The Egyptian Journal of Hospital Medicine (July 2021) Vol. 84, Page 1908-1913

Elastic Stable Intramedullary Nailing Femoral Shaft Fractures in Children from Six to Ten Years Age

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ABSTRACT

Background: Diaphyseal fractures of the femur (DFF) are common long-bone injuries in children and adolescents. DFF represent 1.5% of fractures in childhood.

Objective: This study aimed to evaluate the clinical, functional and radiological outcome of femoral shaft fractures, which are managed by elastic stable intramedullary nailing (ESIN) in pediatric age 6-10 years.

Patients and Methods: A prospective clinical randomized trial study was conducted on18 children underwent elastic stable intramedullary nailing (ESIN) for treating femoral shaft fractures at Orthopedic department, Zagazig University Hospitals during the period from April to December 2020. Plain X- rays of the femur Antero-posterior (AP) & Lateral (Lat.) views (from hip to the knee joint) was taken. **Results**: The time to surgery was 1.39 ± 1.12 days ranging from 1 to 6 days, the time till full union was 9.4 ± 1.76 weeks ranging from 7 to 12 weeks, more than half of the studied group (55.5%) ranged from 7 to 9 weeks and the time of full weight bearing was 9.6 ± 1.7 weeks ranging from 7 to 12 weeks, half of the studied group (50.0%) ranged from 7 to 9 weeks. So, the final outcome was 83.3% had excellent functional outcome, 11.1% of them had satisfactory functional outcome and 5.6% had poor functional outcome. 88.8% didn't have any complications, 5.6% of them had irritation and 5.6% had superficial infection.

Conclusion: ESIN is the choice treatment for transverse and short oblique shaft fractures in patients aging from 6 to 10 years old.

Keywords: Femoral shaft fractures, Femur, ESIN, Intramedullary nail.

INTRODUCTION

Femoral shaft fractures are a frequent pediatric orthopedic injury that account for fewer than 2% of all pediatric fractures. 90 percent of femoral shaft fractures in children are caused by motor vehicle accidents. The yearly incidence of femoral shaft fractures from road traffic accidents is estimated to be between 1.0 and 2.9 million [1]. Pediatric femur shaft fractures tend to unite rapidly and have a tremendous remodeling potential. Consequently, a wide range of deformity of the initial healed bone is considered acceptable. The acceptable angulation in the coronal and sagittal planes varies from 30º at birth to 15º at 10 years. Rotational malalignment does not remodel and deformity more than 10 in the axial plane is not acceptable. Limb shortening of up to 15 mm can be compensated in children up to 12 years of age by growth acceleration [1, 2].

A variety of factors influence whether a femoral shaft fracture should be treated conservatively or surgically, including the patient's age and weight, the kind of fracture, accompanying injuries/polytrauma, and the family's socioeconomic status [3].

Elastic stable intramedullary nails (ESINs) have become the standard treatment of femur shaft fractures in children between 5 and 15 years because of favorable results and lack of major complications. It is a closed surgical procedure that allows early weight bearing and walking. The technique of ESIN was developed by the team from Nancy in 1982 and represents a compromise between conservative and surgical therapeutic approaches [4, 5]. ESIN fits all of the minimally invasive bone surgery requirements, including a shorter operating time, little soft tissue dissection, fewer incisions and consequently fewer scars, less discomfort, quicker mobilisation, and relatively simple implant removal [6].

Implantation of flexible nails is performed through very small incisions and does not endanger the physes or the blood supply to the femoral head. The implant is sufficiently elastic to respect normal bony curvature and acts as a load sharing (internal splint) that maintains reduction until callus formation appears. It aims at rapid restoration of bone continuity and no joint stiffness, and early rehabilitation [7].

This study was performed to evaluate the clinical, functional and radiological outcomes of femoral shaft fractures, which are managed by elastic stable intramedullary nailing (ESIN) in pediatric age from 6 to 10 years old.

