

Original Article

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Diaphyseal Femoral Fracture in Skeletally Immature Patients Comparative Study between Elastic Nails and Plating

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Background: Diaphyseal femoral fractures account for 7.6 percent of long bone fractures and 1.4-1.7 percent of total fractures in skeletally immature patients. This study aimed to compare the outcome of operative fixation of femoral shaft fracture, between Titanium elastic intramedullary nails (TEINs) and Plating in skeletally immature patients. Methods: From June 2021 to November 2021, a prospective clinical research was undertaken on 24 patients with diaphyseal femoral fracture at Zagazig University Hospitals (ZUH) in Egypt and Tripoli Central Hospital in Libya. Patients were divided into 2 groups, 12 cases in each group, first group underwent fixation with Titanium elastic intramedullary nails (TEINs), 2nd group underwent open reduction and internal fixation by plate and screws. All patients had Radiological evaluation to affected whole limb after exclude any serious injury with six months follow-up. **Results**: There was statistically significant difference (p value<0.001) regarding operative blood loss between the two groups with mean blood loss was (75.0±24.36) ml for Titanium nail group and (175.0±58.69) ml for plate group. In the Titanium nail group, the mean time to fracture consolidation was (13.08±1.97) weeks while in plate group was (10.16±1.85) weeks with significant difference (p < 0.001). Complications were relatively higher in Titanium nail group. Conclusions: In our series nail showed more favorable outcome, less surgical morbidities and better rehabilitation as evident by - Less blood loss during surgery; Shorter operative time; Accepted time required for union.

ABSTRACT

Keywords: Titanium elastic nail; Compression plate; Elastic Nails; Femur fracture in children

INTRODUCTION

High velocity road traffic accidents are the most prevalent causes of femoral fractures in skeletally immature patients, followed by motorcycle falls, falls from great heights, and abuse in younger age children, which is the most common fracture type requiring hospitalization in children[1,2].

Diaphyseal femoral fractures account for 7.6 percent of long bone fractures and 1.4–1.7 percent of total fractures in skeletally immature patients[**3**].

The aim of fracture treatment in skeletally immature patients is rapid healing without complications, easy nursing care, rapid rehabilitation and minimal negative psychological impact on children and their families[4].

There is a growing trend for operational fixation in skeletally immature patients with diaphyseal femoral fractures in order to achieve quick healing and prevent extended immobility[**5**].

Multiple fixation procedures are available to the surgeons but the optimal approach is a point of debate in skeletally immature patients [6].

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Among the recent years, various studies and authors used and reported various approaches for treating femoral shaft fractures in skeletally immature individuals, some of these techniques as conservative, as traction followed by hip spica casting, or interventional procedures such as closed reduction and internal fixation (CRIF) with elastic nails, open reduction and internal fixation (ORIF) with plate, and external fixators. **[7]**.

Usually the preferred treatment of isolated femoral shaft fracture in preschool age is closed reduction with conservative Spica casting, elastic intramedullary nailing in children weight <50kg, has satisfactory outcomes, in adolescents and children weight >50kg the rigid intramedullary nailing and sub muscular plating widely used[8].

The most prominent causes producing debate in these cases are the developing treatment modalities provided and a lack of high quality evidence studies establishing one therapy modality to be superior than another, despite the fact that elastic nails have been the best rated treatment since 1990, with features like its shortening operation time, minimally invasive, and early mobilization, less cost with shortening hospital stay.[2] However, new reports of problems such as shortening, mal-union, and nonunion, as well as technical challenges in the technique, have suggested that plating may be an acceptable option to elastic intramedullary nails in comminuted or length unstable fractures,[9] provided excellent stability and maintenance of length in unstable fractures, but required a large exposure, resulting in extensive soft tissue injury and stripping of the fracture site and skin scarring[4]. The purpose of this study was to compare the results, complications and outcomes of two different fixation methods: plates and titanium nails of femoral shaft fractures in skeletally immature patients' children aged up to 16 years.

