accidents. Effective management of these fractures is crucial for ensuring proper bone healing and restoring function, as improper treatment can lead to complications such as malunion, nonunion, or growth disturbances. The Titanium Elastic Nail System (TENS) has emerged as a preferred method for the surgical management of pediatric diaphyseal tibial fractures due to its minimally invasive nature, excellent biomechanical properties, and favorable outcomes.¹The treatment of diaphyseal tibial fractures in children presents unique challenges compared to adults. Children have a greater potential for bone remodeling and a faster healing process due to the presence of a thick periosteum and active growth plates. Consequently, the treatment strategies must accommodate the dynamic nature of the growing skeleton while minimizing the risk of growth plate damage. Nonsurgical methods, such as casting and bracing, have traditionally been used for treating these fractures. However, surgical intervention becomes necessary in cases where closed reduction is unsuccessful, the fracture is unstable, or there is significant displacement.²TENS, also known as elastic stable intramedullary nailing (ESIN), has gained popularity as a surgical option for managing pediatric diaphyseal fractures. This technique involves the insertion of flexible, pre-bent titanium nails into the medullary canal of the bone. The nails are inserted from the metaphyseal ends and positioned to provide three-point fixation, ensuring adequate stability and promoting natural alignment of the fracture. The elasticity of the nails allows for micromovement at the fracture site, which stimulates callus formation and accelerates healing.³

One of the primary advantages of TENS is its minimally invasive approach, which reduces surgical trauma and preserves the periosteal blood supply. The smaller incisions and limited soft tissue dissection associated with TENS result in lower infection rates. reduced postoperative pain, and shorter hospital stays compared to traditional open reduction and internal fixation (ORIF) methods.⁴ Additionally, the titanium material of the nails is biocompatible, providing sufficient strength to support the fracture while being less likely to interfere with imaging studies. The application of TENS in pediatricorthopedics has been extensively studied, demonstrating high rates of fracture union and excellent functional outcomes. Studies have reported that TENS provides stable fixation, allowing for early mobilization and weightbearing, which is particularly beneficial in pediatric patients who are typically more active and less compliant with prolonged immobilization. The technique has also been associated with fewer complications, such as implant irritation, nail migration, and refracture, compared to other methods.^{5,6}Despite its numerous benefits, the use of TENS is not without challenges. The technique requires a thorough understanding of the biomechanical principles and precise surgical skills to optimal outcomes.⁷The selection achieve of appropriate nail size and the correct placement of the nails are critical for ensuring adequate stabilization and minimizing the risk of complications. Additionally, the indication for TENS may be limited in cases of very small children or complex fracture patterns, where alternative fixation methods might be more suitable.⁸The postoperative care following TENS involves close monitoring of the patient to assess the progress of fracture healing and to detect any potential complications early. Follow-up includes clinical evaluation and radiographic assessment at regular intervals to ensure proper alignment and callus formation. Most patients can resume normal activities within a few weeks, and the nails are usually removed after the fracture has fully healed, typically within six to twelve months.

MATERIAL AND METHODS

A total of 50pediatric patients with diaphyseal tibial fractures were enrolled in the study. The inclusion and exclusion criteria were as follows:

Inclusion Criteria

- 1. Pediatric patients aged between 5 and 16 years.
- 2. Patients diagnosed with diaphyseal tibial fractures confirmed by radiographic evidence.
- 3. Patients eligible for surgical intervention using TENS.
- 4. Patients and their guardians who provided written informed consent to participate in the study.

Exclusion Criteria

- 1. Patients with open fractures.
- 2. Patients with pathological fractures due to underlying bone diseases.
- 3. Patients with pre-existing neuromuscular disorders affecting the lower limbs.
- 4. Patients with incomplete medical records or those lost to follow-up.

Preoperative assessment included a thorough clinical examination and detailed medical history. Baseline investigations included complete blood count (CBC), coagulation profile, and pre-anesthetic evaluation. Radiographic evaluation was performed to classify the fracture type and plan the surgical intervention.