PATIENTS AND METHODS

A prospective clinical randomized trial study was conducted on18 patients (13 males, 5 females) aged from 6 to 10 years old and the mean age was 7.7 years with fracture shaft of femur (11 suffered from right side fracture and 7 had left side fracture). The study was conducted in the Orthopedic Department, Zagazig University Hospital and treated surgically by elastic intramedullary nailing. There were 16 cases with closed fracture and 2 cases with open fracture Gustilo's type I.

Received:8 /4 /2021
Accepted:4 /6 /2021

There were 12 cases with transverse fracture, 4 cases with oblique fracture and 2 cases with short spiral fracture.

Inclusion criteria: Age and sex: between 6 and 10 years; boys or girls. Fracture: diaphysis of femur: Non pathologic origin, closed fracture or Gustilo's type I and II. Fracture in the area between lesser trochanter and 5 cm proximal to distal femoral epiphysis.

Exclusion criteria: Age less than 6 years or more than 10 years. Open fractures: infected second degree or more, significant systemic co-morbidities/injuries. Patients' parents not willing to participate in the study. Patients unfit for surgery or anesthesia.

Pre-operative:

All patients underwent full clinical examination to know the type, mechanism and time of injury, any previous injuries, previous surgical interventions, any medical comorbidity and medications. All the cases of trauma were examined by trauma team. The initial assessment was directed to the airway, breathing and circulation (ABCs). Plain X- rays of the femur antero-posterior (AP) & Lateral (Lat.) views from hip to the knee joint were taken. Laboratory investigations including complete blood count (CBC), renal function tests (RFT) and bleeding profile. The procedure was performed under general anesthesia.

Surgical technique:

The procedure was done with the patient in supine position with C. arm guide. Under complete aseptic conditions and after dropping. Incisions on the medial and lateral sides (about 2.5 cm in length) were done about 2 cm proximal to the physis (Figure 1). Under fluoroscopy guidance, the drill bit or awl was used to make a hole in the cortex of the bone at angle of 45 degrees in the coronal plane. The distal femoral metaphysis was opened 2.5 cm proximal to the distal femoral physis. The nail size measured by the diameter of the narrowest point of medullary canal on the x-ray. The diameter of one nail must be 40% of the narrowest canal diameter.

"Nail diameter = 0.4 x diameter of medullary canal" [8]. Nails were contoured according to the type and location of the fracture and the nail tip pointing to the concave side of the bowed nail. The apex of the bow was at the level of the fracture. This shape allowed the nail to generate optimal resistance to deforming forces [9]. Both medial and lateral rods were inserted to the level of the fracture. At this point, the fracture reduction was optimized if necessary (Figure 2).

The two nails then were driven into the proximal end of the femur, one toward the femoral neck and the other toward the greater trochanter. After the nails were introduced across the fracture and before they were seated, fluoroscopy is used to confirm satisfactory reduction of the fracture. The nails were pulled back about 2 cm and the end of each nail was cut, then driven back to the femur to prevent irritation of the soft tissues. The ends of the nails were exposed just enough to allow easy removal after healing of the fracture (Figure 3).

Figure (1): Medial incision.

