



# ELASTIC STABLE TITANIUM FLEXIBLE INTRAMEDULLARY NAILS VERSUS PLATES IN TREATING FEMORAL SHAFT FRACTURES IN CHILDREN

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## Abstract

**Background:** The fundamental idea behind fracture therapy is to first achieve a precise fracture reduction before using an immobilization technique that will keep the reduction in place. In order to compare open reduction internal fixation (ORIF) by plate vs Nancy nails in the management of diaphyseal femur fracture in children, the objective of this study was to evaluate the radiographic and functioning results.

**Methods:** This prospective, randomised work was carried out on 30 individuals with diaphyseal fractures of the femur. Patients divided into 2 equal groups: group A (Plate group): was treated by ORIF using plates and screws and group B (Nancy group): was treated by fixation using Nancy nails.

**Results:** Correlations between operative parameters as intraoperative blood loss in the two groups showed statistically substantial variations in favor of Nancy nails. However, no statistically substantial variations were existed among the two groups as regard time of the operation, intraoperative blood transfusion, functioning results assessed at the end of 6-month period and the correlations between radiological union regarding time to union, angulation and rotational deformity. Infections risk was higher in the Plate group despite using the same antibiotic and applying the same precautions in both groups but there was no statistical significance.

**Conclusions:** The operative parameters were superior with Nancy nails in the management of pediatric fractures of shaft femur compared with ORIF by plate and screws.

**Keywords:** Intramedullary Nails, Elastic Stable Titanium, Plates, Femoral Shaft Fractures

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## Introduction:

Femoral Fractures in children are the most prevalent orthopedic injury requiring hospitalization. Causes of pediatric femoral fractures include motor vehicle accidents, falls, pedestrian injuries, child abuse and minimal trauma which cause a fracture in abnormal bones <sup>[1]</sup>.

Clinically patients with fracture femur suffer from pain, inability to ambulate, swelling and deformity (shortening and external rotation). Diagnosis is usually established clinically together with plain X-rays in anteroposterior- and lateral-views of the femur <sup>[2]</sup>. Pediatric shaft femur fracture can be managed by conservative treatment through traction following by spica casting, or via spica casting, intramedullary fixation, external fixation, or plate fixation. For children 6 to 12 years old, the choice of treatment is controversial <sup>[3]</sup>.

Pediatric femoral fractures may be effectively treated with plate fixation. The technique's familiarity and the availability of equipment are benefits. Furthermore, tight attachment in anatomic alignment permits quick mobilization. On the other hand, it disrupts fracture hematoma and carries the risk of bleeding and infection <sup>[4]</sup>.

Intramedullary fixation has been gaining popularity. Several methods have been used including rush-pins and multiple wiring. Surgeons working in Nancy city, France were able to use Elastic stable intramedullary nailing (ESIN) as a load-sharing, rigid, yet elastic internal splinting device to maintain reduction with high stability. It applies the concept of relative stability inducing callus formation. Disadvantages include soft tissue irritation, non-anatomical reduction and high risk of radiation exposure <sup>[5, 6]</sup>.

The purpose of this study was to compare the results of the managing of shaft femur fracture by using ESIN VS open reduction internal fixation (ORIF) by plate regarding the functional and radiological outcomes. Preoperatively, all patients will be evaluated by a standardized evaluation scheme thorough history, clinical examination, functional evaluation and radiological evaluation.

## Patients and Methods:

This prospective randomised study was performed on 30 individuals ranging in age from 6 to 13 yrs old, both genders, with clinical criteria of kids who had femur diaphyseal fractures, independent walking

children, mid-shaft fractures of the femur, closed fractures and isolated femur fracture.

After receiving clearance from the Kasr El-Ainy Faculty of Medicine's Ethical Committee, the research was carried out. The patient or the patient's relatives provided their explicit written approval.

Exclusion criteria were patients below 6 or above 13 years old, epiphyseal and metaphyseal fractures, open, pathological fractures and associated fractures.

