Combined Elastic Stable Intramedullary Nail and External Fixation Versus Elastic Stable Intramedullary Nail Alone in the Management of Length-Unstable Pediatric Femoral Fractures: A Prospective Randomised Controlled Clinical Study

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Abstract:
Background: Femoral shaft fractures account for approximately 1.6% of fractures in the pediatric population. However, the optimal treatment modality for length-unstable fractures is still controversial.
Objectives: Our study aims to compare combined elastic stable intramedullary nail (ESIN) and external fixation (EF) versus ESIN alone in the management of length-unstable femur fractures in pediatric patients in terms of surgical, functional, and radiological outcomes.
Patients and Methods: Forty patients (20 in each group) with length-unstable femur fractures. First group was managed by ESIN and EF, and the other group was managed by ESIN alone. Both groups were compared in terms of surgical, functional, and radiological outcomes.
Results: The mean follow-up period was 8.4 ± 1.2 months in the ESIN group and 9.1 ± 1.6 months in the ESIN/EF group. Radiological outcomes, as measured by Beaty's criteria, have shown a statistically significant difference between groups. However, both groups has similar functional outcomes and rate of postoperative complications.
Conclusion: This study has demonstrated superiority of ESIN/EF over ESIN alone in terms of radiological outcomes with no significant differences as regards functional outcomes and postoperative complications.
Keywords: Length-unstable, Elastic stable intramedullary nail, External fixator.

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Introduction

Femoral shaft fractures represent approximately 1.6% of fractures in the pediatric population **(Kocher et al., 2009; Stoneback et al., 2018)**. Surgical treatment has been considered gold standard in management of diaphyseal femoral fractures in pediatric population (**Sutphen et al., 2016**). Different surgical options include elastic stable intramedullary nails (ESIN), external fixation (EF), submuscular plating (SMP), and combined techniques.

Length-unstable fractures refer to comminuted or spiral fractures where the length of the fracture line is two times or more the diameter of the femoral shaft at the fracture level. **(Kuremsky and Frick, 2007)**. This type of fractures often results in shortening more than 2 cm of femoral Length **(Samora et al., 2013)**, and associated with longer recovery time and higher risk of postoperative adverse events up to 80% as reported by **(Sink et al., 2005)**. However, the optimal treatment modality for length-unstable fractures is still controversial **(Soni et al., 2012)**.

ESIN are generally preferred in length-stable femoral fractures owing to early recovery, short hospital stay, minimal soft tissue dissection, and fewer complications (**Ramseier et al., 2010**). Nevertheless, the role of ESIN in length-unstable fractures remains unclear (**Ramseier et al., 2010; Siddiqui et al., 2020**). EF is theoretically a better option for length-unstable fractures. However, Many authors have shown high incidence of pin-tract infection, unacceptable shortening, longer union time, and refractures associated with EF alone **(Bar-On et al., 1997; Wani et al., 2016)**.

In their study which included 21 patients with length-unstable femoral fractures managed mostly by ESIN, Sink et al. reported an overall complication rate of 57% **(Sink et al., 2005)**. The authors concluded that methods other than ESIN should be used in children with length-unstable femoral fractures **(Flynn et al., 2001) (Sink et al., 2005) (Sink et al., 2010)**. Similarly, the American Association of Orthopedic Surgeons (AAOS) recommended the use of ESIN for transverse and short oblique diaphyseal femoral fractures. They recommended against usage of ESIN for management of length-unstable femoral fractures owing to the high rate of adverse events **(Jevsevar et al., 2015)**.

In this prospective study, we aim to compare clinical and radiological results of combined ESIN and EF with ESIN alone in pediatric femoral fractures with length instability. We hypothesized that combined ESIN and EF would achieve better outcomes compared to ESIN alone.

Patients and methods

This is a Prospective randomized comparative study including 40 patients (20 in each group) with length-unstable femur fractures. The Research Ethics Committee of our institution has approved the study protocol. Informed consent was obtained from the participants' parents.

All patients were enrolled according to the following inclusion criteria:

a) Age ≤ 11 years old.
b) Weight < 50 kg.
c) Closed, length-unstable femoral diaphyseal fractures.

The following exclusion criteria were implemented:

a) Pathological fractures.
b) Previous femur fractures or instrumentation.
c) Polytraumatized patients.
d) Bilateral fractures.

