

## Original Research Article

# Observational study on titanium elastic nailing in femoral shaft fractures in children

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**Received:** 02 December 2018

**Revised:** 17 December 2018

**Accepted:** 18 December 2018

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## ABSTRACT

**Background:** Nowadays femoral fractures in children are more commonly managed with operative fixation rather than conservative treatment because of more rapid recovery and avoidance of prolonged immobilization. Our aim of study was to assess the outcome of titanium elastic nailing in femoral shaft fracture in children.

**Methods:** Twenty five children in age group 5-15 years with femoral shaft fracture were stabilized with two titanium nails. Children were followed up for one year. The operative outcome was evaluated using criteria of Flynn. Complications associated with procedure were recorded and analyzed.

**Results:** The final outcome was excellent in 67% (19 of 25) of patients, satisfactory in 16% (4 of 25) of patients and poor in 8% (2 of 25) of patients. Poor outcome was due to limb length discrepancy, pain in the knee and angular malalignment.

**Conclusions:** We concluded that titanium elastic nailing is an ideal method of femoral shaft fixation in children.

**Keywords:** Femoral shaft fractures, Children, Titanium elastic nailing

## INTRODUCTION

Fracture of shaft of femur is a common fracture in children, which has usually been treated conservatively. In children, fractures of femoral shaft are commonly treated by various types of traction for about three weeks, followed by plaster cast immobilization.<sup>1</sup> This safe form of treatment has two major drawbacks. The first is that prolonged bed rest separates the child from his normal environment; the second is the cost of such periods in hospital and the use of beds which might serve other patients. Because of rapid healing and spontaneous correction of angulations, most of the femoral shaft fractures in children younger than five years of age can be treated conservatively. But, above six years of age, such fractures when treated non operatively could have, loss of reduction, malunion, intolerance and

complications associated with plaster. Near the end of skeletal maturity, accurate reduction is necessary as angular deformity is no longer correctable by growth.<sup>2</sup>

Therefore, the best treatment in older child i.e. between five to fifteen years of age is a matter of debate. Since the last two decades, there has been a growing tendency towards an operative approach in femoral shaft fractures in children of school going age. Successful treatment with external fixation, plating and solid ante grade intramedullary nailing has been reported. However, the risk of certain complications (particularly pin track infection and refracture after external fixation or avascular necrosis after solid antegrade intramedullary nailing) has prevented these methods from becoming adopted as the best treatment.

An ideal fixation device for paediatric femur fractures would act as a load sharing “internal splint” maintaining reduction for a few weeks until callus forms. Most important, implantation should endanger neither the physis nor the blood supply of the femoral head. Both Ender’s nail and Titanium elastic nails offer these features. Ender nails are stainless steel implants which were used for paediatric femur fractures since long. For more than two decades, French surgeons have started using titanium implants for “elastic stable intramedullary nailing” stating “Ender’s nail are not elastic enough for treating children”. The principle of Titanium elastic nail (TEN) fixation differs from that of Ender’s technique. Ender nails are stacked to improve canal-fill. But TEN techniques require balancing the forces of the two opposing flexible implants.<sup>3</sup> Titanium elastic nailing, otherwise known as Elastic Stable Intramedullary Nailing has revolutionized the management of fracture shaft of femur in children. Several recent studies suggested that elastic intramedullary nailing meets the requirements of this ideal device. After positive reports from Nancy, France (1988), titanium elastic nails became popular in Europe, but limited availability prevented their widespread use in North America. Before a planned general release in America, TENs were trialed at several major paediatric trauma centers.<sup>4</sup> Although initial skepticism and good results with conservative treatment limited their use, now-a-days these nails are used more and more in long bone fractures in children.

The Titanium Elastic Nail in treatment of paediatric femur fractures has been reported to be a simple, load sharing internal splint allowing mobilization and maintenance of alignment for a few weeks until bridging callus forms. The device exploits a child’s denser bone, rapid healing and ability to remodel, without risking the physis or blood supply to femoral head. The perceived advantages of this technique includes early union due to repeated micro motion at fracture site, early mobilization, early weight bearing, easy implant removal and high patient satisfaction rate. Taking into consideration the above facts, we conducted this study of “Observation on titanium elastic nailing in femoral shaft fractures in children” in Dept of Orthopaedics, S.C.B. Medical college, Cuttack from June 2014 to December 2017.

