



TENS Versus Plate Fixation in treatment of Pediatric Femoral Shaft Fracture. A Randomised Control Trial Study

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Abstract

Background: Femur fractures are one of the most prevalent injuries in children. Femoral shaft fractures are the most common orthopedic injury that requires hospitalization, accounting for around 1.6 percent of all bone injuries in children. Treatment for femoral shaft fractures in children is determined by the patient's age and weight, as well as the type of fracture. Traction and hip Spica were the usual treatments for all femoral shaft fractures that needed a lengthy stay in the hospital until recently. However, in recent decades there has been a shift toward increased use of surgery such as intramedullary nailing and plate fixation because of decrease impairment, increase convenience and decrease cost of care. There are increasing reports in literature that operative treatment more satisfactory results than non-operative but the treatment of choice in children are still controversial.

Aims and Objective: To compare the functional outcome in patients who underwent surgery for the femoral shaft fracture using the titanium elastic nail and the plate fixation.

Methods: This is prospective and comparative study was carried out in the department of orthopedic surgery, unit IV and V Taihe Hospital affiliated to Hubei University of Medicine, Shiyan, Hubei, China from April 2018 to February 2019. A total of 20 patients were enrolled in this study and divided equally into 2 groups TENS and plate 10 patients on each group.

Results: Out of 20 patients 10 (50%) patients treated with TENS and 10 (50%) were treated with plates. Mean age of total patients was 6.65 ± 2.110 years. road traffic accident is the main cause of injury in both group which comprises 5 (50%) patients in TENS group and 4 (40%) patients in plate group. Majority of the fractures were in the middle third of the femoral shaft. The mean blood loss in TENS group was 16 ± 6.146 ml while in plates group 160 ± 45.947 ml. which shows significant between two groups with ($p = 0.00 < 0.005$). The average operating time in TENS group was found to be 54 ± 14.298 minute while in case of plating group was 127 ± 22.998 minute with ($p = 0.000 < 0.05$). Average time of union in TENS group was 8.10 ± 2.846 weeks and in plate group was 9.80 ± 1.989 weeks. Which is insignificant with ($p = 0.139 > 0.05$). among total 17 (85%) patients had no complications, Superficial infection found in 2 (10%) patients with plates group. and delayed union was found in 1 (5%) patient in with TENS group with ($p = 0.217 > 0.05$). There is no significance difference found with respect to complication between both groups. The final outcome assessed by Flynn's criteria, showed that 14 {7 (70%) were from TENS group and 7 (70%) from plate group} had excellent results. 6 {3 (30%) from TENS group 3 (30%) from plate group} had satisfactory and None of them have poor result in both group. These differences were not found to be statistically significant ($p = 1.000 > 0.05$).

Keywords: Titanium Elastic Nail; Plate Fixation; Pediatric Femur Fracture; Femoral Shaft Fracture

Abbreviation

TENS: Titanium Elastic Nailing System; RTA: Road Traffic Accidents; AO: Arbeitsgemeinschaft Für Osteosynthesefragen; VS: Versus

Introduction

In children, fractures of the femoral shaft are commonly treated by various types of traction for about three weeks, followed by plaster cast immobilization. This risk-free treatment has two big disadvantages. The first is that prolonged bed rest separates the child from his normal environment; The second factor is the cost of such stays in the hospital, as well as the use of beds which could be used for other patients [1]. Despite the fact that femur fractures are uncommon in children, they are the most prevalent fractures requiring hospitalization. They are linked to extended hospital stays, immobility, and a significant financial load on the health system as well as caretakers [2,3]. The most common significant pediatric injuries treated by orthopedic surgeons are femoral shaft fractures, that are often caused by blunt trauma. 78% percent of femoral fractures involve the shaft [4,5]. Diphyseal femur fractures account for 1.4% -1.7% of all pediatric fractures [6,7]. The most of incidents in infants involve falls and abuse of child. Motor vehicle collisions are the main cause of severe injuries in teenagers. As a general rule, the fracture pattern becomes more complex as the energy that caused the fracture increases [8]. The decision of the best line of treatment of pediatric lower limb fracture remains controversial. Management is influenced by associated injuries or multiple trauma, fracture personality, age, built of child, weight of patient, cost, associated injuries/polytrauma, fracture characteristics, family situation. The choice of management may also be determined by surgical experience and local trends in practice [3,4,7,9]. Pavlik harness, Spica casts, flexible intramedullary nailing, strong trochanteric entry nailing, sub muscle plating, external fixators in the case of open fractures, are some of the options recommended [7,10]. There is broad consensus on the non-operative management of children under the age of six. Operative treatment is recommended for children more than 12 years of age, only the surgical options vary [11]. The prevailing consensus is that femoral fractures in children under the age of four should be treated conservatively. And above the age of 16 are candidates for locked intramedullary nailing. Treatment in Children between 4-16 years is a controversial [12]. Traditional compression plating provides excellent stability and main-

