

## Comparison Between Elastic Stable Intramedullary Nailing and Conservative Management in Children with Diaphyseal Femoral Fractures

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### ABSTRACT

**Objective:** To compare the outcome between elastic stable intramedullary nailing (ESIN) and conservative management with hip spica cast in children with diaphyseal femoral fractures.

**Study Design:** Quasi-experimental study.

**Place and Duration of Study:** Orthopedic Surgery Department, Federal Government Polyclinic Hospital, Islamabad, Pakistan, from Jan 20 -21.

**Methodology:** Seventy-two (n=72) children with diaphyseal femoral fractures were included and divided into two Groups. Group-A patients were treated with ESIN, whereas Group B patients were treated with Hip Spica Cast. Post-procedure, patients were followed up, and outcomes were determined. Data was analyzed using a Statistical Package for Social Sciences 22.

**Results:** The mean age of seventy-two (n=72) children was  $6.86\pm 2.45$  years. 40(55.56%) were males and 32(44.44%) were females. The mean length of postoperative hospital stay in Group A was  $1.72\pm 0.66$  days, while in Group B it was  $1.44\pm 0.65$  days ( $p=0.077$ ). The mean time taken for assisted weight bearing in Group A was  $57.88\pm 11.75$  days, while in Group B it was  $67.13\pm 8.65$  days ( $p<0.001$ ). The mean time taken to return to school in Group A was  $71.05\pm 12.72$  days, while in Group B it was  $78.55\pm 13.20$  days ( $p=0.017$ ).

**Conclusion:** ESIN for femoral diaphyseal fracture was associated with early return to assisted weight bearing and early return to school.

**Keywords:** Elastic Stable Intramedullary Nailing, Femur, Fracture, Hip Spica Cast.

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### INTRODUCTION

Children are more likely to suffer from femoral diaphysis fractures as compared to adults. This is because their skeletons differ anatomically and biomechanically, and their physical activity is also unusual. These fractures are pretty common in the pediatric population that have orthopedic injuries, especially in association with trauma, with a reported prevalence of 1.6%.<sup>1</sup> A recent demographic analysis conducted by Mansoor et al., in Pakistan has identified femoral shaft fractures as one of the three most prevalent types of fractures observed in infants and toddlers, accounting for 35% of all fractures in newborns and 17% in toddlers.<sup>2</sup> Commonly observed consequences following femoral diaphyseal fracture in children include non-union, angular/rotational deformity, and leg length disparity.<sup>3</sup> Conservative

management has been the traditional way to treat femoral diaphyseal fractures in children through spica casting and spica casting after traction. However, an increasing trend towards surgical management has been reported in recent times.<sup>4</sup>

This trend shift may have happened due to research indicating that surgical intervention for pediatric femur fractures leads to earlier patient mobilization, shorter hospitalization, and quicker reintegration into everyday routine and educational activities.<sup>5</sup> A research analysis by Medda *et al.*, concluded that in comparison to conservative management with spica casting, surgical management provided better outcomes in terms of union and sagittal/coronal angulations in children with femoral diaphyseal fractures.<sup>6</sup> Similarly, a study by Hwaizi *et al.*, compared the outcomes of Elastic Stable Intramedullary Nailing (ESIN) with conservative management using spica casting, reported that hospitalization duration [ $4.4\pm 2.1$  vs.  $3.3\pm 1.2$  days], time to return to school [ $9.8$  vs  $6.7$  weeks] and time to

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weight bearing [9.8±1.7 vs 6.3±2.5 weeks] was significantly shorter with ESIN as compared to spica casting ( $p<0.05$ ).<sup>7</sup> On the other hand, the invasiveness of the surgical treatment with ESIN makes patients more prone to develop complications as compared to management by a conservative approach.<sup>8</sup>

Owing to such disparities in the previously available literature, the definitive method of management (either surgical or conservative) that can be opted to treat children with femoral diaphyseal fractures remains a controversial decision.<sup>9</sup> Although some studies do exhibit promising results in favor of surgical management with ESIN, the favored mode of management that is practiced locally in our country is conservative management with spica casting. Therefore, a study needed to be conducted to compare the outcomes between ESIN and conservative management in children with femoral diaphyseal fractures, with a particular focus on our local pediatric population.