## METHODS

The present study “Observation of titanium elastic nailing in femoral shaft fractures in children” was undertaken in the Department of Orthopaedics, S.C.B. Medical College, Cuttack during the period of June 2014 to December 2017. A total of 25 patients (children) with fractures of shaft of femur admitted to the Department were included in the study group. Patients having other associated injuries were also included in this study group. Children having age <5 yrs and >15 yrs, segmental fracture, Winquist types III and IV comminuted fractures, previously diagnosed neuromuscular disease, osteomalacia, pathological fractures, and history of

previous fracture or deformity were excluded from the study.

Soon after admission, the child was kept on an above knee skin traction set till surgery. This helped to prevent movement at the fracture site and to reduce pain and spasm of the surrounding muscle. Antero-posterior and lateral radiographs of the thigh showing both the knee and hip joint were taken. A routine chest x-ray, pelvic x-ray and USG of abdomen and pelvis were done to exclude any associated injury.

The following points were looked for in the radiographs:

- The location of fracture.
- The morphology of fracture.
- Fracture orientation in sagittal and frontal plane.
- Presence of secondary fracture line like that of associated fracture neck of femur.
- Presence of comminution, signifying high energy injury.
- Fracture associated with any fracture and separation of physis or not.

Preoperative x-ray of contra lateral femur was used to estimate the nail diameter. Measurement of the narrowest diameter of the medullary canal with a ruler was done. The proper nail diameter is no more than forty percent of the width of the canal. All the patients were administered preoperative antibiotics and the operative site was prepared overnight. General anaesthesia was preferred in majority of cases and in some cases caudal anaesthesia was given.

Titanium elastic nails are available in five diameters: 2.0 mm, 2.5 mm, 3.0 mm, 3.5 mm and 4.0 mm; and are 440 mm in length. The nails are color-coded for easy identification. The narrowest diameter of the medullary canal was measured with a ruler. The proper nail diameter is no more than forty percent of the width of the canal. The following sizes are typically used for children of average stature:

- 6–8 years old 3.0 mm nails
- 9–11 years old 3.5 mm nails
- 12–14 years old 4.0 mm nails

Two nails of the same diameter were used, so the opposing bending forces are equal, avoiding malalignment. The nail tip is flattened and curved so that their convex surfaces glance off when it hits the opposite cortex during insertion. The patient was positioned supine on a fracture table with a traction boot. The image intensifier was positioned on the opposite side of the affected femur for AP and lateral views of the leg from knee to hip. The surgeon has the access to both the lateral and medial aspects of the distal femur. The fracture was reduced and the alignment was confirmed with fluoroscopy in both the AP and lateral views. The leg from hip to knee was prepared and draped for reduction and intra operative imaging. The rotational alignment was

obtained by aligning the iliac crest, patella and the first web space of the foot in comparison with the opposite leg. The both nails were contoured into a bow shape with the nail tip pointing to the concave side of the bowed nail. The incision was given on the lateral or medial aspect of the distal femur, starting 3 cm above the physis and extending distally for 2.5 cm. The entry point for the nail was 2.5 cm–3.0 cm proximal to the physis. Nails were inserted from the medial and lateral side and driven up to the level of the fracture

The fracture was visualized with fluoroscopy. The nail was advanced into the proximal fragment only enough to ensure reduction was maintained. The second nail was drove across the fracture using the Insertor and Slide Hammer and into the proximal fragment. This nail was advanced until it was just distal to the proximal physis. The other nail was advanced to the same level. The two

nails were diverged in opposite directions, medial towards the neck and lateral towards the greater trochanter physis for optimal rotational stability. The end of the nails should remain just short of epiphysis. If the fracture was distracted, the traction was released and impact was given to the patient's heel. The nails were pulled back approximately 2 cm; the end of each nail was cut. The final nail position and fracture reduction was confirmed with fluoroscopy. The end of the nail was protruded 10–20 mm outside the cortex and sits approximately 10–15° above the surface in its final position. When the nail was over-inserted, the Locking Pliers was used to grip and retract the nail. Intravenous antibiotics were continued for 5 days. Vital signs were monitored regularly. For unstable long oblique fractures or comminuted fractures, immobilization with a below knee POP cast with bar was given.

