

Experience with Titanium Elastic Nails (TENS) for Femur Fracture and its Complications among 5-15 Years Age Group in Odisha: A Prospective Study

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ABSTRACT

Introduction: Paediatric femur fracture management is still a controversial issue, because of the natural healing power of this age group. One school of thought endorses conservative management i.e., hip spica cast and other group of orthopaedic surgeons with advent of newer surgical techniques prefer surgical management of this fracture.

Aim: To analyse the results of paediatric femur fracture treated with Titanium Elastic Nails (TENS) among 5-15 years age group in Odisha.

Materials and Methods: This was a prospective observational study of 25 cases of paediatric femur fracture treated with TENS in Department of Orthopaedic, Sriram Chandra Bhanja Medical College and Hospital (SCBMCH), from July 2017 to December

2019 and functional results were analysed with Flynn TEN scoring criteria. Radiological assessment was done by Anthony scale for grading of callus formation.

Results: Excellent results were achieved in 19 (76%), satisfactory in 4 (16%) and poor in 2(8%) cases as per Flynn criteria. Average time for full weight bearing was after the fracture union which was evident in radiology with a mean of 7.9 weeks (range 6-12 weeks). The common complications were pain around knee 6(24%), limb length discrepancy 6(24%) followed by bursa at tip of nail in 5 (20%) that subsided after nail removal.

Conclusion: TENS is an effective modality of surgical method for paediatric femoral shaft fracture with precise technique and proper after care.

Keywords: Flynn criteria, Functional outcome, Paediatric femur fracture

INTRODUCTION

Till today paediatric femur fracture management is a controversial issue. Until recently application of traction followed by cast application was the preferred method of treatment of diaphysial femur fracture in children [1,2]. This method stood the test of time as it was relatively easy with rare permanent complications like limb length discrepancy or malunion due to the amazing healing power of this age [3].

However, with advent of newer technique, orthopaedic surgeons have tried variety of other methods to avoid prolonged immobilisation specially in polytrauma children [4,5]. Recent study has also shown the increased awareness of the psychosocial and the economic effect of spica cast immobilisation on children and their families [6]. Operative management offers huge advantage to child and family, by short hospitalisations, free movement without cast, better hygiene and shorter school absence.

External fixation has yielded good results with complications like short term loss of knee motion and pin tract infection are common but easy to treat [7]. Osteosynthesis with plate is another option, but seems a bit more aggressive for paediatric femur fracture in terms of blood loss, soft tissue injury where other less invasive options are available [8]. Ante grade IM nailing is better than cast for adolescents but not in paediatric age group with possible complications like avascular necrosis of head of femur, trochanteric growth arrest and coxa vara [9,10].

Hence, ideal implant for the paediatric femur fracture would be a simple, intramedullary nail maintaining alignment of fracture and allowing early mobilisation until bridging callus formation [11]. And all these features are available with titanium elastic nail which is simple, flexible, available in all sizes and elastic enough to insert easily, used in retrograde manner without injuring the growth plate around hip or knee [12].

Many studies [13,14] are available with excellent to good results for paediatric femur fracture fixed with TENS but usually associated with complications like entry site irritation, limb length discrepancy, malalignment. Only one study has been conducted in Eastern India like Odisha where this institution exists [15]. Hence, the present study is an attempt to analyse the results as well as the complications of paediatric femur fracture fixed with TENS to find out its efficacy in our population.

MATERIALS AND METHODS

This was a prospective observational study conducted in Department of Orthopaedics, Sriram Chandra Bhanja Medical College and Hospital after ethical committee approval (No. 971) from July 2017 to December 2019. Twenty five cases (n=z2pq/d2, z-confidence coefficient =1.96, p-proportion of outcome 0.5, q(1-p)=0.5, d-absolute precision 0.2, n=24) of paediatric femur fracture fixed with TENS under fluoroscopic control were included. An informed consent was obtained from all patients. Patients with closed shaft of femur fracture between age group 5-15 years were included in the study. Open fractures, fractures involving the epiphyseal ends and fracture associated with neurovascular injury were excluded from the study. The surgery was performed within 3-5 days of injury. The duration of the surgery was 30-45 minutes.

