Elastic Stable Intramedullary Nailing Functional and Clinical Outcomes among Femoral Fractures in Pediatrics Aged 4-11 Years

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ABSTRACT
Background: In children, femoral shaft fractures are often treated using elastic stable intramedullary nailing (ESIN). Objective: To evaluate the functional as well as clinical outcomes of ESIN for femoral fractures in children aged 4-11 years.

Patients and Methods: At Orthopedic Surgery Department of Zagazig General Hospital 18 cases diagnosed as pediatric femoral fractures were stabilized using flexible intramedullary nailing.

Results: Skin irritation due to nail endings was the most prevalent consequence and was seen in 7 patients. Other complications were superficial infection (n=2), limb length inequity (n=2) and varus angulation (n=1). At 3 months follow-up, all patients had complete range of motion in their hips and knees; three patients (27.77%) had slight restriction in knee flexion, but this was recovered by 6 months follow-up. Excellent Flynn elastic nail scoring results were demonstrated in 72.22%, satisfactory results in 27.77% and none of the patients showed poor results.

Conclusion: Flexible Intramedullary Nailing resulted in the best possible functional and radiological outcomes for patients with femoral shaft fractures and is a safe treatment option.

Keywords: Elastic Stable Intramedullary Nailing, Outcomes, Children.

INTRODUCTION
Nearly about two percent of fractures among pediatrics are femoral shaft fractures. The femoral diaphysis is fragile during childhood and can be broken during everyday activities (childhood games); nevertheless, most adolescent femur fractures are caused by high-energy trauma, such as those sustained in car accidents (1).

Age, body mass index, accompanying lesions, fracture type, surgeon preference, patient socioeconomic status, and fracture location are just few of the variables that can impact how a femoral shaft fracture is treated in a child (2).

Pediatric femoral shaft fractures are commonly treated with ESIN or elastic stable intramedullary nailing. Nail elasticity facilitates the development of micromovements that lead to the production of an external callus at the fracture site. This therapy does not affect growth plates, allowing for early mobilization (3).

The procedure is carried out in accordance with the guidelines of minimally invasive surgery. Without opening the fracture, the hematoma can be kept in place during surgery. When performing osteosynthesis, the nails are often placed away from the fracture site, making the risk of bacterial contamination extremely low (4).

When compared to external fixation and plate fixation, it offers the advantages of being easily removed, decreasing the patient's time spent in the hospital, being cost-effective, and having a smaller emotional impact on the patient (5).

When a fracture is treated using an elastic nail, the area is not rigidly fixed. However, this has drawbacks in unstable fractures including comminuted and lengthy spiral fractures, which occur frequently in youngsters. Particularly in patients with excess body fat (>50 kg) and in children older than 11 years old, they may become shorter and more angular (6).

The purpose of this research was to examine the clinical and functional outcomes and consequences of Elastic Stable Intramedullary Nailing (ESIN) for children aged 4-11 years old who had suffered a femur fracture.

PATIENTS AND METHODS

Patients:
At Orthopedic Surgery Department of Zagazig General Hospital 18 cases diagnosed as pediatric femoral fractures were stabilized using flexible intramedullary nailing. Patients were distributed into two groups as the following:

Group (1); patients between 4-<8 years and Group (2); patients between 8-11years.

Inclusion criteria:
- Children between 4-11 years.
- Both genders were included.
- Patients with isolated femoral fractures.
- Mode of trauma include both low and high velocity injuries.

Exclusion criteria:
- Age less than 4 years or more 11 years.
- Patients with bilateral femoral fractures.
- Multiple trauma patients with other surgical injuries.
- Comminution of the bone, types 2-4 (Winquist classification).
- Injury to the cervico-trochanteric or femoral condyle area.

