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Flexible Nails versus Plate for Fixation of Fracture Shaft Femur in Children from 5-12 Years

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ABSTRACT
Background: Pediatric femoral shaft fractures are the most common fractures requiring hospitalization in children and often require prolonged immobilization or surgery. Various techniques have been used to avoid complications in children. This study aimed to evaluate the early clinical and functional outcome after surgical management of femoral shaft fracture in children between 5 to 12 year either by plate or flexible nails.
Patients and methods: This study was carried on 24 patients; 12 patients managed by elastic stabile intramedullary nailing (ESIN) and 12 patients managed by plate. All the patients were subjected to history and physical examination, together with plain X-ray antro-posterior and lateral views of femur from hip to knee. Functional outcome was assessed by using Flynn's TENS outcome score, applied to both the groups at the end of follow up.
Results: Mean age of study group was 9.17 (SD 2.12) ranged from 5 years to 12 years. About 62.5% of cases were males and 37.5% were females. Fractures were 70.8% transverse, 25% oblique, and 4.2% spiral. The mean operation time was 36.88 (SD 7.34) minutes and the mean clinical union was 11.58 (SD 2.28) weeks. Time to metal removal was 7.56 (SD 2.80) months. About 8.3% of patients had major complication, and 12.5% had mild complications. Three-fourth of cases had excellent score. ESIN had better outcomes and fewer complications compared with plate.
Conclusion: ESIN is the implant of choice for femoral diaphyseal fractures in children aged from 5-12 years.
Keywords: Fracture Shaft Femur; Flexible Nails; Plate; Intramedullary Nailing, Children.

INTRODUCTION

Femoral diaphyseal fractures account for nearly 2 % of all bony injuries in children, and are the most common orthopedic injury requiring hospitalization [(1)]. Males more commonly sustain femur fractures, as they account for greater than 70% of injuries. There is a bimodal age distribution of fractures, first in early childhood, where falls are the predominant cause of injury, then again peaking in adolescence where motor vehicle collisions cause most of the fractures [(2)].

In the past, femoral fractures in all children were commonly treated with immediate spica casting or a period of traction followed by casting [(3)]. Non-surgical treatment with spica casting remains the standard for infants and toddlers less than 5 years; however, school-age children are now more commonly undergoing surgical intervention. Surgical treatment has reduced the burden of care for families, shortened hospital stays, and decreased the early disability and disruption in the families' lives [(4)]. In skeletally immature children aged older than five years, surgical fixation is the standard of care and is recommended by the American Academy of Orthopaedic Surgeons over nonoperative methods such as spica casting and skeletal traction [(4)].

The use of flexible nails (FNs), which enables rapid mobilization with few complications, is a well-established method for treating length-stable fractures in children aged 5 to 12 years. Its advantages include small incisions and relatively simple instrumentation [(4)].

Plating techniques have been a popular alternative to ESIN and were primarily indicated in oblique fracture, comminuted fractures, long oblique fracture or patients overweight. The benefits of plates include a lower incidence of mal-union and stronger axial and torsional stability in loading [(5)]. In addition, plate osteosynthesis allows stable fixation with good results in the pediatric population. Traditional plates require extensive exposure with soft tissue disruption. Minimally invasive plating and submuscular techniques have evolved to reduce soft tissue dissection [(6)].

Therefore, this study aimed to evaluate the early clinical and functional outcome after surgical management of femoral shaft fracture in children between 5 to 12 year either by plate or flexible nails and to analyze any possible complications.

PATIENTS AND METHODS

This is an interventional prospective comparative study in patients admitted at Department of Orthopedic and Traumatology Surgery of Zagazig University hospital. The study was carried out on 24 patients with age group (5-12 years) and sex type (15 male - 9 female) the side affected was (13 left side - 11 right side).
The patients were randomly divided into two groups according to method of reduction and fixation: Group (A) involved 12 patients: Fluoroscopic guided reduction and fixation by Elastic Stabile Intramedullary Nailing (ESIN) was done. Group (B) involved 12 patients: Open reduction and fixation by plate and screws were done.

Inclusion criteria: Patients with a closed or open fracture (Gustilo type 1), age: 5 -12 years, and simple or comminuted fracture.

Exclusion criteria: Patients with an open fractures (Gustilo type 2,3), accompanying fracture in the lower limbs and pathological fractures or neurovascular

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injury. Fracture around hip or knee joint. Comorbidities with major musculoskeletal manifestation, such as osteogensis imperfect and cerebral palsy.