Patients were hospitalised for an average of one week.

All patients were evaluated with complete blood count, anteroposterior and lateral view of the affected limb, the normal limb and followed-up with standard preoperative protocol. All were posted for surgery under caudal or general anaesthesia after obtaining preoperative fitness and consent for surgery. All except four cases were reduced closely and fixed with TENS

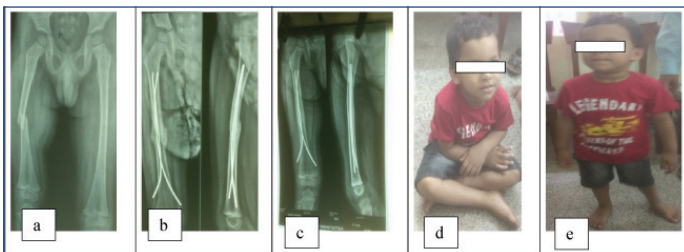
(Manufacturer-OrthoMax™) under image intensifier retrogradely without injuring the distal femoral epiphysis. In four cases, fracture site was opened for reduction because of soft tissue interposition (Open technique) and in rest 21, reduction was achieved with traction table without opening the fracture site (Close technique) using small F Tool (Synthes™). In each follow-up visit, we assessed range of movements, limb length discrepancy, pain around knee, hardware prominence and radiological examination for assessing union.

The knee mobilisation was started in immediate postoperative period as per the patient comfort.

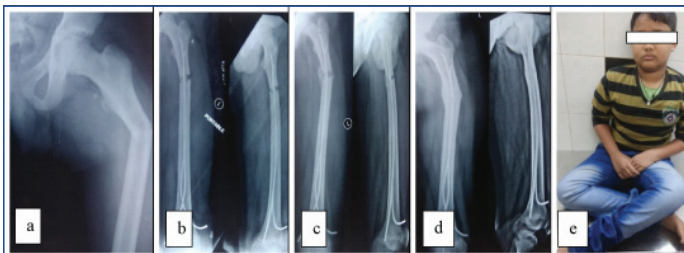
Average time for full weight bearing was after the fracture union which was evident in radiology with a mean of 7.9 weeks (range 6-12 weeks)

Restriction of knee movement was noted in three cases. Rest 22 cases achieved full range of motion in knee within 4-6 weeks.

Patients were followed-up at six weeks, three months, six months and one year [Table/Fig-1]. Non weight-bearing was advised for first six weeks and gradually weight-bearing allowed with confirmation of Grade 3 callus formation on radiology as per Anthony et al., scale [9] for grading of callus formation [Table/Fig-2,3]. Functional assessment was done according to TENS criteria by Flynn JM et al., [Table/Fig-4] [12] implant removal was done in all cases between 4-6 months of surgery.



[Table/Fig-1]: X-rays and clinical pictures of Case-I (a) X-ray fracture right femur (AP); b) Immediate post-op; c) six months post-op; d) Cross leg sitting at six months; e) Full weight bearing.



[Table/Fig-2]: X-rays and clinical pictures of Case-II (a) Preoperative X-ray of left femur proximal third fracture; b) Immediate postop; c) X-ray at six weeks showing Anthony Grade 2 callus; d) X-ray at six months; e) Clinical picture at six months).

Grade	X-ray finding
Grade 0	No identifiable fracture healing
Grade 1	Primary bone healing with little or no new bone formation
Grade 2	Periosteal new bone formation on two sides of femur
Grade 3	Periosteal new bone formation on three or four sides of femur

[Table/Fig-3]: Anthony et al., scale for grading of callus formation [9].

Variables	Excellent	Successful	Poor
Limb length discrepancy	<1 cm	<2 cm	>2 cm
Sequence disorder	5 degree	10 degree	>10 degree
Pain	Absent	Absent	Present
Complication	Absent	Mild	Major complication and/or extended period for resolvable morbidity.

