e-ISSN: 0975-9506, p-ISSN:2961-6093

Available online on www.ijpqa.com doi: 10.25258/ijpqa.16.10.21

International Journal of Pharmaceutical Quality Assurance 2025; 16(10); 120-127

Original Research Article

Clinical and Radiological Outcome of Paediatric Shaft Femur Fractures Managed by Titanium Elastic Nail System Versus Submuscular Plate Osteosynthesis: A Comparative Study

Arshad Ahmed[1], Sarthak Laha[2], Ram Prasad Sinha[3], Rajiv Roy[4]

[1]MBBS, MS (Orthopaedics), Assistant Professor, Department of Orthopaedics, Calcutta National Medical College, 32 Gorachand Road, Kolkata, West Bengal – 700014, India
[2]MBBS, MS (Orthopaedics), Senior Resident, Department of Orthopaedics, Diamond Harbour Government Medical College and Hospital, Diamond Harbour, South 24 Parganas, West Bengal, India
[3]MBBS, MS (Orthopaedics), Assistant Professor, Department of Orthopaedics, Diamond Harbour Government Medical College and Hospital, Diamond Harbour, South 24 Parganas, West Bengal, India
[4]MBBS, MS (Orthopaedic Surgery), Professor, Department of Orthopaedics, Calcutta National Medical College, 32 Gorachand Road, Kolkata, West Bengal – 700014, India

Received: 25-08-2024 / Revised: 13-09-2025 / Accepted: 14-10-2025
Corresponding Author: Dr. Sarthak Laha
Conflict of interest: Nil

Abstract:

Background: Pediatric femur fractures constitute about 1.6% of all pediatric fractures and pose significant treatment challenges. While Titanium Elastic Nail System (TENS) is commonly used due to its minimally invasive nature, it may be less effective in comminuted or segmental fractures and in heavier children. Submuscular bridge plating has emerged as an alternative, particularly for complex or metaphyseal fractures.

Aims: This study aimed to compare the clinical and radiological outcomes of TENS and submuscular plating in children aged 6–14 years with shaft femur fractures.

Methods: A prospective comparative study was conducted at Calcutta National Medical College and Hospital between October 2022 and April 2024, involving 40 patients. Twenty patients underwent submuscular plating (Group A) and 20 received TENS (Group B). Outcomes assessed included union time, functional results (FLYNN Score), and complications such as limb length discrepancy (LLD), angulation, infection, and implant-related issues.

Results: No significant differences were observed in union time (10.1 weeks for plating vs. 9.6 weeks for TENS, $p = 0.3806$) or operative time, blood loss, or overall functional outcomes. Minor complications such as LLD and angulation were more frequent in the TENS group. All fractures united within three months, with no cases of nonunion or malrotation. Two superficial infections and implant prominence occurred in the TENS group only.

Conclusion: Both TENS and submuscular plating offer comparable outcomes for pediatric femoral shaft fractures in stable patterns. Submuscular plating is a valid alternative, though further large-scale studies are needed to guide management of more complex cases.

Keywords: Pediatric Femur Fracture, Titanium Elastic Nail System (TENS), Submuscular Plate Osteosynthesis, Fracture Union, Functional Outcome and Flynn Score.

This is an Open Access article that uses a funding model which does not charge readers or their institutions for access and distributed under the terms of the Creative Commons Attribution License (http://creativecommons.org/licenses/by/4.0) and the Budapest Open Access Initiative (http://www.budapestopenaccessinitiative.org/read), which permit unrestricted use, distribution, and reproduction in any medium, provided original work is properly credited.