Pre-operative evaluation:

All study patients underwent the following clinical examination as full detailed history, general examination for chest, head, abdomen and other injuries. Thereafter, all factures were subjected to local examination of the limb for evaluation of the neuro-vascular integrity and to determine if the fracture is open or closed. Finally, radiological examination by anterior-posterior and lateral views of femur showing knee and hip joints were done.

Methods:

I.Intramedullary nail operation:

Flexible nailing is most effectively performed on a fracture table, with a fracture reduced to near anatomic position before incisions are made. Alternatively, a fluoroscopic table can be used, but the surgeon should assure that reduction can be obtained prior to the start of the procedure, and extra assistance may be necessary. Two nails of similar size should be used, and they should be as large as possible. It is known that using nails that were too small, or mismatched in size, increases the rate of complications. Thus, it was very unusual to use nails smaller than 3.5 mm, except in the very youngest children.

The patient is in supine position. Incisions are made on the medial and lateral side distal to the insertion site in the bone. The distal femoral metaphysis is opened 2.5 cm proximal to the distal femoral physis using a drill or awl. The drill is then steeply angled in the frontal plane to facilitate passage of the nail through the dense pediatric metaphyseal bone. After the nails are driven across the fracture and before they are seated, fluoroscopy is used to confirm satisfactory reduction of the fracture and to ensure that the nails did not comminute the fracture as they were driven into the proximal fragment. The nails are pulled back approximately 2 cm; the end of each nail is cut, and then driven back securely into the femur. The end of the nail should lie adjacent to the bone of the distal femoral metaphysis, exposed just enough to allow easy removal once the fracture is healed **(Figure 1)**.

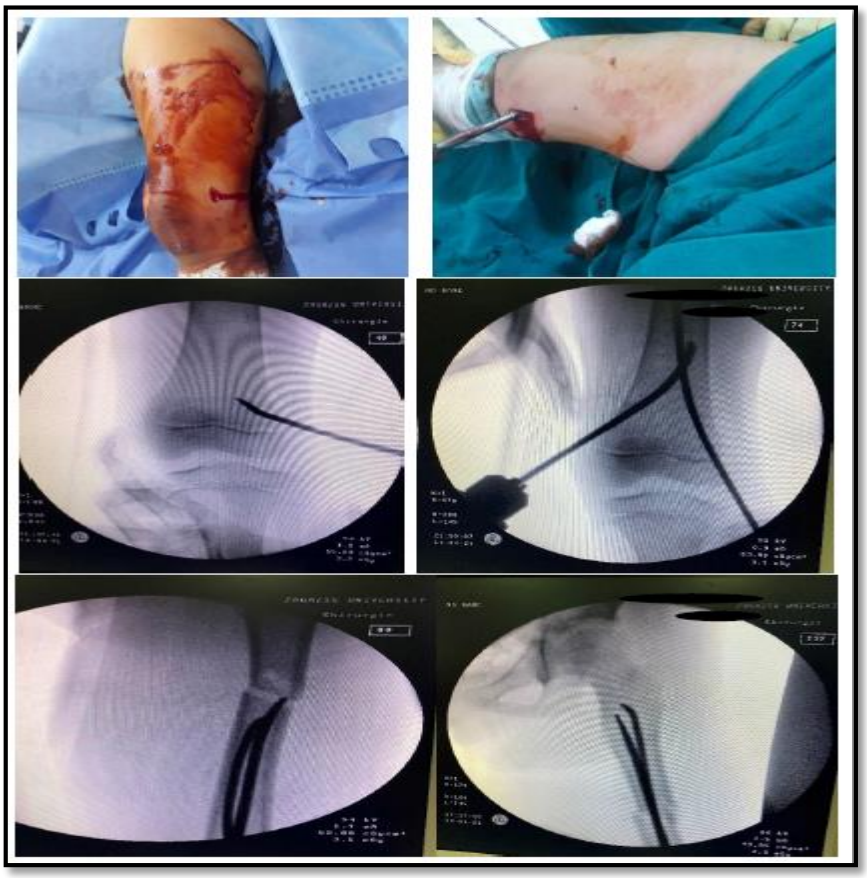

Figure (1): Surgical technique of ESIN.

