Titanium elastic nailing for paediatric femoral shaft fractures: a prospective descriptive study

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ABSTRACT

Background: Femoral shaft fracture is the most common major paediatric orthopaedic fractures. For generations traction and casting was the standard treatment for all femoral shaft fractures in children. Over the past two decades the advantages of fixation and rapid mobilisation have been increasingly recognised. Aim: To assess the functional and clinical outcome after closed reduction and internal fixation with titanium elastic nail in diaphyseal femoral fractures between 5 to 16 years.

Methods: The study was conducted in the Department of Orthopaedic Surgery, Regional Institute of Medical Sciences (RIMS), Imphal, Manipur, from September 2013 to April 2015. Thirty children (20 boys and 10 girls) in the age group of 5 to 16 years with recent femoral diaphyseal fractures were stabilised by titanium elastic nails [TENS]. Results were evaluated according to Flynn’s scoring criteria.

Results: After 25 months of follow up all thirty patients were available for evaluation. Radiological union were achieved in a mean time of 11.5 weeks. Mean duration of hospital stay was 15.23 days. According to Flynn’s criteria of TENS outcome score results were excellent in 66.7% patients, Satisfactory in 30% patients, Poor in 3.3% patient. All patients had early return to school. Per operative technical problems included failure of closed reduction in 2 cases.

Conclusions: Titanium elastic nailing is an effective treatment in diaphyseal fractures of femur in properly selected patients.

Keywords: TENS, Femoral fracture, Intramedullary nailing, ESIN

INTRODUCTION

Femoral fractures are among common injuries in the paediatric 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

Most of the femoral fractures in children less than 5 years are treated by conservative methods and children more than 16 years with intramedullary nailing. As far as the children with femoral shaft fractures in the age group of 6 to 16 years concerned there is controversy which is unsolved since several decades with several available treatment options: traction followed by hip spica, intramedullary nailing, external fixation, flexible stable intramedullary nails and plate fixation. Whatever the method of treatment, the goals should be to stabilise the fracture, to maintain length and alignment, to promote
bone healing, and to minimise the morbidity and complications for the child and his/her family.³

Metaizeau and the team from Nancy, France, developed the technique of elastic stable intramedullary nailing (ESIN) using titanium nails in 1982. Titanium elastic nails are minimally invasive, minimally traumatizing, stable under movement and partial loadbearing, biological and child friendly osteosynthesis.⁴

Titanium nails are inserted above the level of physis thereby avoiding damage to the physis avoiding growth disruption. The biomechanical principal of the titanium elastic nail (TEN) is based on the symmetrical bracing action of two elastic nails inserted into the metaphysis, each of which bears against the inner bone at three points.⁵⁶ early immediate stability to the involved bone segment, early mobilization and return to the normal activities of the patients, with very low complication rate are the salient features of TENS.⁷⁸

Aim

Aim of the study was to assess the functional and clinical outcome after closed reduction and internal fixation with titanium elastic nail in diaphyseal femoral fractures between 5 to 16 years.

METHODS

This was a prospective descriptive study conducted in the Department of Orthopaedic Surgery, Regional Institute of Medical Sciences (RIMS), Imphal, Manipur. Study was done in all children between 5-16 years of age irrespective of sex with diaphyseal fractures of femur meeting the inclusion and the exclusion criteria. Only those children’s were included who were between 5 – 16 years of age, had closed fracture of diaphysis of the femur and Patients where follow up of 6 months is possible. Metaphyseal fractures, open fractures, pathological fractures, fractures with head injury were excluded from the study.

Ethical approval was taken from Institution Ethical Committee, RIMS Imphal, Manipur. Informed consent was taken from all participants. Patients coming RIMS casualty with fracture shaft of femur after initial vitals stabilization fracture was immobilized with skin traction and thomas splint, plain radiographs of AP and lateral views of thigh including hip and knee joints was taken to assess the extent of fracture comminution, geometry and the dimensions of the fracture. Nail size was calculated by measuring the diameter of isthmus and it’s calculated by Flynn et al’s formula.⁹

Diameter of nail= width of the narrowest point of the medullary canal on Antero-posterior and lateral view X 0.4mm (Figure 1).

