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Clinical and functional outcome of elastic stable intramedullary nailing in pediatric femoral fractures in the age group of 5-16 years

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ABSTRACT

Background: Fractures of the femur are the most incapacitating fractures. The best treatment for children between five to sixteen years of age is still debated. The ESIN has the benefits of early immediate stability to the involved bone segment, permitting early mobilization and return to the normal activities of the patients, respect for the physes, minimal scarring with lower complications. The purpose of this study was to present this study results following fixation of femoral shaft fractures with titanium elastic nails between the age 5-16 years of age.
Methods: A total 52 patients in the age group of 5-16 years with femoral shaft fractures were stabilized using flexible nailing. Clinical and radiological follow-up was for a minimum period of 24 months. The final results were analysed using Flynn's criteria.
Results: Mean age at surgery was 7.4 years (range 5.6-14.3 years). The average duration of surgery was 65.3 (45-95) minutes and the mean duration of hospital stay was 8 (5-14) days. Skin irritation due to nail ends was the most common complication followed by significant lengthening (n=6), infection (n=2), significant shortening (n=2), varus angulation (n=2) and delayed union (n=2). The final outcome was excellent in 65.4% cases, satisfactory in 30.8% cases and three patients had poor outcomes as per Flynn's scoring criteria.
Conclusions: In this study, ESIN showed good clinical and radiographic results in the age group 5 to 16 years, with minimal complications and high parent satisfaction consistent with previous studies but lesser number of mid adolescent age groups in the present study is a limitation.

Keywords: Elastic nailing, Flexible nail, Fracture femur, Paediatric

INTRODUCTION

Femoral fractures are among common injuries in the pediatric age group treated by an orthopaedic surgeon. These fractures typically occur either in early childhood when weak woven bone is changing to the stronger lamellar bone or during adolescence when children are subject to high-energy trauma from motor vehicle accidents or from sports.[1] Femoral shaft fractures represent approximately 1.6% of all bony injuries in children.[2,3] In the last two decades there was an increased interest in the operative treatment of pediatric fractures, although debate persisted over its indications.[4]

Historical treatment is with plaster of paris cast.[5] There is little disagreement concerning the treatment of long bone fractures in children less than 5 years (plaster of paris cast) and adolescents older than 16 years (locked intramedullary nailing).[4,5] But regarding the optimal treatment between age 5 to 16 years controversy persists, with several

available options: traction followed by hip spica and intramedullary nailing, external fixation, flexible stable intramedullary nails and plate fixation.[6,7] Whatever the method of treatment, the goals should be to stabilize the fracture, to maintain length and alignment, to promote bone healing, and to minimize the morbidity and complications for the child and his/her family.[6]

Treatment of pediatric fractures dramatically changed in 1982, when Metaizeau and the team from Nancy, France, developed the technique of elastic stable intramedullary nailing (ESIN) using titanium nails.[7] The flexibility of the titanium elastic nails (TENs) allows it to be inserted at a point which avoids disruption of the growth plate.[8] The aim of this biological, minimally invasive fracture treatment is to achieve a level of reduction and stabilization that is appropriate to the age of the child. The biomechanical principle of the titanium elastic nail (TEN) is based on "3 point principle" (the symmetrical bracing action of two elastic nails inserted into the metaphysis, each of which bears against the inner bone at three points).[7-9] The ESIN has the benefits of early immediate stability to the involved bone segment, which permits early mobilization and return to the normal activities of the patients, respect for the physes, minimal scarring with very low complication rate.[9,10] Added to this repeated micromotion at fracture site enables early union.

The purpose of this study was to present this study results following fixation of femoral shaft fractures with titanium elastic nails between the age 5- 16 years of age.

METHODS

This was a longitudinal study and authors prospectively selected closed fractures along with Gustilo Anderson type 1 and 2 compound fracture shafts of femur with minimal commination (type 1 according to Winquist classification) between ages 5 to 16 years for the study.