Postoperative care and follow up:

A knee immobilizer is beneficial in the early postoperative course to decrease knee pain and quadriceps spasm. When the flexible nailing technique is used for length-unstable fracture, walking (or one leg) spica is recommended, generally for about 4 to 6 weeks

until callus is visible on radiographs. Gentle knee exercises and quadriceps strengthening can begin, but there should be no aggressive passive motion of the knee, which increases the motion at the fracture site and increases quadriceps spasm. Full weight bearing generally is tolerated by 6 weeks.

The patient will be assessed clinically and radiologically immediately post-operative and every 2 weeks then after 1 month and every month after operation with mean follow up not less than 6 months after operation. All patients were followed until fracture union occurred. The follow up period was not less than 6 months after operation. Results were analyzed both clinically and radiologically.

II. Operation details of plate:

In a sterile operating room environment, after general anesthesia had been given, the patient is placed on a radiolucent table and the entire extremity is prepared and draped. The femur is approached laterally. The vastus lateralis is retracted anteriorly to expose the femur. Soft tissue attachments to the bone are preserved as much as possible. Fragments are lagged into place and secured with a dynamic compression plate. A Narrow DCP or Broad DCP plate is used in children. Both interfragmentary compression and dynamic compression techniques can be used to achieve stability and anatomic alignment **(Figure 2).**

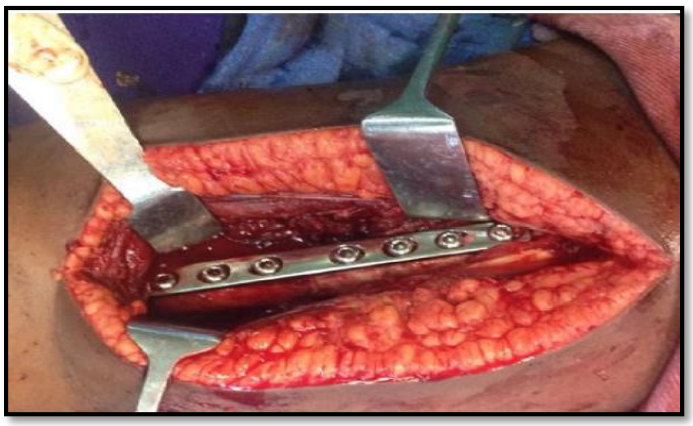

Figure (2): Intra operative picture of femur plating.

Postoperative care and follow up:

Immediate postoperative: Patients were received in recovery room for observation. Limb elevation with pillow was given to all patients. Distal pulses and toe movements were checked for distal neurovascular deficit. Stretch pain also checked to rule out compartment syndrome. Intravenous antibiotics were taken for 2 days followed by oral antibiotic for 3-5 days according to wound condition. Postoperative pain controlled by simple analgesia. Patients encouraged to dorsiflex the ankle gently. Drain is checked for loss of blood. If significant loss was detected, it can be replaced by packed RBCs.

Early postoperative**:** patient wound dressing changed on 2nd day post-operative. If wound is healthy then gentle knee exercises and quadriceps strengthening should be begun, but there should be no aggressive passive motion of the knee, which increases stress at the fracture site and increases quadriceps spasm. Late postoperative: sutures were removed on 12th post-operative day and physical therapy continued.

The patients were assessed clinically and radiologically immediately post-operative and every 2 weeks then after 1 month and every month after operation with mean follow up not less than 6 months after operation. All patients were followed until fracture union occurred. The follow up period was not less than 6 months after operation. Results were analyzed both clinically and radiologically.

Time of clinical union was defined as the period between operation and full weight bearing without external support along with radiographically healed fracture (cortical continuity in all 4 cortices).

Post-operative Clinical evaluation:

Using Titanium Elastic Nails Outcome Scoring system, outcomes of fractures treated with both TENs and plating were classified as excellent, satisfactory, or poor based on residual leg-length inequality, fracture malalignment, pain, complications, and unplanned surgery for the treatment of complications. A patient's overall outcome was determined by the category with the worst result.

The presence or absence of pain was recorded based on the last follow-up visit. Presence of pain was defined as persistent complaints of pain, whereas absence of pain was no or intermittent complaints of pain

Fracture malalignment was determined based on review of radiographs at latest follow-up. Angulation was measured in the coronal and sagittal planes, and the greatest was recorded. Leg length discrepancy was determined based on the clinical examination or review of full-length bilateral lower extremity radiographs, if available, at the latest follow-up.

Range Of Motion ROM of both hips and knees at the affected and the sound side were measured using geometry. NSA was measured on x ray of the pelvis in anteroposterior view showing both hips.