All patients were subjected to initial management and resuscitation. Detailed history taking including: age, sex, medical co-morbidities, and mechanism of injury was recorded preoperatively. General examination (general patient health and associated injuries), and local examination (overlying skin, swelling, deformity, and neurovascular status) were carried out.

Plain radiographs, including an antero-posterior (AP) pelvic view, AP and lateral radiographs of the affected femur showing hip and knee joints were performed for diagnosis, and assessment of the fracture pattern and length stability.

All patients were randomly assigned to undergo surgical fixation using either ESIN/EF or ESIN alone.

Surgical Technique

1- Patients were positioned supine on a radiolucent operating table.
2- Closed reduction was done under fluoroscopic guidance and maintained by manual traction. Traction was applied during fracture reduction, ESIN insertion, as well as application of the external fixator.
3- Skin incision: A 2-cm incision was made starting at the entry point and extending distally. This allowed space to advance the nails at angle to the cortex.
4- Deep dissection: Fascia and muscle were split to expose the cortex of the femur.
5- Opening the canal: An awl was placed directly onto the bone to perforate the near cortex, under fluoroscopic guidance, perpendicular to the bone (**Fig. 1**). Caution was taken not to hammer

the awl to avoid penetrating the far cortex. When the medullary canal was entered, the awl was lowered to 45° to the shaft axis, and advanced with oscillating movements to produce an oblique canal.

Fig.1. Awl insertion perforating near cortex.

6- The entry points of the two elastic nails were 2-3 cm proximal to the growth plate, and in the middle of the femoral shaft in the sagittal plane.

7- The first nail was inserted through the lateral entry point into the intramedullary canal and advanced towards the fracture site with an oscillating manoeuvre. The nail diameter was predetermined to accommodate 35 - 40% of the narrowest diameter of the femoral medullary canal (**Flynn et al., 2001**) (**Lascombes et al., 2013**) . The second nail was inserted from the medial entry point by the same manner (**Fig.2**).

Fig. 2. Second ESIN penetrates medial cortex towards fracture site**.**

8. After passing both nails through the fracture site, both lateral and medial nails were advanced to the proximal fragment.

9- An external fixator was applied to the underlying ESINs (**Fig.3**). This was achieved by inserting one or more Schanz proximally and distally to the proximal and distal crossings of the ESINs, respectively. The contralateral limb was used to assess the length and alignment of the femur.

Fig.3. Two Schanz screws added to the underlying ESINs**.**

Post-operative care

Analgesics were administrated postoperatively. Third-generation cephalosporin was administered for 5 days postoperatively.

Functional joint exercises were initiated on the first day after surgery for both knee and hip joints. Patients were discharged after 1-2 days postoperatively.

Regular clinical and radiological evaluation of all patients was carried out at 2-week intervals for 2 months and then monthly. Weight bearing was allowed after radiological evidence of fracture healing. The EF was removed 5 to 8 weeks after the initial surgery based on the presence of callus formation. The elastic nails were removed after 6 to 12 months (**Fig.4**).

Outcome Measurement

Radiological Evaluation

Plain AP and lateral radiographs were obtained. All changes in the position of the fracture (quality of fracture reduction), implant, any complications and fracture union compared with the post-operative radiographs. Radiological outcomes were assessed at each postoperative follow-up visit using Beaty's criteria **(Beaty, 1995)**: malunion was defined as coronal malalignment more than 10° or sagittal malalignment more than 15° anteriorly **(Sagan et al., 2010)**.

Clinical Evaluation

At each follow-up visit, clinical evaluation was performed in terms of range of motion (ROM) of ipsilateral hip and knee and a comparison to the uninjured side was also done.

Clinical outcome was evaluated by using Flynn's Titanium Elastic Nail (TEN) grading system **(Flynn et al., 2001)**.

Results

The mean follow-up period was 8.4 ± 1.2 months in the ESIN group, and 9.1 ± 1.6 months in the ESIN/EF group.