Surgical Technique

The Titanium Elastic Nail System (TENS) was used for the surgical management of diaphyseal tibial fractures. The surgical procedure was standardized and performed under general anesthesia. The key steps included:

- **1. Patient Positioning**: Patients were positioned supine on a radiolucent operating table.
- 2. Fracture Reduction: Closed reduction of the fracture was attempted under fluoroscopic guidance. In cases where closed reduction was not achievable, a mini-open approach was utilized.
- **3. Insertion of Nails**: Two Titanium Elastic Nails were selected based on the diameter of the medullary canal. Nails were inserted retrogradely from the distal metaphysis to the proximal fragment under fluoroscopic control.
- **4. Fracture Stabilization**: The nails were advanced to achieve three-point fixation, ensuring adequate stabilization of the fracture.
- 5. Closure: The insertion points were closed with absorbable sutures, and a sterile dressing was applied.

Postoperative Care

Postoperative care involved:

- **1. Pain Management**: Appropriate analgesics were administered based on the pain assessment.
- **2. Mobilization**: Early mobilization with partial weight-bearing was encouraged as tolerated by the patient, progressing to full weight-bearing over 4 to 6 weeks.
- **3.** Follow-Up: Patients were followed up at 2 weeks, 6 weeks, 3 months, and 6 months post-surgery. Follow-up included clinical assessment

and radiographic evaluation to monitor fracture healing and alignment.

Outcome Measures

The primary outcome measure was the rate of fracture union, defined as the presence of bridging callus on radiographs and the absence of pain or tenderness at the fracture site. Secondary outcome measures included:

- **1. Functional Outcomes**: Assessed using the Pediatric Outcomes Data Collection Instrument (PODCI) scores.
- **2. Complications**: Including infection, nail migration, and refracture.
- **3. Time to Union**: Measured from the day of surgery to the confirmation of clinical and radiological union.
- 4. Length of Hospital Stay: Duration from the day of admission to discharge.

Statistical Analysis

Data were analyzed using Statistical Package for the Social Sciences (SPSS) version 25.0. Descriptive statistics were used to summarize demographic and clinical characteristics. Continuous variables were expressed as mean \pm standard deviation (SD), and categorical variables as frequencies and percentages. Comparative analysis was performed using the chi-square test for categorical variables and the t-test for continuous variables. A p-value of less than 0.05 was considered statistically significant.

RESULTS

The study included 50 pediatric patients with diaphyseal tibial fractures treated using the Titanium Elastic Nail System (TENS). The age distribution of the patients showed that 8 patients (16%) were between 5-7 years, 10 patients (20%) were between 8-10 years, 20 patients (40%) were between 11-13 years, and 12 patients (24%) were between 14-16

years. Gender-wise, there were 30 males (60%) and 20 females (40%).

The primary outcome measure focused on the rate of fracture union. Among the 50 patients, 48 (96%) achieved fracture union, defined as the presence of bridging callus on radiographs and the absence of pain or tenderness at the fracture site. This left 2 cases (4%) of non-union, reflecting a high success rate for the TENS procedure.

Functional outcomes were evaluated using the Pediatric Outcomes Data Collection Instrument (PODCI) scores. The average scores in various categories were: Upper Extremity and Physical Function at 85.4, Transfer and Basic Mobility at 90.2, Sports and Physical Function at 82.1, Pain and Comfort at 78.5, and Happiness at 88.7. These results indicate generally positive functional outcomes post-treatment, with the highest score in Transfer and Basic Mobility and the lowest in Pain and Comfort.

The study recorded several complications, including 1 case (2%) of infection, 3 cases (6%) of nail migration, and 1 case (2%) of refracture. These complications underscore the importance of careful monitoring and management during and after the use of TENS.

The time to union, which was measured from the day of surgery to the confirmation of clinical and radiological union, varied among patients. Specifically, 10 patients (20%) achieved union in less than 8 weeks, 30 patients (60%) between 8-12 weeks, and 8 patients (16%) in more than 12 weeks. There were 2 cases (4%) of non-union. The majority of patients (60%) achieved union within 8 to 12 weeks, indicating a relatively quick recovery period for most.

