



# Understanding with Titanium Elastic Nails (TENS) for Femur Fracture and its Impediments among 4-14 Years Age Group in Nepal: A Prospective Study

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Date of Submission: 20-08-2023

Date of Acceptance: 31-08-2023

## ABSTRACT-

**Introduction:** Because the natural Fracture healing power of this age group, managing femoral fractures in children remains a controversial issue. Some schools advocate conservative management, with hip spica cast, but with advancement of newer surgical techniques, other groups of orthopedic School prefer surgical management of fracture shaft of femur even in this age group. **Objectives:** Analysis of outcomes of pediatric femoral fractures treated with titanium elastic nails (TENS) in the age group of 4–14 years. **Methodology:** This study is a prospective study of sample size of 64 femoral fractures in children treated with TENS from September 2020 to February 2021 at the Tankisinwari Birat Medical College Teaching Hospital, Biratnagar, Nepal and analyzed functional outcomes based on the Flynn TEN score. Radiological Evaluation for the degree of callus formation was done as per Anthony Scale. **Results:** By Flynn's criteria, there were 55 (88.7%) excellent results, 6 (9.7%) successful results and 1 (1.6%) poor result. The mean time to full weight bearing after radiologically detectable fracture union was 7.1 weeks. **Conclusion:** TENS is an effective surgical procedure for femoral fractures in children with adequate surgical skills and appropriate post-surgical care.

**Keywords:** TENS, Femur Fracture, Functional Outcome, Regression Modelling

## I. INTRODUCTION-

Currently, the treatment options of femoral shaft fracture in children is a controversial topic. Until recently, application of a post-reduction hip spica cast was the preferred method for the treatment of femoral shaft fractures in children. This conservative treatment with hip spica cast has been tested over time, because of the natural power of fracture healing in this age group with minimum chances of any permanent complications, such as malunion or limb shortening.

However, with the advancement of new surgical skills, orthopedic surgeons have tried many other ways to avoid long period of immobilization due to hip spica cast, especially in pediatric polytrauma. Recent studies had made parents aware of the emotional and economic impact of prolong casting of children with hip spica. Surgical treatment offers children and families many benefits like short hospital stay, freedom of spica cast, early mobilization of limb and child, better hygiene and shorter school delays. (1-9)

External frame fixation has good results with complication such as short-term loss of knee movement and frequent manageable pin tract infection but is hard to take care for parents due to heavy external hardware.

Plate osteosynthesis is another option with, but is more aggressive surgical approach in given age group with significant blood loss and soft tissue injury and a long permanent surgical scar, where other minimal invasive approach is available.

Antigrade Intramedullary nails are better for adolescence than a spica cast, but not with pediatric age group due to possible complications like AVN of head of femur, Growth arrest at greater trochanter and Varus deformity of head of femur.

Therefore, a simple intramedullary implant that will maintain alignment of fracture till bridging callus formation without much aggressive soft tissue injury or prolong immobilization, is an ideal implant.

All these qualities are available with TENS, which is simple and flexible and are available in all sizes and are easily flexible to insert them, which can be used with minimal invasive technique, without injuring the physical plate around the hip or knee. (10-14)

There are several studies for functional outcomes for femur fractures in children treated with TENS with good to excellent results, To our belief not a single study has been published from eastern part of Nepal<sup>(15-18)</sup> Therefore, this study is an attempt to analyze the outcomes and



complications of TENS fixation for femoral shaft fracture in children and determine its effectiveness in our population.

#### Objectives-

1. To analyze the results of pediatric femoral fractures treated with titanium elastic nails (TENS) in patients aged 5-14 years at Birat Medical College Teaching Hospital.
2. To access clinical and functional outcomes of pediatric femoral fractures treated with Titanium Flexible Nail (TENS) in patients aged 5-14 years.

## II. METHODOLOGY-

This was a prospective observational study conducted at Birat Medical Teaching Hospital, Tankisinwari, Biratnagar, Nepal from September 2020 to February 2021. Institutional ethical approval was obtained for this study. 64 cases of pediatric femoral fracture in between 4 to 14 years of age group, surgically treated by TENS under fluoroscopic control have been included. Approval was obtained from all patients. Compound fracture, fracture extending intraarticular and metaphyseal region and fractures associated with neurovascular damage were excluded from the study. The operation was performed within 3-5 days of the injury. The surgical time was 30-45 minutes. Average patient hospital stay was for about a week.

All patients were pre operatively evaluated for pre-operative blood examination, antero-posterior and lateral x-ray views of the involved as well as contralateral limb x-ray. All patients underwent surgery under caudal or general anesthesia after obtaining pre anesthetic fitness and consent for surgery. In three cases, the fracture has to fixed by making a small incision at fracture site due to soft tissue interposition rendering fracture irreducible for close attempts, rest of sixty-one patients were successfully reduced by closed manipulation under fluoroscopic guidance.

