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Outcomes of Titanium Elastic Nails (TENS) for Unstable Femoral Shaft Fracture Among children aged 6-13 years in Nepal: A Prospective Study

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ABSTRACT

Introduction: Because of the innate fracture healing capacity in pediatric age group Titanium Elastic Nailing System (TENS) is an ideal stabilization method for diaphyseal femur fractures, especially in length stable fractures (transverse and short oblique) owing to its load sharing properties and minimum complications. However, the outcome of TENS in axially unstable pediatric femoral diaphyseal fractures (long oblique, spiral and comminuted) is not uniform and is still debated.

Objectives: Analysis of radiological and functional outcomes of length unstable pediatric femoral fractures treated with titanium elastic nails (TENS) in the age group of 6–13 years.

Methodology: A prospective study of 42 unstable pediatric femoral fractures treated with TENS from November 2022 to October 2023 at Birat Medical College Teaching Hospital, Biratnagar, Nepal was conducted and analyzed with functional and radiological outcomes.

Results: As per Flynn's criteria 37 patients (88.1%) had excellent results, 4 patients (9.5%) had successful results, and 1 patient (2.3%) had poor result. The mean time to full weight bearing after radiological fracture union was 8.1 weeks.

Conclusion: Closed reduction and TENS fixation is an effective surgical procedure even for length unstable femoral diaphyseal fractures in children if appropriate surgical techniques and post-surgical care are followed.

INTRODUCTION

Currently, management of femoral shaft fracture in the pediatric age group has diverse options. Until recently, applying a post-reduction Hip spica cast was the preferred method for treating femoral shaft fractures in children.^{1,2} This conservative treatment with Hip spica cast has been tested over time, this is because of the innate healing power in this age group with minimum chances of any permanent complications, such as malunion or limb shortening.³

However, with the advancement of new surgical skills, orthopedic surgeons have tried many other ways to avoid periods of prolonged immobilization due to Hip spica cast, especially in pediatric polytrauma.^{4,5} The emotional and economic impact of prolonged casting using hip spica is another area of concern for the parents and family members.⁶ Surgical fixation offers several benefits like freedom of joint stiffness due to spica cast, early mobilization of limb and child, better personal hygiene and shorter school delays.

Tubular external frame fixation though have good results with some complications such as short-term loss of knee movement and frequent but manageable pin tract infections but is difficult to take care for parents due to heavy external hardware.⁷ Plate osteosynthesis is also another option but is more aggressive in given age group

with significant blood loss and soft tissue injury and leaves a permanent surgical scar, in the surgical era when other minimally invasive surgical techniques are available.⁸ For adolescent diaphyseal femur fracture intramedullary antegrade nails are better than a spica cast, but not in pediatric age group due to frequent complications like avascular necrosis of head of femur, growth arrest at the greater trochanter and varus deformity of neck of femur.^{9,10}

Titanium Elastic Nail System (TENS) being flexible, simple, and easy to use with a minimally invasive technique, without injuring the physeal plate around the femoral head, greater trochanter or distal femur is an ideal intramedullary implant that maintains the alignment of fracture till bridging callus formation without much aggressive soft tissue injury or prolonged immobilization.^{11,12}

There are several studies for femoral diaphyseal fractures in children treated with TENS nail showing good to excellent results.^{13, 14} However, the results of TENS in length unstable pediatric diaphyseal femoral fractures remain controversial with variable outcomes in different studies.¹⁵⁻¹⁷

To best of our knowledge not many studies have been published from our part of the world that evaluate the outcomes of TENS for length unstable pediatric femur fractures. Therefore, we conducted this study to analyze the outcomes of TENS fixation for length-unstable pediatric femoral shaft fractures in our population.

METHODOLOGY

Our study is a prospective observational study conducted at Birat Medical Teaching Hospital, Tankisinwari, Biratnagar, Nepal from November 2022 to October 2023. Institutional ethical approval was obtained for this study with IRC number 288/2078-2079. A total of 43 cases with length unstable pediatric femoral fracture in between 6 to 13 years of age group were included in our study and were surgically treated by closed reduction and TENS fixation under fluoroscopic guidance. Fracture patterns such as long oblique, spiral, and comminuted were defined as length unstable fractures. In this study we included the pediatric femoral fractures, which are classified as 32-D/5.1 and 32-D/5.2 as per the AO pediatric comprehensive classification of long bone fractures. Open fractures, fractures associated with neurovascular injury, and polytrauma patients were excluded from the study. Informed consent was taken from the guardians of all patients. The surgical intervention for fracture fixation was performed within 2-5 days of the injury.