**Table 1: Functional assessment scoring.**

	Excellent	Successful	Poor
<b>Limb length discrepancy</b>	<1 cm	<2 cm	>2 cm
<b>Sequence disorder</b>	5 degree	10 degree	>10 degree
<b>Pain</b>	Absent	Absent	Present
<b>Complication</b>	Absent	Mild	Major complication and/or extended period for resolvable morbidity.

Patients were followed up every month for 6 months and thereafter every 2 monthly interval for 12 months and then at 6 monthly intervals at 18, 24 and 30 months. Radiographs were taken at regular interval to access the union status; malalignment etc. Regular physiotherapy was advised for first 4 months. Full weight bearing was allowed after union of the fracture which was ascertained both clinically as well as radiologically. According to TEN criteria by Flynn the results are classified as excellent, successful or poor.<sup>5</sup>

#### **Sample size calculation**

We have done a pilot study done prior to the main study with 6 patients which showed expected proportion of limb length discrepancy as 9. Sample size of population was done by using a power of 0.8, assumed significance level of  $\alpha=0.05$ , and a pooled standard deviation of 1.06, the minimum sample size calculated was 20. Union time, limb length discrepancy and functional assessment were analyzed using an unpaired t-test or Mann Whitney U test, depending on the normal distribution of data. The Chi-square test was employed to analyze post-operative complications and malunions. The statistical softwares SAS 9.2, SPSS 20.0, Stata 10.1, MedCalc 9.0.1, Systat 12.0 and R environment ver.2.11.1 were used for the analysis of the data and Microsoft word. P value less than 0.05 was considered statistically significant.

## **RESULTS**

In the present study, 25 cases of femoral shaft fractures in children were treated in the Department of Orthopaedics,

S.C.B. Medical College and Hospital, Cuttack. All cases were treated with titanium elastic nail (TEN). In our series of 25 patients treated by titanium elastic nail, the age of children varied from 5 to 15 years. Out of 25 patients, 18 were male and 7 were female.

**Table 2: Demographic data.**

Paramaters	Mean±S.D	Range (Max-Min)
<b>Age (years)</b>	7.82±3.59	(5-15)
<b>Sex(m:f)</b>	18:7	
<b>Weight (kg)</b>	21.26±5.95	(14-32)
<b>Surgical Time (minutes)</b>	60.75±16.11	(34-78)
<b>Radiological Union (weeks)</b>	8.2±2.45	(5-12)

The most common cause of the fracture was road traffic accident (RTA) in 15 cases, followed by fall from height in 8 cases. Two patients had sports injuries. 18 patients had fractures of right side while 7 cases had fractures of left side. 21 cases were closed and 4 cases were open fractures among which 2 cases were Gustilo grade-I compound and 2 cases were grade-II compound. Among the 25 femoral shaft fractures in 25 patients, 16 fractures were present in the middle 1/3rd, 6 were in upper 1/3rd and 3 in distal 1/3rd. In our study of 25 femoral shaft fractures, 11 patients had transverse pattern, 7 had oblique, 4 had spiral and 3 had comminuted fractures. The cases without any associated injury were operated within 5 days of injury after stabilization of general condition. Patients with head injury and chest injury were

operated within 5-10 days of injury. Close reduction was possible in 21 cases and open reduction was done in remaining 4 cases. 2.5 mm in 5 cases, 3 mm in 9 cases, 3.5 mm in 10 cases and 4mm nail was used in 1 case. Union was assessed clinically and radiologically every month till complete healing. Union occurred in all cases with an average time of 7.9 weeks (6-12 weeks) (Table 3).

**Table 3: Time of union.**

Time of union	No. of patients	Percentage (%)
6-8 weeks	14	56
8-10 weeks	9	36
>10 weeks	2	8
<b>Total</b>	<b>25</b>	<b>100</b>

Five patients had nail site irritation with bursitis leading to infection in 2 cases which required early removal of implant. There was no case of nonunion or delayed union in our series. There was no rotational malalignment. No case of implant failure or refracture after implant removal was noted. Pain in the knee occurred in 5 cases and in thigh in 1 case. Limb length discrepancy occurred in 6 cases. 3 cases had stiffness in knee. Angular malalignment occurred in 4 cases which were >5 degree (Table 4).