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This is what all of the participants in this research had to go through:
1. A thorough review of the patient's medical history and an orthopedic examination.
2. X-ray anteroposterior on affected side, pelvis and an (AP) and a cross table lateral view of the involved femur.
3. All patients had full preoperative lab investigation before surgery including:
   Complete blood picture, Random blood sugar, Viral screen, Coagulation studies (PT/PTT) as well as Kidney and liver function tests.
4. Surgical technique:
   Patients were given prophylactic antibiotics and then operated on while under spinal or general anesthesia on a fracture table. A small incision was made in the skin, and an awl was inserted medially and laterally slightly above the distal femoral physis. The fracture site was aligned by gently bending nails of a certain length so that their apexes were at the same level.
   After the fracture was reduced, two C-shaped nails were inserted into the proximal fragment and driven home. Both the greater trochanter and the femoral neck were pushed forward until the nails were at their maximum length. Everything was done while being viewed on a fluoroscope.

Guidelines for Postoperative Care and Monitoring:

   On the first postoperative day, patients were given instructions on how to train their quadriceps, and by the second day, they were able to begin aided weight bearing with a toe touch. Typically, patients were sent home on the second day following surgery. Postoperative radiographs were analysed to determine the degree of reduction, the position of the implant, and the presence or absence of sagittal, coronal, or rotational malalignment. Leg length inequality, limb rotation and alignment, knee motion, and irritation of the nail tip were measured at each follow-up. Patients were checked on at 2, 4, 6, and 8 months.
   Depending on callus formation and fracture site tenderness, patients were gradually allowed to bear weight. At the last follow-up, we looked for things like coronal or sagittal malalignment, limb length disparity, and obvious implant-related problems.
   There were two categories of complications: minor and major. An issue is considered minor if it can be treated without further medical intervention and does not result in permanent disability. Problems that required additional surgery or caused permanent disability were considered to be among the most serious. According to Flynn et al. (6) descriptions of a rating system for the outcomes of femoral ESINs, the results were rated as either outstanding, satisfactory, or poor. Leg length inequality, misalignment, discomfort, and the occurrence of minor and major problems all go into the Flynn score.

Ethical consent:

   An approval of the study was obtained from Zagazig University Academic and Ethical Committee. Every patient’s guardian signed an informed written consent for acceptance of participation in the study. This work has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans.

Statistical analysis

   In order to analyze the data acquired, Statistical Package of Social Sciences (SPSS) version 20 was used to execute it on a computer. In order to convey the findings, tables and graphs were employed. The quantitative data was presented in the form of the mean, median, standard deviation, and confidence intervals. The information was presented using qualitative statistics such as frequency and percentage. The student's t test (T) was used to assess the data while dealing with quantitative independent variables. Pearson Chi-Square and Chi-Square for Linear Trend (X²) were used to assess qualitatively independent data. The significance of a P value of 0.05 or less was determined.

RESULTS

   The mean age was 8.4± 3.5 years and ranging from 4 to 11 years. There were 50% aged from 4 to <8 years, while there were 50% aged from 8 to 11 years. There were 77.8% males and 22.2% females among age group 1. There were 66.7% males and 33.3% females among age group 2. The gender gap between the two age groups did not reach statistical significance. There were 77.8% had fracture in right side and 22.2% had fracture in left side among group 1. There were 88.9% had fracture in right side and 11.1% had fracture in left side among group 2. When comparing the two age groups, there was no discernible difference in fracture side. The mechanism of injury was 33.3% motor vehicle accident, 55.6% fall from height, and 11.1% sports injuries among group 1. Among group 2, the mechanism of injury was 22.2% motor vehicle accident, 66.7% fall from height, and 11.1% sports injuries. Regarding the causes of injuries, neither age group differed significantly from the other (Table 1).
Table (1): Demographics, side of fracture and mechanism of injury among studied patients