Introduction

Pediatric femoral shaft fractures are among the most prevalent traumatic injuries in children, often resulting from high-energy trauma such as vehicular accidents or falls [1]. The femur, being the longest and strongest bone in the body, presents unique challenges in pediatric orthopedics due to its role in weight-bearing and its proximity to the growth plate [2]. Management strategies have evolved significantly over the years, with surgical interventions becoming more refined to address the specific needs of the growing skeleton [3].Two prominent surgical techniques employed in the management of pediatric femoral shaft fractures are the Titanium Elastic Nail (TEN) system and Submuscular Plate Osteosynthesis (SMP) [4]. The TEN system, introduced in the early 1980s, utilizes flexible titanium nails inserted into the femoral shaft to provide internal fixation. This method is favored for its minimally invasive approach and the ability to preserve the periosteal blood supply, which is crucial for bone healing in children [5]. TEN is particularly effective in length-stable, transverse, or

short oblique fractures in children under 11 years of age or those weighing less than 50 kg [6]. On the other hand, Submuscular Plate Osteosynthesis involves the placement of a locking compression plate beneath the muscle layer, providing rigid fixation [7].

This technique is often employed in more complex or unstable fractures, including those with comminution or at the proximal or distal ends of the femur. SMP offers the advantage of stable fixation, which is essential for fractures that are length-unstable or involve the metaphyseal regions [8]. The choice between TEN and SMP is influenced by various factors, including the child's age, fracture pattern, and the surgeon's experience. While TEN is associated with shorter operative times and less blood loss, it may be less effective in managing complex or unstable fractures. Conversely, SMP provides stable fixation but may be associated with longer operative times and increased risk of complications such as infection or damage to surrounding structures. Several recent studies have compared the clinical and radiological outcomes of these two techniques. Li et al. reported that both TEN and SMP provide satisfactory outcomes, but TEN was associated with shorter operative times and quicker recovery, whereas SMP offered more stable fixation in complex fractures [6]. Similarly, Hayat et al. observed no significant difference in functional outcomes between TEN and SMP, but TEN was linked to fewer complications related to hardware failure [7]. The evolving landscape of pediatric femoral shaft fracture management underscores the importance of individualized treatment plans. Factors such as fracture type, patient age, and the potential for growth disturbances must be carefully considered when selecting the appropriate surgical intervention [9]. Furthermore, the advent of newer technologies and techniques continues to influence treatment paradigms, highlighting the need for ongoing research and adaptation in clinical practice [10]. This study aims to provide a comprehensive comparison of the clinical and radiological outcomes of the Titanium Elastic Nail system and Submuscular Plate Osteosynthesis in the management of pediatric femoral shaft fractures. By evaluating factors such as union rates, complication profiles, and functional recovery, we seek to contribute valuable insights that can inform clinical decision-making and enhance patient care in this challenging area of pediatric orthopedics.

Materials and Methods

Study Design: Prospective Comparative Study, Hospital based

Place of Study: Calcutta National Medical College and Hospital.

Study Duration: October 2022 – April 2024.

Study Population: Patients admitted with fracture shaft of femur in the Department of Orthopaedics, Calcutta National Medical College and Hospital.

Sample Size: Study was conducted on 40 patients admitted under the Department of Orthopaedics in Calcutta National Medical College and Hospital, over a period of 12 months, after obtaining the permission from institutional ethical committee and taking informed and written consents from the patients.

Study Variables

1. Age & Sex
2. Side of injury, Mode of injury, Pattern of fracture, Location of fracture, Type of fracture (Winquist and Hansen classification), Operative time Amount of blood loss during operation & Time to union.
3. Limb length discrepancies, Malalignment (Angulation in coronal plane (varus or valgus, Angulation in sagittal plane (apex anterior or posterior) & Clinically obviousmal rotation.
4. Complications (Non Union, Infection, Implant prominence & Reoperation functional Outcome According To Flynn Score.

Inclusion Criteria

1. Age between 6 to 14 years.
2. Gustilo-Anderson grade 1, grade 2 open fracture.
3. No preoperative neurovascular injuries.

Exclusion Criteria

1. Age <6 years and >14 years.
2. Gustilo-Anderson grade 3 onwards open fractures.
3. Patients with associated injuries pathological fractures, underlying neurovascular disorders, metabolic bone disease.