**Table 4: Post operative complications.**

Complication	No. of patients	Percentage (%)
Nail site bursitis	5	20
Infection (ulceration at nail tip)	2	8
Pain in knee/thigh	6	24
Limb length discrepancy	6	24
Stiffness of knee	3	12
Angular malalignment (>5 degree)	4	16
Nonunion	0	0
Delayed union	0	0
Rotational malalignment	0	0
Implant failure	0	0
Refracture	0	0

Limb length discrepancy was measured clinically comparing with the other limb. Average lengthening of 11 mm (9-13 mm) was noted in 4 cases and average shortening of 6 mm (5-7 mm) was noted in 2 cases after 6 months of surgery. 19 cases had no limb length discrepancy (Table 5).

Restriction of knee joint range of motion was noted in 3 cases with average range from 0-110 degree. 21 cases had 0-5 degrees of malalignment, 3 cases had 5-10 degree and 1 case had >10 degrees of angular malalignment (Table 6).

**Table 5: Limb length discrepancy.**

Limb length discrepancy	No. of patients	Percentage(%)
Lengthening	4	16
Shortening	2	8
No discrepancy	19	76

**Table 6: Angular malalignment.**

Angular malalignment	No. of patients	Percentage (%)
0-5 degree	21	84
5-10 degree	3	12
10-15 degree	1	4

Functional assessment was done by TEN scoring criteria by Flynn et al. After analyzing the final score of each patient according to the above criteria, results were classified as excellent, satisfactory and poor. In our series excellent results were obtained in 19(76%) cases, satisfactory in 4 (16%) cases and poor in 2(8%) cases (Table 7).

**Table 7: Functional assessment.**

Results	No. of patients	Percentage (%)
Excellent	19	76
Satisfactory	04	16
Poor	02	08
<b>Total</b>	<b>25</b>	<b>100</b>

## DISCUSSION

Until recently, skeletal traction and application of a cast was the preferred method for treatment of diaphyseal femoral fractures in children and young adolescents. This method stood the test of time because it was relatively conservative and permanent complications impairing future function were rare. Although a spica cast is safe and effective for many patients, operative stabilization is particularly suited for children who sustain multiple injuries from high-energy trauma, children with a head injury or spasticity and children of school going age i.e. older than 5 years of age. Studies by Reeves et al have also increased our awareness of the psychosocial and economic effects of spica cast immobilization on children and their families.<sup>6</sup>

External fixation has yielded good results. Temporary losses of knee motion and pin-track infection are common, but easy to treat. Refracture after fixator removal is more troublesome. Even with early dynamization, external fixators may shield the fracture site from the forces necessary to encourage sufficient callus formation. Solid antegrade IM nailing is better than casting for adolescent femur fractures. Reports of avascular necrosis by Stans et al and trochanteric growth



arrest and coxa valga by Gonzalez-Herranz et al have tempered enthusiasm for antegrade IM nailing in children with open proximal femoral physes.<sup>7,8</sup>

The ideal device to treat paediatric femur fractures would be a simple, load-sharing internal splint allowing mobilization and maintenance of alignment for a few weeks until bridging callus forms. The device would exploit a child's denser bone, rapid healing, and ability to remodel, without risking the physes or blood supply to the femoral head. Both Ender nails and TENs offer these features. Ender nails are stainless steel implants that proved to be inadequate for adult femur fractures, but effective for pediatric femur fractures. In a small prospective, randomized study, Baron et al reported better results with flexible nails than with external fixation.<sup>9</sup> Ender nails are not elastic enough for treating children<sup>7</sup> courted by Ligier et al.<sup>10</sup> The material properties of titanium confer advantages for an implant used to stabilize pediatric femur fractures. The modulus of elasticity of 316L stainless steel is 187 GPa, making it 80% stiffer than the titanium (105 GPa) alloy of the nails in this study. Titanium's elasticity limits the amount that the nail is permanently deformed during insertion. More important, elasticity promotes callus formation by limiting stress shielding. Titanium also has excellent biocompatibility. The principle of TEN fixations differs from that of the Ender technique. To improve fixation, Ender nails are "stacked" to improve "canal fill." As promoted by the French originators Ligier et al. TEN techniques require balancing the forces of the two opposing flexible implants. Therefore it is important to select nails 40% of the narrowest diaphyseal diameter, contour the nails with a similar gentle curvature, and use medial and lateral starting points that are at the same level in the metaphysis. To avoid soft tissue irritation, only a small amount of nail is left outside the distal metaphyseal cortex, and the nail should not be bent out into the soft tissues. Radiological and clinical union occurred with an average of 7.9 weeks (range 6-12 weeks) in our series. 56% cases achieved union within 6-8 weeks.