tains fracture length and alignment but complicated by a high risk of hardware failure, nonunion, larger incision considerable blood loss and difficulty in removing plate. Excessive periosteal stripping can cause overgrowth of the femur upon healing, resulting in a leg-length asymmetry [3,13]. Flexible intramedullary nailing has been one of the choices of stabilization in femoral shaft fractures. When two bent nails cross one other, the elastic nail turns traction forces into compressive forces on the fracture site, and it also provides three-point fixation within the canal. By increasing oscillation and a limited stress shielding effect on the fracture site, the elasticity of elastic nails promotes callus development. Perceived advantages are shorter operative time less blood loss, early union limited incision acceptable scar and early removal of implants [3,10,13].

Objectives

Primary objective of this study is to find out the clinical and functional outcomes of pediatric femoral shaft fracture treated with TENS vs plate fixation. Secondary objectives are to calculate the surgery time. union time, hospital stay, modes of injury and to compare them with TENS versus plate fixation.

Methods

This is prospective and comparative study was carried out in the department of orthopedic surgery, unit IV and V Taihe Hospital affiliated to Hubei University of Medicine, Shiyan, Hubei, China from april 2018 to February 2019. A total of 20 patients were enrolled in this study and divided into 2 groups of 10 patients each. First group of patients were treated with Titanium Elastic Nail (TENS) using CRIF and second group of patients were treated with Plate fixation using ORIF. Statistical analysis was done using the statistical package for the social sciences (SPSS)25.0 statistical software, Microsoft word and excel version 2016. The study was comparative study among two groups of patients.

Statistical methods

T- test was used for comparison and chi square test was used to calculate association between different variables and compared with p value.

Inclusion and exclusion criteria

Age between 3 to 11 years, no preoperative neurovascular injury, Grade I and II open fracture, femoral shaft fracture. And patients with sufficient radiograph and regular follow up were included in

study. But patients of Age < 3 and > 11 years, Patients who had associated injury patients, Pathological fracture, Grade III open fracture, Underlying neuromuscular disorder, metabolic bone disorder and polytrauma patients were excluded.

Ethical clearance

Ethical clearance was taken from Hubei university of medicine and Taihe hospital and permission was granted from department of orthopedics unit IV and V.

Results

Out of 20 patients 10 (50%) patients treated with TENS and 10 (50%) were treated with plates. Mean age of plate group was 6.30 ± 2.214 years and TENS group 7.0 ± 2.055 years with ($p = 0.473$) and mean age of total patients found to be 6.65 ± 2.110 . there is no significance difference between age of patients treated with plates and TENS. 14 (70%) were male and 6 (30%) were female in total among which 9 (90%) male in plate group and 5 (50%) were male in TENS group, and females were 1 (10%) in plate group and 5 (50%) in TENS group with p-value ($0.051 > 0.05$) which is insignificant. Out of 20 patients 19 were closed fracture. And 1 was open fracture in plate group. In our study road traffic accident is the main cause of injury in both group which comprises 5 (50%) patients out of 10 patients in TENS group and 4 (40%) patients in plate group. Other cause of injury comprises 5 (35%), while in plate group 2 (20%) due to fall, 2 (20%) due to sports and 2 (20%) due to other cause ($p = 0.145 > 0.05$). Majority of the fractures were in the middle third of the femoral shaft. In plate group 3 (30%) at proximal, 5 (50%) middle third and 2 (20%) were distal while in TENS group 1 (10%) at proximal, 8 (80%) were at middle third and 1 (10%) at distal with ($p = 0.363$). According to the AO classification, 4 (20%) were type 32-A1, 6 (30%) were type 32-A2, 6 (30%) were type 32-A3, 2 (10%) were type 32-B1, 1 (5%) were type 32-B2, 0 (0%) were type 32-C1 and 1 (5%) were type 32-C2. with ($p = 0.340 > 0.05$). However, there was no significant difference was found with respect to Age, sex, type of fracture, mode of injury and fracture level and AO classification between two groups. The mean blood loss in TENS group was 16 ± 6.146 ml while in plates group 160 ± 45.947 ml. which is significant between two groups with ($p = 0.00 < 0.05$). The average operating time in TENS group was found to be 54 ± 14.298 minute while in case of plating group it was found to be 127 ± 22.998 minute. Which shows highly significance difference between two groups with ($p = 0.000 < 0.05$). Average