METHODS

The study had been conducted on 24 patients with diaphyseal femoral fracture. 12 cases underwent fixation with Titanium elastic intramedullary nails (TEINs) (7 males and 5 females) the mean age (9.43 ± 2.61) years and the

second group with 12 underwent open reduction and internal fixation by plate and screws (8 males and 4 females) the mean age (10.23 ± 3.61) years. Approval was obtained through the Institutional Review Board (IRB), as well as informed written consent from all patients' parents, who were given an explanation of the surgery, potential risks, and follow-up regimen. This research was carried out with the accordance World Medical in Association's (WMA) code of ethics for human studies (Declaration of Helsinki). Criteria for inclusion: Age and gender skeletally immature patients: Male up to 16 years old, Female up to 14 years old. Fracture femoral fracture. Closed fracture. Non pathologic origin. Exclusion Skeletally mature patients. criteria: Open fractures. Significant systemic co-morbidities / injuries. Patients unfit for surgery or anesthesia. Children whose parents will not give consent for the study.

Pre-operative:

All patients underwent full clinical examination to detect any associated injuries, ecchymosis and neurovascular injury on the affected limb. Plain X-rays of the femur were obtained in the Anteroposterior (AP) and Lateral (Lat.) perspectives (from the hip to the knee joint). Complete blood count (CBC), RBS, and Renal function tests (RFT) were among the tests performed at the lab. The surgery was carried out under general anesthesia. Prophylactic broad-spectrum antibiotic (Third generation cephalosporin) was taken with the induction of anesthesia (intravenously 30–60 min before surgery).

Surgical technique:

Elastic nails group

After anesthesia, the patient was placed on a radiolucent table in a supine posture. Then we started draping the limb from iliac crest to the Ankle. Two Elastic nails are chosen according to their diameter depending on the age and medullary canal diameter, measure the isthmus of the medullary cavity on the X-ray image. The diameter of the individual nail (A) should be 30–40% of the diameter of the medullary cavity (B).

Choose nails with identical diameter to avoid varus or valgus mal positioning. For the nail entry, define nail insertion points; for the retrograde technique, the insertion points on the femur are 1–2 cm, about one to two fingerbreadth proximal to the upper pole of the patella; a 1-2 cm long skin incision was made in the supracondylar area medial and lateral; then subcutaneous fat and deep fascia were opened bluntly until reaching the bone.

For effective symmetrical bracing, an open medullary cavity with perfectly matching openings on both sides is required. Insert the awl vertically against the bone and firmly make a centre mark with rotating movements, then move the awl down to a 45° angle in reference to the shaft axis, the opening should be slightly larger than the selected nail diameter. Check the position and insertion depth of the awl with the image intensifier.

Under Fluoroscopy, we put the nail on the skin and the level of the fracture was determined and we bend both nails at this level, the peak of the arch should be at the level of the fracture zone, and the arch should be continued by the nail tips.

Insert the first nail into the medullary cavity with the nail tip at right angles to the shaft (1), then turn the inserter through 180° (2) and align the nail tip with the axis of the medullary cavity (3), and use the C-arm X-ray to double-check the location of the nail tip.

Advance the first nail to the fracture site, manually up to the fracture site, using rotating movements or gentle taps by hammer against the striking surface of the inserter, then advance the second nail, at the opposing insertion point, thereby producing the first crossover of the nails, then advance the nails alternately across the fracture site. Check the passage of the nails with the image intensifier in both planes also on the other side of the fracture site (**Fig. 1**).

After the tip of both nails reaches above lesser trochanter, we cut them off before achieving a final position to drive them in a little. The nail ends are left just enough to grab later when removing but not too much to irritate the soft tissue (about 1 cm proud).

Plate group:

After anesthesia, all patients were placed in a supine position with the, drape the limb from the iliac crest to the ankle. Proceed with the Lateral approach to the femur by incising the skin, then the subcutaneous fascia and Iliotibial band in line with the skin incision, then bluntly separate the vastus lateralis from lateral intermuscular septum and elevate the muscle extraperiosteally using Hohman retractors. careful detection and ligation of perforator vessels is achieved. Expose the fracture site then remove any soft tissue interposition between the proximal and distal ends of fracture, then reduction is achieved and maintained by traction and rotation of the limb by using bone reduction clamps. Apply stainlesssteel DCP plate, fixed to the bone with at least 3-4 screws in the proximal and 3-4 screws distal to the fracture ,4 screws proximal and distal to the fracture site provide adequate stability (Fig. 2). Closure of the wound was done in layers over the drain and, immobilization.