Any complication that led to unplanned surgery was considered a major complication. Complications that resolved with non-operative management or did not require any treatment were considered minor.

Ethical Consideration:

An approval of the study was obtained from Zagazig University Academic and Ethical Committee. Written informed consent of all the participants was obtained. 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

Data collected and encoded using Microsoft Excel software. Data were then imported into Statistical Package for Social Sciences (SPSS version 20.0) software for analysis. According to the type of data, qualitative represented as numbers and percentages, while quantitative data represented by mean ± SD. Chi-square test ($\chi 2$) and Fisher's exact test to calculate difference between two or more groups of qualitative variables. Independent samples t-test was used to compare between two independent groups of normally distributed variables. P-value was set at ≤ 0.05 for significant results, and ≤ 0.001 for highly significant results.

RESULTS

The present study conducted on 24 patients, divided into two equal groups; the first one was treated by ESIN and the other one treated by plating. Mean age of study group was 9.17 (SD 2.12) ranged from 5 years to 12 years. About 62.5% of cases were males and 37.5% were females **(Table 1).**

Table (1): Demographic data for the study group:

Variable		N / Mean	% / SD	Median (IQR)	Range
Group	ESIN	12	50.0%		
	Platin	12	50.0%		
Age		9.17	2.12	9 (8 - 11)	(5 - 12)
Sex	Male	15	62.5%		
	Female	9	37.5%		

About 45.8% of cases had right side injury and 54.2% had left side injury. The most common mode of injury in our study was fall from height (58.3%). Fractures were 70.8% transverse, 25% oblique, and 4.2% spiral **(Table 2)**.

Table (2): Injury data for the study group:

Variable		N	%
Side	Right	11	45.8%
	Left	13	54.2%
Mechanism of injury	FFH	14	58.3%
	RTA	7	29.2%
	FHO	3	12.5%
Associated injury	No	23	95.8%
	Head injury	1	4.2%
Type of fracture	Transverse	17	70.8%
	Oblique	6	25.0%
	Spiral	1	4.2%

Regarding operation data, the mean operation time was 36.88 (SD 7.34) minutes and the mean clinical union was 11.58 (SD 2.28) weeks. Time to metal removal was 7.56 (SD 2.80) months. In the present study, the average time taken for clinical union in patients treated with plate was 13.17 weeks and in patients treated with ESIN was 10 weeks which was statistically significant ($P \leq 0.01$) **(Table 3)**.

Table (3): Operation data for the study group.

Variable		N / Mean	% / SD	Median (IQR)	Range
Time to fixation (days)	1	13	54.2%		
	2	8	33.3%		
	3	2	8.3%		
	4	1	4.2%		
Time to fixation (days)		1.63	0.82	1 (1 - 2)	(1 - 4)
Nail Technique	Closed	11	91.7%		
	Semi-open	1	8.3%		
Operation Time (minutes)		36.88	7.34	40 (30 - 45)	(25 - 45)
Image radiation exposure time (Seconds)		25.00	4.26	25 (20 - 30)	(20 - 30)
Radiological union (weeks)		8.46	1.82	8 (7 - 10)	(6 - 12)
Clinical Union (weeks)		11.58	2.28	11.5 (10 - 13)	(8 - 16)
Time to metal removal (month)		7.56	2.80	7 (5 - 10)	(4 - 12)

About 8.3% of patients had major complication, 12.5% had mild complications. 75% of cases had excellent score **(Table 4).**

Table (4): Post-operative follow up for the study groups

Variable		Both Group N. 24	ESIN Group N. 12	Plate Group N. 12	P-value
Complications	No	19 (79.2%)	11 (91.67%)	8 (66.67%)	0.385
	Mild	3 (12.5%)	1 (8.33%)	2 (16.67%)	
	Major	2 (8.3%)	0 (0%)	2 (16.67%	
Score	Poor	2 (8.3%)	0 (0%)	2 (16.67%	0.525
	Successful	4 (16.7%)	2 (16.67%)	2 (16.67%)	
	Excellent	18 (75%)	10 (83.33%)	8 (66.67%	

DISCUSSION

The treatment of shaft femur fractures in children between to ages 6 and 12 years has been the most controversial. Many patients may be treated successfully with casting [7].

Various surgical techniques have been used recently to avoid complications of casting and traction in children, these include flexible or rigid intramedullary rods, plating and external fixation especially in children with multiple system injuries,

head injury or after failure to maintain reduction with conservative methods [5].