time of union in TENS group was 8.10 ± 2.846 weeks and in plate group it was 9.80 ± 1.989 weeks with ($p = 0.139 > 0.05$) The statistical difference comes out to be insignificant. In comparing mean hospital stay we found that plate group patients stayed longer in hospital with compare to TENS group (11.40 ± 5.232 days VS 5.50 ± 1.780 days), this difference shows significance ($p = 0.003 < 0.05$). no surgical complication was found in 17 (85%) patients. Superficial infection found in 2 (10%) patients with plates group and none in the TENS group. delayed union were found in 1 (5%) patient treated with TENS group and angulation was not found in both the groups. There is no significance difference found with respect to complication between both the groups with ($p = 0.217 > 0.05$). The functional results, as assessed by Flynn's criteria, showed that majority of the patients in the study had excellent functional results of which 7 (70%) were from TENS group and 7 (70%) belonged to plate group. In 6 patients satisfactory functional result was found of which 3 (30%) were from TENS group and 3 (30%) were from plate group. No cases found to have poor result in both group. These differences were not found to be statistically significant ($p = 1.000 > 0.05$).

Variables	Plate group n = 10	Tens group n = 10	P value	Total n = 20
Mean age \pm SD (years)	6.30 \pm 2.214	7.0 \pm 2.055	0.473	6.65 \pm 2.110
Sex			0.051	
Male	9(90%)	5 (50%)		14 (70%)
Female	1(10%)	5 (50%)		6 (30%)
Fracture type			0.305	
Open	1 (10%)	0 (0%)		1 (5%)
Closed	9 (90%)	10 (100%)		19 (95%)
Cause of injury			0.145	
RTA	4 (40%)	5 (50%)		9 (45%)
Fall	2 (20%)	5 (50%)		7 (35%)
Sports	2 (20%)	0 (0%)		2 (10%)
Others	2 (20%)	0 (0%)		2 (10%)
Fracture level			0.363	
Proximal third	3 (30%)	1 (10%)		4 (20%)
Middle third	5 (50%)	8 (80%)		13 (65%)
Distal third	2 (20%)	1 (10%)		3 (15%)

AO classification			
32 A1	1(10%)	3(300%)	4 (20%)
32 A2	4 (40%)	2 (20%)	6 (30%)
32 A3	3 (30%)	3 (30%)	6 (30%)
32 B1	0 (0%)	2 (20%)	2 (10%)
32 B2	1 (10%)	0 (0%)	1 (5%)
32 C1	0 (0%)	0 (0%)	0 (0%)
32 C2	1(10%)	0 (0%)	1 (5%)

Table 1: Demographic and clinical data of both groups.

Variables	TENS group n = 10	Plate group n = 10	P value
Mean blood loss (ml)	16 ± 6.146	160 ± 45.947	0.000
Mean surgery time (Minutes)	54 ± 14.298	127 ± 22.998	0.000
Mean time for union (weeks)	8.10 ± 2.846	9.80 ± 1.989	0.139
Mean hospital stay (days)	5.50 ± 1.780	11.40 ± 5.232	0.003
Mean follow up (months)	6.80 ± 1.814	8.80 ± 1.135	0.001

Table 2: Intraoperative and post-operative outcomes of both groups.

Final outcome	Plate group n = 10	TENS group n = 10	P value	Total n = 20
Excellent	7 (70%)	7 (70%)	1.000	14 (70%)
Satisfactory	3 (30%)	3 (30%)		6 (30%)
Poor	0 (0%)	0 (0%)		0 (0%)

Table 3: Final outcomes using Flynn's criteria of both groups.