Inclusion criteria

All patients who had at least 12 months minimum follow-up was included in this study.

Exclusion criteria

Patients below 5 or above 16 years of age, pathological fractures, type 2-4 comminuted fractures (Winquist classification) and fractures involving femoral condyles or cervicotrochanteric area were excluded from this study.

Table 1: Anthony et al scale for grading callus formation.[6]

Grade	Grading callus formation
Grade 0	No identifiable fracture healing
Grade 1	Primary bone healing with little or no periosteal new bone formation
Grade 2	Periosteal new bone formation on two sides of the femur
Grade 3	Periosteal new bone formation on three or four sides of the femur

Ethical approval for the research study was obtained from the Institutional ethics committee. A total of 52 patients between age five to sixteen years of age were surgically treated for diaphyseal femoral fractures in department of orthopedics, Government Medical College, Thiruvananthapuram between the study period 2014 and 2017. All patients were followed until healing at intervals 3, 6, 12 and 24 months. Average follow-up of 13.7 months (range 12-24 months). At each visit limb alignment and rotation, range of motion of hip and the knee, wound and skin condition were recorded. Tenderness at fracture site and lower extremity lengths were determined by clinical examination. Progression of union at fracture site was assessed radiologically by using Antony et al scale (Table 1) for grading callus formation.

Table 2: Flynn's outcome score (Flynn et al).[7]

Results at 24 weeks	Excellent	Satisfactory	Poor
Limb-length inequality	<1.0 cm	<2.0 cm	>2.0 cm
Malalignment	5 degrees	10 degrees	>10 degrees
Unresolved pain	Absent	Absent	Present
Other complications	None	Minor and resolved	Major and lasting morbidity

Final follow-up assessed for coronal or sagittal mal-alignment, limb length discrepancy and any obvious implant related complications. None patients were lost to follow-up. The complications were divided into minor and major complications. Minor being complications that resolved without additional surgery and not resulting in long term morbidity. Major complications where those in which further operation required and long-term morbidity ensued. Results were classified as excellent, satisfactory, or poor based on the outcome scoring system for femoral TENs described by Flynn et al (Table 2). The Flynn scoring system is based on the presence of leg length inequality, malalignment, pain, and minor and major complications.

Surgical technique

Authors followed the surgical technique similar to that described by previous studies in the literature. Pre-operative preparation of patients included overnight fasting, preparation of extremity including the genitalia

with preoperative systemic antibiotic (just before induction of patients).

Nail selection

Titanium elastic nails are available in 5 diameters: 2 mm, 2.5 mm, 3.0 mm, 3.5 mm and 4.0 mm. Nails are 440 mm long. Nail diameter is calculated using the formula, 0.4×internal minimum diameter of bone. The nails are colour coded for easy identification (Figure 1). Authors always select two nails of the same diameter so the opposing bending forces are equal.

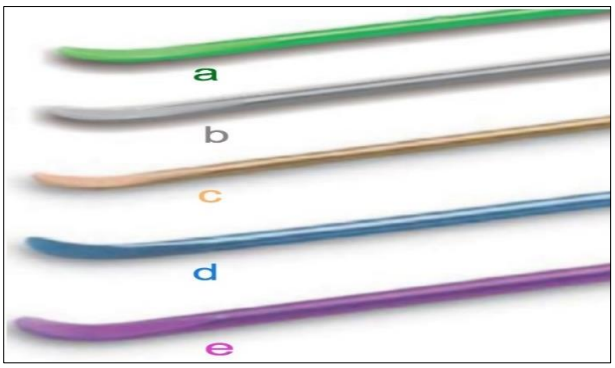

Figure 1: Color coding of nail sizes (a) 2.0 mm (b) 2.5 mm (c) 3.0 mm (d)3.5 mm and (e) 4.0 mm.