Statistical Analysis: Data were entered into Microsoft Excel and analyzed using SPSS version 27.0 (SPSS Inc., Chicago, IL, USA) and GraphPad Prism version 5. Numerical variables were expressed as mean ± standard deviation, while categorical variables were presented as counts and percentages. Independent samples (unpaired) t-tests were used to compare means between two groups, and paired t-tests were applied for related observations to improve statistical power. Categorical data were analyzed using the Chi-square (χ^2) test or Fisher's exact test, as appropriate, with Pearson's chi-square test employed when the test statistic followed a chi-squared distribution under the null hypothesis. P-values were derived from the corresponding test statistics, and statistical significance was set at $p \leq 0.05$.

Result

Table 1: Association of both groups according to Age &Sex

	Method			P-Value
		Plate	Tens	Total	
Age in group	06-10	13(65%)	15(75%)	28(70%)	0.4901
	11-14	7(35%)	5(25%)	12(30%)	
	Total	20(100%)	20(100%)	40(100%)	
Sex	Female	6(30%)	5(25%)	11(27.5%)	0.7232
	Male	14(70%)	15(75%)	29(72.5%)	
	Total	20(100%)	20(100%)	40(100%)	

Table 2: Association of both groups according to Side, Mode, Pattern, Location and Win quist type

	Method				P-Value
		Plate	Tens	Total	
Side	Left	7(35%)	8(40%)	15(37.5%)	0.7439
	Right	13(65%)	12(60%)	25(62.5%)	
	Total	20(100%)	20(100%)	40(100%)	
Mode	Fall	5(25%)	7(35%)	12(30%)	0.7439
	RTA	15(75%)	13(65%)	28(70%)	
	Total	20(100%)	20(100%)	40(100%)	
Pattern	Oblique	2(10%)	4(20%)	6(15%)	0.3758
	Transverse	18(90%)	16(80%)	34(85%)	
	Total	20(100%)	20(100%)	40(100%)	
Location	Distal third	3(15%)	3(15%)	6(15%)	0.8329
	Mid shaft	16(80%)	15(75%)	31(77.5%)	
	Proximal third	1(5%)	2(10%)	3(7.5%)	
	Total	20(100%)	20(100%)	40(100%)	
Win quist type	Grade 0	17(85%)	15(75%)	32(80%)	0.4291
	Grade 1	3(15%)	5(25%)	8(20%)	
	Total	20(100%)	20(100%)	40(100%)	

Table 3: Association of both groups according to Limb Length discrepancies, Coronal angulation, Sagittal angulation, Infection, Implant prominence and Flynn score

	Method				P -Value
		Plate	Tens	Total	
Limb Length discrepancies	<1 cm	2(10%)	3(15%)	5(12.5%)	0.5175
	1-2 cm	0(0%)	1(100%)	1(100%)	
	More than 2	0(0%)	0(0%)	0(0%)	
	Nil	18(90%)	16(80%)	34(85%)	
	Total	20(100%)	20(100%)	40(100%)	
Coronal angulation	5 degree	2(10)	2(10)	4(10)	1
	10 degree	0(0%)	0(0%)	0(0%)	
	>10 degree	0(0%)	0(0%)	0(0%)	
	Nil	18(90%)	18(90%)	36(90%)	
	Total	20(100%)	20(100%)	40(100%)	
Sagittal angulation	5 degree	3(15%)	2(10%)	5(100%)	0.5488
	10 degree	0(0%)	1(5%)	1(2.5%)	
	>10 degree	0(0%)	0(0%)	0(0%)	
	Nil	17(85%)	17(85%)	34(85%)	
	Total	20(100%)	20(100%)	40(100%)	
Infection	Nil	20(100%)	18(100%)	38(100%)	0.1467
	Superficial	0(0%)	2(10%)	2(5%)	
	Total	20(100%)	20(100%)	40(100%)	
Implant prominence	Nil	20(100%)	18(90%)	38(95%)	0.1467
	Present	0(0%)	2(10%)	2(5%)	
	Total	20(100%)	20(100%)	40(100%)	
Flynn score	Excellent	20(100%)	18(90%)	38(95%)	0.1467
	Satisfactory	0(0%)	2(10%)	2(5%)	
	Total	20(100%)	20(100%)	40(100%)	