After making an incision, about 2cm in length, 2cm proximal to distal femoral epiphysis, on both lateral and medial side, entry to medullary canal is made by a bone awl by piercing the cortex of femur. Then appropriate size of TENS nails was chosen under image guidance (approximately 40 % of the inner diameter of diaphysis at isthmus). For better three-point stability nail each nail was pre-bent over the length of femur three times the diameter of isthmus. Nails were then introduced within the canal and driven in proximal fragment with rotary movements of T-handle or by mallet. After a satisfactory fixation nails tip were cut

around 2.5 cm from entry point, buried and wound were closed in layers.

Post operatively we did not immobilized the fractured limb, rather we encouraged early knee movements,

At each follow-up visit, we examined range of movement at knee joint, any discrepancy in length, persistent pain around knee, bursitis or any ulcer due to Prominence of TENS tip, and radiographic evaluation for fracture healing.

Knee movements are started on first postoperative day depending on the patient's comfort. Patients were followed at 2 weeks for suture removal, then at 6 weeks, 3 months and 6 months, 12 months of period. All patients were advice for not to bear weight till six weeks of period or till radiological union was confirmed.

There are two variables selected, as follows:

- ❖ Response variables –Mean time for Hospital Stay, Mean time for radiological union, Flynn criteria results.
- ❖ Exploratory variables - age, weight, gender, knee pain, infection.

The total count sampling technique was used in this study and the sample size was 62. The data collection method used specially designed semi-structured questionnaires. The follow-up study was taken from the preoperative radiograph to the 6-month follow-up.

All collected data is checked, compiled and entered into MS Excel and analyzed by SPSS. The anonymity and confidentiality of the study participants were preserved. The regression model was used as the statistical analysis of this study. The details of the regression modeling are given in the following sections.

## III. STATISTICAL ANALYSIS

**Regression Modeling:** A regression model is used to analyze the data in this study. The regression analysis compiles a statistical analysis system to measure the correlation between changes based on one or more independent variables. Linear regression is the most common form of visual inspection and finds the best line for your data based on the mathematical criteria specified.

## IV. RESULTS-

### Summary Statistics:

A total of 62 patients. Follow-up was possible for 45 boys (72.6%) and 17 girls (27.4%). The average age of patients aged 4 to 15 years is 8.11 years. There were 42 patients (67.7%) with fracture on the right side and 20 patients with (32.3%) fractures on the left side. Types of injuries



were due to 15 falls (24.2%), RTA 42 (67.7%), and 5 play-ground injuries (8.1%).

Fractures location were 7 (11.3%) distal diaphysis, 14 (22.6%) proximal shaft and 41 (66.1%) middle shaft of femur involved.

Eleven patients (17.7%) underwent general anesthesia and 51 (82.3%) under spinal anesthesia.

Nail diameter used were 3mm in 20 patients, 3.5mm in 24 patients and 4mm in 18 patients.

Implant removal was done at 8 months in 7 patients, at 9 months in 40 patients and at 12 months in 15 patients.

Demographic profiles for all patients are described below [Table 1-5].

**Table 1: Frequency Distribution of Sex of Patients**

	f	%	Valid %	Cumulative %
Female	17	27.4	27.4	27.4
Male	45	72.6	72.6	100.0
Total	62	100.0	100.0	

**Table 2: Frequency Distribution of Fractured Side**

	f	%	Valid %	Cumulative %
Left	20	32.3	32.3	32.3
Right	42	67.7	67.7	100.0
Total	62	100.0	100.0	

**Table 3: Frequency Distribution of Mode of Trauma**

	f	%	Valid %	Cumulative %
Fall	15	24.2	24.2	24.2
RTA	42	67.7	67.7	91.9
Sport	5	8.1	8.1	100.0
Total	62	100.0	100.0	

**Table 4: Frequency Distribution of Site**

	f	%	Valid %	Cumulative %
Distal	7	11.3	11.3	11.3
Proximal	14	22.6	22.6	33.9
Middle	41	66.1	66.1	100.0
Total	62	100.0	100.0	

**Table 5: Frequency Distribution of Anesthesia**

	f	%	Valid %	Cumulative %
General	11	17.7	17.7	17.7
Spinal	51	82.3	82.3	100.0
Total	62	100.0	100.0	

**Regression Analysis:** Table 6 shows the regression analysis for patients' biweekly infections. With a few exceptions, all indicators have an insignificant effect on the model (ie, p-value > 0.05). Here, the r-squared value is 0.089 and the adjusted r-squared value is 0.042 [Table 6].

Table 7 shows the regression analysis for patients' biweekly infections. With a few exceptions, all indicators have an insignificant effect on the model (ie, p-value > 0.05). Here the r-squared value is 0.025 and the adjusted r-squared value is 0.050 [Table 7].