There was no significant statistically difference (*P* > .05). between the two groups regarding age, weight, gender, mechanism of injury and type of fracture as well as period of follow up (**Table. 1**)

Table 1. Baseline Characteristics

Variables	ESIN (n = 20)	ESIN+EF (n = 20)	*P* value
Age (years)			.072*
Mean ± SD	8.6 ± 1.7	7.8 ± 1.2	
Range	5 – 11	4 – 11	
Weight (kg)			.091*
Mean ± SD	36.7 ± 3.1	37.1 ± 3.2	
Range	25 – 45	22 – 48	
Gender			.445**
Boy	11 (55%)	12 (60%)	
Girl	9 (45%)	8 (40%)	
Mechanism of Injury			.165**
RTA	8 (40%)	10 (50%)	
Falling from height	7 (35%)	6 (30%)	
Sports injury	5 (25%)	4 (20%)	
Type of Fracture			.253**
A2.1	12 (60%)	11 (55%)	
B1.1/B2.1	4 (20%)	5 (25%)	
C2.1/C3.1	4 (20%)	4 (20%)	
Follow-up (months)			.085*
Mean ± SD	8.4 ± 1.2	9.1 ± 1.6	
Range	6 – 12	6 – 12	
* Independent sample t test; ** Chi-square test.			

Surgical Outcomes

The mean operative time and Fluoroscopy Time were significantly shorter in cases managed by ESIN alone (50.2 ± 5.7 Vs 65.1 ± 6.2 minutes) and (70.2 ± 7.2 Vs 90.1 ± 8.2 seconds) respectively.

While there was no significant difference between two groups regarding length of hospital stay, time to union, and time to metal removal (**Table. 2).**

Table 2. Surgical Outcomes (n = 40)

Variables	ESIN (n = 20)	ESIN+EF (n = 20)	*P* value
Operative Time (minutes)			.000
Mean ± SD	50.2 ± 5.7	65.1 ± 6.2	
Range	30 – 70	55 – 90	
Fluoroscopy Time (seconds)			.000
Mean ± SD	70.2 ±	90.1 ± 8.2	

	7.2		
Range	40 – 90	60 – 120	
Length of Hospital Stay (days)			.077
Mean ± SD	2.8 ± 0.6	3.1 ± 0.5	
Range	1 – 5	2 – 5	
Time to Union (weeks)			.152
Mean ± SD	5.8 ± 1.3	6.2 ± 1.1	
Range	4 – 8	5 – 8	
Time to EF Removal (weeks)			-
Mean ± SD	-	6.5 ± 1.4	
Range	-	5 – 8	
Time to ESIN Removal (months)			.417
Mean ± SD	8.5 ± 1.4	9.1 ± 2.1	
Range	6 – 12	7 – 12	
Independent sample t test			

Functional Outcomes

Despite that more cases in the ESIN/EF group were achieved excellent and satisfactory results than those in the ESIN group (95% versus 85%), that was not statistically significant (*P*= .368) (**Table. 3**).

Table 3. Flynn's Titanium Elastic Nails Grading System (n = 40)

Variables	**ESIN (n = 20)**		**ESIN+EF (n = 20)**		***P* value**
	No.	**%**	**No.**	**%**	
Functional Outcomes					.368
Excellent	10	50	14	70	
Satisfactory	7	35	5	25	
Poor	3	25	1	5	
Chi-square test.					

Radiological Outcomes

Radiological assessment revealed more satisfactory results in the ESIN/EF group than in the ESIN group (90% versus70%) which is statistically significant difference (*P* = .008) (**Table.4**).

Table 4. Beaty's criteria (n = 40)

	ESIN (n = 20)		ESIN+EF (n = 20)		*P* value
	No.	%	No.	%	
Radiological Outcomes					.008
Satisfactory	14	70	18	90	
Poor	6	30	2	10	
Chi-square test.					

Complications

In the ESIN group, one (5%) patient developed knee stiffness, three (15%) demonstrated LLD, and two (10%) had limb malalignment. In the ESIN/EF group, two (10%) patients developed pin tract infections that resolved following administration of antibiotic therapy and daily dressing. One patient had knee stiffness. None of the ESIN/EF group showed LLD or malalignment. With no statistically significant difference between the two groups regarding postoperative complications (*P* > .05) (**Table. 5**).

Table 5. Complications (n = 40)

Variables	ESIN (n = 20)		ESIN+EF (n = 20)		*P* value
	No.	%	No.	%	
Pin Tract Infection	0	0	2	10	.371
Joint Stiffness	1	5	1	5	1.000
Leg Length Discrepancy	3	15	0	0	.279
Limb Malalignment	2	10	0	0	.192
Chi-square test.					