Table 4: Distribution of mean Age (Years), Operative time (min), Blood loss (ml) and Union time (weeks)

		Number	Mean	SD	Minimum	Maximum	Median	p-value
Age (Years)	Plate	20	9.4	2.7606	6	14	9	0.6659
	Tens	20	9.05	2.305	6	14	9	
Operative time (min)	Plate	20	78.5	17.0217	60	120	72.5	0.3937
	Tens	20	74.75	9.3857	60	90	75	
Blood loss (ml)	Plate	20	91.25	33.7122	50	175	87.5	0.4357
	Tens	20	83.75	25.9997	50	125	75	
Union time (weeks)	Plate	20	10.1	1.9973	8	13	10	0.3806
	Tens	20	9.6	1.5355	8	12	10	

Table 3: Association of both groups according to Malrotation, Non-union and Reoperation

	Method			
		Plate	Tens	Total
Malrotation	Nil	20(100%)	20(100%)	40(100%)
	Total	20(100%)	20(100%)	40(100%)
Non union	Nil	20(100%)	20(100%)	40(100%)
	Total	20(100%)	20(100%)	40(100%)
Reoperation	Nil	20(100%)	20(100%)	40(100%)
	Total	20(100%)	20(100%)	40(100%)

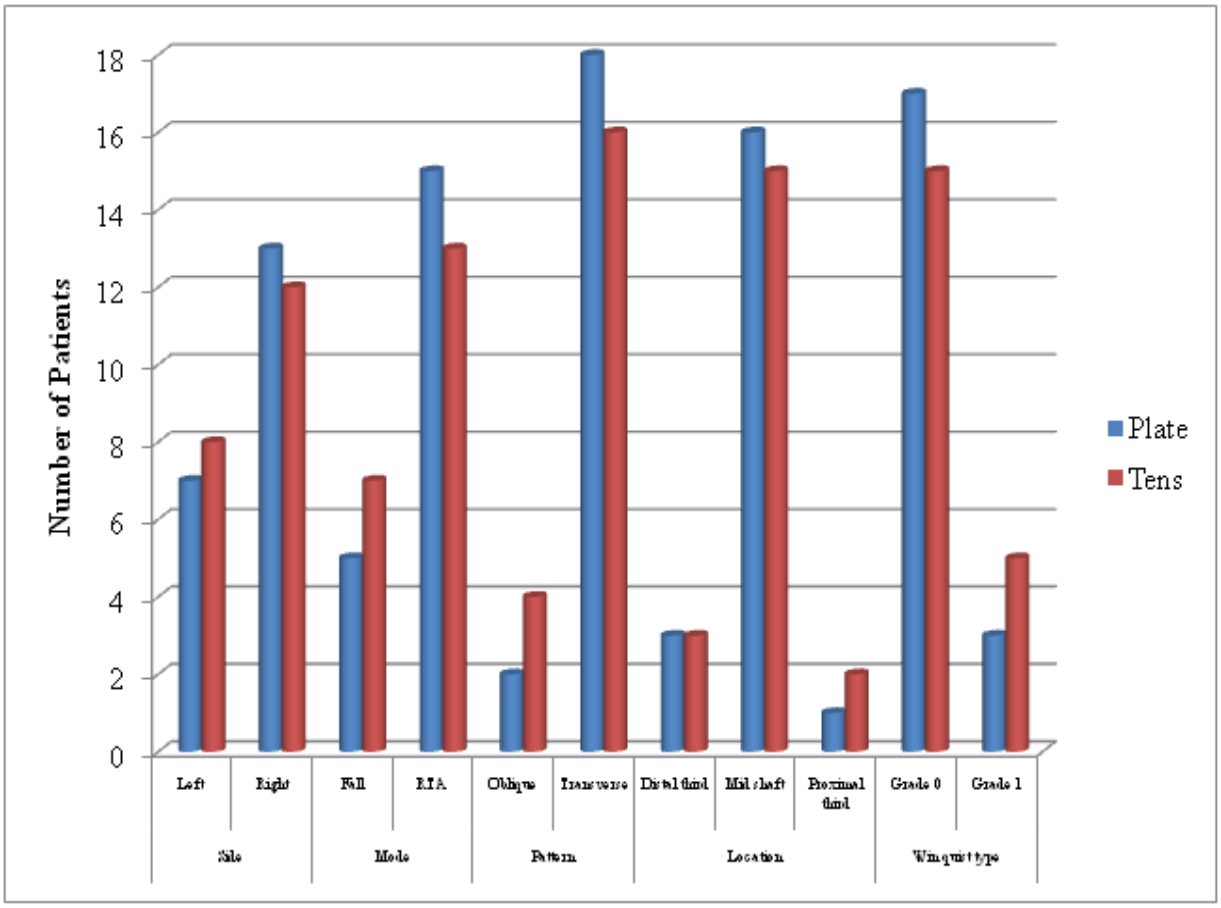


Figure 1: Association of both groups according to Side, Mode, Pattern, Location and Win quist type

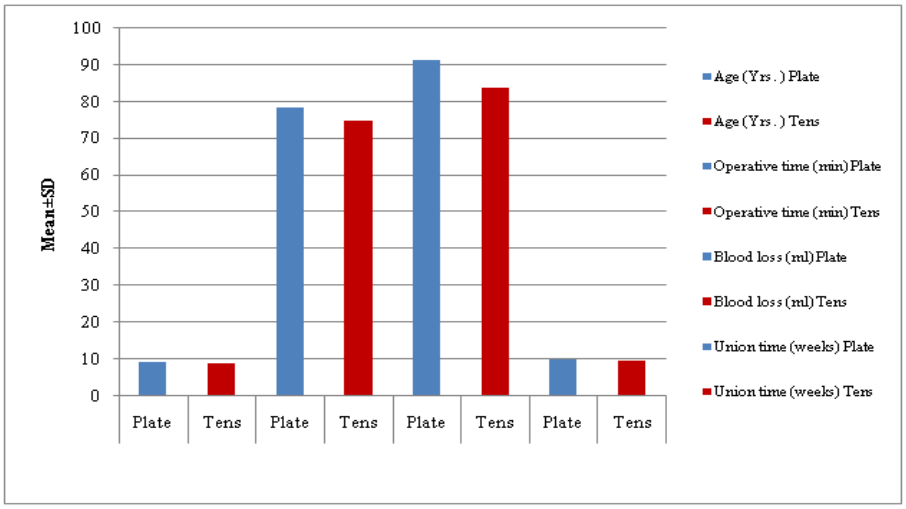


Figure 2: Distribution of mean Age (Years), Operative time (min), Blood loss (ml) and Union time (weeks)

Pre-op x-ray

Immediate post-op

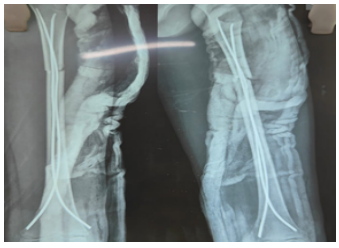
3 months post- op

Hip and knee ROM at 3 months

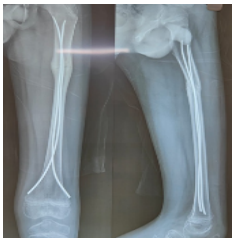
Hip and knee ROM at 3 months

Case 1: Submuscular plating

Pre-op X-ray



Immediate post-op



3 months post-op

Hip and knee ROM at 3 months

Case 2: Titanium elastic nail system (TENS)