Table 6: Regression Analysis for Two Weeks Infection in Patients

	UnStd. Coef.		Std. Coef.	t-value	p-value
	Beta	SE	B		
Intercept	-.353	.191		-1.849	.070
Age of Patients	.013	.016	.143	.830	.410
Sex of Patients	.068	.060	.141	1.123	.266
Weight of Patients	.006	.007	.145	.845	.402

Adjusted R-Square = 0.042, F-value = 1.894, p-value = 0.141, R-Square = 0.089

Table 7: Regression Analysis for six months Infection in Patients

	UnStd. Coef.		Std. Coef.	t-value	p-value
	Beta	SE	B		Beta
Intercept	-.209	.453		-.462	.646
Age of Patients	.020	.037	.094	.529	.599
Sex of Patients	.003	.143	.002	.018	.986
Weight of Patients	.007	.017	.079	.443	.659

Adjusted R-Square = 0.050, F-value = 0.501, p-value = 0.683, R-Square = 0.025



Figure 1: Pre-operative X-Ray



Figure 2: Immediate Post-operative X-Ray



Figure 3: Six Months Follow-up X-Ray



Figure 4: TENS Removed after 6 Months X-Ray

## V. DISCUSSION-

The main mode of injuries in our study group was road accident (RTA) in 42 (67.7%), followed by a fall from a height of 15 (24.2%) cases. One study reported 88% of the RTA case in their series. Another study reported that 48% of series fell from a height and 33% had RTAs. In 15 cases (24.20%), multiple traumas other than femoral fractures occurred. Some other studies have also reported 10% of head and thoracic injuries.

In our study, 41 (66.1%) fracture was in middle diaphysis, 14 (22.6%) fractures were around proximal diaphysis and 7 (11.3%) fractures were in the distal third of diaphysis of femur. Related studies reported all the fractures in the middle diaphysis. Another study reported 15 (68.1%) fractures around middle third of the femoral diaphysis.<sup>(19-25)</sup>

The transverse fracture was the most common pattern, and 27 (43.6%) cases were transverse fracture in our study. This was supported by some studies indicating that closed, non-comminuted, simple transverse diaphyseal fractures are the most common femoral fractures in children. In a study by LeeYHD et al, 35 (56%) fractures were transverse out of 63 cases.

The time for clinical as well as radiological union is 7.1 week (6-8 week) in average in our study. Another study reported a median radiological union period of 7 weeks (5-9 Weeks). Saikia evidenced radiological union in an average of 8.7 weeks (6-8 Weeks).<sup>(26-28)</sup>

Prominent TENS nail tip around knee and skin irritation leading to Bursitis is seen in 8 cases

in our study, 3 of them presented as ulceration in between 3 to 6 months of follow up, they all responded well to short term oral antibiotics and completely resolved on implant removal. This is similar to a study by Saikia who reported four cases of nail site irritation and two superficial infections which needed oral antibiotics<sup>(18)</sup>. Pain and mild restriction in flexion at knee noted in 8 (12.9%) cases on follow up at 6 months, and was resolved on TENS removal. Slongo encountered the similar problem for knee pain due to hardware prominence<sup>(8)</sup>.

In this study at end of six month of follow-up, 5 patients had limb length discrepancy, 3 patients had 10 mm lengthening, 1 patient had 15 mm of lengthening and 1 patient had 10 mm of shortening. However, none of these patients have any symptoms regarding LLD and were not intervened further. A recent study showed that there was a difference in limb length of up to 1 cm in six children.<sup>(29-32)</sup>

In our study Varus deformity by 5 degrees was seen in 1 patient, valgus deformity by 10 degrees in 3 patients were seen, thus total 4 cases of angular malalignment were encountered. Flynn JM et al also found similar results of angular deformity of >5 degree in six cases and >15 degree in two out of 58 cases<sup>(33)</sup>.

The functional evaluation was performed using the TEN evaluation criteria as explained by Flynn JM et al. Excellent results were obtained in 55 (88.7%), 6 (9.7%) and 1 (1.6%) patients in our series. One study found excellent results in 13 (59%), satisfactory 6 (27.2%), and 3 (13.6%) cases.