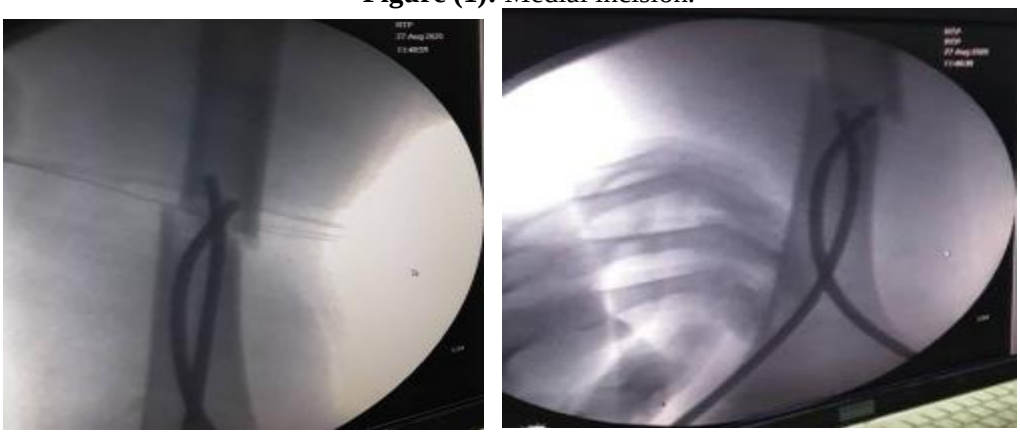

Figure (2): 2 nails inserted to the level of the fracture.

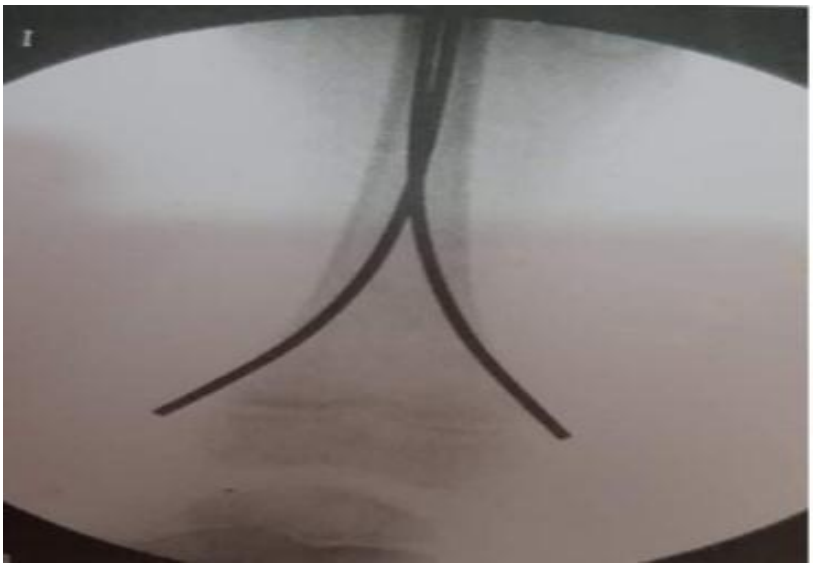

Figure (3): Cut end of 2 nails.

Post-operative follow-up:

The Thomas splint was applied for rotational stability postoperatively.

Immediate postoperative anteroposterior and lateral radiographs were done. All patients were followed up at two weeks post-operatively for removal of sutures, then every 6 weeks post-operatively for check of x-ray and assessment of callus formation. The patients were followed for assessment of range of motion of the knee, knee pain, deformities, and limb length discrepancy (LLD). The patients were followed at six months post-operative for final outcome and Flynn's scoring criteria were applied.

Ethical consent:

An approval of the study was obtained from Zagazig University Academic and Ethical Committee.

Every patient' parent signed an informed written consent for acceptance of the operation. This Work was performed according to the code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans.

Statistical analysis

Data were checked, entered and analyzed using SPSS version 23 for data processing. Chi square test ($\chi 2$) to calculate difference between two or more groups of qualitative variables. Quantitative data were expressed as mean ± SD (Standard deviation). The threshold of significance was fixed at 5% level (P-value).

RESULTS

Table (1) showed that the mean age of the studied group was 7.7 ± 1.6 years ranging from 6 to 10 years, half of the group (50.0%) had age ranged from 6 to 8 years and the other 50.0% ranged from 8 to 10 years. 61.1% of the studied group were right sided affected and 38.9% of them were left sided affected. Middle femur was the commonest fracture level (50.0%) of the studied group followed by proximal level (27.8%) and 11.1% had distal fracture level. The transvers fracture was the commonest fracture type (66.7%), followed by oblique fracture (22.2%) and 11.1% had spiral fracture. The commonest mechanism of injury was RTA among 61.1% of the studied group, followed by fall down and falling from height 16.7% for each of them, then direct trauma among 5.6% of the studied group.