Participant groups were split into two: group A (Plate group): was managed by ORIF using plates and screws and group B (Nancy group): was treated by fixation using Nancy nails.

**Randomization:** The patients were randomized by sealed opaque envelop technique by alternating between both techniques.

All patients underwent the following: taking of the history, clinical assessment, radiological evaluation (plain x-ray) along with laboratory tests [complete blood count (CBC), platelet count (PC), prothrombin time (PT), international normalized ratio (INR), alanine aminotransferase (ALT), aspartate aminotransferase (AST), blood urea nitrogen (BUN), random blood sugar (RBS), and creatinine].

Evaluation of all patients in both groups was done as follow: Operative time, blood loss, blood transfusion, radiation exposure, time to union, leg-length discrepancy, deformity, non-union, infection and Flynn Scoring system. (Table 1)

**Table 1: Evaluation of all patients in both groups was done as follow**

	Excellent result	Satisfactory result	Poor result
<b>Limb-length inequality</b>	< 1.0 cm	< 2.0 cm	> 2.0 cm
<b>Malalignment</b>	5 degrees	10 degrees	> 10 degrees
<b>pain</b>	Non	Non	present
<b>Complication</b>	Non	Minor and resolved	Major and lasting morbidity

After admission, the broken limb received skin traction while the bony prominence was properly padded. adequate mobilization and analgesia while in bed. General anesthesia was used for all patients' anesthesia. Along with the onset of anesthesia, a preventative broad-spectrum antibiotic (3rd generation cephalosporin) was administered. (30–60 minutes prior to the operation, intravenously).

### Operative technique

**Plate group:** The lateral posture was used for each participant with the affected femur upward. Drap the limb from the iliac crest to the ankle. The skin was first cut, followed by the subcutaneous fascia and iliotibial band aligned with the skin incisions as we continued with the lateral approaches to the femur. Next, we bluntly separate the vastus lateralis from lateral intermuscular septum and elevate the muscle extraperiosteally using Hohman retractors. 4.5-mm narrow stainless-steel DCP plate was prebented, at least 3 screws distally to the fractures and 3 screws proximally attached to the bone. Closure of the wound was done in layers over the drain.

**Nancy group:** On a radiolucent table, the patient was lying down in the supine position. Then we started draping the limb from iliac crest to the Ankle. Two flexible nails were chosen according to their diameter depending on the age and medullary canal diameter (9 patients used 3mm, 3 patients used 3.5mm, 3 patients used 4 mm). Under Fluoroscopy, we put the nail on the skin then the level of the fracture was determined and both nails were bent at this level. Up till the bone, deep fascia and subcutaneous fat were established bluntly. To expose the nearby cortex and route it proximally into the medullary cavity, an owl was placed at the entrance location. The previous steps were repeated on the other side. Pre-bent nails of similar diameter (40% diameter of the canal) and similar curvature

were introduced from medial and lateral entry points till the level of fracture while reducing the fracture. Reduction of fracture under image intensification was achieved by traction then pass nail across the fracture site. After the tip of both nails was reached above lesser trochanter, we cut them off before achieving a final position to drive them in a little. In the outpatient clinic, each patient was monitored in the following manner:

- Two weeks later: There was a follow-up injury and the sutures were removed.
- Four weeks later: We began knee range-of-motion exercises without weight bearing.
- At six weeks: Based on a follow-up x-ray, participants began putting some weight on their feet.
- Three months later: A further x-ray was taken.
- Six months later: Further imaging and the Flynn scoring system were performed.

### Sample Size Calculation:

A total of thirty patients: fifteen patients underwent fixation by Nancy nails (Nancy group) and fifteen individuals had internal fixation by plate and screws during open reduction (Plate group). The mean age for group A was 9.62 years while in group B, the mean age was 8.23 years.

### Statistical analysis

SPSS v26 (IBM Inc., Chicago, IL, USA) was used for the statistical analysis. Quantitative parameters were displayed as mean and standard deviation (SD)

and contrasted between the two groups using unpaired Student's t-test. Qualitative parameters were displayed as frequency and percent (%) and

analyzed using the Chi-square or Fisher's exact test when appropriate. A two-tailed P value < 0.05 was considered statistically significant.

