Clinical and radiological evaluation of minimally invasive intramedullary fixation by titanium elastic nails in paediatric long bone fractures of lower limb: a prospective study

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ABSTRACT

Background: Elastic stable intramedullary nailing for the treatment of paediatric femur and tibial diaphyseal fractures was introduced by Prevot and colleagues in 1979. It follows three-point fixation principle that provides internal support in presence of cortical contact and an intact soft-tissue envelope. This technique has many advantages, including better reduction, dynamic axial stabilization, shorter hospitalization with early rehabilitation and low complication rate.

Methods: This is a prospective observational study done at Kauvery Medical Centre, Trichy between May 2017 to May 2018 consisting of 39 children between age 5 to 16 years with diaphyseal fractures of femur and tibia. The fractures were treated by closed reduction and internal fixation with titanium elastic intramedullary nailing. The patients were evaluated clinically and radiologically and followed for an average of 6 months. Outcome was assessed using transcutaneous electrical nerve stimulation (TENS) scoring system used by Flynn et al.

Results: Our series consisted of 39 patients (22 cases with fracture shaft of femur and 17 cases with fracture shaft of tibia), 33 males and only 6 females. Average time for radiological union was 9.89 weeks. All patients had full range of hip and ankle motion and 2 (5.1%) patients had mild restriction in knee flexion at 12 weeks.

Conclusions: Elastic stable intramedullary nailing is an ideal method for treatment of paediatric femoral and tibial diaphyseal fractures due to lower complication rate and good functional outcome in comparison to other methods of treatment.

Keywords: Femur diaphyseal fractures, Tibial diaphyseal fractures, Titanium

INTRODUCTION

Treatment of paediatric fractures between 5-16 years of age changed dramatically in 1982, when Metaizeau et al. France, introduced flexible stable intramedullary pinning (FSIMP) using titanium pins as treatment modality. In last two decades, operative treatment of paediatric fracture becomes popular although the debate over surgical indications persist. Femoral shaft fractures account for 1.6% of all paediatric injuries. In children up-to 5 years of age, closed reduction and spica cast application is an ideal treatment for most diaphyseal fracture.

In skeletally mature adolescents, antegrade solid intramedullary nailing is the standard treatment. There is a debate regarding best treatment for children between 5-16 years of age. Compared with younger children,
patients in this age group have high risk of shortening and malunion when treated conservatively.4

Children treated by traction with spica cast application have to face physical, social and psychological trauma of prolonged immobilization. External fixation, plating and intramedullary nailing are other surgical modalities available. There is risk of pin tract infection and refractures after external fixation and osteonecrosis after solid femur nail.5

In past few years, flexible intramedullary nailing is popularised for stabilizing femoral fractures of school going age group.5 Elastic stable intramedullary nail system (ESIN) is simple, effective and minimally invasive technique which gives stable fixation with early return of normal functions.6,7 This study was intended to assess the results following treatment of fracture shaft of femur by elastic intramedullary pinning technique.

For majority of tibial shaft fractures in children, closed reduction and casting is the gold standard of care. Occasionally, reduction cannot be achieved or maintained due to excessive shortening, angulation, or malrotation at the fracture site which makes surgical intervention necessary. Other indications for operative treatment include open fracture, poly trauma and compartment syndrome.5

Historically, external fixation and plate and screw fixation were the only treatment options available for those unstable tibial shaft fractures that required operative fixation due to their physeal sparing nature. Complications include infection, limb lengthening and refracture.9 Reamed locked intramedullary nails are effective in skeletally mature patients but poses unnecessary risk to proximal tibial growth plate.

Elastic stable intramedullary nailing of long bone fractures in skeletally immature patients is popularised because of its effectiveness and low risk of complications. Many studies documented use of this technique in femur especially its advantages of closed insertion, preservation of fracture hematoma, and a physeal-sparing entry point.10 Only few studies stated the use of flexible intramedullary nails in tibia.11

The purpose of this study was to evaluate the results following fixation of unstable femur/tibial shaft fractures with ESIN.