In our study, a total of 40 patients were included, with 20 patients in the Plate group and 20 patients in the Tens group. In the Plate group, 13 patients (65%) were aged 6–10 years and 7 patients (35%) were aged 11–14 years. In the Tens group, 15 patients (75%) were aged 6–10 years and 5 patients (25%) were aged 11–14 years. The difference in age distribution between the two groups was not statistically significant (p = 0.4901). Regarding sex distribution, the Plate group consisted of 6 females (30%) and 14 males (70%), while the Tens group had 5 females (25%) and 15 males (75%). There was no statistically significant difference in sex distribution between the two groups (p = 0.7232).

In our study, regarding the side of fracture, in the Plate group, 7 patients (35%) had left-sided fractures and 13 patients (65%) had right-sided fractures. In the Tens group, 8 patients (40%) had left-sided fractures and 12 patients (60%) had right-sided fractures. There was no statistically significant difference between the groups in terms of fracture side (p = 0.7439). Regarding the mode of injury, in the Plate group, 5 patients (25%) sustained fractures due to a fall and 15 patients (75%) due to road traffic accidents (RTA). In the Tens group, 7 patients (35%) had fractures due to a fall and 13 patients (65%) due to RTA. The difference in mode of injury between the groups was not statistically significant (p = 0.7439). In terms of fracture pattern, in the Plate group, 2 patients (10%) had oblique fractures, and 18 patients (90%) had transverse fractures. In the Tens group, 4 patients (20%) had oblique fractures, and 16 patients (80%) had transverse fractures. This difference was not statistically significant (p = 0.3758). Regarding fracture location, in the Plate group, 3 patients (15%) had fractures in the distal third, 16 patients (80%) in the mid-shaft, and 1 patient (5%) in the proximal third. In the Tens group, 3 patients (15%) had distal third fractures, 15 patients (75%) had mid-shaft fractures, and 2 patients (10%) had proximal third fractures. There was no statistically significant difference in fracture location between the groups (p = 0.8329). Finally, according to Winquist classification, in the Plate group, 17 patients (85%) were Grade 0 and 3 patients (15%) were Grade 1. In the Tens group, 15 patients (75%) were Grade 0 and 5 patients (25%) were Grade 1. The difference in Winquist grading between the groups was not statistically significant (p = 0.4291).

