Original Article

In paediatric femoral shaft fractures implementation of elastic stable intramedullary nail (ESIN) - A retrospective study

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Abstract

Background: Among all pediatric bony injuries 1.6% is accounted by highly incapacitating femoral shaft fractures. Management of these fractures is largely directed by age, fracture pattern, associated injuries, built of the child and socioeconomic status of the family. We retrospectively, evaluated the implementation of elastic stable intramedullary nail (ESIN) in surgical management of femoral shaft fractures in children and its complications. **Materials and Methods:** Sixty children were treated with titanium elastic nails (TEN) from June 2011 to August 2015 at Vinayaka Missions Medical College, Karaikal, at the end of the study there were 56 children for follow-up. Fractures were classified according to Winquest and Hansen's as Grade I (n=36), Grade II (n=14), Grade III (n=6) and compound fractures by Gustilo and Anderson's classification, Grade I (n=8), Grade II (n=4). There were 42 mid-shaft fractures, 8 proximal third shaft fractures, 6 distal third shaft fractures. The final results were clinically evaluated by using Flynn's criteria and radiologically by Anthony's criteria. **Results:** The mean duration of follow-up was 18 months (range 12 – 36 months). All fractures healed radiologically with grade III callus formation at 8 – 11 weeks (mean 9.6 weeks). The results were analysed using Flynn's criteria and were excellent in 46 children (82%) and satisfactory in 10 children (18%). The most common complication in our study to be noted was soft tissue discomfort produced by the nail ends near the knee (25%, n=14). Other complications include limb shortening (n=5), varus malunion (n=4), pin site infection (n=5) and nail migration (n=2). There was no delayed union,non-union or refractures. **Conclusion:** ESIN is a safe, minimally invasive, relatively easy to use and provides an excellent functional outcome in terms of patient satisfaction in properly selected pediatric shaft of femur fractures. **Level of Evidence:** Level III, Retrospective cohort study.
Keywords: Femur, Intra-medullary fracture fixation, bone nailing, malunited fracture.

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INTRODUCTION

Femoral shaft fractures are the most common paediatric injuries treated by orthopaedic surgeons resulting in high direct and indirect medical costs[1]. The occurrence of femoral fractures is 20 – 25 per lakhs children per year[2]. The treatment ranges from closed reduction with hip spica, Bryant's traction and surgical stabilization with devices like plate and screws, nails, Elastic Stable Intramedullary Nail (ESIN) and external fixators[1]. Each modality has its own set of merits and demerits. Most paediatric fractures are treated conservatively, as nonsurgical management has been the standard mode of treatment for most young children, because of rapid healing and spontaneous correction of angulation, the long term results were usually satisfactory[1]. The cost of care is low and the outcome is generally good. In older children, conservative treatment results in loss of reduction, malunion, psychological intolerance to both the child as well as the family and complications associated with plaster hence, in the last two decades there has been a growing tendency towards a more operative approach in children over six years of age. In

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children between 6-16 years, ideally the fracture needs an internal splint that shares load, maintains reduction and does not endanger the growth plates or blood supply of the femoral head and minimizes morbidity as well as complications[3]. Plating offers rigid fixation on the other hand, it requires a larger exposure resulting in increased blood loss, resurgery for implant removal and scarring as well as it is a load bearing device and refracture is at a risk[4]. Antegrade nailing is used in children near skeletal maturity[5]. External fixators are mainly used in open fractures[6]. ESIN was introduced for femoral fractures by Nancy group in 1979[3].Titanium implants are increasingly used for ESIN as it has an excellent biocompactibilty along with its elasiticity limits the amount, that the nail is permanently deformed during insertion and also promotes callus formation by limiting stress shielding. TEN acts as an internal splint, maintains length and alignment that allows rapid mobilization while permitting enough fracture site motion for callus formation and potentially has low risk of osteonecrosis, physeal injury and refracture[7]. Due to its promising results and less serious complications it remains the ideal treatment of choice for stabilization of paediatric femoral fractures. We analyzed retrospectively the results of paediatric femoral shaft fractures fixed with ESIN at our institute.