Lastly, the length of hospital stay for the patients was recorded. The distribution was as follows: 12 patients (24%) stayed for less than 5 days, 30 patients (60%) stayed between 5-10 days, and 8 patients (16%) stayed for more than 10 days. Most patients (60%) had a hospital stay of 5-10 days, suggesting that the TENS procedure facilitates relatively short hospitalization periods.

 Table 1: Demographic Characteristics of Patients

Variable	Frequency (n=50)	Percentage (%)
Age (years)		
5-7	8	16%
8-10	10	20%
11-13	20	40%
14-16	12	24%
Gender		
Male	60	60%
Female	40	40%

 Table 2: Primary Outcome Measure

Outcome Measure	Number of Patients (n=50)	Percentage (%)
Fracture Union	48	96%
Non-Union	2	4%

Table 3: Functional Outcomes: PODCI Scores

Category	Average PODCI Score (Out of 100)
Upper Extremity and Physical Function	85.4
Transfer and Basic Mobility	90.2
Sports and Physical Function	82.1
Pain and Comfort	78.5
Happiness	88.7

Table 4: Complications

Type of Complication	Number of Patients (n=50)	Percentage (%)
Infection	1	2%
Nail Migration	3	6%
Refracture	1	2%

Table 5: Time to Union

Time to Union (Weeks)	Number of Patients (n=50)	Percentage (%)
<8	10	20%
8-12	30	60%
>12	8	16%
Non-Union	2	4%

Table 6: Length of Hospital Stay

Length of Stay (Days)	Number of Patients (n=50)	Percentage (%)
<5	12	24%
5-10	30	60%
>10	8	16%

DISCUSSION

This study involved 50 pediatric patients with diaphyseal tibial fractures treated using the Titanium Elastic Nail System (TENS). The demographic characteristics of the patients indicated a balanced distribution across age groups and genders, similar to previous studies by Flynn et al. (2001) and Lascombes et al. (2006), which also noted a higher incidence of tibial fractures in male pediatric patients due to higher activity levels.^{9,10} The primary outcome measure was the rate of fracture union, with 96% of patients achieving union. This high union rate is consistent with previous research by Flynn et al. (2001), which reported a 94% union rate in pediatric tibial fractures treated with TENS. Similarly, Ligier et al. (1988) found a 95% union rate in their study of pediatric femoral fractures treated with elastic nails. These studies underline the efficacy of TENS in promoting fracture healing in pediatric patients.¹¹ Functional outcomes, assessed using the Pediatric Outcomes Data Collection Instrument (PODCI) scores, showed positive results across various categories. The highest average score was in Transfer and Basic Mobility (90.2), while the lowest was in Pain and Comfort (78.5). These findings align with those of Cullen et al. (1998), who demonstrated that children treated with flexible intramedullary nails had excellent functional recovery and low levels of residual pain. This suggests that TENS not only ensures fracture union but also facilitates a good functional recovery.¹² The complications observed in this study included infection (2%), nail migration (6%), and refracture

(2%). These rates are comparable to those reported by Ligier et al. (1988), who found similar complication rates in their cohort.¹¹ The low incidence of infection and refracture indicates that TENS is a safe treatment modality when proper surgical techniques and postoperative care are employed. However, the nail migration rate in this study was slightly higher than the 4% reported by Flynn et al. (2001), suggesting a need for careful monitoring of nail placement and stability during follow-up.9 The time to union varied, with the majority of patients (60%) achieving union between 8 to 12 weeks. This timeframe is consistent with the findings of Gordon et al. (2007), who reported an average time to union of 10 weeks in pediatric tibial fractures treated with elastic nailing. The relatively quick union time observed in our study further supports the effectiveness of TENS in facilitating rapid bone healing in children.¹³ The length of hospital stay in our study was typically between 5-10 days for most patients (60%). This is slightly longer than the average hospital stay of 4-7 days reported by Flynn et al. (2001), but still indicates a relatively short hospitalization period. The variation in hospital stay could be attributed to differences in postoperative care protocols and patient recovery rates.9

CONCLUSION

In conclusion, the results of this study demonstrate that TENS is an effective and safe method for managing diaphyseal tibial fractures in pediatric patients, with favourable hematological and clinical outcomes. The findings are consistent with established literature and provide further evidence supporting the use of TENS in pediatric orthopedic surgery.

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