Figure 1: Measuring the size of the nail such that both the nails occupy 80 percent of the medullary cavity (as calculated by Flynn’s formula).

Figure 2: Instruments required.

Instruments required (Figure 2):
1. Inserter-synthes (product number:359.219) with hammer guide- synthes (product number:359.218)
2. Lock pliers-synthes (product number:359.204)
3. Bevelled tamp-synthes (product number:359.206)
4. Titanium elastic nails
5. Bone awl-synthes (product number:359.213)

Figure 3: Completely draped after painting.
After admission to ward all routine investigations were done and patients were operated as early as possible once the patient became fit for surgery. Preoperative sliding skin traction applied to fractures more than one week to avoid intraoperative difficulty in reduction. Operation was carried out in general/spinal anaesthesia. A systemic antibiotic, usually a 3rd generation cephalosporin was administered just before induction of patients by anaesthetists. After placing the patient supine on a radiolucent table, thigh is painted and draped (Figure 3). Traction table was used in older children. Preliminary reduction was done and checked under IITV. Femoral reduction instrument (F tool) was used in older children or in an old fracture. Physis of the femur was identified by fluoroscopy and the location was marked on the skin. A 2 to 2.5 cm longitudinal skin incision was made over the medial and lateral surface of the distal femur, starting 2 cm proximal to the distal femoral epiphyseal plate. Using a bone awl small hole is made which is entered at an acute angle into medullary cavity (Figure 4). Then propersize nail is selected which is pre bent 3 times of the required curvature with maximum convexity at the fracture site. Nail was loaded on the T handle and advanced through the entry point by twisting movements until it reaches the fracture site (Figure 5). Then second nail introduced from the other side and passed through the fracture site simultaneously. Proximal extent of the nail is confirmed by IITV (Figure 6). The tips of the nail that entered the lateral femoral cortex were made to come to rest just distal to the trochanteric epiphysis. The opposite nail was also made to lie at the same level towards the calcar region; too short nails were avoided. Distally nails were cut so that 1cm of nail remains outside the cortex. In all cases same sized nail was used and maximum possible diameter of the nail was used.

Results

| Variables 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 |

Excellent: When there was anatomical or near anatomical alignment, no leg length discrepancy with no preoperative problems.

Satisfactory: When there was acceptable alignment and leg length with resolution of preoperative problems.

Poor: In the presence of unacceptable alignment or leg length with unresolved preoperative problems.

RESULTS

The study was done in the Department of Orthopaedics, Regional Institute of Medical Sciences, Imphal, during the period from September 2013 to August 2015. A total of 30 patients were randomly selected. No patients were lost to follow-up. In the present study 15 (50%) of the patients were 5-8 years, 13 (43.3%)were 9 to 12 years and 2(6.7%) were 13 to 16 years age group with the average age being 9 years. There were 10 (33.3%) girls and 20 (66.7%) boys in the present study. In the present study RTA was the most common mode of injury (40%).
Self-fall accounted for 36.7% and fall from height for 23.3%. In 60% of the patients right side was affected. In our study, transverse fractures accounted for 16 (53.3%) cases, comminuted fractures- 2 (6.7%), oblique fractures – 9 (30%), spiral fractures – 3 (10%) and there were no segmental fractures. Fractures involving the middle 1/3rd accounted for 18 (60%) cases, proximal 1/3rd – 7 (23.3%) and distal 1/3rd – 5 (16.7%) of cases in our study. In the present series, 4 (13.3%) patients underwent surgery within 2 days after trauma, 9 (30%) in 3 – 4 days and 17 (56.7%) after 5 days. Duration of surgery was < 30 mins in 1(3.3%) case, 30- 60 mins in 10 (33.3%) cases, 61-90 mins in another 14 (46.7%) cases and 91-120 mins in 5 (20%) of the cases (Table 2).