Table (2) showed that the mean time to surgery of the studied group was 1.39 ± 1.12 days ranging from 1 to 6 days, most of the studied group (83.3%) waited only one day, (11.1%) two days and (5.6%) 6 days.

The mean time till full union among the studied group was 9.4 ± 1.76 weeks ranging from 7 to 12 weeks, more than half of the studied group (55.5%) ranged from 7 to 9 weeks**.**

The mean time of full weight bearing among the studied group was 9.6 ± 1.7 weeks ranging from 7to 12 weeks and half of the studied group (50.0%) ranged from 7 to 9 weeks.

Table (3) showed that 83.3% of the studied group didn't have limb length discrepancy, 11.1% had 1cm lengthening and 5.6% had 1 cm shortening. Regarding pain intensity, most of the studied group (94.4%) didn't have pain, while only 5.6% of them had mild pain. Concerning deformity, about two thirds (77.8%) of the studied group didn't have deformity while < 5 ° varus, < 5° anterior and < 5° posterior were occurred in 11.1%, 5.6% and 5.6% of the studied group respectively.

Table (4) showed that most of the studied group (88.8%) didn't have any complications, 5.6% of them had irritation and 5.6% had superficial infection.

Table (1): Patients characteristics among the studied group

Variable	The studied group (18) Mean ± SD (Range) median	
Age (years):	7.7 ± 1.6 (6-10) 7.5	
Variable	**NO (18)**	**%**
Age grouping		
6-8 years	9	50.0%
8-10 years	9	50.0%
Sex		
Male	13	72.2%
Female	5	27.8%
Side affected		
Right	11	61.1%
Left	7	38.9%
Fracture level		
Distal	2	11.1%
Middle distal junction	1	5.6%
Middle Proximal junction	1	5.6%
Middle	9	50.0%
Proximal	5	27.8%
Fracture type		
Oblique	4	22.2%
Spiral	2	11.1%
Transvers	12	66.7%
Mechanism of injury		
Fall from height	3	16.7%
Direct trauma	1	5.6%
RTA	11	61.1%
Fall down	3	16.7%
Injury		
Open	2	11.1%
Closed	16	88.9%
Range of motion of knee		
Full R.O.M	17	94.4%
10 degree flexion limitation	1	5.6%

Table (2): Time among the studied group

Variable	NO (18)	%
Time to surgery		
1 day	15	83.3%
2 days	2	11.1%
6 days	1	5.6%
Time of union		
7-9 weeks	10	55.5%
9-12 weeks	8	45.5%
Time of full weight bearing		
7-9 weeks	9	50.0%
9-12 weeks	9	50.0%

Table (3): Flynn's Score among the studied group

	Variables	NO (18)	%
Flynn's Score			
Limb Length Discrepancy	No	15	83.3%
	1 cm Lengthening	2	11.1%
	1 cm Shortening	1	5.6%
Deformity	No	14	77.8%
	Less than 5° Varus	2	11.1%
	Less than 5° Anterior	1	5.6%
	Less than 5° Posterior	1	5.6%
Pain	No	17	94.4%
	Mild	1	5.6%
Final outcome			
final outcome by Flynn's Score	Excellent Satisfactory Poor	15 2 1	83.3% 11.1% 5.6%

Table (4): Complications distribution among the studied group

Complications	NO (18)	%
No	16	88.8%
Irritation	1	5.6%
Superficial infection	1	5.6%

DISCUSSION

The mean age of the studied group was 7.7 ± 1.6 years ranging from 6 to 10 years; half of the group (50.0%) had age ranged from 6 to 8 years and 50.0% ranged from 8 to 10 years. Most of the studied group (72.2%) were males and 27.8% of them were females. The same age was reported in a study of **Govindasamy *et al.*** [9] in a total of 52 children were included in their retrospective analysis, the average age of the studied group was 9.5 years (range 6 – 16) at the time of injury, there were 30 boys (57.6%) and 18 girls (42.4%) in their study. In addition, **Frei *et al.*** [8] reported the same age and sex composition as there were 22 children (14 boys [63.6%], 8 girls [36.4%]).