Nail site irritation was the most common complication. In our study five (20%) patients had nail site irritation with bursitis leading to infection in 2 cases which required early removal of implant. Pain in the knee occurred in 5 cases which responded to anti-inflammatory analgesics and two cases needed additional antibiotics for ulcerations. Review of these cases showed in three cases nails were left too long and excessively bent; and in two cases insertion sites were too high. Insertion points that are too diaphyseal lead to severe muscle irritation. We examined the range of motion of the knee at each visit and final assessment done at 4 months. We encountered stiffness of knee in 3 cases with range of motion from 0-110 degree. This was due to protrusion of nail in the distal femur causing blockage of the iliotibial tract, thus inhibiting knee flexion. Slongo et al reported the similar cause for knee stiffness due to excessive length of nail.

All 3 cases regained full range after nail removal.<sup>11</sup> These were our initial operated cases and in subsequent cases we advanced the nail so that they lie against the supracondylar flare of the femur with a small portion of nail left outside. The nails ends were cut straight rather than bending them to avoid symptoms at the insertion site. We had good results then.

Limb length discrepancy occurred in 6 (24%) cases. 4 cases had limb lengthening (average 11mm) and 2 cases had shortening (average 6mm). The limb length discrepancy was not described as a complaint by the patients and their relatives. None of them required additional surgery. In a series of 31 patients who were followed up for a median of 2 years, Hoshian et al found a leg-length discrepancy of up to 1 cm in 6 children.<sup>12</sup> In a series of 112 children with 118 diaphyseal fractures.<sup>13</sup> Jubel et al noted a mean lengthening of the injured leg of 2.4 mm. Heinrich et al reported that 22% of their patients had an extension over 5 mm, and 11% had a shortness under 5 mm.<sup>14</sup> In our series angular malalignment occurred in 4 cases which were > 5 degree. In a study by Memduh et al found angulation less than 10 degrees toward varus/valgus or antero/posterior only in four femurs (11.4%).<sup>15</sup> Herndon et al reported that malunion developed in seven of 24 patients who were treated with traction while no malunion was observed in 21 children who were treated using intramedullary nailing.<sup>16</sup> In the antegrade elastic intramedullary nail (TEN) practices carried out by Carey and Galpin et al no clinically significant rotational or angular deformity were found while an angulation less than five degrees was evident in the frontal and coronal plate of the radiographic follow-up.<sup>17</sup> In an antegrade and retrograde TEN study by Galpin et al reported that 35 out of 37 patients had excellent improvement in terms of angular deformity.<sup>18</sup> Flynn et al reported 6 out of 58 cases were having angular malalignment >5 degree with 2 cases having >15 degree. Functional assessment was done by using TEN scoring criteria by Flynn et al.<sup>5</sup> In our series excellent results were obtained in 19 (76%) cases, satisfactory in 4 (16%) cases and poor in 2 (8%) cases. Saikia et al had found excellent results in 13 (59%) cases, satisfactory in 6 (27.2%) cases and poor in 3 (13.6%) cases.<sup>19</sup> Singh et al found excellent results in 25 cases, satisfactory in 8 cases and poor in 2 cases.<sup>20</sup> All above studies agree with our study findings.

## CONCLUSION

Titanium elastic nailing (TEN) is an effective and viable treatment option in selected cases of femoral diaphyseal fractures in 5-15 years age group. The management of such fractures in this age group is still controversial with proponents of both conservative and surgical methods. There has been resurgence for operative fixation at present. The indications for TEN for paediatric femoral fractures are expanding as their advantages are realized and complications of other operative methods of stabilization are reported.

*Funding: No funding sources*

*Conflict of interest: None declared*

*Ethical approval: Not required*

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**Cite this article as:** Bahinipati J, Mohapatra RGA. Observational study on titanium elastic nailing in femoral shaft fractures in children. *Int J Res Orthop* 2019;5:32-7.