Table 2: The demographic and clinical characteristics of subjects (n=30).

| Clinical variables                  | Total number of patients (n=30) |
|------------------------------------|---------------------------------|
| **Age in years**                   |                                 |
| 5-8                                | 15 (50%)                        |
| 9-12                               | 13 (43.3%)                      |
| 13-16                              | 2 (6.7%)                        |
| **Gender**                         |                                 |
| Male                               | 20 (66.7%)                      |
| Female                             | 10 (33.3%)                      |
| **Mode of Injury**                 |                                 |
| RTA                                | 12 (40%)                        |
| Fall                               | 11 (36.7%)                      |
| Fall from height                   | 7 (23.3%)                       |
| **Pattern of fracture**            |                                 |
| • Transverse                       | 16 (53.3%)                      |
| • Oblique                          | 9 (30%)                         |
| • Spiral                           | 3 (10%)                         |
| • Segmental                        | 0 (0%)                          |
| • Commnitted                       | 2 (6.7%)                        |
| **Time interval between trauma & surgery** |               |
| • < 2 days                         | 4 (13.3%)                       |
| • 3-4 days                         | 9 (30%)                         |
| • 5-7 days                         | 17 (56.7%)                      |

In our study union was achieved in <3 months in 23 (76.7%) of the patients and 3 – 4.5 months in 6 (20%). Average time to union was 11.5 weeks. Unsupported full weight bearing walking was started in <12 weeks for 24 (80%) of the patients, between 12 and 18 weeks in 5 (16.7%) and at 20 weeks in 1 (3.3%) patient. The average time of full weight bearing was 11.5 weeks. One patient had major complication required second operation and 10 patients had minor complication (Table 3).

Results were excellent in 66.7% patients, Satisfactory in 30% patients, Poor in 3.3% patient (Figure 6).

Table 3: The clinical outcome: post-operative minor complications (n=30).

| Complications                                                                 | No. of cases (percentage) |
|-------------------------------------------------------------------------------|---------------------------|
| **Pain**                                                                      | 6 (20%)                   |
| **Infection**                                                                 |                           |
| • Superficial                                                                  | 0 (0%)                    |
| • deep                                                                        |                           |
| **Inflammatory reaction**                                                     | 0 (0%)                    |
| **Delayed union and non-union**                                               | 0 (0%)                    |
| **Limb lengthening**                                                          |                           |
| • < 2 cm                                                                      | 1 (3.3%)                  |
| • > 2 cm                                                                      |                           |
| **Limb shortening**                                                           |                           |
| • < 2 cm                                                                      | 1 (3.3%)                  |
| • > 2 cm                                                                      |                           |
| **Sinking of the nail into the medullary cavity**                             | 1 (3.3%)                  |
| **Mal alignment**                                                             |                           |
| • Varus angulation                                                             | 1 (3.3%)                  |
| • Valgus angulation                                                            |                           |
| • Anterior angulation                                                          |                           |
| • Posterior angulation                                                         |                           |
| • Rotational malalignment                                                      |                           |
| **Loss of reduction requiring new reduction or surgery**                      | 1 (3.3%)                  |

DISCUSSION

In the present study average age being 9 years. Flynn JM et al in their study assessing 49 cases of children ranged from 6-16 years with a mean age of 10.2 years.11 Ramachandra et al studied children ranged from 9-12 years with a mean of 10.2 years.12 Saikia et al studied children from 6-16 years with a mean of 10.8 years.2 There were 10 (33.3%) girls and 20 (66.7%) boys in the present study.
The sex incidence is comparable to other studies in the literature. Moroz et al in their study there were 171 (74.7%) males and 58 (25.3%) females. Bhaskar et al in their study out of 60 patients there were 38 (63.4) boys and 22 (36.6) girls. In the present study RTA was the most common mode of injury accounting for 11 (40%) cases, self-fall accounted for 11 (36.7%) cases and fall from height accounted for 7 (23.3%) of the cases. Flynn et al in their study assessing 234 cases, 136 (58.1%) were following RTAs, 46 (19.6%) were following self-fall and remaining 43 (28.8%) were as a result of fall from height. Bandyopadhay et al in their study of 70 patients 42 patients (60%) the mechanism of injury was due to motor vehicle accident, 22 (31.42%) were due to fall from height while remaining 4 (8.58%) were due to sports injury. The average duration of surgery in our study was 69.6 minutes. In Singh et al study, the average duration of surgery was 63 minutes. In a study by Saikia et al the duration of surgery ranged from 50 – 120 minutes with a median of 70 minutes.