General/spinal anesthesia was administered, and the patient was positioned supine on radiolucent table. In case of older children, the limb may be placed on a fracture table with traction boot. The image intensifier is positioned on the lateral side of the affected femur for anteroposterior and lateral view of the thigh from hip to knee allowing the surgeon to access both medial and lateral aspects of the distal femur. Reduce the fracture and confirm alignment with 'c' arm both AP and lateral views. Painting and draping the leg from hip to knee was done only after attempting reduction.

Nails are contoured according to the type and location of the fracture. Both nails are contoured into a bow shape with nail tip pointing towards the concave side. The apex of the bend should be at fracture site. Both concavities face each other and nails intersect proximal and distal to the fracture site.

The entry point is medial and lateral at the top of the flare of the femoral condyles, so that after insertion, they will tend to bind against the flare of the condyle. Too low nail entry can damage physes also have high chance of loosening and backing out. The skin incision is often made in the metaphyseal region, close to the growth plate. It is advisable to make a 15-30 mm incision right away which allows retraction of superficial veins and sensory nerves, muscle dissection in line with their fibers. If necessary, periosteum and partially elevated. Usually two retractors and drill sleeves provide adequate visualization and protection of tissues. The next largest drill bit relative to diameter of nail is selected. To penetrate the cortex perpendicular drilling is done, followed by a curved bone awl to enlarge the hole in 45° angulations.

Both the nails are attached to the T-handle (or the inserter) and inserted into the bone through the entry hole, with its curved tip properly oriented. Image intensifier can be used to align the nail tip so the convex side will glance off from the far cortex. Sufficient reduction of the fragment is achieved when half of medullary canal overlap. F tool can be used to assist in reduction. The nail is advanced 2cm into proximal fragment and then rotated. Motion of the proximal fragment demonstrates that the nail is in the proximal fragment. At this point it is advanced further. By rotating this nail further reduction of fracture can be accomplished, and then second nail in inserted. Distal positioning of the first rod is done only after second rod crosses the fracture site. If the first rod is advanced too far, it will shift the fragments and make passing of the second rod difficult.

After confirming the orientation of both nails finally impacted into the cancellous bone of the upper metaphysis, maintaining reduction were done (Figure 1). If there is difficulty in reduction, altering the position of the nail can assist in achieving reduction. Varus or valgus angulation can be corrected by rotation of the nail 180° such that concavity faces the same direction of deformity. Trailing ends are bent to about 45° prior to trimming and recessed into the medullary canal using the appropriate impactor, leaving sufficient length (1 to 2 cm outside the cortex) proud of the bone surface to facilitate later removal. In some cases, the trailing ends are not bent; they are simply allowed to lie against the cortical wall after trimming. The wound is closed in layers.

Post-operatively, patients were advised active quadriceps strengthening exercises as early as possible depending on the stability of fixation. Active hip, knee/knee and ankle mobilization with non-weight bearing crutch walking started after 2 weeks. Full weight bearing was started by 8-12 weeks depending on the fracture configuration and callus response. Nail removal is usually done after 6 to 12 months.

Statistical analysis

The data is entered in Microsoft excel and analyzed using SPSS (statistical package for social sciences) software released by IBM Corp. Released 2012. The quantitative variables are expressed as mean and standard deviation and the qualitative variables are expressed as proportions. Parametric (Student's t-test) and nonparametric (Mann-Whitney U test) statistical tests were used to compare the final results.

RESULTS

A total of 52 consecutive patients were treated with ESIN for femoral fractures between the age group 5 to 16 years

of which forty patients were male and remaining twelve were females. The mean age at surgery was 7.4 years (range 5.6-14.3 years). In the present study 44 (84.6%) patients had closed fracture of femur and the most common fracture pattern was transverse accounting for 42.3% (n=22) cases (Table 3-7). Out of the total 52, difficulty in closed reduction was incurred in only 6 cases where open reduction was done. The average duration of surgery in this study was 65.3 (45-95) minutes and the mean duration of hospital stay was 8 (5-14) days.