MATERIALS AND METHODS

As per the hospital records retrospectively, we found 60 children between the age group of 6-16 years were treated at our institution from June 2011 to August 2015 among which 56 were available for follow-up. Data collected included details of the patient (age, gender),description of the fracture(type, location, pattern),surgery(open/closed),presence of fracture angulation or rotational malalignment, details of fracture union and rehabilitation milestones (non-weight bearing, partial and full weight bearing, return to school) along with presence of any complications. There were 36 boys and 20 girls in our study with an average age of 9.2years (range 6 – 16) at the time of injury. The most common mechanism of injury was road traffic accident (n=39,70%)followed by fall from height (n=17,30%). 42 fractures were in the middle third followed by, eight proximal one-third and six distal-third fractures in which 34 right sided fractures (60%) and 22 left sided fractures (40%) were noted. Fracture patterns included transverse (n=28), oblique (n=16),spiral(n=7) and comminuted (n=5).Fractures were classified according to Winquest and Hansen's classification as Grade I(n=36),Grade II (n=14) and Grade III(n=6). Associated injuries were present in 11 patients, five had minor head injury and six had associated upper limb fractures, three had fracture both bone forearm right side, two had type I epiphyseal injury distal radius right side and last one had type I monteggia fracture left side. We had eight grade I open fractures and four grade II open fracture. All cases after complete pre-op evaluation were taken up for surgery within 10 days (mean 3.6 days). We had inclusion and exclusion criteria for our study.

Inclusion Criteria

Children between 6-16 years with closed fractures and grade I and II open fractures.

Exclusion Criteria

Children <6 and >16 years, grade III open fractures, non-ambulatory children, metabolic bone disease, pathological fractures, children with neuromuscular disorders, segmental and severely communited fractures grade IV.

Technique

Under regional anaesthesia after prophylactic antibiotics, the child was placed supine on fracture table with adduction of the affected limb by 10^0. Closed reduction was performed by manual traction and gentle rotation along with use of F-tool (a radiolucent device), the arms of the F-tool were re-adjusted depending upon the fracture configuration and bulk of thigh, alignment was confirmed in both planes by an image intensifier and was used to make an entry for the placement of skin incision and dividing the fascia-lata in most cases. We used antegrade entry only in cases where the fracture was in distal third or the cortex distally found communited to hold the distal nail entry site. We used 2 nails of same diameter, which was calculated by pre-operative radiograph using:

1. Flynn *et al*'s formula[8], diameter of nail=width of narrowest point of the medullary canal on AP and LATERAL view X 0.4 mm.
2. Kasser and Beaty formula[9], nail size=internal diameter/2-0.5 mm.

Nails come in five diameters from 2.5mm to 4.5mm in fixed length. The nails are color coded for identification. The drill was inclined at an angle of 10 degree, the nail tip was also bent to facilitate placement and to allow the nail to bounce of the opposite cortex at the time of insertion. Two nails were introduced upto the fracture site and both nails should pass the fracture site nearly simultaneous to prevent angulation at the fracture site. In 12 cases we did minimal open reduction. The nails were put in double 'C' construct to ensure three point fixation and for proper rotational stability nails were further advanced into the proximal fragment to diverge laterally towards the greater trochanter and medially within the femoral neck so that early mobilization was possible[7]. Care was taken to make sure the nails do not cross the growth plate proximally and distally. The nail was cut at the entry site so that 1 cm of nail remains outside of the

cortex. Too much bending was avoided to prevent impingement and bursa problems. There was cock screwing of nails in four cases (7%), we revised it intraoperatively. Post operatively Intravenous antibiotics continued for three days. Suture removal was done at tenth day. No postoperative external immobilization was used and gradual mobilization was started. The children were followed up at 1,2,3,6 month's interval until fracture union. At each visit, progression of union at fracture site was assessed radiologically, tenderness at the fracture site was determined by clinical examination along with limb alignment, rotation, length discrepancy, range of motion of hip and knee and any other complications. Full weight bearing was started when radiograph revealed soft callus at the fracture site. The children were evaluated clinically by Flynn's criteria[8] (table 1) and radiologically by Anthony's criteria[10](table 2) at the end of six months and at the end of one year.