**Results:**

No statistically substantial variation was existed among the two groups regarding operative time,

intraoperative loss of blood and time to union (Table 2).

**Table 2: Comparison between the two studied groups according to operative time, intraoperative blood loss and time to union**

	Group A	Group B	P-value
Intraoperative time (min)	70.38±24.02	63.46±26.49	0.362
Blood loss (ml)	70.38± 24.02	63.46±26.49	0.362
Time to union (weeks)	8.92±1.26	7.69±1.65	0.057

Data are presented as mean ± SD.

no statistically substantial variation was existed among both groups as regard leg length

discrepancy (LLD), rotational deformity and Flynn score after 6 months (Table 3).

**Table 3: Comparison between the two studied groups according to LLD, rotational deformity and Flynn score after 6 month**

		Group A N (%)	Group B N (%)	P value
Rotational deformity	cm 0	15 (100.0%)	13 (86.66%)	0.1
	Below 2 cm	0 (0.0%)	2 (13.33%)	
	2 cm	0 (0.0%)	0 (0.0%)	
Rotational deformity	No	15 (100.0%)	14 (93.33%)	1
	< 10 degrees	0 (0.0%)	1 (6.66%)	
Flynn score	Excellent	11 (73.33%)	12 (80%)	0.249
	Satisfied	4 (26.66%)	3 (20%)	
	Poor	0 (0.0%)	0 (0.0%)	

Data are presented as number (%).

