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Clinical and Radiological Evaluation of Minimally Invasive Intramedullary Fixation by Titanium Elastic Nails in Paediatric long Bone Fractures of the Lower Limb: A Prospective Study

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Abstract
Long bone fractures in the lower limbs are common in the paediatric population, posing challenges due to the growing skeleton and the need to minimize disruption to growth plates and surrounding tissues. Minimally invasive intramedullary fixation using titanium elastic nails (TENs) offers several advantages, including smaller incisions and reduced soft tissue damage, which can enhance fracture healing and reduce recovery time. This prospective study, conducted over 2 years at Madhubani Medical College, included 45 paediatric patients aged 4 to 16 years with lower limb long bone fractures treated with TENs. Clinical and radiological outcomes were assessed through follow-up visits at 1 month, 3 months, 6 months and 1 year, focusing on parameters such as pain levels, range of motion, weight-bearing capacity, fracture union time and complication rates. The study found significant improvements in pain levels, range of motion and weight-bearing capacity over the follow-up period. The mean time to fracture union was 10.3 weeks at 6 months and 12.7 weeks at 1 year. Fracture alignment and callus formation showed substantial improvement, with minimal complications such as nail migration and malunion. TENs provide effective, minimally invasive treatment for paediatric lower limb long bone fractures, promoting pain reduction, enhanced mobility and increased weight-bearing capacity, with a low complication rate.

INTRODUCTION

Long bone fractures in the lower limbs are common injuries in the paediatric population, often resulting from high-energy trauma or falls. These fractures pose unique challenges due to the growing skeleton and the need to minimize disruption to the growth plates and surrounding soft tissues. Traditional treatment methods, such as casting or open reduction and internal fixation, may not always provide optimal outcomes and can be associated with prolonged immobilization, higher complication rates and delayed return to function[1-3].

Minimally invasive intramedullary fixation using titanium elastic nails (TENs) has emerged as a promising alternative for managing paediatric long bone fractures[4]. This technique offers several advantages, including smaller incisions, reduced soft tissue damage and preservation of the periosteal blood supply, which can enhance fracture healing and reduce recovery time[5]. Additionally, the elasticity of titanium nails allows for dynamic stabilization, promoting early mobilization and weight-bearing.

Despite the growing popularity of TENs in paediatric orthopaedic surgery, there remains a need for comprehensive clinical and radiological evaluations to establish their efficacy and safety. This prospective study aims to assess the outcomes of minimally invasive intramedullary fixation using titanium elastic nails in paediatric patients with lower limb long bone fractures. By analysing both clinical and radiological parameters, this study seeks to provide valuable insights into the effectiveness, complications and overall impact of this technique on the recovery and quality of life in paediatric patients.

MATERIALS AND METHODS

This prospective study was conducted at Madhubani Medical College for the duration of 2 years and included paediatric patients aged 4-16 years with long bone fractures of the lower limb treated with minimally invasive intramedullary fixation using titanium elastic nails (TENs). A total of 45 patients were included based on the non-probable sampling technique using the convenience sampling method as per inclusion and exclusion criteria. Inclusion criteria comprised patients with diaphyseal fractures of the femur, tibia, or fibula, while exclusion criteria included pathological fractures, fractures with neurovascular injuries and patients with metabolic bone diseases. Preoperative evaluation involves detailed patient history, physical examination and imaging studies including X-rays and where necessary, CT scans. Surgical procedures were performed under general anaesthesia using a standard technique for TENs insertion, ensuring minimal disruption to the growth plates and soft tissues. Postoperative care included early mobilization protocols and regular follow-up visits at 1 month, 3 months, 6 months and 1 year. Clinical outcomes were assessed using parameters such as pain levels, range of motion, weight-bearing capacity and time to fracture union. Radiological evaluations involved periodic X-rays to monitor fracture alignment, callus formation and potential complications such as nail migration or malunion. Data were analysed using statistical methods to compare preoperative and postoperative outcomes, with significance set at $p<0.05$. This methodology ensured a thorough evaluation of the clinical and radiological outcomes of minimally invasive intramedullary fixation with TENs in paediatric long bone fractures.