METHODS

This is a prospective observational case series of 39 patients between 5-16 years of age with diaphyseal fractures of femur/tibia treated by titanium elastic nails in Department of Orthopaedics at Kauvery Medical Centre, Trichy between May 2017 to May 2018. This study was conducted after getting approval from ethical committee and scientific committee of Kauvery Medical centre, Trichy.

Inclusion criteria were children and adolescent patients from 5 to 16 years, displaced diaphyseal fractures of tibia/femur, fractures with head injury, children of both gender and fitness for anaesthesia.

Exclusion criteria includes patients less than 5 years of age and more than 16 years of age, metaphyseal Fractures, patients unfit for Anaesthesia, Comminuted and segmental fractures, patients not willing for surgery, open fractures, fracture involving the distal 1/3rd of femoral shaft.

After clinical and radiological evaluation, preoperative routine investigations were done. Under regional anaesthesia, all patients underwent closed reduction and internal fixation using titanium elastic nails on fracture table with help of image-intensifier using SOP.

Implant used

Titanium elastic nails are available in five diameters 2, 2.5, 3, 3.5 and 4 mm and are 440mm in length. The nails are colour coded for easy identification. Two nails of same diameter are preferred so that opposing bending forces are equal.5

![Figure 1: Colour coding of titanium nails.](image)

1.5 mm-dark blue, 2 mm-green, 2.5 mm-pink, 3 mm-gold, 3.5 mm-blue, 4 mm-purple.

Nail diameter (calculation)

The diameter of the individual nail is selected as per Flynn et al formula.10

Diameter of nail= \{width of the narrowest point of the medullary canal on AP and lateral view\}×0.4 mm
Nail length (calculation)

The nail for femur should extend from the level of distal femoral physis to a point approximately 2 cm distal to the capital femoral physis and 1 cm distal to the greater trochanteric physis and for tibia it should extend 2 cm distal from proximal physis till 5mm proximal to the distal physis.

Postoperative protocol

X-ray was taken and the limb was kept elevated over a pillow. On postoperative 2nd and 5th day dressing changed. Patients are advised only bed rest with active knee and ankle movement exercises. Full weight bearing is started by 8-12 weeks depending on the fracture configuration and callus response.

Clinical and radiological follow-up was done at 6, 12 and 24 weeks. Complications were noted.

Excellent: When there was anatomical or near anatomical alignment, no leg length discrepancy with resolution of pre-operative problems.

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

Poor: Presence of unacceptable malalignment or leg length with unresolved preoperative problems.

Table 1: Transcutaneous electrical nerve stimulation (TENS) outcome score (Flynn et al).

<table>
<thead>
<tr>
<th>Variables at 24 weeks</th>
<th>Excellent</th>
<th>Satisfactory</th>
<th>Poor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Limb-length inequality</td>
<td>&lt;1.0 cm</td>
<td>&lt;2.0 cm</td>
<td>&gt;2.0 cm</td>
</tr>
<tr>
<td>Mal-alignment</td>
<td>5 degrees</td>
<td>10 degrees</td>
<td>&gt;10 degrees</td>
</tr>
<tr>
<td>Unresolved pain</td>
<td>Absent</td>
<td>Absent</td>
<td>Present</td>
</tr>
<tr>
<td>Other complications</td>
<td>None</td>
<td>Minor and resolved</td>
<td>Major and lasting morbidity</td>
</tr>
</tbody>
</table>

Table 2: Additional variables included in our study.