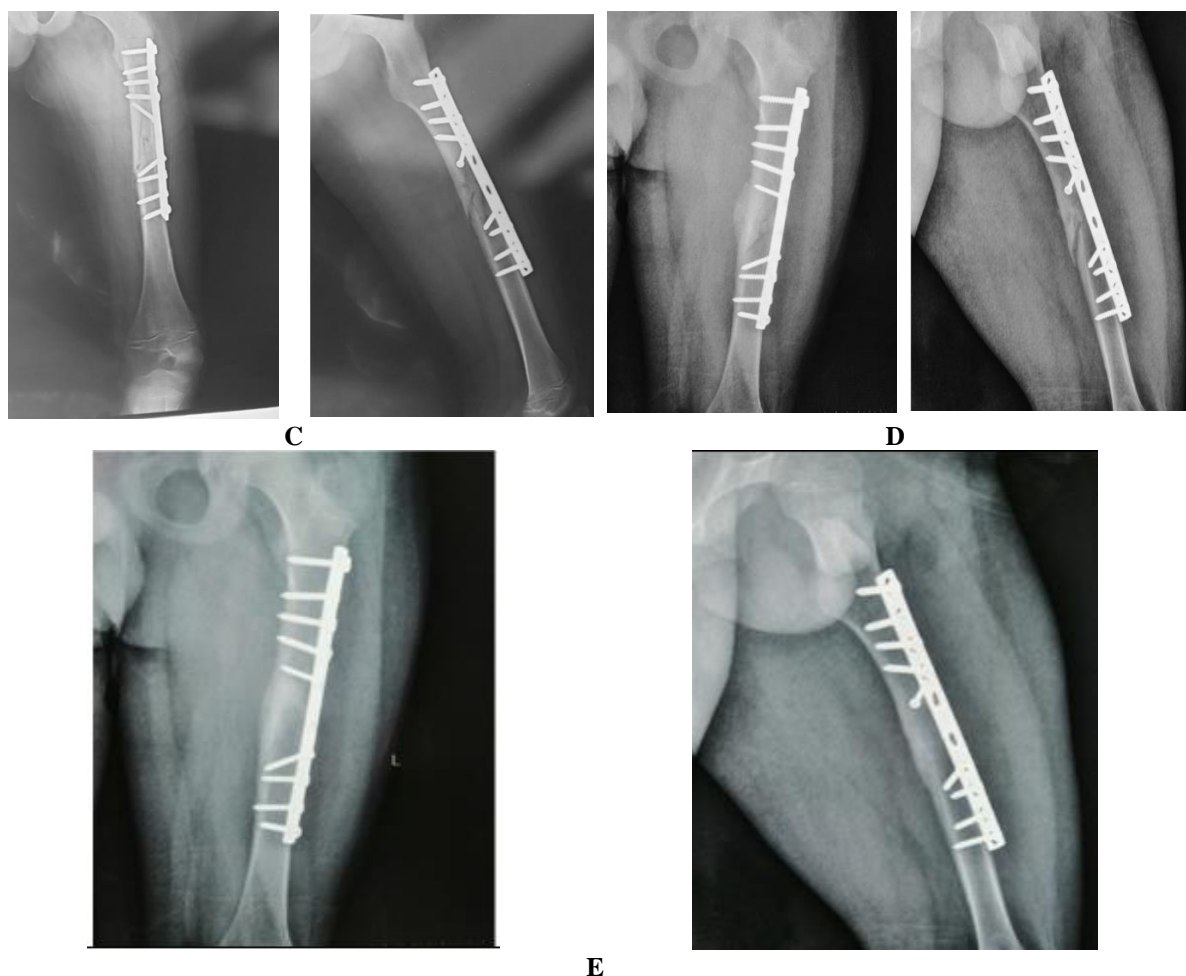
**Case 1**

12-year-old male patient presented with isolated fracture mid-shaft left femur type 32-D/5.1 according to AOPCCF classification from RTA. On admission, primary survey, clinical assessment, and plain X-rays in the AP and lateral views were ordered. Skin traction for the initial reduction of the fracture was applied. The patient was prepared for ORIF. Figure 1

At 3-month period: follow-up x-ray and full weight-bearing. After 6-month period: Follow-up x-ray and assessment of Flynn score. **Functional assessment after six months were:** no malalignment. No LLD. Absent knee pain. Full knee ROM. No limping. Clean healed wound. Flynn's scoring at 6 months was excellent. **Radiological assessment after six months were:** Fracture union. No angular deformity. No rotational deformity.

**Follow up:** At 2 weeks: removal of sutures. At 6 weeks: follow-up x-ray and partial weight-bearing.





**Figure 1:** AP and Lateral view X-rays (A) with Skin traction applied, (B) post-operative X-rays, (C) follow-up at 6 weeks, (D) follow-up at 3 months and (E) follow-up s at 6 months

**Case 2:**

7-Year-old male patient presented with isolated fracture mid-shaft left femur type 32-D/4.1 according to AOPCCF classification from RTA. On admission, primary survey, clinical assessment, and plain X-rays in the AP- and lateral-views were ordered. Skin traction for the initial reduction of the fracture was used. The participant was prepared for Nancy nail fixing on the same day of admission (Figure 2).

**Follow up:** At 2 weeks: follow-up x-ray and sutures was removed. At 4 weeks: removal of slab and non-

weight bearing exercises. At 6 weeks: follow up x-ray and partial weight-bearing.

At 3-month period: follow-up x-ray and full weight-bearing. After 6-month period: Follow-up x-ray and assessment of Flynn score. Functional assessment after six months was: No malalignment. No LLD. Absent knee pain. Full knee ROM. No limping. Clean healed wound. Flynn's scoring at 6 months was excellent. Radiological assessment after six months was: Fracture union. No angular. Deformity. No rotational deformity.



**Figure 2: AP and lateral X-rays (A) with a mid-shaft fractured femur, (B) immediately postoperative, (C) at 2 weeks postoperative, (D) after 6 weeks (E) at 3 months follow-up and (F) at 6 months follow-up**

**Discussion**

The usage of intramedullary fixation has been gaining popularity and numerous surgeons recommended it. The use of elastic stable IM (Nancy) nails allows functional reduction, stable three point's fixation allowing relative stability with micro-motion which encourages healing and union. Operative time in this work was less in Nancy group compared to Plate group with no statistically substantial variation among both groups. Our study was comparable with Yi Luo et.al. [7] and Wang et

al. [8] which stated a rise in operative time of Plate Group contrasted to Nancy group but there were statistically significant (p-value =0.07) (p-value =0.04) (p-value <0.05).