<table>
<thead>
<tr>
<th>Variables</th>
<th>Group 1 (No.=9)</th>
<th>Group 2 (No.=9)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (year) Mean± SD</td>
<td>8.4± 3.5</td>
<td>4, 11</td>
<td></td>
</tr>
<tr>
<td>Age groups</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group 1 (4 - &lt;8)</td>
<td>9 (50)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group 2 (8-11)</td>
<td>9 (50)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Variables</td>
<td>Group 1 (No.=9)</td>
<td>Group 2 (No.=9)</td>
<td>P value</td>
</tr>
<tr>
<td>Male n (%)</td>
<td>7 (77.8)</td>
<td>6 (66.7)</td>
<td>0.500</td>
</tr>
<tr>
<td>Female n (%)</td>
<td>2 (22.2)</td>
<td>3 (33.3)</td>
<td></td>
</tr>
<tr>
<td>Right n (%)</td>
<td>7 (77.8)</td>
<td>8 (88.9)</td>
<td>0.805</td>
</tr>
<tr>
<td>Left n (%)</td>
<td>2 (22.2)</td>
<td>1 (11.1)</td>
<td></td>
</tr>
<tr>
<td>Motor vehicle accident</td>
<td>3 (33.3)</td>
<td>2 (22.2)</td>
<td>0.711</td>
</tr>
<tr>
<td>Fall from height</td>
<td>5 (55.6)</td>
<td>6 (66.7)</td>
<td></td>
</tr>
<tr>
<td>Sports injuries</td>
<td>1 (11.1)</td>
<td>1 (11.1)</td>
<td></td>
</tr>
</tbody>
</table>

The mean time to fixation was 2.4± 1.6 days among group 1 and 2.5± 1.7 days among group 2. In regards to time to fixation, neither age group differed significantly from the other (Table 2).

Table (2): Time to fixation among the participants.

<table>
<thead>
<tr>
<th>Variables</th>
<th>Group 1 (No.=9) Mean± SD</th>
<th>Group 2 (No.=9) Mean± SD</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time to fixation</td>
<td>2.4±0.56</td>
<td>2.5± 0.6</td>
<td>&gt;0.999</td>
</tr>
</tbody>
</table>

The mean operation time was 39.4± 5.6 among group 1 and 40.5± 5.9 among group 2. Operation time did not differ significantly between the two age groups (Table 3).

Table (3): Operation time among the participants.

<table>
<thead>
<tr>
<th>Variables</th>
<th>Group 1 (No=9) Mean± SD</th>
<th>Group 2 (No=9) Mean± SD</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operation time</td>
<td>39.4± 5.6</td>
<td>40.5± 5.9</td>
<td>0.066</td>
</tr>
</tbody>
</table>

The mean time to union was 8.5± 2.4 weeks among group 1 and 8.6± 2.5 weeks among group 2. No statistically significant difference was found between the two age groups in terms of union duration (Table 4).

Table (4): Time to union among the participants.

<table>
<thead>
<tr>
<th>Variables</th>
<th>Group 1 (No.=9) Mean± SD</th>
<th>Group 2 (No.=9) Mean± SD</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time to union (weeks)</td>
<td>8.5± 2.1</td>
<td>8.6± 2.1</td>
<td>0.900</td>
</tr>
</tbody>
</table>

The mean time to metal removal was 4.5± 1.5 months among group 1 and 4.6± 1.8 months among group 2. The time it took to remove metal did not differ significantly between the two age groups (Table 5).

Table (5): Time to metal removal among the participants.

<table>
<thead>
<tr>
<th>Variables</th>
<th>Group 1 (No.=9) Mean± SD</th>
<th>Group 2 (No.=9) Mean± SD</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time to metal removal</td>
<td>4.5± 1.01</td>
<td>4.6± 1.02</td>
<td>0.660</td>
</tr>
</tbody>
</table>

Seven participants experienced the most common consequence, skin irritation from the nail ends. Other complications were superficial infection (n=2), limb length inequility (n=2) and varus angulation (n=1). In 14 kids, the nails were yanked out at a median of 22 (6-38) weeks after surgery. The procedure to remove the nails was successful and without incident. There was no refracture, and all patients restored their complete hip and ankle range of motion by the 3-month follow-up. However, three patients (27.77 percent) still experienced modest knee flexion limitation, although this improved by the 6-month follow-up.
Excellent results were demonstrated in 72.22%, satisfactory results in 27.77% and no patients had poor outcomes (Table 6).