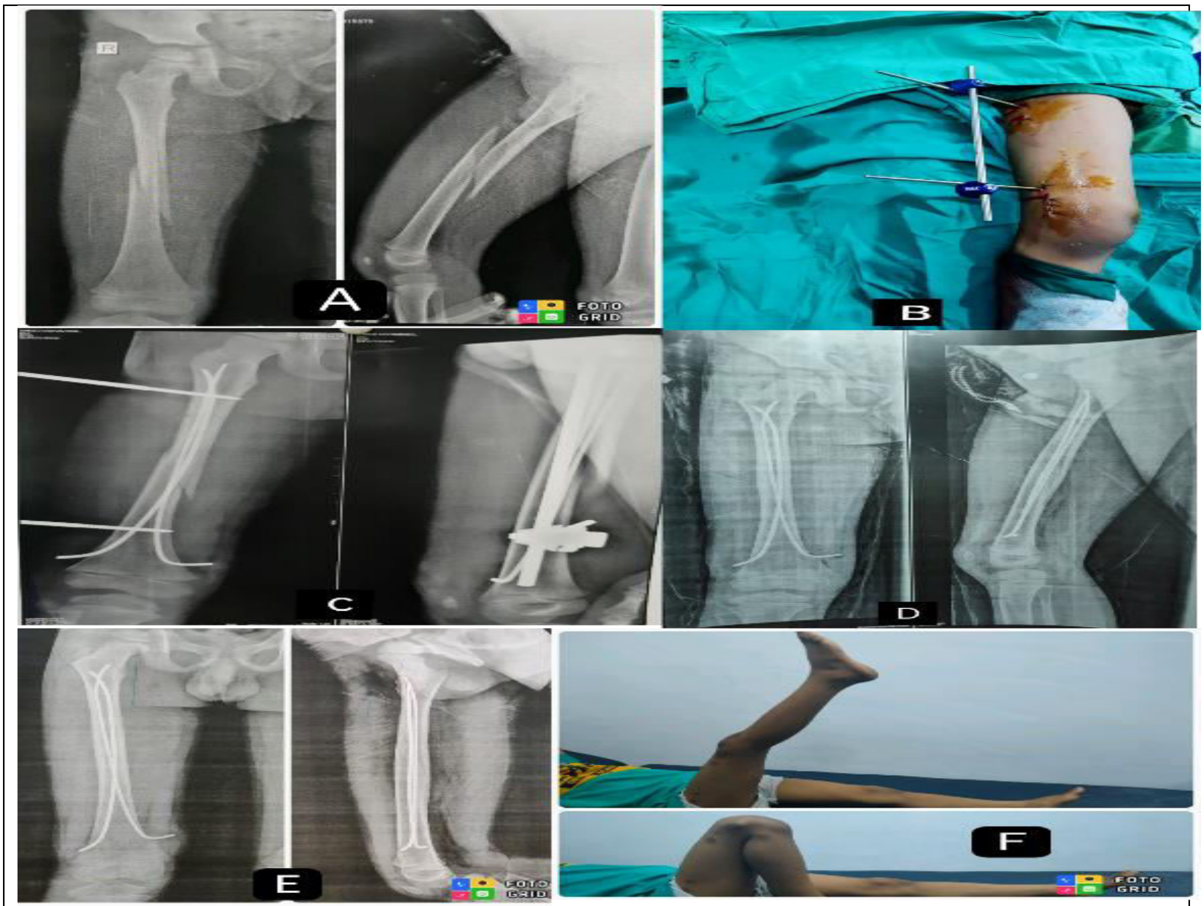

Fig. 4. Five years old boy presented with length unstable fracture of his right femur (A), managed by ESIN + EF (B-C), EF removed (d) and then ESIN retained until full union (f) with good function after nails removal (f).

Discussion

The main findings of this study were that combined ESIN, and EF provided better radiological outcome for length-unstable fracture femur in pediatric population in comparison with ESIN alone. However, no significant differences were detected regarding functional outcomes and postoperative complications.

Several studies have demonstrated ESIN as a safer and more effective treatment option in paediatric femoral fractures compared to EF. A meta-analysis by **(Chen et al., 2020)** demonstrated a lower rate of postoperative re-fracture and postoperative infection associated with ESIN. Furthermore, a low rate of limb-length discrepancy, hospitalization, clinical healing time, and bone healing time were reported with ESIN.