Intraoperative blood loss in this is work was more in the Plate group than the Nancy group with a statistically substantial variation among the two groups (p-value < 0.001). Our study was comparable with Yi Luo et al [7] and Wang et al. [8] who reported that a statistically substantial variation was existed among the Plate group and Nancy group in

intraoperative blood loss (p-value =0.057) (p-value =0.006) (p-value <0.05).

Time to union in this work was shorter in the Nancy group than the Plate group but no statistically substantial variation was existed among both groups (p-value =0.057). Our results were comparable to Yi Luo et al.<sup>[7]</sup> who stated that time to union was shorter in Nancy group than Plate group but there was no statistically significant (P =0.48). Also, Wang et al.<sup>[8]</sup> reported that union time in Nancy group was substantially less than in the Plate group (p <0.005). Milligan et al.<sup>[9]</sup> reported that mean time to union was less in Plate group than Nancy group but there was no statistically substantial (P =0.098). Olivo CA, et al.<sup>[10]</sup> reported that more time to union was in Nancy Group than Plate group.

Wound infection was more in the Plate group than the Nancy group but no statistically substantial variation was existed among both groups. Wang et al.<sup>[8]</sup> stated that infection rate was greater in Nancy group than the Plate group but no statistically substantial variation was existed among the two groups (P > 0.05).

The angular deformity was higher in Nancy group than Plate group but no statistically substantial variation was existed among both groups. Our study was comparable with Milligan et al.<sup>[9]</sup> who reported that angular deformity was greater in Nancy group than Plate group but there was not statistically significant. Also Olivo CA et al.<sup>[10]</sup> reported that angular deformity was higher in Nancy group than Plate group. Wang et al.<sup>[8]</sup> reported that angular deformity was higher in Plate group than Nancy group but there was no statistically significant. Also, Yi Luo et al.<sup>[7]</sup> stated that there was no angulation deformity detected in the study. The rotational deformity was higher in Nancy group than the Plate group but no statistically substantial variation was existed among both groups. Our study was comparable with Olivo CA, et al.<sup>[10]</sup> who stated that rotational deformity was greater in Nancy group than Plate group. Yi Luo et al.<sup>[7]</sup> reported that there was no rotational deformity detected in the study.

LLD rate was higher in Nancy group than Plate group but no statistically substantial variation was existed among both groups. Our study was comparable with Olivo CA, et al.<sup>[10]</sup> who stated that the LLD rate was greater in Nancy group than Plate group. However, Milligan et al.<sup>[9]</sup> reported that the Plate group had more incidence of LLD than Nancy group with no statistically substantial variation among both groups. Yi Luo et al.<sup>[7]</sup> reported that there was not clinically detectable LLD.

The Flynn score was superior in Nancy group than the Plate group but no statistically substantial variation was existed among both groups. However, Milligan et al.<sup>[9]</sup> who reported that the Plate group was superior to Nancy group but no statistically substantial variation was existed in this score among both groups.

Other studies did not compare the rate of improvement according to the Flynn scoring system. Limitations: Increasing the sample size, Increasing the follow up duration.

#### Conclusions:

The operative parameters were superior with Nancy nails in the treatment of pediatric shaft femur fractures compared with ORIF by plate and screws as it shows better outcome over ORIF by plate and screws. It can be used in all fracture types with minimal scar and shows better outcome than Plate fixation. Nancy nails benefit from being straightforward, biological, simple to apply, less invasive, and requiring no blood transfusion after surgery.

In addition, it takes less time to unionize and doesn't significantly disrupt the growth of bones. Poor rotational control and a requirement for intraoperative irradiation are the potential problems.

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**Conflict of Interest:** Nil

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