Table (6): Complications among the participants.

<table>
<thead>
<tr>
<th>Complications</th>
<th>NO. of patients</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Entry site irritation</td>
<td>7</td>
<td>38.88</td>
</tr>
<tr>
<td>Superficial infection</td>
<td>2</td>
<td>11.11</td>
</tr>
<tr>
<td>Limb length inequality</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;1.0 cm</td>
<td>1</td>
<td>5.55</td>
</tr>
<tr>
<td>1-2 cm</td>
<td>1</td>
<td>5.55</td>
</tr>
<tr>
<td>&gt;2.0 cm</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Varus angulation</td>
<td>1 (8 degree)</td>
<td>5.55</td>
</tr>
</tbody>
</table>

Figure (1): Elastic stable intramedullary nails for a diaphyseal femoral fracture in a 9-year-old girl. (a) Preoperative radiograph. (b) Immediate postoperative radiograph. (c) Six-month follow-up of 9 years aged female. Mode of Trauma: Car accident, Complaint: pain, tenderness and edema over the right thigh and limitation of the movement of the hip and knee joints, Previous history: no history of congenital, chronic diseases or operations, X-ray was done in both A-P and Lateral view, she was diagnosed with Transverse fracture at the shaft of the right femur, managed by two retrograde elastic nails were inserted, complications was just irritation at the insertion point of the nails, one week after the operation, The patient has been followed every two weeks. He started to walk after 40 days. Imaging was done to detect union. Nails removed after 8 months.
DISCUSSION

One of the most common causes of hospitalization for pediatric orthopedics is femoral shaft fractures. The femoral shaft's rich vascularity ensures quick recovery and an excellent outlook. Treatment for femoral shaft fractures in children varies according to age and severity of injury, with surgery stabilization being the preferred method (7).

Children between the ages of 5 and 15 who suffer a femur fracture are increasingly opting for surgical intervention. Plates, external fixators, hard locking nails, and flexible intramedullary nails are all used in surgical procedures for children and adolescents (8). Since current treatments permit early mobilization, the risks of hospitalization and bed rest are reduced. When compared to traditional therapies like hip spica casts and external fixators, modern methods like elastic stable intramedullary nailing (ESIN) have been shown to be superior in terms of fracture reduction and immobilization time (5).

Regarding the demographic data in our study, the mean age was 8.4 ± 3.5 years and ranging from 4 to 11 years. There were 50% aged from 4 to <8 years while there were 50% aged from 8 to 11 years. There were 77.8% males and 22.2% females among age group 1. There were 66.7% males and 33.3% females among group 2. In terms of gender, there was no discernible variation in the ages of groups.

In contrast to us, Panchal (9) did a similar study at Shri Krishna Hospital on 40 pediatric patients with fractures of the diaphysis of the femur who had elastic stable intramedullary nailing over a three-year period. Participants' ages ranged from 5 to 15 years old, with an average age of 8.2 years. The majority of the children are between the ages of 4 and 10. Out of 40 patients, 24 (60%) were males and 16 (40%) were females.

Flynn and colleagues (10) conducted a similar study in which eighty-three children were studied prospectively. The study's age range was six to sixteen years, with an average age of 10.2. In terms of gender, there were 60 males and 23 females. During our study, we analyzed the side of the fracture among the participants. There were 77.8% had fracture in right side and 22.2% had fracture in left side among group 1. There were 88.9% had fracture in right side and 11.1% had fracture in left side among group 2. No statistically significant difference was seen between the two age groups in terms of fracture side. In contrast to our findings, Gyaneshwar and colleagues (11) research revealed that the left side was involved in 70.59% of the studied cases. In the same line with our results, Panchal's (9) findings showed that the majority of fractures (61%) occurred on the right side (9).