In a study by **(Ramseier et al., 2010)**, 194 diaphyseal femoral fractures in 189 children and adolescents were treated with ESIN, EF, rigid intramedullary nail fixation, or plate fixation. They found that ESIN was associated with the lowest rate of postoperative complications.

On the other hand, Narayanan et al. demonstrated that although ESIN is a versatile method for fixation, it has been noted that fractures with fragmentation of 25% or more are more susceptible to reduction loss and revision surgery. **(Narayanan et al., 2004)**. Another study by **(Frei et al., 2019)**, showed that fixation of unstable femoral fractures using ESIN, unstable femoral fractures resulted in rotational malalignment. Two of these children suffered retro torsion of the femoral neck, while another child experienced diminished anteversion. Consequently, 27% of patients reported poor functional outcomes as measure by Flynn's criteria.

Other techniques, such as EF, rigid intramedullary nailing and submuscular plating, may provide better alternative to ESIN in unstable femoral fractures. However, several limitations have been reported. Rigid nailing can result in growth arrest and avascular necrosis of the proximal femoral epiphysis. In addition, submuscular plating is commonly associated with high incidence of refracture owing to stress shielding and valgus deformation. **(Gordon et al., 2003)** **(Heyworth et al., 2013)**. EF is a quick and minimally invasive technique for the management of pediatric femoral fractures in patients younger than 11 years of age **(Andreacchio et al., 2016)**. However, the incidence of pin track infections and refractures after removal is quite noticeable. **(Guo and Su, 2021)** **(Ramseier et al., 2010)**.

To avoid such complications, Anderson et al suggested augmentation of ESIN with external fixation to provide additional rotational or longitudinal stabilization. They described a series of two patients who underwent combined ESIN and EF for a closed unstable diaphyseal femoral fracture. Both patients attained radiographic and clinical fracture union at a duration of 8 weeks postoperatively **(Anderson et al., 2017)**.

(Lu et al., 2022) reported a larger series of 28 patients presented with unstable femoral fractures undergoing combined ESIN and EF. The majority of patients had excellent radiographic and functional outcomes. Only four complications were reported postoperatively.

Our results were consistent with the findings of previous authors. We found that the use of combined ESIN and temporary EF has several advantages. The system preserves the limb length and alignment, while allowing the control of rotation without the need for prolonged immobilization **(Flynn et al., 2001)**.

It does not completely seal the medullary cavity, and endosteal callus formation is not inhibited **(Lascombes et al., 2013)**. EF could be adjusted and tuned to the fracture pattern. It could also be used in patients with weight over than 50 kg; **(Moroz et al., 2006)** and **(Canavese et al., 2016)** stated that there is a greater possibility of adverse effects with ESIN in patients above 50 kg; nevertheless, in our study the system could be used in this group of patients with no adverse effects.

Regardless of the aforementioned benefits, the adding of external fixator might increase the operation time, compared with simple ESIN fixation, and the placement of Schanz pins after insertion of ESIN, may be challenging. Additionally, combined ESIN and EF carries high risk of pin site infection and joint stiffness, as stated after using EF alone **(Guo and Su, 2021) (Ramseier et al., 2010)**. On the other hand, we only reported two cases with postoperative infection. Local treatment and early removal of the EF promoted healing without any consequences. Surprisingly, the infection rate in our cohort was low compared to previous studies using EF alone **(Guo and Su, 2021) (Ramseier et al., 2010)**. Joint stiffness was encountered once in our study. The lower rates of infection and stiffness in our study were probably attributed to the early removal of EF at a mean duration of 6.5 weeks. Moroni et al. found that joint stiffness increases between the 3rd and the 7th week after fracture, and Schanz-pin loosening begins after the 8th week **(Moroni et al., 2002)**. Therefore, the EF should be removed as soon as bone callus has consolidated and before pin loosening occurs. Once EF was removed, patients are advised to pursue active exercises in order to regain full knee ROM.

Conclusion

This study has demonstrated superiority of ESIN/EF over ESIN alone in terms of radiological outcomes with no significant differences as regards functional outcomes and postoperative complications.

Ethical approval: The Research Ethics Committee of our institution has approved the study protocol.

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

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