RESULTS

The mean duration of surgery was 70 minutes (range 40-100 minutes). The mean hospital stay was 7.5 days (5 - 15 days), the hospital stay was longer in children with head injury and associated other injuries, there was no post-operative infection in our study even in open fractures. The mean age was 9.2 years and average body weight was 29.5kg (range 14 – 62). Minimum nail size used was 2.5mm while maximum nail size used was 4.5mm. Out of 56 children available for evaluation, within a mean follow-up of 18 months (range 12 – 36 months) callus was first noted on follow-up radiograph at mean of 3.4 weeks (range 3.0-6.4 weeks). All fractures in our study united with grade III callus in average of 9.6 weeks (8-11 weeks) and full weight bearing was started at the same time and was intiated to attend school as well. Functional range of movement of knee was achieved in an average of 8.2 weeks (6 – 12 weeks).Clinical evaluation revealed full range of motion of hip, knee and ankle in all patients at final follow-up. Radiological evaluation was done by Anthony's criteria. All children had grade III callus at the end of 11 weeks. Three children with head injury had large sized and very early callus formation which decreased with passage of time and the final result was excellent. There was no nonunion or delayed union in our study. Clinical evaluation was done using Flynn's criteria. The results were excellent in 46 children (82%)(Figure 5 – 7) and satisfactory in ten children (18%). No child had poor result. The most common problem encountered in our present study was skin irritation and impingement due to the distal nail ends in 14 cases (25%)(Table 3). We had asymptomatic nail migration in two cases (4%)(Figure 8,9). All these problems settled upon nail removal. Out of 56 cases, 5 cases (9%) had limb length shortening, out of which, four children had shortening of less than 5 mm which was insignificant. In one child, with comminuted fracture, who weighed 62 kg at age 14 had shortening of 15 mm. Angular mal alignment was defined as an angulation of $> 10^0$ in the coronal plane or $>15^0$ in sagittal plane[11]. In our study we had varus malunion of >5 degree in coronal plane in four children(7%)(Figure 1-4).Rotational malalignment was termed as "excessive" if it was more than 10 degree[12]. We did not have any children with rotational malalignment. Five children (9%) had pin site infection which settled with regular dressing and oral antibiotics. Nails were routinely removed at the end of one year after fracture union. In two cases we had had asymptomatic proximal migration of the nail which penetrated the proximal cortex. So we removed the nail from the other side. No complications were associated with the nail removal procedure and no refractures was observed after nail removal till date.

Table 1: Flynn's Criteria

Variables	Excellent result	Satisfactory result	Poor result
Length discrepancy	<1 cm	<2cm	>2cm
Mal-alignment	5 degrees	5 to 10 degrees	>10 degrees
Pain	No	No	Yes
Complications	None	Minor and solved	Major and/or residual morbidity

Table 2: Anthony Radiological Criteria

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.

Table 3: Complications

Intra-operative	Postoperative	Leg-length discrepancy
Difficulty/loss of reduction(12) Rods exchanged/improper size selection (2) Penetration of proximal cortex(0) Cock screw phenomenon(4) Blood loss (0)	Nonunion/delayed union(0) Re-fracture(0) Nail tip irritation(14) Malalignment(4) Asymptomatic nail migration(2) Pin site infection(5)	Shortening (5) <1 cm(4) <2 cm(1) >2cm(0) Lengthening (0)
Total-18	**Total -25**	**Total -5**


Figure 1


Figure 2


Figure 3


Figure 4


Figure 5


Figure 6


Figure 7

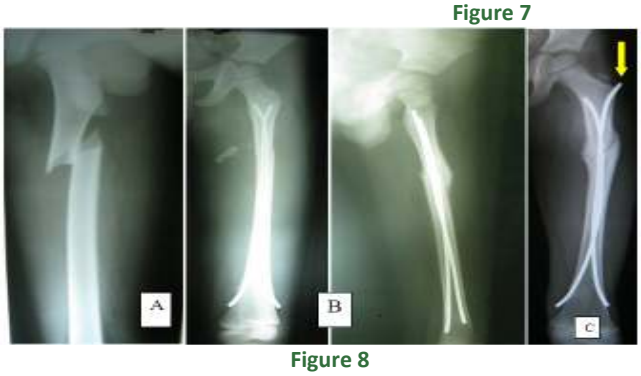

Figure 8

Figure 9

Legend

Figure 1: Right sided long oblique fracture both in AP and Lateral view; **Figure 2:** A – immediate post op, B – 1 month post op X-ray showing varus angulation; **Figure 3:** 6 months follow-up X-ray with varus mal-union of 5^0 and minimal shortening of 0.5cm; **Figure 4:** Satisfactory results achieved as per Flynn's criteria; **Figure 5:** Pre operative middle third shaft of femur fracture; **Figure 6:** A - Immediate post op X-ray, B - 3 Months Old Post -Operative X-Ray Showing Grade 3 Callus Formation; **Figure 7:** Post op clinical picture showing good results according to Flynn's criteria

Figure 8: A – Proximal third shaft of femur fracture, B – 2 months post op X-ray with grade II callus formation with minimal varus angulation, C – 3 months old post-op X-ray with grade III callus formation with a proximal migration removed through proximal entry.