In our study, regarding limb length discrepancies, in the Plate group, 2 patients (10%) had a discrepancy of less than 1 cm and 18 patients (90%) had no discrepancy. In the TENS group, 3 patients (15%) had a discrepancy of less than 1 cm, 1 patient (5%) had 1–2 cm discrepancy, and 16 patients (80%) had no discrepancy. The difference between the groups was not statistically significant (p = 0.5175). For coronal angulation, in the Plate group, 2 patients (10%) had a 5-degree angulation and 18 patients (90%) had no angulation. Similarly, in the TENS group, 2 patients (10%) had a 5-degree angulation, and 18 patients (90%) had no angulation. This difference was not statistically significant (p = 1). Regarding sagittal angulation, in the Plate group, 3 patients (15%) had a 5-degree angulation, and 17 patients (85%) had no angulation. In the TENS group, 2 patients (10%) had a 5-degree angulation, 1 patient (5%) had a 10-degree angulation, and 17 patients (85%) had no angulation. The difference was not statistically significant (p = 0.5488). Concerning infection, all 20 patients in the Plate group had no infection. In the TENS group, 18 patients had no infection and 2 patients (10%) developed superficial infection. This difference was not statistically significant (p = 0.1467). For implant prominence, all 20 patients in the Plate group had no implant prominence. In the TENS group, 18 patients had no prominence, while 2 patients (10%) had implant prominence. The difference between groups was not statistically significant (p = 0.1467). Regarding functional outcomes assessed by Flynn score, all 20 patients in the Plate group had an excellent outcome. In the TENS group, 18 patients (90%) had excellent results and 2 patients (10%) had satisfactory results. The difference was not statistically significant (p = 0.1467). In our study, a total of 40 patients were included, with 20 patients in the Plate group and 20 patients in the TENS group. The mean age in the Plate group was 9.4 ± 2.76 years, while in the TENS group it was 9.05 ± 2.31 years (p = 0.6659), showing no significant difference. The mean operative time was 78.5 ± 17.02 minutes in the Plate group and 74.75 ± 9.39 minutes in the TENS group (p = 0.3937), which was not statistically significant. The mean intraoperative blood loss was 91.25 ± 33.71 ml in the Plate group and 83.75 ± 26.0 ml in the TENS group (p = 0.4357), with no significant difference. The mean union time was 10.1 ± 2.0 weeks in the Plate group and 9.6 ± 1.54 weeks in the TENS group (p = 0.3806), which was also not statistically significant. In our study, regarding malrotation, all 20 patients in the Plate group and all 20 patients in the TENS group had no malrotation. For non-union, all 20 patients in the Plate group and all 20 patients in the TENS group achieved union, with no cases of non-union observed. Regarding reoperation, none of the patients in either the Plate group or the TENS group required reoperation, with all 20 patients in each group avoiding further surgical intervention.

Discussion

In our study, a total of 40 pediatric patients with femoral shaft fractures were included, with 20 patients each in the Plate and TENS groups. The demographic characteristics, including age and sex distribution, were comparable between the groups (p > 0.05), as were fracture-related variables such as side, mode of injury, fracture pattern, location, and Winquist grading. Postoperative outcomes including

limb length discrepancies, coronal and sagittal angulation, infection, implant prominence, and Flynn functional scores were also similar between the groups. The mean operative time, intraoperative blood loss, and union time showed no statistically significant difference between Plate and TENS fixation. Malrotation and non-union were absent in all patients, and no reoperations were required. These findings are consistent with previous studies that have compared Plate and TENS fixation in pediatric femur fractures. Al-Doori et al. [11] reported comparable union rates and functional outcomes between TENS and plate fixation in children aged 5–12 years.

Similarly, Hosseini et al. [12] observed no significant differences in complication rates, limb length discrepancies, or functional recovery between the two methods. Milligan et al. [13] reported excellent functional outcomes with both techniques, although TENS offered shorter operative times and less soft tissue dissection. Zhang et al. [14] noted reduced intraoperative blood loss and faster fracture healing with TENS, though overall clinical outcomes were similar. Additionally, studies by Flynn et al. [15], Ligier et al. [16], and Metaizeau et al. [17] have supported the efficacy of both fixation methods in terms of union, alignment, and functional recovery.

Further research by Moroz et al. [18], Parikh et al. [19], and Sink et al. [20] reinforces that the choice of fixation may be guided by fracture type, surgeon preference, and patient factors rather than outcome differences, as both Plate and TENS techniques yield reliable results in pediatric femoral fractures. Overall, our study corroborates that both fixation methods are effective and safe, with no significant differences in clinical or radiological outcomes.

Conclusion

This prospective comparative study found no significant differences in union rates or functional outcomes between Titanium Elastic Nail System (TENS) and submuscular bridge plating for pediatric femoral shaft fractures in children aged 6–14 years. Both techniques showed high rates of union and excellent functional results, with no major complications reported. TENS was associated with slightly less blood loss, while submuscular plating proved effective even in more complex fracture patterns.

Given the comparable outcomes, submuscular plating emerges as a viable alternative to the standard elastic stable intramedullary nailing (ESIN) for stable fractures. However, due to the study's small sample size and limited representation of length-unstable fractures, larger, multicenter studies with longer follow-up are necessary to guide optimal management of complex pediatric femoral fractures.