[Table/Fig-4]: TENS criteria by Flynn JM et al., [12].

RESULTS

A total of 25 patients; 18 (72%) males and 7 (28%) females were available for follow-up. Mean age varied from 5-15 years with peak at 5-9 years (68%). Right side was involved in 18 (72%) patients and left in 7 (28%). The mode of injury was due to Road traffic accidents 15 (60%), fall 8 (32%) and sports 2 (8%). Six (24%) patients were associated with polytrauma like head injury, chest injury or other bone fracture. In 16 (64%), fracture involved the middle third, upper third in 6 (24%) and lower third in 3 (12%) patients. Eleven patients (44%) had transverse, 7 (28%) oblique and 4 (16%) had spiral fracture and 3 (12%) had comminuted fracture. Demographic profile for all patients are discussed below [Table/Fig-5].

Variable	Value (n%)
a) Gender	
Male	18 (72%)
Female	7 (28%)
b) Side involved	
Right	18 (72%)
Left	7 (28%)
c) Type of fracture (configuration)	
Transverse	11 (44%)
Oblique	7 (28%)
Spiral	4 (16%)
Comminuted	3 (12%)
d) Mean age	
	5-9 yrs
e) Cause of injury	
Road traffic accident	15 (60%)
Fall from height	8 (32%)
Sports	2 (8%)
f) Time interval from trauma to surgery	
0-3 days	8 (32%)
3-5 days	14 (56%)
>5 days	3 (12%)
g) Patients with polytrauma	
	6 (24%)
h) Location of the Fracture	
Upper third	6 (24%)
Middle third	16 (64%)
Lower Third	3 (12%)

[Table/Fig-5]: Patients demographic profiles.

Twenty-one (85%) fractures were reduced closely and limited open reduction was required in 4 (16%) cases due to soft tissue interposition. The nail diameter was 40% of the narrowest diameter of the medullary canal which was measured by radiographic ruler [15]. It was measured in the anteroposterior view of the contralateral normal femur.

Nail diameter used were 3.5 mm in 10 patients (40%), 3 mm in 9 (36%), 2.5 mm in 5 (20%) and 4 mm in 1 (4%). Average period of union radiologically was 7.9 weeks (6-12 weeks) by using Anthony et al., scale for grading of callus formation [9]. Functional assessment was done as per TEN scoring criteria described by Flynn JM et al. It was excellent in 19 cases (76%), satisfactory in 4 (16%) and poor in 2 cases (8%) [Table/Fig-6]. Complications were hardware prominence and bursitis in 5 cases (20%), [Table/Fig-7] pain around knee 6 cases (24%), restricted knee motion 3 cases (12%), limb length discrepancy 6 cases (24%). There were no non-union or implant breakage [Table/Fig-8].

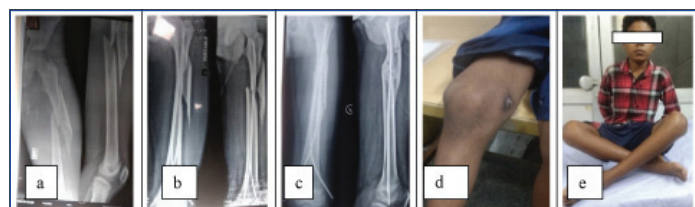
Follow-up of all the cases were done in six weeks, three months, six months and one year with maximum follow-up for 24 months.

DISCUSSION

The most common cause of injury in our study group was Road Traffic Accident (RTA) 15 (60%) cases followed by fall from height

Sl no	Limb length discrepancy	Malalignment	Pain	Complication	Results
1	-	<5	-		ER
2	-	<5	-		ER
3	-	<5	-		ER
4	9 mm L	5-10	P	Bursitis +Stiffness	SR
5	-	<5	-		ER
6	-	<5	P	Bursitis	SR
7	-	<5	-		ER
8	10 mm L	5-10	P		SR
9	-	<5	-		ER
10	-	<5	-		ER
11	13 mm L	10-15	P	Bursitis + Ulceration +Stiffness	PR
12	5 mm S	<5	-		ER
13	-	<5	-		ER
14	-	<5	-		ER
15	-	<5	-		ER
16	12 mm L	5-10	P	Bursitis+ Ulceration +Stiffness	PR
17	-	<5	-		ER
18	-	<5	-		ER
19	-	<5	-		ER
20	-	<5	-		ER
21	-	<5	-		ER
22	7 mm S	<5	P	Bursitis	SR
23	-	<5	-		ER
24	-	<5	-		ER
25	-	<5	-		ER