Figure 9: 3 months old post-op clinical picture with good results according to flynn's criteria

DISCUSSION

The ideal choice in treatment of femoral shaft fractures is controversial. It remains a constant challenge to the orthopaedics fraternity. Conservative management results in complication such as malunion, joint stiffness and delay in functional recovery in older children and also results in prolonged hospitalization causing increased hospital bed occupancy ratio as well as financial loss to the family which lead to the emergence of operative fixation for these variety of fractures[13,14]. TEN is elastic stable intramedullry nail which works on the principle of symmetric bracing action of two nails with same modulus of elasticity which gives three point fixation, rotational, axial, transitional and bending stability by counteracting the distraction and compression forces working at the fracture site[15,16]. In the present series, all fractures were united within 11 weeks of fixation with no non-union or delayed union. Children who had transverse fracture pattern had a shorter union time. Oh *et al* observed that all 31 fractures in his series healed within 12weeks without delayed union[17]. Buechsenchuetz *et al* reported that in 42 patients treated with ESIN all fractures healed at a mean of 88 days from injury[18]. Hospitalization time has been considerably decreased with TEN. In present series it was 7.5 days on average and return to school was intiated on 9.6 weeks on average causing less disturbance in the continuation of the studies in children. The partial and complete weight bearing in the series averaged 4.2 and 9.6 weeks respectively. In children with comminuted fracture, head injury and associated other injuries affected the mobility of the patients in turn delaying the weight bearing. Oh *et al* used ender nails and observed walking without assistive devices at an average of 9.7 weeks[17]. Flynn *et al* and Mazda *et al* observed walking without assistive devices at an average of 8.5 and 9.5 weeks respectively in patients using TENs[1,19]. The indication of TEN is expanding, as their advantages are realized and complications are very less compared to other methods of fixation. Following are the main advantages noted : they are readily available in different diameters at affordable cost, as they don't disturb the fracture hematoma when done as closed procedure the chances of infection is very minimal. There is a chance of avascular necrosis of femoral head when applied in retrograde manner [20,21]. An important determinant for surgical outcome is the good knowledge of the fracture geometry and location. According to our study, TEN gave excellent results in transverse, short oblique fractures. Transverse, short oblique and minimally comminuted fractures are suitable for TEN as stated by Flynn *et al* and Narayanan *et al*[1,22]. The chance of entry site irritation was the most common problem (25%) encountered in our study as compared to other studies. Ligier *et al* observed 13 cases of skin ulceration or local inflammatory reaction due to nail protrusion out of 123 cases[23]. In our series, it could have been avoided with proper selection of insertion site and proper advancement of the nail to lie against the supracondylar flare. We had two cases of nail migration in the present series that probably was caused due to the poor technique. Two cases of proximal migration were observed by Karaoglu *et al* in the series of 31 femoral fractures stabilized with ender nails[24]. As we used two nails of same thickness after proper pre-bending we had varus angulation in only four cases which would have been avoided with adequate bracing. This enlightens us that a cautious approach is always required in treating unstable fracture patterns and fractures in obese children[25,26,27]. So this mal-alignment can be overcome by additional plaster stabilization or by traction or a brief period of bed rest or use of femoral brace. Limb length discrepancy was seen in five cases in which three had angulation at the fracture site[28,29,30,31]. Few more years of follow up will be required to determine the precise difference in limb length of these patients. In our study, there was superficial pin infection in five cases which would have been accounted due to the poor hygienic activities. We had per-operative technical difficulties in 12 cases where we had to open the fracture site due to failure of closed reduction due to soft tissue interposition. This might be due to improper traction or splintage or due to delayed surgery by associated injuries. In four cases we had cork screw phenomenon which was deducted by image intensifier and replaced in correct manner. We evaluated our clinical results using Flynn's criteria in our study. We had excellent results in 46 children (82%) and satisfactory results in 10 children (18%) and nil poor results. Our results were comparable to other studies which were done in similar manner viz, Flynn *et al*,

Narayanan *et al*[1,22]. In our study nails were removed at end of one year as an outpatient procedure under anesthesia, without any complication during or after the procedure. Our study had certain limitations as it was single centered, so the results should be generalized with caution. We didn't compare other modalities of fixation with TEN. Long term results of the treatment were not analyzed.

CONCLUSION

ESIN is minimally invasive, safe, physeal protective, relatively easy to use and an effective treatment for fracture femur in properly selected children with minimal complications. Most of the complications are in fact due to improper technique which can be eliminated by strictly adhering to the basic principles and technical aspects. We recommend TEN for pediatric femoral shaft fractures in children. Conflict of interest: The authors declare that there was no conflict of interests in conducting this study

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