RESULT AND DISCUSSIONS

As seen in Table-1, The study included a total of 45 paediatric patients with long bone fractures of the lower limb who were treated with minimally invasive intramedullary fixation using titanium elastic nails. The average age of the patients was 10.5±of 3.6 years. The cohort consisted of 27 males and 18 females, indicating a slightly higher prevalence of fractures among males. The fractures were distributed across different locations: 44.4% in the femur, 40.0% in the tibia and 15.6% in the fibula. The average duration of follow-up for the patients was 55.43±7.8 months, providing a substantial period for assessing clinical and radiological outcomes. The mean Body Mass Index (BMI) of the patients was 18.7±2.3 kg/m², reflecting the typical range for paediatric patients.

As seen in Table 2, Pain levels, assessed using the Visual Analog Scale (VAS), showed a significant and progressive decrease from a mean of 5.2±1.4 at 1 month to 0.5±0.4 at 1 year ($p<0.001$). The range of motion in degrees exhibited a marked improvement, starting from 45.3±10.2 at 1 month and increasing to 135.6±4.3 by 1 year ($p<0.001$). Weight-bearing capacity also showed substantial enhancement, with patients being able to bear an average of 10.2±2.5 kg at 1 month, which increased to 45.0±3.7 kg by 1 year ($p<0.001$). The time to fracture union was recorded at 6 months and 1 year, with a mean duration of 10.3±2.1 weeks at 6 months and 12.7±3.4 weeks at 1 year. The statistical significance of these improvements, as indicated by the p-values, underscores the effectiveness of minimally invasive intramedullary fixation with titanium elastic nails in promoting pain reduction, enhanced mobility and increased weight-bearing capacity in paediatric patients with long bone fractures of the lower limb.

As depicted in Table 3, Fracture alignment improved significantly over time, with the mean deviation decreasing from 2.5±0.8 degrees at 1 month to 0.8±0.3 degrees at 1 year ($p=0.045$). Callus formation, an indicator of bone healing, showed a progressive increase, with 15 patients showing callus formation at 1 month, 25 at 3 months, 40 at 6 months,

Table 1: Demographic and Baseline Characteristics of the Study Population

Parameter	Value
Age (years) (Mean±sd)	10.5 ± 3.6
Gender (M/F)	27/18
Fracture Location	
- Femur	20 (44.4%)
- Tibia	18 (40.0%)
- Fibula	7 (15.6%)
Duration of Follow-up (months)	55.43 ± 7.8
BMI (kg/m²)	18.7 ± 2.3

Table 2: Comparison of Clinical Outcomes at Different Follow-up Periods

Parameter (Mean ± SD)	1 Month	3 Months	6 Months	1 Year	p-value
Pain Level (VAS)	5.2 ± 1.4	3.1 ± 1.1	1.8 ± 0.9	0.5 ± 0.4	<0.001
Range of Motion (Degrees)	45.3 ± 10.2	90.4 ± 15.6	120.7 ± 8.9	135.6 ± 4.3	<0.001
Weight-Bearing Capacity (Kg)	10.2 ± 2.5	20.4 ± 4.3	35.6 ± 5.2	45.0 ± 3.7	<0.001
Time to Fracture Union (Weeks)	-	-	10.3 ± 2.1	12.7 ± 3.4	-

Table 3: Radiological Outcomes at Different Follow-up Periods

Parameter (Mean ± SD)	1 Month	3 Months	6 Months	1 Year	p-value
Fracture Alignment (Degrees)	2.5 ± 0.8	1.5 ± 0.6	1.2 ± 0.5	0.8 ± 0.3	0.045*
Callus Formation (Yes/No)	15/30	25/20	40/5	45/0	<0.001*
Nail Migration (Yes/No)	2/43	1/44	1/44	0/45	0.231
Malunion (Yes/No)	0/45	1/44	1/44	1/44	-

Table 4: Complications and Additional Interventions

Complication/Intervention	Number of Cases (n=45)	Percentage (%)
Superficial Infection	2	4.40%
Deep Infection	1	2.20%
Nail Migration	3	6.70%
Malunion	1	2.20%
Non-union	0	0%
Reoperation	2	4.40%
Length of Hospital Stay (days)	3.8 ± 1.2	-

Table 5: Fracture Type and Treatment Outcome

Fracture Location	Mean Time to Union (Weeks)	Mean Fracture Alignment (Degrees)	Callus Formation (%)	Nail Migration (%)	p-value
Femur	11.0 ± 2.0	1.0 ± 0.5	100%	5%	0.015*
Tibia	10.5 ± 1.8	1.5 ± 0.6	94.40%	7%	0.071
Fibula	12.0 ± 3.0	1.2 ± 0.4	85.70%	14.30%	0.043*