Complications	Plate group n = 10	TENS group n = 10	P value	Total n = 20
Superficial infection	2 (20%)	0 (0%)	0.217	2 (10%)
Angulation	0 (0%)	0 (0%)		0 (0%)
Delayed union	0 (0%)	1 (10%)		1 (5%)
None	8 (80%)	9 (90%)		17(85%)

Table 4: Frequency chart for surgical complication.

Correlation between variables

Age group (n = 40)	Complications			P value
	Superficial infection	Angulation	Delayed union	
3 - 5	0	0	0	0.313
6 - 8	3	0	2	
9 -11	0	0	0	
Total	3	0	2	

Table 5: Comparison of age group with the complications.

Shows No significance association of age with complication ($p = 0.313$).

Sex	Mode of injury				P value
	RTA	Fall	Sports	Other	
Male	6 (42.9%)	5 (35.7%)	1 (7.1%)	2 (14.3%)	0.731
Female	3 (50%)	2 (33.3%)	1 (16.7%)	0 (0%)	
total	9 (45%)	7 (35.0%)	2 (10%)	2 (10%)	

Table 6: Comparison of sex with mode of injury.

No significance association of sex with mode of injury ($p = 0.731$).

Age group (n = 40)	Mode of injury				P value
	Fall	RTA	Sports	Other	
3 - 5	2 (41.6%)	6 (50%)	0 (0%)	1 (8.4%)	0.2007
6 - 8	7 (38.88%)	8 (44.44%)	2 (11.12%)	1 (5.56%)	
9 -11	1 (10%)	4 (40%)	4 (40%)	1 (10%)	
Total	13 (32.5%)	18 (45%)	6 (15%)	3 (7.5%)	

Table 7: Comparison of age group with mode of injury.

No significance association of age group with mode of injury ($p = 0.2007$).

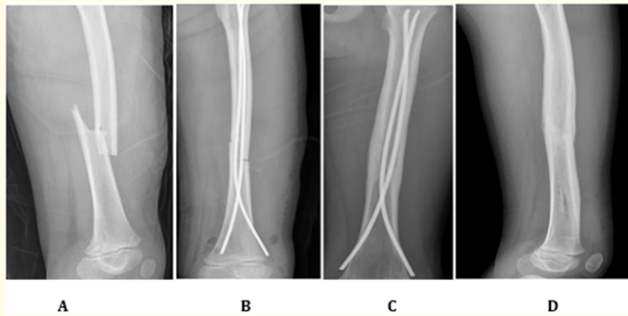


Figure 1: x ray image of 8 years male with left femoral shaft fracture.

(A) Shows AP view of preop x-ray. (B) Post operative image after fixation with TENS. (C) 3 Months post operative image. (D) Complete union and nail remove.



Figure 2: 14-year female with femoral shaft fracture managed with plate fixation. (A) pre-operative AP x-ray, (B) Postoperative x-ray shows reduced fracture.

Discussion

The treatment of pediatric femoral shaft fractures has in recent times moved away from the traditionally conservative approach to a more surgical one. However different methods of treatment have been explained in different literature, on our study among 20 patients each patient were randomly chosen for treatment methods and classified into TENS and plate group and treated accordingly. The study included totally 20 cases in the aged between 5