Post-operative follow up:

IV antibiotic was continued for 3 days then shifted to an oral broad-spectrum antibiotic to all patients for 1 week. Post-operative hemoglobin (Hb) was done to all patients. Drains were kept for 24 hours. Slab were removed after 2 weeks. All patients were followed up on two weeks after surgery for suture removal, start non-weight bearing and measure range of motion after 4 weeks for a follow-up X-ray, and learn patients and their relative exercises of the hip and knee, After 6-8 weeks for follow up x-ray, starting partial weight bearing according to the radiological union, after 3 months for a follow-up x-ray. Flynn's scoring standards were used to assess the patients' ultimate outcomes six months after surgery.

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Statistical analysis

Data were checked, entered and analyzed using Statistical Package for the Social Sciences (SPSS version 20.0) for data processing. Data were expressed as number and percentage, quantitative continues group represent by mean \pm SD, the following tests were used to test differences for significance; Difference and association of qualitative variable by Chi square test (X2). Differences between quantitative independent groups by t test. P value was set at <0.05 for significant results & <0.001 for high significant result.

RESULTS

We studied 24 patients with range of age 5-16 years and allocate them in two groups; 12 in Titanium Nail Group and 12 in Plate Group.

No significant difference founded between groups regard Mechanism of injury and the majority were RTA. No significant difference between groups and the majority were class (A) in both groups (**Table 1**).

Operation duration was significantly shorter in nail group and blood loss was significantly lower in nail group (**Table 2**).

No significant difference regarding hospital stay but union time was significantly longer in nail group (**Table 3**).

No significant difference or association except infection as it significantly association with plate group (**Table 4**).

There was no significant difference between groups regard ROM or Flynn's score for outcome (Table 5).

 Table (1): Mechanism of injury and Classification distribution between groups

			Titanium Nail Group	Plate Group	t/ X ²	Р
Mechanism of injury	RTA	Ν	9	8		
		%	75.0%	66.7%		0.65
	Sport	Ν	3	4	0.202	
		%	25.0%	33.3%		
AO classification	Α	Ν	8	9		0.65
		%	66.7%	75.0%		
	В	Ν	4	3	0.202	
		%	33.3%	25.0%		
Total		Ν	12	12		
		%	100.0%	100.0%		

	Titanium Nail Group	Plate Group	Т	Р
Operation duration/minutes	39.58±5.41	76.66±8.34	12.907	0.00**
Blood loss / ml	75.0±24.36	175.0±58.69	4.899	0.00**

Table (3): Hospital stay and Union time distribution between groups

	Titanium Nail Group	Plate Group	t	Р
Hospital stay/ days	3.75±0.75	3.66±0.77	0.266	0.792
Union Time/ weeks	13.08±1.97	10.16±1.85	3.733	0.001**

			Group		X ²	Р
		Titanium Nail Group	Plate Group	Λ^2	P	
Discrepancy	No	Ν	7	10		
		%	58.3%	83.3%		
	Yes	Ν	5	2	1.81	0.17
		%	41.7%	16.7%		
Infection	No	Ν	12	9		
		%	100.0%	75.0%		
	Yes	Ν	0	3	3.42	0.06*
		%	0.0%	25%		
Deformity	No	Ν	8	11		
		%	66.7%	91.7%		
	Yes	Ν	4	1	2.27	0.13
		%	33.3%	8.3%		
Stiffness	No	Ν	10	12		
		%	83.3%	100.0%		
	Yes	Ν	2	0	2.18	0.14
		%	16.7%	0.0%		
Total		Ν	12	12		
		%	100.0%	100.0%		

Table ((4):	Com	plication	distribution	between	groups
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Table (5): Outcome distribution between groups

			Titanium Nail Group	Plate Group	t/ X ²	Р
	Encollort	Ν	9	8		
	Excellent	%	75.0%	66.7%		
FLYNN	FLYNN Satisfactory	Ν	1	3	1.39	0.499
		%	8.3%	25.0%		
	n	Ν	2	1		
	Poor		16.7%	8.3%		
NTotal%		12	12			
		%	100.0%	100.0%		



Figure 1: Introducing Elastic nails through entry point till fracture level then advance the nails alternately across the fracture.