Table 3: Age distribution of patients studied.

Age in years	Number of patients	%
5-8	30	57.7
9-12	18	34.6
13-16	4	7.7

Table 4: Gender distribution of patients studied.

Gender	Number of patients	%
Male	40	76.7
Female	12	23.1
Total	**52**	100.0

Table 5: Injury pattern.

Injury pattern	Number of patients	%
Closed	44	84.6
Compound	8	15.4
Total	52	100.0

Table 6: Type of reduction.

Type of reduction	Frequency	%
Closed	46	88.5
Open	6	11.5
Total	52	100.0

Figure 2: Case No 7 Radiological and Functional Outcome a) Pre-operative Radiograph b) Immediate Post-operative Radiograph c) Radiograph at 6 months d) & e) Functional Outcome at 1 year.

Skin irritation due to nail ends was the most common complication and was encountered in 16 out of the 52 patients. Other complications were significant lengthening (n=6), infection (n=2), significant shortening (n=2), varus angulation (n=2) and delayed union (n=2) (Table 8).

Table 7: Outcome.

Outcome	Number of patients	%
Excellent	34	65.4
Satisfactory	16	30.8
Poor	2	3.8

Table 8: List of complications.

Complications	No. of patients	%
Infection		
Superficial in entry site	2	3.8
Delayed union	2	3.8
Limb lengthening		
<1 cm	2	3.8
1-2 cm	6	11.5
>2 cm	0	0
Limb shortening		
<1 cm	0	0
1-2 cm	1	1.9
> 2 cm	2	3.8
Entry site irritation	16	30.4
Malalignment		
Varus angulation	2 (13^0, 8^0)	3.8

Figure 3: Case No 17 Radiological and Functional Outcome a) Pre-operative Radiograph b) Immediate Post-operative Radiograph c) Radiograph at 6 months d) e) & f) Functional Outcome at 1 year.

All patients achieved full range of hip and ankle motion at 3 months follow-up with 14 (26.9%) patients having mild restriction in knee flexion which was regained at 6 months follow-up. The final outcome was excellent in 34 (65.4%)

cases, satisfactory in 16 (30.8%) cases and three patients (5.8%) had poor outcomes as per Flynn's scoring criteria (Figure 2, Figure 3). Nail removal was done between 6 to 12 months in all patients except for two patients who had delayed union.

DISCUSSION

Femoral fractures account for approximately 2% of all pediatric fractures and the choice of treatment varies with age.[11] One of the time-tested treatment modality is conservative treatment with traction, hip spica etc. Conservative treatment is associated with limitations like prolonged skin traction, long hospitalization, significant discomfort, poor hygienic care, and delayed weight-bearing.[12,13] During the last few decades, more surgeons are opting for surgical fixation of pediatric femur fractures using either plate, intramedullary nailing, ender nail or titanium nailing. Surgical fixation has advantages like early immobilization, faster return to school and better nursing care.[13,14] An ideal implant for the pediatric femur fracture should be a load sharing intramedullary device with simple construct, which allows free movement of knee and hip while maintaining the normal alignment and length of the extremity without interfering vascularity and normal anatomy until the union is achieved.[15] ESIN provides all these features and has gained popularity especially in the treatment of pediatric femoral fractures. Previous studies in the literature also documented that ESIN provides both stability and elastic mobility.[9,13]

Currently controversy exists regarding the ideal treatment for femur fractures between age 5 to 16 years.[14,16] In the present study, authors used ESIN for intramedullary fixation of femoral fractures between this age group. Flynn et al reported better results in terms of periods of hospitalization, standing, and return to school in intramedullary TENS group compared to those treated with traction.[16] In this study even though there was no comparison group, authors noticed early mobilization as well as return to school.