The median age at injury was 7.5 years (range: 2.0–15.0). The predominance of male may be because of the fact that the increased risk of boys for all fractures due to higher-risk plays activities being more acceptable for boys. Also they are more exposed to outside environment like riding vehicle and sports in comparison to their female counterparts and this is supported by **Mughal *et al.*** [10] who found that the male: female ratio was 2.2:1 in their study.

Regarding the affected side, 61.1% of the studied group were right sided affected and 38.9% of them were left sided that might be explained by leg dominance. This is in contrast with **Frei *et al.*** [8] who found that in15 children, 68.2% the left femurs were fractured. One child (4.5%) sustained multiple traumas in a railway incidence.

In regard to fracture site, we found that middle femur was the commonest fracture level (50.0%) of the studied group, followed by proximal level (27.8%) and 11.1% had distal fracture level. This is in concordance with **Govindasamy *et al.*** [9] who found that 36 fractures were in the middle third followed by, seven proximal third and five distal third fractures in which 28 right sided fractures (58%) and 20 left sided fractures (42%) were noted.

In the current study, the transvers fracture was the commonest fracture type (66.7%) of the studied group, followed by oblique fracture (22.2%) and 11.1% had spiral fracture. This is similar to **Akinyoola *et al.*** [11] whose study included 134 patients and reported that the fracture line was transverse in 38.4%, oblique in 26.1%, spiral in 24.6%, comminuted in 10.1% and greenstick in 0.7%. Also, our present study is in agreement with **Frei *et al.*** [8] who observed 9 transverse (40.9%), 6 spirals (27.3%), 4 comminuted (18.2%) and 3 long oblique (13.6%) fractures.

Concerning mechanism of injury, the commonest mechanism of injury was road traffic accident (RTA) among 61.1% of the studied group, followed by falling down and falling from height 16.7% for each of them, then direct trauma among 5.6% of the studied group. 88.9% of the studied group had closed injury, while 11.1% of them had open injury. Most of the studied group (94.4%) had full R.O.M while only 5.6% of them had 10 degree flexion limitation. These are similar to **Govindasamy *et al.*** [9] where the most common mechanism of injury was RTA (n=34, 70%), followed by fall from height (n=14, 30%) and the clinical evaluation of patients in **Govindasamy *et al.*** [9] study revealed full range of motion of hip, knee and ankle in all patients at final follow-up period.

The mean time to surgery of the studied group was 1.39 ± 1.12 days ranging from 1 to 6 days. Most of the studied group (83.3%) waited only one day, 11.1% two days and 5.6% 6 days. The mean time till full union among the studied group was 9.4 ± 1.76 weeks ranging from 7 to 12 weeks. More than half of the studied group (55.5%) ranged from 7 to 9 weeks. The mean time of full weight bearing among the studied group was 9.6 ± 1.7 weeks ranging from 7 to 12 weeks. Half of the studied group (50.0%) ranged from 7 to 9 weeks. This is consistent with **Nascimento *et al.*** [12] whose study reported that the mean traction time before surgery was 5.3 days, with a minimum of 1 and a maximum of 14 days. All fractures were reduced by closed reduction. The mean period of hospitalization for ESIN insertion was 9.4 days. After surgery, the mean time for healing was 7.7 weeks. Partial weight bearing was allowed after 3.3 weeks on average (ranging from 1 to 8 weeks). The average time for total weight bearing allowance was 8.8 weeks [12]. Also, our results are similar to **Govindasamy *et al.*** [9] whose study resulted in that all fractures had united with grade III callus in average of 9.7 weeks (9-12 weeks) and full weight bearing was started at the same time and was initiated to attend school as well. Functional range of movement of knee was achieved in an average of 8.6 weeks (6 to 14 weeks). Functional range of movement of knee was achieved in an average of 8.6 weeks (6 to 14 weeks).