<table>
<thead>
<tr>
<th>Variables</th>
<th>Excellent</th>
<th>Satisfactory</th>
<th>Poor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Range of movements</td>
<td>Full range</td>
<td>Mild restriction</td>
<td>Moderate–severe restriction</td>
</tr>
<tr>
<td>Time for union</td>
<td>8–12 weeks</td>
<td>13–18 weeks</td>
<td>&gt;18 weeks</td>
</tr>
<tr>
<td>Unsupported weight bearing</td>
<td>8–12 weeks</td>
<td>13–18 weeks</td>
<td>&gt;18 weeks</td>
</tr>
</tbody>
</table>

RESULTS

Age distribution

In present study 21 patients (53.8%) are of 5-8 years, 9 patients (23.1%) are of 9-12 years and 9 patients (23.1%) are of 13-16 years of age.

Gender distribution

In present study, 33 patients (84.60%) are male and 6 patients (15.40%) are female.

Mode of injury

27 patients (69.2%) had road traffic accident, 10 patients (25.6%) had self-fall and 2 patients (5.1%) had fall from height.

Incidence of femoral and tibial fractures

22 patients (56.4%) had femoral fractures and 17 patients (43.6%) had tibial fractures.

Pattern of fractures

13 patients (33.3%) had oblique fractures, 12 patients (30.8%) had spiral fractures and 14 patients (35.9%) had transverse fractures.

Time interval between trauma and surgery

20 patients (51.3%) got operated in <2 days, 10 patients (25.6%) between 3-4 days, 7 patients (17.9%) between 5-7 days and only 2 patients (5.1%) after 7 days.

Duration of surgery (in minutes)

Six patients (15.4%) had <30 minutes surgical time, 21 patients (53.8%) between 30-60 minutes, 10 patients (25.6%) between 60-90 minutes and only 2 patients (5.1%) had 90-120 minutes.

Post-operative immobilization

Thirty two patients (82.1%) were immobilised for 6 weeks and 7 patients (17.9%) were immobilised for 9 weeks post-operatively.
Time for radiological union

Thirty patients (76.92%) had radiological union up to 10 weeks and 9 patients (23.07%) had more than 10 weeks.

Range of movements at 24 weeks (in degrees)

At 24 weeks post-operatively, 35 patients (89.70%) had full range of movements, 2 patients (5.10%) had mild restriction, 1 patient (2.60%) had moderate restriction and 1 patient (2.60%) had severe restriction.

Time of full weight bearing

Thirty patients (76.90%) had full weight bearing in less than 12 weeks, 7 patients (17.90%) between 12-18 weeks and 2 patients (5.10%) in more than 18 weeks.

Complication rate in present study

Complications were present in 8 patients (20.5%) whereas complications were absent in remaining 31 patients (79.5%).

Incidence of various complications

The most common complication was bursa over the nail tip in 4 patients (10.30%).

DISCUSSION

Age incidence

In the present study 21 (53.8%) of the patients were 5-8 years, 9 (23.1%) were 9 to 12 years and 9 (23.1%) were 13 to 16 years of age group with the average age being 9.05 years. Ligier et al studied children ranged from 5-16 years with a mean of 10.2 years. Sankar et al studied children ranged from 7.2-16 years with a mean age of 12.2 years.

Gender incidence

There were 6 (15.4%) females and 33 (84.6%) males in the present study. The gender incidence is comparable to other studies in literature. In the study Ligier et al. out of 118 cases, 80 (67.7%) were boys and 38 girls. In the study of El-Adl et al. Out of 66 patients, there were 48 (72.7%) male and 18 (27.3%) females.

Bone affected

We studied 22 (56.4%) femoral and 17 (43.6%) tibial fractures. El-Adl et al had 48 (65.7%) femoral and 25 (34.3%) tibial fractures.

Fracture pattern

In our study, transverse fractures accounted for 14 (35.9%) cases, oblique fracture- 13 (33.3%), spiral fractures- 12 (30.8%) and there was no segmental

Table 3: Functional outcome in terms of range of movements, radiological union and weight bearing among subjects.