[Table/Fig-6]: Functional assessment by TEN scoring criteria by Flynn JM et al., [12]. L: Long; S: Short; ER: Excelent result; SR: Satisfactory result; PR: Poor result; P: Present



[Table/Fig-7]: X-rays and clinical pictures of Case-III (a) X-ray fracture left femur; (b) Immediate postop; (c) six months postop; (d) Complication showing nail tip protrusion; (e) Restricted knee flexion on cross leg sitting.

Complications	No. of cases	Percentage
Pain in knee	6	24%
Infection		
Superficial	2	8%
Deep	0	
Delayed union and non union	0	
Limb length discrepancy	6	24%
Lengthening	4	16%
Shortening	2	8%
Malalignment		
a. Varus Angulation	2	8%
b. Valgus Angulation	2	8%
c. Anterior	0	
d. Posterior	0	
e. Rotational	0	
Bursa at the tip of nail	5	20%
ROM of knee restricted	3	12%

[Table/Fig-8]: Complications of TENS.

8 (32%). Loder RT et al., reported 88% cases of RTA in their series [16]. Whereas Houshian S et al., reported 48% fall from height and 33% RTA in their series [17].

We had encountered polytrauma injuries other than femur fracture in 6 (24%) cases. Lee ZL et al., had associated injuries in 12 out of 18 children i.e., 66.6% [5]. Houshian S also reported 10% cases of associated head and chest injury [17].

In our series, 16 (64%) fractures were in the middle third, 6 (24%) in upper third and 3 (12%) in distal third. Loder RT et al., reported all cases in middle third [16]. Saikia KC similarly reported 15 cases (68.1%) in the middle one third of femur [18].

Transverse pattern is the most common pattern, 11 (44%) were found in the present study. This has been supported by Rockwood and Wilkin's who stated that simple transverse, closed, non comminuted injury is the most common (>50%) femoral fracture in children [19]. Lee YHD et al., reported 35 (56%) transverse, 15 (24%) oblique, and 13 (21%) spiral fractures in his series of 63 patients [20].

Radiological and clinical union was observed with an average of 7.9 weeks (6-12 weeks) in our series. A 56% cases achieved union within 6-8 weeks. Houshian S et al., reported median union time of 7 (5-9) weeks [17]. Saikia KC et al., similarly achieved union in an average 8.7 weeks (range 6-12 weeks) [18].

Hardware prominence around knee and nail site irritation were seen in 5 (20%), all responded to analgesic and subsided with implant removal. Saikia KC et al., had four cases of nail site irritation leading to two superficial infections which needed oral antibiotics [18]. Restricted range of motion of knee was noted in 3 (12%) cases at six months, this was due to protrusion of nail tip in the distal femur and all regained full range after nail removal. Slongo TF reported the similar cause for knee stiffness due to excessive length of nail [8].

Limb length discrepancy noticed in 6 (24%) cases, four cases of lengthening average 11 mm and two had shortening average 6 mm. This limb length discrepancy was not described as a complaint by the patient and none of them required additional surgery. Houshian S et al., found a leg-length discrepancy of up to 1 cm in six children [17].

In our series, angular malalignment occurred in 4 (16%) cases which were >5 degree. Heybeli M et al., had angulation less than 10 degrees toward varus/valgus or antero/posterior only in four femurs (11.4%) [21]. Flynn JM et al., reported angular malalignment of >5 degree in six cases and >15 degree in two out of 58 cases [12].