and 11 years with mean age 6.65 ± 2.110 . whereas mean age of plate grouping was 6.30 ± 2.214 and in tens group was 7.0 ± 2.055 . Engström, *et al.* (2020) found that the median age for a femur fracture was 6 years in boys (IQR, 3.0– 12.0) and 7 years in girls (IQR 3.0–10.0) ($p = 0.6$) [2]. xu, *et al.* (2018) found that The average age of the patients was 8.3 ± 2.0 years (range, 5–11.9 years [14]. In the study done by Bastawisy and Hussein MD, *et al.* (2019) The average age of all patients was 9.5 years [15]. Sela, *et al.* in 2013 published an article with mean age 5 years, range 0–16). But he had also classified age with mechanism of injury and modes of treatment [5] thus we can say that the mean age of patients differ according to different center and also based on geographical location. Bastawisy and Hussein MD, *et al.* (2019) did comparative study between TENS and plate in pediatric femur fracture showing male predominance [15] our results also have male predominance in total. S. BRIDGMAN, R. WILSON (2004) also published a paper which also shows male predominance of femoral fracture at any age group [16]. In our study 19 (95%) were closed fracture and 1 (5%) was type 1 open fracture which was managed with iv antibiotics and daily dressing and traction after no sign of infection was noted then managed with plate. Engström, *et al.* (2020) BMC found out that of the 709 fractures, 62 were proximal (9%), 453 shaft (64%) and 194 distal (27%). Shaft fractures were the most common type of fracture in every age group. [2]. our study also had similar results of involving mid shaft fracture in 13 (65%). in a study done by Flynn JM, *et al.* (2004) found that out of 243 cases, 134 (58.1%) were following RTA [17] our result also have total 9 (45%) patients have RTA as mechanism of injury. According to AO classification of fracture we had maximum number of patients with A2 and A3 equally of 30%. And A1 20%. So in our study maximum number of patients have simple oblique and transverse type fracture followed by simple spiral fractures. Xu, *et al.* (2018) found that the average operation time of group TENS was 41.2 minutes; the average blood loss of surgery was 8.2 mL. and the average operation time of open plating group was 98 minutes and the average blood loss was 70 mL [14]. Bastawisy and Hussein MD, *et al.* (2019) found 35.94 ± 38.78 cc blood loss in TENS and 109.36 ± 40.47 cc in plate ($p = 0.001^*$). and surgery time was 36.25 ± 9.55 minute in TENS and 73.79 ± 8.94 minute in plate with ($p = < 0.001^*$) [15]. where as in our study mean blood loss is 16 ± 6.146 ml in TENS group and 160 ± 45.947 ml in plate group ($p = 0.000$). so there is significantly less blood loss in TENS group than plate group. in our study we found that the surgery time of TENS group was significantly less 54 ± 14.298 min-

utes than in plate group 127 ± 22.998 minutes ($p = 0.000$), which justify with other literature that the surgical time and blood loss is less in TENS than in plate fixation. Average time of union in TENS group was 8.10 ± 2.846 weeks and in plate group it was 9.80 ± 1.989 weeks. The statistical difference comes out to be insignificant (p -value 0.139), whereas Baruah, *et al.* (2014) found mean union time in TENS was 11.1 weeks and plating was 11.3 weeks. [18], which is quite closer with our study. In comparing mean hospital stay we found that plate group patients stayed longer in hospital as compare to TENS group (TENS 5.50 ± 1.780 days and plate 11.40 ± 5.232 days), this difference shows significance between hospital stay of patients with ($p = 0.003$). Flynn, *et al.* (2004) [17], Greisberg, *et al.* [19] also found hospital stay of plate group was longer than TENS group. (8 days vs 15 days by Flynn, and 5 days vs 12 days by greisberg, respectively). Most of literature have also reported short hospital stay with TENS. None of surgical complication found in 17 (85%) of the patients. Superficial infection found in 2 (10%) patients with plates group but none in the TENS group. Angulation was not noted in both the groups and delayed union were found in 1 (5%) patient treated with TENS group with ($p = 0.217$) There is no significance difference found with respect to complication between both the groups. Whereas Shemshaki, *et al.* [20] also found 4 out of 55 patients had superficial infection while treating with flexible nailing. Baruah, *et al.* [18] also observed 10% superficial infection while treating with plate fixation.

Final Outcome

The final outcome was assessed using Flynn's criteria among which majority of the patients in the study had excellent functional results of which 7 (70%) were from TENS group and 7 (70%) belonged to plate group. In 6 patients satisfactory functional result was found of which 3 (30%) were from TENS group and 3 (30%) were from plate group. None of them have poor result in both group. These differences were not found to be statistically significant (p -value 1.000).

We also calculated correlation between the variables which shows no significance association of age group with complication ($p = 0.313$). No significance association of age group with mode of injury ($p = 0.2007$) and no significance association of sex with mode of injury ($p = 0.731$)

Conclusion

Based on the results of this study we concluded that both TENS and plate fixation in treating femoral shaft fractures offer high union rates and better outcome in children aged between 5 to 11 years. But TENS has the benefit of minimal blood loss, shorter operative time and hospital stay as well as earlier union and small incision for insertion of the nail which is cosmetically more acceptable compared with plate fixation. Hence, the results of this study suggest that titanium elastic nailing system is the more appropriate implant for treating pediatric femoral shaft fracture than plate fixation.

Limitation

However, to differentiate superiority between TENS and plate fixation, large sample size and multicenter prospective study with longer and regular follow up time is required.

Conflict of Interest

The author denies any conflict of interest regarding funding source and publication of this article.

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