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Functional outcome of pediatric femoral shaft fractures treated with TENS nailing: A case series of 25 patients

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Abstract
TENS (Titanium Elastic nailing system has become the standard treatment for pediatric femoral shaft fractures in the age group 6-14 years. The other treatment options are traction plus spica casting and external fixation. In spite of excellent results described in various studies, there still exists disunity in the orthopedic fraternity with regards to its usefulness. The aim of this study is to determine the outcome of pediatric femur fractures treated with TENS nailing. Between September 2020 and November 2022, 25 children within the age group of 3-12 years with femoral shaft fractures were included in the study. Two TENS nails of precalculated size were inserted in a retrograde fashion under fluoroscopic guidance. Patients were followed up at regular intervals to assess clinical and radiological parameters. Final results were evaluated using Flynn's clinical criteria. Results: There were 14 males and 11 females with an average age of 6.8years. Fracture levels included N=6 subjects (24%) proximal third fractures. N=15 (60%) subjects with Middle third fractures. N=4 (16%) subjects presented with Lower third fractures. Open injuries were present in 6 cases and 19 cases with closed injuries. The mean injury to surgery interval was 2.37 days, mean hospital stay was 7.3 days and mean time to union was 8.16 weeks. Severe complications were severe skin irritation with bursitis requiring early nail removal in one case, delayed union in one case, Results were excellent in 13(52%) patients, satisfactory in 10 (40%) patients and poor in 2(8%) patients. Conclusion: TENS is safe, reliable and an effeciant method of fixation owing to its simplicity, minimal invasiveness, ease of insertion and removal, TENS additionally has better cosmesis, rapid union with short rehabilitation, less psychosocial stress to the patient and family.

Keywords: Pediatric femur shaft fractures, TENS, functional outcome, flynn's criteria

Introduction
Fractures of the femoral shaft are quiet common in children, and represents 2% of all bony injuries [1]. The incidence of pediatric femoral shaft fractures is 20-25 per lakh children per year [31]. These injuries require hospitalization, causing considerable disability with physical and psychological stress to both the patient and their parents [2]. These fractures are commonly caused by high energy trauma such as motor vehicle accidents or significant falls [3]. They may also be pathological fractures. The treatment of these injuries depends mainly on the age, fracture location, pattern of fracture and whether the fracture is closed or open. Fractures in children younger than five years of age are treated with skin traction followed by casting or early spica casting with good results [4]. Fractures in patients more than 15 years of age are treated with interlocking intramedullary nail as in adults [5]. Children in the age group of 6-14 years have varied treatment options including traction followed by casting, TENS nailing, ORIF, Intramedullary nailing external fixation with no clear uniformity in the literature [6-8].
More fractures in this age group are now treated operatively rather than conservatively owing to developments in surgical treatment modalities and implants over the last 30 years. Nonoperative treatment with traction and casting often results in prolonged bed rest, increased hospital stay, knee stiffness, malunion and may also cause plaster related complications. It may also cause psychosocial disruption [4, 6].
The benefits of operative treatment over non-operative treatment are that operative treatment aids in proper reduction, is a more stable fixation, rapid mobilization is possible, decreased hospital stay, less disruption of social life, early return to school and lastly can be used in

patients with open fractures, multiple injuries, head trauma [9-12]. External fixation is mainly used in open injuries settings and is associated with complications of pin tract infection, knee stiffness [7, 13]. The Parents of these patients are usually not compliant with external fixation as a treatment modality owing to its cosmetic appeal. The use of rigid antegrade intramedullary nailing in Pediatric age group risks the development of avascular necrosis of femoral head, physeal damage and growth arrest of greater trochanter causing secondary coxa valga and thinning of femoral neck [5, 14].

TENS nailing is now the go to method for treatment of femoral fractures in age group of 6-14 years. Initially introduced by Nancy group in 1979 [9], several other authors have reported promising results with TENS [11, 12, 15]. TENS acts as a load sharing internal splint providing relative stability for callus formation, helps maintain alignment and length of bone and permits rapid mobilization of adjacent joints [16]. It is a minimally invasive procedure requiring small incision, lower blood loss, with easy insertion and removal, with a low risk of physeal damage or refracture and is also cosmetically appealing as opposed to External fixation methods. We conducted a prospective study on 25 patients who presented to kamineni academy of medical sciences to assess the clinicoradiological outcome and complications of pediatric femoral shaft fractures treated with Flexible intramedullary nailing in 3-12 years age group.

Materials and Methods

This study is a single center based prospective study conducted between the year September 2020 and November 2022. A total of 25 patients who presented to the Center with isolated closed femur shaft fractures between the age groups 3-12 years, hemodynamically stable patients, operated with titanium elastic nailing system were included in the study. Patient's age, sex weight, mode of injury, level of fracture, duration of surgery, immobilization and complications were noted.