Functional assessment was done by using TEN scoring criteria by Flynn JM et al., [12] In our series, excellent results were obtained in 19 (76%), satisfactory 4 (16%) and poor in 2 (8%) patients. Saikia KC et al., had excellent results in 13 (59%), satisfactory 6 (27.2%) and poor in 3 (13.6%) cases [18]. Santosha and Gulrez S had excellent results in 20, satisfactory in nine and poor in one case [11]. Bahinipati J and Mohapatra RA, had excellent result in 76% and poor in eight [15].

Most common disadvantage of this technique is the hardware prominence at the entry site which causes irritation and restriction of knee movement that usually subsides with implant removal. Limb length discrepancy noted in some is never been an issue because of rapid remodeling potential of this age [11]. This method has huge advantages to child and family, by short hospitalisations, free movement without cast, better hygiene and shorter school absence.

It is superior to other techniques as it is minimally invasive, gives sufficient axial stability, and allows early mobilisation and more rapid return to function. Santosha and Gulrez S treated 30 cases with TENS and followed up the patients for two years. They got excellent results in 20 (66.7%) cases, satisfactory in 9 (30%) and poor results in 1 (3.3%) as per Flynn's criteria. Average union time was 11.5 weeks. Most common complication was the soft tissue discomfort near the knee produced by the nail ends. They observed shortening in one case. They concluded TENS to be an ideal implant for paediatric femoral fracture with proper operative technique and after care [11].

Kumar BB and Mohan SS, did a short term study of 40 patients. All were radiologically united at 8-10 weeks period (mean 9 weeks). They reported

excellent results in 33 (82.5%), satisfactory in 7 (17.5%) and noticed complications like limb lengthening in six cases, varus malalignment in four cases, rotational malalignment in three cases. They concluded TENS to be an easy, safe and effective method of management of paediatric femur fracture in a minimally invasive way [13].

Kawalkar A and Badole CM, in their study of 11 patients, noted 100% fracture union between 8-12 weeks, complications like

knee stiffness in three cases, shortening of more than 2 cm in one case and superficial infection in one case. They concluded TENS to be a simple, rapid and effective treatment for paediatric femur fracture between 5-15 years age group [14].

The results of the present study are comparable with other series of management for paediatric femoral shaft fracture discussed below [Table/Fig-9] [11,13-15,17,18,21].

Study	No. of cases	Union time in weeks	Limb length discrepancy	Flynn score (excellent)	Satisfactory	Poor	Nail tip bursitis
Santosha and Gulrez S [11]	30	11.5	1 (<1 cm)	20 (66.7%)	9	1	
Kumar BB et al., [13]	40	9	6	33 (82.5%)	7	-	7 (17.5%)
Kawalkar A et al., [14]	11	9	1 (>2 cm)	6 (54.5%)	4	1	3 (27%)
Bahinipati J et al., [15]	25	8.2	6	76%	16%	8%	20%
Houshian S et al., [17]	31	7	6 (1 cm)	-	-	-	1
Saikia KC et al., [18]	22	8.7	3 (<1.5 cm)	13 (59%)	6	3	4 (18%)
Heybeli M et al., [21]	35	7.4	7 (<2 cm)	25 (71.4%)	9 (25.7%)	1 (2.9%)	
Present study	25	7.9	6 (<1 cm)	19 (76%)	4 (16%)	2 (8%)	5 (20%)

[Table/Fig-9]: Studies showing results of TENS in femoral shaft fractures [11,13-15,17,18,21].

Limitation(s)

The cons of this study are small sample size to say it as the treatment modality of choice. Also, TENS may not be a good choice of implant for the fracture near the ends of the femur. As it is not a comparative study with other surgical alternative like plate or external fixation, we cannot say it as a superior modality than others.

CONCLUSION(S)

Titanium elastic nailing system is an effective and minimally invasive method of treatment for femur fracture in children. The biomechanical principle of using two symmetrical titanium elastic nails, supporting inner bone at three points produce bending, axial, translational and rotational stability, allows certain amount of micro-motion at the fracture site thus ensuring optimal development of external callus.

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