Table 6: Comparison of Preoperative and Postoperative Radiological Parameters

Radiological Parameter	Preoperative (Mean ± SD)	Postoperative (Mean ± SD)	p-value
Fracture Alignment (Degrees)	5.2 ± 1.0	0.8 ± 0.3	<0.001*
Callus Formation (Grades)	0.0 ± 0.0	2.0 ± 0.5	<0.001*
Nail Position (mm from Centre)	-0.5 ± 0.3	0.2 ± 0.1	0.012*
Fracture Healing (X-ray Scores)	1.5 ± 0.8	3.8 ± 0.4	<0.001*

and all 45 patients at 1 year (p<0.001). Nail migration was minimal, occurring in 2 patients at 1 month, 1 patient at 3 and 6 months, and none at 1 year, with a p-value of 0.231, indicating no significant difference over time. Malunion, defined as an improper alignment of the fracture, was rare, with only one case reported at 3, 6 and 1-year follow-up periods, indicating consistent alignment throughout the study. These radiological outcomes demonstrate the efficacy of titanium elastic nails in maintaining proper fracture alignment and promoting bone healing in paediatric long-bone fractures of the lower limb.

Table-4 shows. Superficial infection occurred in 2 cases (4.40%), while deep infection was noted in 1 case (2.20%). Nail migration was observed in 3 cases (6.70%), indicating a relatively low incidence. Malunion was documented in 1 case (2.20%) and there were no instances of non-union. Reoperation was required in 2 cases (4.40%), reflecting the need for additional surgical intervention in a small percentage of patients. The average length of hospital stay for these patients was 3.8±1.2 days. These findings suggest that while complications were relatively infrequent, they highlight the importance of monitoring and addressing potential issues to ensure optimal outcomes in paediatric patients undergoing this surgical procedure.

As seen in Table-5, For femur fractures, the mean time to union was 11.0±2.0 weeks, with a mean fracture alignment of 1.0±0.5 degrees. Callus formation was observed in 100% of cases and nail migration occurred in 5% of cases, with a statistically significant p-value of 0.015. Tibia fractures had a mean time to union of 10.5±1.8 weeks and a mean fracture alignment of 1.5±0.6 degrees. Callus formation was seen in 94.40% of cases, and nail migration in 7%, with a p-value of 0.071, indicating no significant difference. Fibula fractures had the longest mean time to union at 12.0±3.0 weeks and a mean fracture alignment of 1.2±0.4 degrees. Callus formation was lower at 85.70%, and nail migration was higher at 14.30%, with a significant p-value of 0.043. These results indicate that femur and tibia fractures generally had better

outcomes in terms of union time, alignment and callus formation compared to fibula fractures, with statistically significant differences in some parameters.

As shown in Table-6, Preoperative fracture alignment averaged 5.2±1.0 degrees, which improved to 0.8±0.3 degrees postoperatively (p<0.001), indicating a substantial correction in alignment. Callus formation, initially graded at 0.0±0.0 preoperatively, increased significantly to 2.0±0.5 postoperatively (p<0.001), reflecting effective bone healing. The nail position relative to the centre improved from -0.5±0.3 mm preoperatively to 0.2±0.1 mm postoperatively (p=0.012), showing better centralization of the nail. Fracture healing, assessed by X-ray scores, improved from a mean of 1.5±0.8 preoperatively to 3.8±0.4 postoperatively (p<0.001), highlighting significant radiological healing. These results demonstrate the efficacy of titanium elastic nails in improving fracture alignment, enhancing callus formation, centralizing nail position, and promoting fracture healing in paediatric long bone fractures of the lower limb.

Our study evaluates the clinical and radiological outcomes of minimally invasive intramedullary fixation using titanium elastic nails in paediatric patients with long bone fractures of the lower limb. Our findings demonstrate significant improvements in various parameters, aligning well with existing literature, while also providing valuable insights specific to our study population.

Our study included 45 paediatric patients with an average age of 10.5±3.6 years. The cohort consisted of 27 males and 18 females, indicating a higher prevalence of fractures among males, which is consistent with other studies, such as the work by Sandeep *et al.,* which also reported a male predominance in paediatric fractures treated with titanium elastic nails[6]. Similar to our study, Ligieret al. conducted research on children aged between 5 and 16 years, with an average age of 10.2 years. Sankar[7] investigated children whose ages ranged from 7.2-16 years, with an average age of 12.2 years.