References

1. Strait RT, et al. Submuscular Plating Versus Elastic Intramedullary Nailing for Pediatric Femoral Shaft Fractures: A Systematic Review. J PediatrOrthop. 2023; 43 (3):e234-e240.
2. Sinha SK, et al. Outcomes of Fracture Shaft Femur in Pediatric Population: A Comparative Study of Titanium Elastic Nailing and Submuscular Plating. J Pediatr Orthop B. 2016; 25(6):523-528.
3. Kirmani TT, et al. Osteosynthesis of Pediatric Femoral Shaft Fractures with Titanium Elastic Nails: A Review of 100 Cases. J Pediatr Orthop. 2020; 40 (5):e334-e339.
4. Abdelgawad AA, et al. Submuscular Bridge Plating for Complex Pediatric Femur Fractures. J Pediatr Orthop. 2013; 33 (5):e60-e65.
5. Luo Y, et al. Elastic Stable Titanium Flexible Intramedullary Nails Versus Plates in Treating Low-Grade Comminuted Femur Shaft Fractures in Children. Orthop Surg. 2019; 11(4):664-670.
6. John R, et al. Current Concepts in Pediatric Femoral Shaft Fractures. Open Orthop J. 2017; 11:353-361.
7. Hayat U, et al. Comparison of Submuscular Locking Plate and Titanium Elastic Nail in Children with Midshaft Femur Fractures. J Pak Med Assoc. 2021; 71(1):210-214.
8. Tella AO, et al. The Outcome of Titanium Elastic Nail Fixation of Pediatric Long Bone Fractures: A Retrospective Analysis. Orthop Rev (Pavia). 2024; 16(1):118449.
9. Niknam K, et al. Trends in the Management of Femur Fractures in Young Children: A Review of Current Practices. J Pediatr Orthop B. 2023; 32 (4):e214-e220.
10. Gyaneshwar T, et al. Treatment of Pediatric Femoral Shaft Fractures by Stainless Steel Elastic Nails: A Comparative Study. J OrthopSurg (Hong Kong). 2016; 24(2):171-176.
11. Al-Doori O, et al. Comparative outcomes of elastic stable intramedullary nailing vs. plate fixation in pediatric femoral shaft fractures. Ortop Traumatol Rehabil. 2024; 26 (1):369-373.
12. Hosseini H, et al. Comparison of treatment results of femoral shaft fracture with two methods of intramedullary nail (IMN) and plate. BMC Surg. 2024; 24:318.
13. Milligan D, et al. Elastic nail fixation versus plate fixation of paediatric femoral shaft fractures. Injury. 2019; 50 (11):1994-1998.
14. Zhang Y, et al. Titanium elastic nails vs locking plate in pediatric femoral shaft fractures. Front Pediatr. 2023; 11:1114265.
15. Flynn JM, et al. Advantages of elastic stable intramedullary nailing in pediatric femur fractures. J Pediatr Orthop. 2001; 21(5):561-566.
16. Ligier JN, Metaizeau JP, et al. Elastic stable intramedullary nailing in children. J Pediatr Orthop. 1988; 8 (2):177-182.

17. Metaizeau JP, et al. Elastic stable intramedullary nailing of femoral shaft fractures in children. Orthop Traumatol Surg Res. 2010; 96(8):839-845.
18. Moroz LA, et al. Complications of elastic stable intramedullary nail fixation of pediatric fractures. J PediatrOrthop. 2006; 26(6):827-834.
19. Parikh SN, et al. Outcomes of plate versus flexible nails for pediatric femoral fractures. J PediatrOrthop. 2010; 30 (8):787-791.
20. Sink EL, et al. A comparison of plating and flexible nailing in pediatric femur fractures. J PediatrOrthop. 2005; 25(1):17-22.