In some other studies, 76% were excellent and 8 were poor. [Table 9, 10]

Table 9:

	No of Cases	Time in Weeks	Traumas
<b>Current Study</b>	15	7.1	24.20%
<b>Milligan et al.</b>	15	6	68.10%
<b>LeeYHD et al.</b>	35	8	56.00%
<b>Saikia et al.</b>	4	8.7	12.90%
<b>Flynn JM et al.</b>	13	8	59.00%

Table 10: Summary of Complications

Complications	No of Cases	Percentage
RTA Cases	42	67.7%
Fractures in Middle Diaphysis	41	66.1%
Fractures in Around Proximal Diaphysis	14	22.6%
Fractures in distal third of diaphysis	7	11.3%
Transverse Fracture	27	43.6%
Excellent Results	13	59.5%
Satisfactory Results	6	27.2%
Poor Results	3	13.6%

In this study we found Hardware prominence as major concern by patients which in few of the cases restricts the movement at knee and sometimes lead to bursitis or ulceration requiring oral antibiotics and regular dressings, but is usually cured by removing the implant. The difference in limb length mentioned in some people has never

been a problem due to its potential for rapid regeneration at this age. This surgical intervention has many benefits for the child and family through short hospital stays, freedom of movement without casts, better health and shorter absences from school. <sup>(34-36)</sup> [Table 8, Figure 1]

Table 8: Frequency Distribution of Final Functional Outcome

	f	%	Valid %	Cumulative %
Excellent	55	88.7	88.7	88.7
Successful	6	9.7	9.7	98.4
Poor	1	1.6	1.6	100.0
Total	62	100.0	100.0	

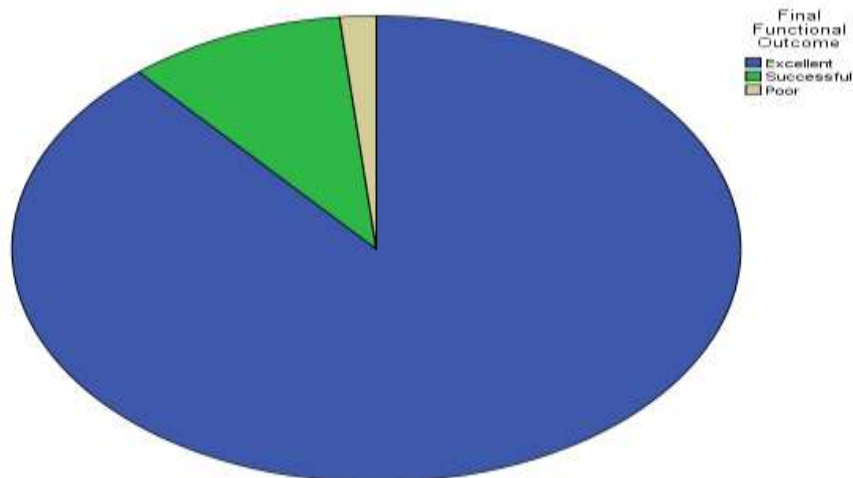


Figure 1: Pie Chart of Final Functional Outcome



We found TENS superior to other treatments because it requires minimal invasion to soft tissues, there is minimal blood loss, provides excellent axial stability, and allows early mobilization of adjacent joints, and faster recovery to pre-injury status of child. The results of our study is very much comparable to other studies as described further.

Another study treated 30 cases of TENS and followed up with the patients for two years. According to Flynn's criteria, they obtained excellent results in 20 cases (66.7%), satisfactory results (30%) in 9 cases and poor results (3.3%) in 1 case. The duration for the radiological fracture healing is 11.5 weeks. The most common complication is pain near knee due to the nail tip. They found limb length shortening in one case. They concluded that TENS, with proper surgical technique and follow-up, is an ideal implant for pediatric femoral fractures.

Another study conducted a short-term study on 40 patients. In their study all patients achieved union within 8 to 10 weeks. They reported excellent results in 33 cases (82.5%), satisfactory results in 7 cases (17.5%) and noted complications such as increased limb length in 6 cases, Varus malformation in 4 cases and rotational malunion in three cases. They concluded that TENS is a simple, minimal invasive, safe and effective way to manage femoral fractures in children.

In another study of 11 patients, 100% during complications such as 8-12 week fractures, 3 knee stiffness, 1 less than 2 cm, and 1 superficial infection. They concluded that TENS is a simple, quick and effective treatment for femoral fractures in children aged 5 to 15 years of age.<sup>(37-40)</sup>

## VI. CONCLUSION-

Titanium flexible nail system is an effective and minimal surgical way to treat femoral diaphyseal fractures in pediatric age group of 4 -14 years of age without much complications. Biomechanically by using double flexible titanium symmetrical solid nails, which hold the inner cortex of femur at three points, providing flexible, axial and rotation stability to fractured femur, at the same time allowing some micro-movement at fracture site for enough callus formation.

## Recommendations-

We recommend further study with longer follow-ups and comparative study with other surgical modalities.

## Limitations of the Study-

The honest study is a small quality of the sample as it can be displayed as treatment of choices. In addition, it needs longer duration of follow-ups. Also as it is not a comparative study with other surgical options like sub-muscular plating, we cannot be sure if TENS is superior to them or not.

## Acknowledgments

We thank our patients who participated in our study, hospital staff, anesthesiologists, Statistician, colleagues for their support.

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