The duration of stay in the hospital ≤ 7 days for 1 (3.3%) patients, 8-10 days for 6 (20%), 11-15 days for 11 (36.7%) and 12 (40%) patients stayed for more than 15 days. One patient was operated 1 month after injury (admission) that stayed for 60 days because she required a reoperation due to implant failure. The average duration of hospital stay in the present study is 15.23 days. Average hospitalization time was 12.5 days in the study conducted by Singh et al. The mean hospital stay was 10 days in Singh et al study. Gross et al conducted a study on cast brace management of the femoral shaft fractures in children and young adults. The average length of hospitalization in their study was 18.7 days. Compared to the above studies conducted on conservative methods and cast bracing, the average duration of hospital stay was less in our study i.e. 13.69 days. The reduced hospital stay in our series is because of proper selection of Patients, stable fixation and fewer incidences of complications.

Average time to union was 11.5 weeks. Saikia et al reported average time for union as 8.7 weeks. Bhaskar et al in their study average time to union was 12 weeks femur. In our study, closed reduction of the fracture, leading to preservation of fracture hematoma, improved biomechanical stability and minimal soft tissue dissection led to rapid union of the fracture compared to compression plate fixation. The average time of full weight bearing was 11.5 weeks. Saikia et al in their study allowed full weight bearing was at average of 8.8 weeks. Singh et al in their study allowed full weight bearing depending on the clinical and roentgenographic progress of fracture union with an average time of 8.3 weeks.

In the present study, 6 (20%) patients had developed pain at site of nail insertion during initial follow up evaluation which resolved completely in all of them by the end of 16 weeks. Flynn et al reported 38 (16.2%) cases of pain at site of nail insertion out of 234 fractures treated with titanium elastic nails. This is the most common sequel after femoral shaft fractures in children and adolescents. One (3.33%) patient had shortening (1 cm) and one
(3.33%) had lengthening (1.2 cm). No patient in our study had major limb length discrepancy (i.e. > ±2cm). Khazzam et al reported, three patients had overgrowth of more than 2 cm. Ferguson et al noted more than 2 cm shortening in 4 children after spica treatment of pediatric femoral shaft fracture. In the present study, limb length discrepancy of more than 10mm was present in 2 (10%) cases. Comparing to limb length discrepancy in conservative methods, limb length discrepancy in our study was within the acceptable limits. One (3.33%) patient presented with varus (4°) angulation. Flynn et al reported 10 (4.3%) cases of minor angulation out of 234 fractures treated with titanium elastic nails. Singh et al reported angulation in both anteroposterior and varus/valgus planes was seen in two cases and one case, in which two different diameter nails had to be used, had posterior bowing of 10° and 10° of varus tilt. Herndon et al compared the results of femoral shaft fractures by spica casting and intramedullary nailing in adolescents. They noticed varus angulation ranging from 7 to 25° in 4 patients treated with spica casting and no varus angulation in surgical group. A difference of more than 10° has been the criterion of significant deformity. No patient in our study had significant rotational deformity.

In the present study, the final outcome was excellent in 20 (66.7%) cases, satisfactory in 9 (30%) cases and there was one patient who had poor outcome (Table 5). Flynn et al treated 234 femoral shaft fractures and the outcome was excellent in 150 (65%) cases, satisfactory in 57 (25%) cases and poor in 23 (10%) of the cases. Singh et al treated 112 patients of femoral fractures, 86 had excellent results, 24 had satisfactory results, and 2 had poor results. Saikia et al in their study of 22 children with femoral diaphyseal fractures reported 13 (59%) excellent, 6 (27.2%) satisfactory and 3 (13.6%) poor results. Singh et al treated 35 fractures and outcome was excellent in 25 (71.4%), satisfactory in 8 (22.8) and poor in 2 (5.8) patients.

**CONCLUSION**

Based on our research findings and results, we conclude that elastic stable intramedullary nailing (ESIN) technique is an ideal method for treatment of femoral diaphyseal fractures in the children in the age group of 5 to 16 years. It is a simple, easy, rapid and effective method for management of paediatric femoral fractures with reasonable time to bone healing. Use of ESINs for definitive stabilization of femoral shaft fractures in children is a reliable, minimally invasive, and physeal-protective treatment method.

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