<table>
<thead>
<tr>
<th></th>
<th>Excellent</th>
<th>Satisfactory</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Count</td>
<td>%</td>
<td>Count</td>
</tr>
<tr>
<td>Range of movements</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mild restriction</td>
<td>0</td>
<td>0.0</td>
<td>4</td>
</tr>
<tr>
<td>Normal range</td>
<td>27</td>
<td>77.1</td>
<td>8</td>
</tr>
<tr>
<td>Radiological union (weeks)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;6 weeks</td>
<td>17</td>
<td>73.9</td>
<td>6</td>
</tr>
<tr>
<td>&gt;6 weeks</td>
<td>10</td>
<td>62.5</td>
<td>6</td>
</tr>
<tr>
<td>Weight bearing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;12 weeks</td>
<td>21</td>
<td>70.0</td>
<td>9</td>
</tr>
<tr>
<td>12 to 18 weeks</td>
<td>6</td>
<td>85.7</td>
<td>1</td>
</tr>
<tr>
<td>&gt;18 weeks</td>
<td>0</td>
<td>0.0</td>
<td>2</td>
</tr>
</tbody>
</table>

Functional outcome

29 patients (69.20%) had excellent outcome whereas 12 patients (30.80%) had satisfactory outcome. Patients having mild restriction in range of movements, 100% had satisfactory outcome and out of those who had normal range of movements, 77.1% had excellent outcome and 22.9% had satisfactory outcome. There was significant association between range of movements and functional outcome.

Figure 4: Incidence of various complications.
fracture. In the study of Ligier et al, out of 123 femoral fractures studied 47 (38.2%) were transverse fractures, comminuted fractures- 25 (20.3%), oblique fractures- 7 (23.3%), spiral fractures- 19 (15.4%) and 4 (3.2%) were segmental fractures.5

Sankar studied 19 tibial shaft fractures out of which 9 (47.3%) were transverse, 7 (36.8%) were oblique, 2 (10.5%) were spiral and 1 (5.2%) was comminuted.12

**Time interval between trauma and surgery**

In the present series, 20 (51.3%) patients underwent surgery within 2 days after trauma, 10 (25.6%) in 3-4 days, 7 (17.9%) in 5-7 days and 2 (5.1%) patients after 7 days. Among 2 cases in which duration was more than 7 days- one was fracture of femur, operated 8 days after trauma (admission) as patient had associated head injury at the time of trauma. Another case was operated 10 days after trauma (admission) as the patient had fever for which he was treated. Patient was operated after becoming afebrile.

Average duration between trauma and surgery was 3.21 days in this study. Gamal et al operated 56.1% of cases between 3-4 days after injury, 21.2% cases between 3-4 days and 22.7% cases after 7 days.13 Saika et al operated 77.27% patients within 7 days of injury.6

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Figure 2: (A) Pre-op X-ray, (B) post-op X-ray (3 weeks), (C) postoperative 6 weeks, (D) postoperative 24 weeks, (E) complete flexion, (F) squatting, (G) extension, (H) flexion, (I) no limb length discrepancy.
Duration of surgery in minutes

In the present study, duration of surgery was <30 mins in 6 (15.4%) case, 30-60 mins in 21 (53.8%) cases, 60-90 mins in another 10 (25.6%) cases and 90-120 mins in 2 (5.1%) of the cases.

Among the 2 cases in which duration was more than 90 minutes-one was proximal third fracture which took 110 minutes and other was spiral proximal third fracture which took 100 minutes. The extended duration of surgery in these cases was due to difficulty in reduction and passage of nail across the fracture site.

The average duration of surgery in our study was 58.33 minutes. In Barlas et al study, the average duration of surgery was 70 mins. In a study by Saikia et al, the duration of surgery ranged from 50-120 mins with a mean of 70 mins.

Time for union

In our study union was achieved in up to 10 weeks in 30 patients (76.92%) and above 10 weeks in 9 patients (23.07%). Average time for union was 9.89 weeks. Oh et al reported average time for union as 10.5 weeks. Aksoy et al compared the results of compression plate fixation and flexible intramedullary nail insertion. Average time to union was 7.7 months (4 to 10 months) in the plating group and 4 months (3 to 7 months) for flexible intramedullary nailing.