In terms of pain reduction, our study showed a significant decrease in VAS scores from 5.2±1.4 at 1 month to 0.5±0.4 at 1 year (p<0.001). This is comparable to results reported by Flynn *et al.* who observed substantial pain relief in children treated with elastic stable intramedullary nailing[8]. The range of motion and weight-bearing capacity improvements in our study also align with findings from a similar study by Zenon[9], highlighting the effectiveness of this minimally invasive technique in restoring function along with pain reduction.

Radiological outcomes in our study showed significant improvements. Fracture alignment improved from 2.5±0.8 degrees at 1 month to 0.8±0.3 degrees at 1 year (p=0.045) and callus formation increased progressively, with 100% of patients showing callus formation at 1 year (p<0.001). These findings are in line with studies by Sakia[10], Zenon[9], Dong[11] and Sandeep[6], which also reported excellent alignment and callus formation with the use of titanium elastic nails.

Nail migration and malunion were minimal in our study, with incidences of 6.70% and 2.20%, respectively. These results are comparable to Bar-on et al. study result where, one out of 19 cases found rotatory malunion requiring remanipulation[12].

Narayan *et al.* reported similarly low rates of malunion (8/79 femoral fracture)[13]. The consistency in radiological alignment and the lack of non-union cases underscore the stability provided by titanium elastic nails.

Our study reported a 4.40% incidence of superficial infection and a 2.20% incidence of deep infection, which are within the expected range reported in paediatricorthopaedic literature.

Similar to our study finding, Narayan *et al*. reported 2(2.5%) cases with superficial infection[13]. Reoperation was required in 4.40% of cases, which is lower than the other studies, such as those by Narayan *et al.,* who reported a reoperation rate of around 12.6%.

The average hospital stay in our study was 3.8±1.2 days, reflecting the efficiency of the procedure and the rapid recovery times, consistent with findings by Flynn *et al.,* who noted short hospital stays and quick return to daily activities[8].

Similar to our study in Nisar *et al.* study, the length of hospital stay following surgery varied between 2 and 3 days for humeral and forearm fractures and 4-6 days for femoral and tibial fractures.14 However, the mean duration for hospital stay was higher than our result with 9.8 days documented in Saikia et study[10].

In Aygun *et al.* study, the hospital stay was 3.50±0.79/4.29±1.54/3.33±0.49 days in femur/tibia/forearm fractures, respectively, and was the highest in tibia fractures (p<0.05).

Our study also analysed outcomes by fracture location. Femur fractures had a mean time to union of 11.0±2.0 weeks, tibia fractures 10.5±1.8 weeks, and fibula fractures 12.0±3.0 weeks. Callus formation was highest in femur fractures (100%) and lowest in fibula fractures (85.70%), with statistically significant differences, indicating varying healing potentials based on fracture location. In Sakia *et al.* study, the Radiological union of the femur was achieved in all cases in a mean time of 8.7 weeks (6-12 weeks)[10]. similarly majority of patients achieved union by 6

weeks with average time to union being 6.86 weeks in a study done by Jalan[15] In a study done by Aygun *et al.* Ulna union time was 13.1±1.8 weeks, which was higher than forearm fractures ($p<0.005$)[16].

Our study demonstrated significant improvements in radiological parameters from preoperative to postoperative assessments. Fracture alignment improved from 5.2±1.0 degrees to 0.8±0.3 degrees ($p<0.001$) and callus formation grades increased from 0.0±0.0-2.0±0.5 ($p<0.001$). These improvements highlight the efficacy of titanium elastic nails in correcting alignment and promoting bone healing, consistent with results reported by Flynn[8] In Nisar *et al*. study, Loss of fracture alignment, the most common complication was noted in 2 patients at 2 weeks following ESIN[14].

CONCLUSION

In conclusion, our study reaffirms the effectiveness of minimally invasive intramedullary fixation using titanium elastic nails in treating paediatric long bone fractures of the lower limb. The significant improvements in clinical and radiological outcomes, along with a low incidence of complications, highlight this technique as a reliable and effective option. Future studies could focus on long-term outcomes and comparative analyses with other fixation methods to further validate these findings.

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