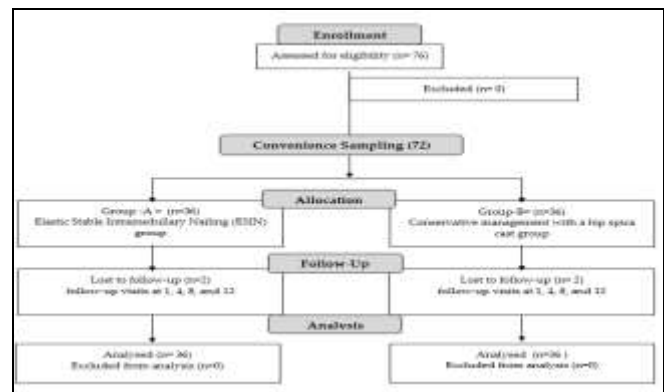
**METHODOLOGY**

This Quasi-experimental study was conducted at the Orthopedic Surgery Department of Federal Government Polyclinic Hospital, Islamabad, Pakistan from Jan 2020 to 2021 after obtaining approval from the ethical review committee, ERC serial no#: F.1-1/2015ERB/SZABMU/435. To calculate sample size, the following parameters were used: 95% confidence level, 80% power of the test, anticipated mean length of hospital stay with spica casting of 4.4±2.1 days, and anticipated mean length of hospital stay with ESIN of 3.3±1.2 days.<sup>10</sup> Based on these, the calculated sample size was 76. However, out of these, 04 patients were excluded from the study due to loss of follow-up, which led to a total sample size of 72 patients (36 in each Group).

**Inclusion Criteria:** Children who were aged between 3 and 12 years, either of the male or female gender, presenting with femoral diaphyseal fracture of either leg occurring within the last 48 hours of presentation were included in the study.

**Exclusion Criteria:** Children with pathological fractures, subtrochanteric and supracondylar fractures, neurological disorders (e.g., myelomeningocele and cerebral palsy), with a documented history of metabolic bone disorders, and who clinically presented with an infection or any comorbid condition that rendered the patient unfit for anesthesia were excluded from the study.

After patient selection through convenience sampling, baseline characteristics, including age, gender, mechanism of injury, and type of fracture, were recorded. Baseline laboratory investigations (for pre-operative assessment) were carried out in all patients. Patients were divided into two Groups. Group-A was labeled as the Elastic Stable Intramedullary Nailing (ESIN) Group, and Group-B was labeled as the Conservative management with a hip spica cast Group. Similar management plans and procedures were followed for both Groups to reduce the bias. In the ESIN Group, parenteral prophylactic antibiotics were given within 1 hour of incision as per hospital protocol and continued for 24 hours postoperatively. The standard technique for ESIN insertion was used, for which general anesthesia was administered. Subsequently, in a retrograde fashion, two identical titanium nails (with a diameter of 40% of the narrowest diameter of the shaft of the femur) were inserted through the distal part of the femur. Fractures were reduced under fluoroscopy. Nails were bent at 30° in the form of a long and smooth curve and were cut distally, retaining 1-2 cm of their length outside the cortex. The extraosseous portion of the nail was not bent away from the bone and was left lying to be flushed with the metaphyseal flare to avoid any irritation in the future. (Figure)



**Figure: Comparing the Elastic Stable Intramedullary Nailing (ESIN) Group with the Conservative Management with a Hip Spica Cast Group**

In Group-B, the procedure was carried out on a pediatric Spica Table. Both the distal and proximal segments were aligned and maintained by steady manual traction. Radiographs were obtained after applying a hip spica cast, and patients were kept in the ward under observation. Patients of both Groups were carefully monitored by a nurse and checked on by a surgeon two hours after the procedure. Outcomes of

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the treatment were determined in terms of length of postoperative hospital stay (in days), average time to assisted weight bearing (in days), and return to school (in days). POP was removed between 8-12 weeks postoperatively after obtaining satisfactory radiographs. After the removal of POP, patients were allowed full weight-bearing mobilization as tolerated. Patients with ESIN were mobilized non-weight bearing for 6-8 weeks and thereafter allowed to weight

Falls in 39(54.17%) children were the most common cause of femoral diaphyseal fracture, followed by being hit by an object in 23(31.94%) patients and road accidents in 10(13.89%) patients. In terms of the type of fracture, 16(22.22%) children had a spiral fracture, 28(38.89%) had an oblique fracture, and 28(38.89%) had a transverse fracture. This comparison between the two treatment Groups is tabulated in Table-II.