Figure.2: Applying the screws to the plate

DISCUSSION

Regarding mechanism of injury among the included patients in our study, the commonest mechanism of injury was rood traffic accidents RTA among 9 patients (75.0%) of Titanium nail group and 8 patients (66.7%) of plate group, followed by sport trauma injuries with 3(25.0%) of Titanium nail group and 4 patients (33.3%) of plate group. No significant difference founded between the two groups.

These classifications were similar to that mentioned by **Allen et al.** [10] that stated the commonest mechanism of trauma was highenergy mechanisms (motor vehicle collision, motorcycle crash, and all-terrain vehicles) accounted for 49.2% of fractures, falls 24.6%, pedestrian struck by vehicle 10.8%, and other (sports, downhill sled crashes, etc.) 15.4%.^[75]

AO/OTA international classification:

The AO/OTA international classification for the classification of fractures was used, where type (A) (simple, transverse or oblique cut), type (B) (middle fragment wedge shaped). The AO classification models comprehensively are documents all fractures type overall the body, which guides the doctors to recognize the fractures and proceed for the proper treatment[11].

The current study AO/OTA classification showed that the majority were classified (A) in

both groups, where 8 patients (66.7%) were classified (A) compared to 4 patients (33.3%) classified (B) with Titanium nail group and 9 patients (75.0%) classified (A) compared to 3 patients (25.0%) classified (B) with plate fixation group with no significant difference among the two groups. Comparable results were identified by Olivo et al.[12] as they showed most of patients were classified A, whereas 10 patients (5 in Elastic Stable Intramedullary Nailing vs 5 in Locking Compression Plates) [12]. Also and Hussein, revealed that 16 **Bastawisv** (53.3%) were classified as type (A) compared to 8 (26.7%) as type (**B**) and 6 (20%) as type (**C**) and demonstrated that 8 (50%) in titanium elastic nails (TEINs) group were subclassified as type (A1) compared to 8 (57.1%) in compression plate group, nevertheless 6 (37.5%) were subclassified as type (B1) in titanium elastic nails (TEINs) group in comparison to 2 (14.3%) in compression plate group [3].

Operation data (Operative time & Blood loss):

The t-test was employed to compare operation time and blood loss between the two treatment groups. There was a substantial difference in operating time and blood loss, according to our findings (the values in plate group are significantly larger than nail group).

Operative time:

In our study there was significant difference (p < 0.001) in operative time between the two groups with mean time of 39.58±5.41 minutes for Titanium nail group and 76.66±8.34 minutes for plate group. These findings were in agreement with **Ahmed et al, Caglar et al., Carlos Acosta Olivo et al. and Said** that they showed significance decrease time in nailing compared to plating [**12,13,15,16**]. In addition to **Jolly et al.,** who found that the average operation time in the TEINs nail group was 37 minutes, compared to 63 minutes in the compression plating group [**2**].

Intraoperative blood loss:

In our study there was statistically significant difference (p value<0.001) regarding operative blood loss between the two groups with mean blood loss was (75.0 ± 24.36) ml for Titanium nail group and (175.0 ± 58.69) ml for Plate group.

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Similar results were reported by **Bastawisy and Hussein**, who stated that the mean blood loss in Titanium elastic nails groups was (35.94 ± 38.78) ml less than the mean blood loss in plate group (109.36 ± 40.47) ml with highly statistical significance (p<0.001) [3]. Reddy et al. reported decreased mean blood loss level in Titanium nailing group (TEINs) (45.3 ± 6.58) ml than that in plating group (106.5 ± 1.89) ml [5]. Similarly, Jolly et al. noted the intraoperative blood loss in the TEINs nail group was 24 ml, whereas in the compression plating group it was 116 ml[2].

Post-Operative Data:

Time of union in weeks:

In our study, the Titanium nail group had a mean time to union (13.08 ± 1.97) weeks, whereas the Plate group had a mean time to union (10.16 ± 1.85) weeks with significant difference (p< 0.001) showing longer union time in the first group.