All patients were pre-operatively evaluated with X-rays antero-posterior and lateral views of the involved as well as contralateral limb. All patients underwent surgery under spinal or general anesthesia after receiving pre-anesthetic fitness and consent for surgery. Fractures were reduced by traction and manipulation under fluoroscopic guidance with the patient being kept on fracture table.

After making an incision, about 2cm in length, 2cm proximal to distal femoral physis, on both lateral and medial side, entry to medullary canal was 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) measured on contralateral limb.¹⁸ 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 medullary canal and driven in proximal fragment with rotary movements of T-handle or by gentle mallet. After a satisfactory fixation nails tip were cut around 2.5 cm from the entry point, buried and the wound were closed in layers.

Postoperatively we immobilized the fractured limb with a long knee immobilizer, and by the second week we encouraged early passive knee movement as tolerated by patient.

At each follow-up visit, we examined the range of movement at the knee joint, any discrepancy in limb length, persistent pain around the knee, bursitis, or any ulcer due to the prominence of nail tip as well as radiographic evaluation for fracture healing.

Patients were followed up at 2 weeks for suture removal, then at 6 weeks, 3 months and 6 months, 12 months post-surgery. All patients were advised not to bear weight till six weeks of surgery or till radiological union was confirmed. Fracture union was assessed radiologically as per Anthony et al scale.¹⁹ Assessment of functional outcomes was done as per TENS criteria by Flynn JM et al.²⁰

The non probability purposive sampling technique was used in this study and the sample size was 43. The data collection method used specially designed semi-structured questionnaires. The follow-up study was taken from the preoperative radiograph to the 12-month follow-up. The collected data was checked and analyzed by SPSS. The anonymity and confidentiality of the study participants were maintained.

RESULTS

A total of 43 patients were included in the study of which one patient lost to follow up. Complete follow-up was possible for 25 boys (59.5%) and 17 girls (40.4%). Demographic profiles for all patients are described below [Table 1]. 22 (55%) patients had fracture on the right side and 20(45%) patients had fractures on the left side. The mode of injury was due to fall from height in 15 patients (35.7%), road traffic accidents in 21 patients (50%), and fall at play-ground injuries in six patients (14.2%).

Table 1: Demographic variables of study population

Variables	Frequency (%)
Mean age	8.7±2.3
Gender	
Male	25 (59.5%)
Female	17 (40.4%)
Side involved in fracture	
Right	22(55)
Left	20(45)
Mode of trauma	
Fall	15(35.7%)
RTA	21(50%)
Sports	6(14.2%)
Pattern of Fracture	
Long Oblique	5(11.9)
Comminuted	18(42.8)
Spiral	19(45.2)
Type of Anesthesia	
Spinal	31(73.8)
General	11(26.2)

The diameter of inserted TENS nail was 3 mm in 15 patients, 3.5mm in 18 patients and 4mm in 9 patients. The average operative time was 30-45 minutes. In three of the cases, the fracture had to be opened by making a small incision at fracture site through the vastus lateralis muscle due to soft tissue interposition rendering fracture irreducible by closed means, in the rest of the 39 patients fractures were successfully reduced by closed manipulation under fluoroscopic guidance. The average duration of hospital stay was 4.3 days (range 3-7 days). The mean time for radiological union of fracture was 7.1 weeks, and the mean time to full weight bearing was 8.16 weeks of surgery. At the final follow up complications due to proud nail tip were bursitis among 3 (7.1%) and ulceration among 3 (7.1%) of the patients. Mild knee pain was noticed among 6 (14.2%) of the patients whereas varus deformity of five degrees was seen in one patient (2.3%), valgus deformity of 10 degrees in two patients (4.7%) and valgus deformity of 15 degrees in one patient (2.3%). Leg length discrepancy was found in 5 (11.9%) of the patients with a range of 10-20mm whereas 5-degree external rotational malalignment was in 2 (4.7%) of the patients. Knee stiffness was not found in any of the cases. Implant removal was done at 5 months in 4 patients, at 9 months in 32 patients, and 12 months in 6 patients. Final functional outcome was calculated as per TEN scoring criteria defined by Flynn JM et al.²⁰ The final TEN Score is given in Table 2.