In this study, in majority of the patients 46 (88.5%) authors could achieve closed reduction and nailing was achieved. In the remaining 6 (11.5%) patients where open reduction was required, the reasons were soft tissue interposition, muscle stiffness and comminution. Regarding the duration of surgery, the average duration of surgery in this study was 65.3 minutes ranging 60 to 90 mins. Similar studies in literature the surgery duration ranged from 50-120 minutes.[17] The average length of hospital stay was 8 days in this study. Authors noticed that the prolonged hospital stay is related to multiple injuries or presence of other associated injuries. In this study 2 cases have associated head injury. In a similar study by Singh et al the mean hospital stay was 10 days.[17] Shemshaki et al reported a short length of stay in the TEN group averaging 20.5±5.8 days while a similar study by Flynn et al reported a mean of 5 days of hospitalization in the TEN group.[15,18]

Authors used plaster slab for providing support irrespective of fixation stability till suture removal which ranges from two to three weeks. Ozdemir et al reported that they used bracing either pelvic and thigh postoperatively after flexible nailing in order to provide earlier motion and weight bearing.[19] However, authors did not use braces in any of this study patients and mobilization was initiated immediately post removal of plaster support. Authors believe two weeks paster support will make the fracture sticky irrespective of initial fixation stability and micromotions produced on initiation of physiotherapy will provide for early fracture union. Union was achieved in 88.5% cases at 3 months follow-up (Figure 2, Figure 3). This is consistent with previous studies in the literature where time for union ranges from 8 weeks to 12 weeks in uncomplicated cases.[18,20] Previous studies of TENs in the femur have shown increased rates of malunion in patients ≥49 kg.[21,22] Authors had two cases of delayed union which was mainly attributed to overweight interfering with fracture site stability. In these two cases union was achieved between 6 to 9 months.

Complications associated with ESIN nailing are mainly caused by technical errors like using thinner nails, implant malorientation and inadequate trimming of exposed nails. In the present study skin irritation at nail insertion site was most common complication (n=16) followed by significant lengthening (n=6), infection (n=2), significant shortening (n=2), varus angulation (n=2) and delayed union (n=2). Significant LLDs (>2 cm shortening or >1 cm lengthening) was noted in 15.2% of the cases. Sela et al reported LLDs in 10.5% of their cases while Flynn et al in their study noted significant LLDs in only 4%.23,15 Other studies in the literature also demonstrated similar complications profile associated with ESIN. Outward bending of the nail to facilitate retrieval was recommended in previous studies, but this can cause anything from irritation to skin necrosis and infection and therefore should be avoided. Review of these cases showed in six cases left over nail ends were too long and bent excessively; and in four cases nail entry sites were higher. Insertion points which are too diaphyseal can also lead to muscle irritation. Keeping nail flush with bone can minimize skin related complications associated with ESIN. None of the patients developed deeper infection.

In this study, treatment with ESIN showed good clinical and radiographic results in the age group 5 to 16 years, with minimal complications and high parent satisfaction even though a second operation is needed to remove the implant. The final outcome was excellent in 34 (65.4%) cases, satisfactory in 16 (30.8%) cases and two patients had poor outcome. The final results reported by previous studies were consistent with this study results.[15,17,20] Nails were removed under anesthesia after 6 months - 8 months of the fracture fixation even though early removal is theoretically possible, because of the chances of refracture with early removals authors preferred delayed removal.

Limitation of the present study is that not enough patients of higher age group were there to describe a consensus regarding treatment with elastic nailing as first choice. Authors also did not follow any weight limit criteria to exclude the patients. Also, long term follow-up was not available to know about further limb length discrepancies.

CONCLUSION

In this study, ESIN showed good clinical and radiographic results in the age group 5 to 16 years, with minimal complications and high parent satisfaction consistent with previous studies but lesser number of mid adolescent age groups in present study is a limitation. Additional studies with higher sample sizes evaluating the clinical outcomes of patients in mid-adolescent age groups are needed.

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