**Table-I: Comparison of Baseline Characteristics Between Study Groups (n = 72)**

Characteristics	Group-A (n = 36)		Group-B (n = 36)		p-value
Age (years)	7.98±2.63		5.75±1.64		<0.001
Gender	Male	22(61.11%)	Male	18(50.00%)	0.343
	Female	14s(38.89%)	Female	18(50.00%)	

**Table-II: Comparison of Mechanism of Injury and Type of Fracture Between Study Groups (n = 72)**

Characteristics	Group-A (n = 36)		Group-B (n = 36)		p-value
Mechanism of Injury	Fall	21(58.33%)	18(50.00%)	0.392	
	Hit by Object	12(33.33%)	11(30.56%)		
	Road Accident	3(8.33%)	7(19.44%)		
Type of Fracture	Spiral	8(22.22%)	8(22.22%)	0.276	
	Oblique	11(30.56%)	17(47.22%)		
	Transverse	17(47.22%)	11(30.56%)		

bear as tolerated following satisfactory radiographs. ESIN was removed in a separate procedure after a minimum of 06 months post-insertion. All patients were followed up in the orthopedic clinic regularly until fracture union, with follow-up visits at 1, 4, 8, and 12 weeks after the procedure for both Groups.

Quantitative variables (age, length of postoperative hospital stay, time taken for assisted weight bearing, and time taken to return to school) were represented using Mean±SD. Categorical variables (gender, mechanism of injury, and type of fracture) were expressed as frequencies and percentages. Categorical variables were compared between Groups by using the chi-square test. Quantitative variables were compared between Groups using independent Sample t-test. A p-value of ≤0.05 was considered significant.

### RESULTS

A total of seventy-two (n=72) patients were included in the study, with 36 patients in the ESIN Group and 36 patients in the conservatively managed with hip spica cast Group. Mean age was 6.86±2.45 years. 40(55.56%) children were males, while 32(44.44%) children were females. A comparison of these baseline characteristics between the ESIN Group and the conservative management with hip spica cast Group is tabulated in Table-I.

While comparing the outcomes between Groups, it was observed that the mean length of postoperative hospital stay in Group A was 1.72±0.66 days, while in Group B, it was 1.44±0.65 days ( $p=0.077$ ). The mean time taken for assisted weight bearing in Group A was 57.88±11.75 days, while in Group B, it was 67.13±8.65 days ( $p<0.001$ ). The mean time taken to return to school in Group A was 71.05 12.72 days, while in Group B, it was 78.55±13.20 days ( $p=0.017$ ). This comparison is demonstrated in Table-III.

**Table-III: Comparison of Outcome Between Groups (n = 72)**

Outcome (days)	Group-A (n=36)	Group-B (n=36)	p-value
Mean Length of Postoperative Hospital Stay	1.72±0.66	1.44±0.65	0.077
Mean Time For Assisted Weight-Bearing	57.88±11.75	67.13±8.65	<0.001
Mean Time To Return To School	71.05±12.72	78.55±13.20	0.017

### DISCUSSION

In this study, the findings have highlighted that ESIN is a better management option for treating femoral diaphyseal fractures in children. Although there was no statistically significant difference in hospitalization stay between the two Groups. Yet the ESIN treatment showed greater potential for becoming

the gold standard in treating femoral fractures, especially in diaphysis.