Table 2: Functional outcome using Flynn’s criteria

Final Functional outcome (Flynn TEN criteria)	Frequency (%)
Excellent	37(88.1)
Satisfactory	4(9.5)
Poor	1(2.3)



Fig 1: Preop X-ray showing length unstable spiral fracture in proximal shaft of femur

Fig 2: Immediate post-op x-ray after TENS fixation,

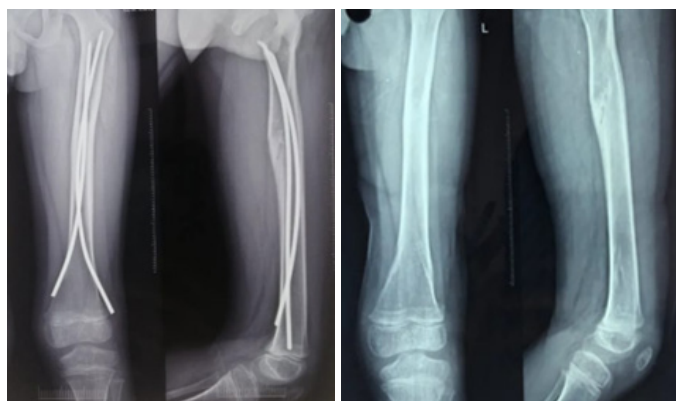


Fig 3: 3 months following fixation showing good fracture union,

Fig 4: Post-op X-ray after patient underwent TENS removal at 9 months

DISCUSSION

TENS nail is a well adopted method of fixation for transverse and short oblique fractures with excellent outcomes in various reports worldwide. The working principle of TENS nail is based on fixation at three points and balanced nailing that provides a constant pressure inside the medullary canal due to elastic property of nails.¹³ However, in certain fracture patterns like long oblique, spiral and comminuted which are inherently unstable, TENS nail fixation is less preferred due to fear of loss of reduction and malunion.

The mean time for radiological union in our series is 8.1 weeks and in around 90% of cases radiological union was seen in between 6-12 weeks of surgery. This result is similar to series by Houshain S et al, who reported a median radiological union period of 7 weeks (5-9 weeks)²¹ as well as by Saikia KC et al, who observed radiological union by an average of 8.7 weeks (6-8 weeks).²²

In our study by the end of six months of follow-up, five patients had limb length discrepancy ranging from 10-20 mm however, none of these patients had any symptoms or complaints regarding limb length discrepancy and thus were not intervened further. These findings are comparable to a study by Houshain S et al, who also found similar difference in limb length of up to 1 cm in six children.²¹

In this series, we found varus deformity of five degrees in one patient (2.3%), valgus deformity of 10 degrees in two patients (4.7%) and valgus deformity of 15 degree was seen in one patient (2.3%). Flynn JM et al, in their series of 58 cases also found similar angular deformity of 5 degrees in six cases and 15 degrees in two cases.¹²

In our study complications due to prominent TENS nail tip around the knee leading to skin irritation and bursitis were seen in 6 cases, 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. Saikia KC et al., in their series also reported four cases of nail site irritation and two superficial infections which needed oral antibiotics.²² Pain and mild restriction in flexion at the knee were noted in 6(14.2%) cases on follow up at 6 months and was resolved on TENS removal. Slongo TF et al also reported similar problem of knee pain due to hardware prominence in their study.²³

The results of our study is comparable to various studies like Santosha and Gulrez S, Kumar BB and Mohan SS, and Kawalkar A and Badole CM^{11,13,14} who found similar rates of union and complications following TENS fixation for pediatric fracture shaft of femur and concluded that TENS is a minimally invasive and effective surgical treatment for femoral shaft fractures in pediatric age group. To our understanding these satisfactory outcomes in our study were possible as we adhered to the principles of TENS nailing and applied knee immobilizer in every case for two weeks following surgery. By applying knee immobilizer, we minimized any possible deforming force at fracture site till callus is formed. Once the callus is formed, both callus and implant start load sharing, at same time preventing any possible movement at the healing area. Gradual mobilization of lower limb at the knee joint after the removal of knee immobilizer and isometric strengthening of quadriceps and hamstrings started after two weeks. Even after knee rehabilitation, we found loss of terminal knee flexion in six patients.

Based on our results and on comparison to other similar studies we conclude that retrograde Titanium Elastic Nailing System (TENS) is a good option for the management of length unstable pediatric femur fractures when supplemented by slab or a knee immobilizer for initial few weeks postoperatively. The initial few weeks of knee immobilization in post-operative period prevents loss of reduction and probably nail tip related complications.

Limitations of the Study Our study has several potential limitations. Being an observational study of single-method fixation, statistical significance of the results could not be obtained. A better study would be either a prospective comparative study comparing different methods of fixation or

a randomized controlled trial. The small number of cases in our study is another limiting factor. Large sample size in single-center or multicentric studies with larger sample size would give more convincing results. But even in high-volume trauma centers, it will take a long duration to have adequate sample size with adequate follow-up.

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

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Conflict of interest None

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