The use of external fixation is very effective for open or severely comminuted fractures**.** But pin tract irritation or infection; is common and occurred in about 45% of cases treated with external fixators. Loss of motion, loss of reduction, malrotation and refracture are also frequent complications that make the use of external fixation as the principal treatment for simple fractures in children six to sixteen years old very difficult [8].

Open reduction with plate fixation has been shown to be successful in treating diaphyseal fractures in children who have multiple injuries [6]. A disadvantage of fixation with a plate is that a second operative procedure is needed in order to remove the plate. Infection, broken plates and delayed union are not rare complication. Also, there is possibly more subsequent femoral overgrowth than occurs with other treatment methods [9].

Intramedullary nailing has been preferred more than plating because of its better mechanical properties and lower incidence of associated infection. The use of intramedullary fixation in general is found to be more compatible with the natural healing process of periosteal callus formation especially with closed intramedullary nailing that avoids periosteal stripping at the fracture site, thus sparing the periosteal blood supply [10].

As surgeons consider different methods to treat paediatric femur fractures and mobilize the injured child, the ideal mode of treatment remains controversial. Intramedullary elastic nails are popular for the management of length-stable femoral fractures in school going children. Though plating is a treatment option for femoral fractures for the ease of application and early mobilization, recently sub muscular plating has been found to be a successful alternative for the management of length- unstable femoral fractures in school-going children [8].

In our study, the mean time taken for clinical union in patients treated with plate was 13.17 weeks, while in patients treated with ESIN was 10 weeks ($P \leq 0.01$).

In plating group the radiological union time (9.75 weeks) is slightly higher when compared to the results reported with the ESIN group (7.17 weeks). In our study, we advised the patients to start toe touch weight bearing with assistive devices as soon as the callus was visible radiologically. Plating group patients started toe-touch walking at around 10 weeks, whereas ESIN group patients started toe-touch walking earlier at 7 weeks.

These results are similar to **Fyodorov *et al.*** [11] (6 weeks) and **Andalib *et al.*** [12] (8.5 weeks) in those treated with plate for femur shaft fractures, and the studies involving ESIN as a treatment modality reported about 4 weeks.

Intra operative radiation exposure to surgeon is high in closed reduction and ESIN group. **Kraus *et al.*** [13] performed retrospective analysis of 63 femoral and 24 tibial shaft fractures and found that the average radiation time in femoral fractures was 70.3 (range 12-193) seconds. Standard compression plating is an open procedure. It can be done without the use of intraoperative fluoroscopy.

In this study, after the procedure, all the patients except the ones who were immobilized were advised to move the hip and knee while lying on the bed from the second day. The presence of a large surgical wound and the associated pain in patients treated with plate may have caused the delay in mobilization. **Carey *et al.*** [14] reported an average time of 5.5 days for mobilization with ESIN.

Similarly **Roaten *et al.*** [15] reported it as 9 days. **Ward *et al.*** [16] reported an average time for mobilization as 6 weeks in patients treated with plates.

In this study, a mean duration of hospital stay in the plating group was 2 days and in the ESIN group, it was only 1 day. Many reports suggested that decreased hospital stay in patients treated with ESIN compared to those treated with plates may probably be because of the extensive surgical exposure in plating group and wound dressings. It was more commonly influenced by the financial constraints of the patient.

In this study, we noted that the limb length discrepancy (LLD) was around 1 case in the plating group and no cases in the ESIN group. There is a wide range of limb length inequality reported in other studies. **Ward *et al.*** [16] reports 4.3% whereas, **Eren *et al.*** [17] reports around 5.4% in femur shaft fractures treated with dynamic compression plate. In patients treated with ESIN, reports by **Ligier *et al.*** [18] and **Singh *et al.*** [19] have recorded 12% and 8.5% of LLD respectively.

In this study, we noted that malalignment (angulation or rotation) was not found in the DCP group and was (3) in the TENS group (varus angulation only, no rotation). None of the cases showed >20° of malalignment. **Carey *et al.*** [14]**, Ligier *et al.*** [18]**, Singh *et al.*** [19] reported 8%, 11% and 8.57% incidence of malalignment in cases treated with TENS respectively.

CONCLUSION

ESIN is the implant of choice for femoral diaphyseal fractures in children aged from 5-12 years. It is advised to make further researches on a large number of patients and long period of follow up.

Conflict of interest: The authors declare no conflict of interest.

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Author contribution: Authors contributed equally in the study.

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