Traditional treatment for femoral diaphyseal fractures in children has been conservative therapy.<sup>11</sup> However, recent studies have revealed a growing inclination towards surgical treatment owing to faster healing of the fractured bone and better outcomes. Hip spica casting has been a commonly employed technique for many years to treat children with femoral diaphyseal fractures without the need for surgery.<sup>12</sup> The most often documented consequences following spica casting for pediatric femur fractures are increased angulation, skin disintegration, and associated problems of the skin.<sup>13</sup>

A study by Difazio *et al.*, reported that Spica cast treatment is associated with numerous skin complications and additional charges. Victims of child abuse may benefit from additional clinical oversight.<sup>14</sup> Additionally, Neilsen *et al.*, conducted a study on determining the effect of titanium elastic nails filled canal on femur fractures of children, and were unable to find any correlation in healing or its effect on deformity.<sup>15</sup>

According to Denisiuk *et al.*, doing surgery to treat femur fractures in children leads to quicker achievement of patient mobility, reduced inpatient stays, faster recovery, and early resumption of normal daily activities and school attendance.<sup>16</sup> Bhuyan *et al.*, concluded that the Titanium Elastic Nailing System (TENS) is a safe and effective method for the treatment of pediatric femoral shaft fractures, because it is minimally invasive, relatively easy to use, and shows good functional and cosmetic results. Flexible intramedullary nails are medical devices that aid in load distribution and provide practical fixing, promoting relative stability and facilitating the healing process of fractures by indirect bone healing or callus production. Moreover, these devices are reasonably affordable, and the process of inserting and removing these nails is comparatively simpler.<sup>17</sup>

Studies conducted by Shemshaki *et al.*, have indicated that intramedullary nailing is more effective than spica casting in treating femoral diaphyseal fractures in children.<sup>18</sup> This study intended to evaluate both of these techniques in our locality. The technique that leads to a shorter postoperative hospital stay, quicker time to assisted weight bearing, and faster return to school would be preferred in the future. This would significantly reduce the burden on inpatient facilities, promote earlier patient recovery, and

enhance overall patient satisfaction. In this study, it was observed that the most common type of femoral fracture was a transverse fracture, followed by oblique and spiral fractures. Similar epidemiological division of the type of femoral fracture was observed in a study conducted by Frei *et al.*<sup>5</sup> In terms of outcome; duration of inpatient stay at the hospital was longer with ESIN as compared to conservative therapy. This was contrary to the results; all of whom reported reduced hospital stay with ESIN. However, in terms of the duration that the children took to start bearing weight with assistance and their return to regular schooling, it was significantly shorter in those who had the femoral diaphyseal fracture treated with ESIN as compared to those who underwent conservative management with hip spica casting.

Similar findings were observed in a study conducted by Soleimanpour *et al.*, that child in whom a femoral fracture is treated with TEN achieves recovery milestones significantly faster than a child treated with traction and spica cast.<sup>19</sup> Another study conducted by Ikram *et al.*, reported a much shorter time period for return to regular schooling as well as assisted weight bearing in children treated with titanium elastic nailing versus spica.<sup>20</sup>

The study recommends measuring the long-term effects of TENS and comparing it with frequently used alternatives. The sample size was relatively small yet sufficient to draw an inference. The follow-up period was only 12 weeks. However, the findings of the current study, along with those of many other studies already published, lend credence to the idea that children with femoral diaphyseal fractures who are treated with ESIN progress through the recovery process more quickly than those who undergo conservative management. More large-scale prospective randomized controlled studies with extended follow-up are needed and recommended to corroborate the findings of the present study.

### LIMITATIONS OF STUDY

This study has certain limitations. It was conducted at a single center, which may limit the generalizability of the findings to other populations or healthcare settings, as variations in clinical practices and patient demographics could influence outcomes. Second, the relatively short follow-up period restricts the ability to assess the long-term effects and durability of the observed outcomes. Finally, the limited sample size reduces the statistical power of the study, increasing the possibility of type II error and potentially affecting the reliability and robustness of the conclusions.

**CONCLUSION**

In conclusion, when comparing patients treated with ESIN and those treated with hip spica cast, ESIN is a better management option for treating femoral diaphyseal fractures in children. There was no statistically significant difference in hospitalization stay between the two Groups. The time to assist weight bearing and the time to return to school were significantly shorter for patients treated with ESIN.

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**Authors' Contribution**

Following authors have made substantial contributions to the manuscript as under:

YU & SJI: Study design, drafting the manuscript, data interpretation, critical review, approval of the final version to be published.

AN & WU: Data acquisition, data analysis, approval of the final version to be published.

NJ: Critical review, concept, drafting the manuscript, approval of the final version to be published.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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