In our study, closed reduction of the fracture, leading to preservation of fracture haematoma, improved bio-
mechanical stability and minimal soft tissue dissection led to rapid union of fracture compared to compression plate fixation.

**Time of full weight bearing**

In the present study, unsupported full weight bearing walking was started in <12 weeks for 30 patients (76.9%), between 12 and 18 weeks in 7 patients (17.9%) and at 20 weeks in 2 patients (5.1%). The average time of full weight bearing was 11.79 weeks.

Sankar et al in their study allowed full weight bearing between 5.7-11.6 weeks an average of 8.65 weeks.\(^\text{12}\)

<table>
<thead>
<tr>
<th>Complications</th>
<th>Present study (% incidence)</th>
<th>Previous studies (% incidence)</th>
<th>Author</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain at the site of nail insertion</td>
<td>13.3</td>
<td>16.2</td>
<td>Flynn et al(^\text{10})</td>
</tr>
<tr>
<td>Superficial infection</td>
<td>2.6</td>
<td>1.7</td>
<td>Flynn et al(^\text{10})</td>
</tr>
<tr>
<td>Range of motion</td>
<td>6.6</td>
<td>0.9</td>
<td>Flynn et al(^\text{10})</td>
</tr>
<tr>
<td>Limb length discrepancy (minor)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lengthening</td>
<td>2.6</td>
<td>5.0</td>
<td>Ozturkman et al(^\text{17})</td>
</tr>
<tr>
<td>Shortening</td>
<td>2.6</td>
<td>2.5</td>
<td>Ozturkman et al(^\text{11})</td>
</tr>
<tr>
<td>Nail back out</td>
<td>2.6</td>
<td>2.6</td>
<td>Carey et al(^\text{19})</td>
</tr>
<tr>
<td>Malalignment (minor)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Varus/valgus</td>
<td>6.7</td>
<td>4.3</td>
<td>Flynn et al(^\text{10})</td>
</tr>
<tr>
<td>Anteroposterior</td>
<td>-</td>
<td>8</td>
<td>Heinrich et al(^\text{19})</td>
</tr>
<tr>
<td>Rotational deformities</td>
<td>-</td>
<td>3.2</td>
<td>Heinrich et al(^\text{19})</td>
</tr>
<tr>
<td>Bursa at the tip of the nail</td>
<td>10.3</td>
<td>2.6</td>
<td>Carey et al(^\text{19})</td>
</tr>
</tbody>
</table>

**Other complications**

Bursa over tip of the nail was noticed in 4 cases in our study and Implant removal was done in all those 4 cases. Bar-on et al noticed proximal migration of the nail in one case.\(^\text{20}\)

**Assessment of outcome**

In the present study, the final outcome was excellent in 27 (69.2%) cases, satisfactory in 12 (30.8%) cases and there were no poor outcome cases.

El Adl et al in their study of 66 children with 48 femoral and 25 tibial shaft fractures reported 75.8% excellent, 24.2% satisfactory and no poor results.\(^\text{13}\) 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.\(^\text{10}\)

Sankar in their study of 19 tibial shaft fractures reported 12 (63.15%) excellent, 6 (31.57%) satisfactory and 1 (5.26%) poor results.\(^\text{12}\) 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.\(^\text{6}\)

**CONCLUSION**

Elastic stable intramedullary nailing is a simple, easy, rapid, reliable and effective method for management of paediatric femoral and tibial fractures between the age of 5 to 16 years, with shorter operative time, lesser blood loss, lesser radiation exposure, shorter hospital stay and reasonable time for bone healing. It is a physcal protective treatment and avoids bone damage or weakening through the elasticity of its construct. It provides a load sharing, biocompatible internal splint with minimal risk of bone infection. It can be considered for treatment of closed paediatric femoral and tibial diaphyseal fractures.

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**Ethical approval:** The study was approved by the institutional ethics committee

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