Clinical evaluation was done after six months using Flynn's criteria which was classified as shown in the following table **Govindasamy *et al.*** [9].

Variables	Excellent result	Satisfactory result	Poor result
Length discrepancy	≤ 1cm	<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

In regard to limb length discrepancy, the current study reported that 83.3% of the studied group didn't have limb length discrepancy, 11.1% had 1cm lengthening and 5.6% had 1cm shortening. Regarding pain intensity, most (94.4%) of the studied group didn't have pain while only 5.6% of them had mild pain. Concerning deformity, about two thirds (77.8%) of the studied group didn't have deformity while < 5 ° varus, < 5° anterior and < 5° posterior occurred in 11.1%, 5.6% and 5.6% of the studied group respectively.

the final outcome was 83.3% had excellent functional outcome, 11.1% of them had satisfactory functional outcome and 5.6% had poor functional outcome. Our outcome is consistent with **Govindasamy *et al.*** [9] whose clinical evaluation was done using Flynn's criteria and their results were excellent in 40 children (83%) and satisfactory in eight children (17%). No child had poor result. Out of 48 cases, 5 cases (10%) had limb length shortening, out of which, four children had shortening of less than 5 mm which was insignificant. The final outcomes of **Nascimento *et al.*** [12] were deformities as valgus in 12 (40.0%), varus in 3 (10.0%), anterior angulation in 23 (76.7%), posterior angulation in 5 (16.7%), other hospitalizations in 28 (93.3%) and complaints in 3 (10.0%).

Nascimento *et al.* [12] found that the final shortening on the limb, after a follow-up period of at least 24 months, occurred in 6.7% of the cases (two patients), with 0.25 cm on average. There was overgrowth in 60% (18) of the patients and the overgrowth was 0.66 cm on average (range 0 to1.50 cm). Complaints about the treatment were noted among three (10%) of the patients. One patient complained about pain in his knee. The second patient complained about knee pain and deformity (18 of valgus) as well. A third patient complained about pain in his thigh. In contrast to our study, **Frei *et al.* [8]** reported that out of 22 children, there were excellent result in 6 (27.3%), satisfactory result in 10 (45.5%) and poor result in 6 (27.3%).

Regarding complications, most of the studied group (88.8%) didn't have any complications, 5.6% of them had irritation and 5.6% had superficial infection. This is similar to **Shemshaki *et al.* [13]** where out of 23 children, three patients had postoperative infection (13%). Also, **Govindasamy *et al.* [9]** found that the most common problem encountered in their study was skin irritation and impingement due to the distal nail ends in 12 cases (25%). Finally, in **Frei *et al.* [8]** study, two of 22 children (9%) experienced reactive bursitis, one child (4.5%) suffered from subcutaneous nerve irritation due to a protruding distal nail end, and one child (4.5%) experienced proximal cortical perforation of the nail end.

CONCLUSION

Elastic stable intramedullary nailing (ESIN) is minimally invasive, safe, physical protective, relatively easy to use and an effective treatment for fracture femur in properly selected children with minimal complications. The surgical method brings few complications and results in good limb alignment, with a short period of hospitalization and early return to daily activities and school. 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 ESIN for pediatric femoral shaft fractures in younger children. Further trials with longer follow-ups and comparison of elastic stable intramedullary nailing (ESIN) with other methods, such as external fixation, in children's femoral fractures are warranted. Further studies should be conducted with more subjects and using further classification scores. Therefore, we recommend obtaining intraoperative Dunn images at the end of the operation to confirm correct rotational alignment of the fracture fragments after stabilization with ESIN. Further multicentric prospective studies are required to confirm our findings.

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