The mechanism of injury among our studied patients was 33.3% motor vehicle accident, 55.6% fall from height, and 11.1% sports injuries among group 1. Among group 2, the mechanism of injury was 22.2% motor vehicle accident, 66.7% fall from height, and 11.1% sports injuries. The mechanism of injury did not differ significantly between the two age groups.

The most common mode of injury among the cases evaluated in several studies was a traffic accident (RTA). They also discovered that head injury was the most common related injury, followed by other long bone fractures (10).

The mean time to fixation in our study was 2.4± 1.6 days among group 1 and 2.5± 1.7 days among group 2. Time to fixation did not differ significantly between the two age groups. The mean operation time was 39.4± 5.6 among group 1 and 40.5± 5.9 among group 2. When comparing the two age groups, there was no discernible variation in the length of the surgical procedure.

In comparison to Gyaneshwar and colleagues' (11) study, most patients underwent surgery after 4 or 5 days.

Our findings revealed that the mean time to union was 8.5± 2.4 weeks among group 1 and 8.6± 2.5 weeks among group 2. Time to union did not differ significantly between the younger and older groups. The mean follow-up periods were 9.2± 2.8 months among group 1 and 9.1± 2.6 months among group 2. Follow up periods did not differ significantly between groups. The mean time to metal removal was 4.5± 1.5 months among group 1 and 4.6± 1.8 months among group 2. Time to metal removal, also did not show statistical difference between groups.

In agreement with our findings, the average union time in the study of Flynn (10) and the study of Saikia (12) was 9 weeks and 8.7 weeks respectively.

In our study, 8 patients were able to sit squat and cross-legged at 6 weeks, and 10 patients were able to sit squat and cross-legged at 12 weeks. Overall Results was superior in 15 (83.33%) of patients.

In our study all patients achieved full range of hip and ankle motion at 3 months follow up with 3 (27.77%) patients having mild restriction in knee flexion which was regained at 6 months follow-up. Excellent results were demonstrated in 72.22%, satisfactory results in 27.77% and none of the patients showed poor results.

Seven participants experienced the most common consequence, skin irritation from the nail ends. Other complications were superficial infection (n=2), limb length inequality (n=2) and varus angulation (n=1). In 14 kids, the nails were pulled out at a median of 22 (6-38) weeks after surgery. The procedure to remove the nails was successful and without incident. There was no re-fracture, and all patients restored their complete hip and ankle range of motion by the 3-month follow-up. However, three patients (27.77 percent) still experienced modest knee flexion limitation, although this improved by the 6-month follow-up.
In our study, all patients achieved full hip and ankle range of motion at 3 months follow-up, 3 (27.77%) patients showed mild limitation in knee flexion, and 6 Recovered at month follow-up. Results were evaluated using Flynn's Elastic Nail Rating System. Excellent results he showed 72.22%, satisfactory results he showed 27.77%, no patient had a bad result.

The consequences of elastic nails for juvenile femoral shaft fractures were studied by Luhmann and colleagues (13) in 40% of their studied cases, Pain and problems at the nail insertion site have been reported.

Panchal and colleagues found that irritation and pain at the entrance site were common side effects. During follow-up visits, however, they were relieved in the majority of the patients. In their study, discrepancy of only up to 1 cm among limb length happened in 5 cases (9).

In addition, according to Khorati and colleagues (14) limb length disparity is uncommon with elastically stable intramedullary nailing (ESIN). Leg length discrepancy, angulation of the fracture, and infection are all rare complication.

CONCLUSION

Treatment of femoral shaft fractures using flexible intramedullary nailing has been shown to be safe and successful, with excellent radiological and functional outcomes. Patients' age, weight, and fracture pattern; hospital facilities and family's psychosocial state should all be considered when deciding on ESIN as the optimal modality for treating femur shaft fractures in children aged 4-11 years old, notwithstanding the technical problems.

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Author contribution: Authors contributed equally in the study.

REFERENCES