These findings were in line with those reported by **Jolly et al.[2]**, who stated that the average time for fracture union in the compression plate group was 10.7 weeks and 14.7 weeks in the Elastic nails TEINs group.,[2] also **Milligan, et al. [17]** and **Olivo CA, et al. [12]** reported that more time to union was in Elastic nails group than Plate group. **Sutphen et al.** in comparative study reported that the plate group had a significantly shorter time to union than the rigid nail group and the elastic nail group [**18**].

Complications:

Common complications of femoral shaft fractures in children are limb length discrepancy LLD, malunion/angulations, rotational deformity, Infection, delayed union and nonunion different treatment methods are being used to treat these patients depending upon type, site and age of child **Basset t et al. [19].**

Elastic intramedullary nails are limited by higher reported complication rates, limb length discrepancy LLD, and malunion, especially for patients heavier than 49 kg. Plating techniques are an important alternative to TEINs, indicated in length-unstable fracture patterns or patients weighing >49 kg. The submuscular plate technique has gained popularity for limited exposure Luo et al. [20].

In the current study and in most of the other studies, here was no significant difference in the complication rate between both methods, except in infection rate, where 3 patients (25%) treated with Plating had infection compared to none had infection in Titanium group (p=0.06) and discrepancy in 2(16.7%) patients with plating group. This finding was in line with Shah et al. [21] who had observed superficial skin infection in 4(6.6%) children and limb length discrepancy (LLD) in 3(5%) children. Our findings were also consistent with Said [16], who found no cases of infection in the TEINs group but two cases of infection (7.1%) in the plating group. In contrast to ours, Shemshaki et al.[22] reported where out of 23 children, three patients had postoperative infection (13%) during the use of Titanium elastic nailing technique [21].

In our study, regarding the complication occurred in Titanium nail group, we had observed limb length discrepancy LLD in 5(41.7%), deformity in 4(33.3%), stiffness and delay union time in 2(16.7%), while no one in this group had an infection. Regarding the complication occurred in Plate group, only one patient (8.3%) had deformity and/or delay of union time, while no patients had stiffness. In the current study, the patients in plating group had minimal complication rate compared to Titanium nails group. These findings were consistent with Xu et al., [23] who identified that TEINs had an equivalent complication rate to plating (18% in the TEINs group vs. 14% in the plate group, P=.073) [23].

Unstable subtrochanteric and proximal fractures particularly in older and obese children when treated with elastic intramedullary nails results in high complication rates like delayed union, malunion, limb length discrepancy LLD and refracture after implant removal, **Sagan et al.**, found a complication rate of 4-38% [24].

Flynn score:

The final functional outcomes evaluated by using Flynn scoring system was classified into excellent, satisfactory, or poor based on residual leg-length inequality, fracture malalignment, pain, complications, and unplanned surgery for the treatment of complications[25].

Our study outcome distribution in Titanium nail group according to Flynn score, showed 9 patients (75%) with an excellent outcome 1 patients (8.3%) with satisfactory outcomes and only 2 patients (16.7%) with poor outcomes. Also, **Lokesh, D. et al.** who reported a study of 30 children with pediatric femoral shaft fractures were fixed with Elastic nails according to Flynn criteria score, the study reported 13 patients had excellent outcomes, 14 patients had good outcomes and 3 patients had poor outcomes[26].

While the outcome distribution in plate group in our study according to Flynn score, showed 8 patients (66.7%) with an excellent outcomes 3 patients (25%) with satisfactory outcomes and only 1 patient (8.3%) with poor outcomes.

There was no significant difference between groups regard ROM or Flynn's score for outcome as we agreed with **Bastawisy and Hussein**, who stated that the final functional outcome difference between the two groups is insignificant according to Flynn's score [3].

CONCLUSION

As evidenced by-Less blood loss during surgery; Shorter operative time; Accepted time required for union in our series, nail had a better outcome, fewer surgical morbidities, and better rehabilitation. To reduce the risk of postoperative complications, both systems require precise preoperative planning and advanced surgical experience.

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