Inclusion criteria

Isolated closed fractures
Isolated Gustilo Anderson Open type 1 injuries

Exclusion criteria

Pathological fractures
Metabolic bone disease
Gustilo-Anderson Type 2 and 3 injuries
Grossly comminuted fractures
Polytrauma patients.

Surgical technique

Pre-op planning was done which included classification of fracture according to Winquist and Hansen classification and level of fracture. The measurement the diameter of the medullary canal at the isthmus was taken to calculate for probable diameter of the elastic nail. This was obtained using Flynn's formula (diameter in mm x 0.4) i.e 40% of canal diameter. Standard aseptic precautions were followed in the operating room. Surgeries were performed under C-arm fluoroscopy, which was used to guide fracture reduction and TENS placement. Two titanium elastic nails were used for each case. The nails were pre-bent before insertion. Insertion was done in retrograde direction. Skin incision of 2 cm size was given over both medial and lateral aspect of lower thigh at the level of the upper pole of patella. Using a 4.5 mm bone awl pin entry was made about 2–3 cm proximal to the physis at an angle directed into the canal. Titanium elastic nails of previously calculated size was inserted and gently hammered across the fracture site and rotated appropriately to engage in a divergent fashion in the proximal physis of the femur. Care was taken to see that the nails did not cross the physis proximally or distally. Approximately 2 cm of nail was left outside the entry site and cut to allow for extraction at a later date. Ends of the nail were not bent. The ends were allowed to lie flush with the bone to avoid skin irritation.

Post-Op Care

Postoperatively, secondary stabilization was done by application of a long knee cast. Static Quadriceps exercises were begun early and knee range of movements begun at 4 weeks after removal of cast. Patients were discharged after patient received antibiotics for 3 days, and comfortable with in bed sitting and edge of the bed sitting in a long leg cast.

The children were followed up at biweekly interval until fracture union. At each visit the progression of fracture union was assessed for radiologically. Tenderness at the fracture site was assessed and clinical examination done to check for limb alignment, rotation, length discrepancy, range of motion of hip and knee and look for other complications. Serial radiographs were chanced for malalignment. Partial weight bearing was started when radiograph revealed grade 3 callus at the fracture site. Full weight bearing was allowed when radiographs revealed grade 2 callus at the fracture site. The children were evaluated clinically by Flynn's criteria after complete fracture union [Table 1] and radiologically Hammer *et al*. criteria [Table 2]. Patients were followed up until 19 weeks post-surgery.

Table 1: Flynn's criteria

Criteria	Excellent	Satisfactory	Poor
Limb length discrepancy	<1 cm	1-2cm	>2cm
Malalignment	<5 degrees	5-10 Degree	>10 degrees
Pain	Absent	Absent	Present
Complication	Absent	Mild/Managable	Major complications

Table 2:- Hammer *et al*. classification of Callus Formation

Grade	Callus	Fracture line	Stage of healing
1	Homogenous bone structure	Oblietrated	Achieved
2	Massive trabeculae crossing fracture line	Barely visible	Achieved
3	Apparent bridging of callus	Discernable	Uncertain
4	Trace no bridging of fracture line	Distinct	Not achieved
5	No callus formation	Disctinct	Not achieved

Results

25 patients had presented with shaft femur fracture. The mean hospital stay was 7.3 days (5-9 days). The mean age was 6.08. N=18 subjects presented to Center following a road traffic accident. N=7 subjects presented to Center following a significant slip and fall. There were 14 boys (56%) and 11 girls (44%). N=6 subjects (24%) presented with proximal third fractures. N=15 (60%) subjects presented with Middle third fractures. N=4 (16%) subjects presented with Lower third fractures. N=6 (24%) were Open grade 1 fractures. N=19 (76%) were Closed fractures.

The mean time of patients being undertaken for operative procedure after hospitalization was 2.37 days (1-4days). In two patients, the fracture site was opened with a small incision to allow intraoperative reduction. Minimum nail size used was 2.5mm while maximum was 4mm according to Flynn's formula. The median duration of surgery was 65.3 minutes (range 40-90 minutes). In the postoperative period, cast and sutures were removed in the second week and knee range of movements started. Coronal and sagittal plane radiographs were taken to determine union and allow weight bearing. Mean weight bearing time was 6.5 weeks (range 6-16 weeks). All fractures were healed. The mean union time was 8.16 weeks (range 8 to 12 weeks). Delayed union was observed in 1 subject. This patient was allowed partial weight bearing at 12 week after achieving grade 2 callus at 12 weeks as opposed to 8 weeks in the remainder of patients. Nail insertion site irritation was the most common complication in our study however it was regarded as a minor complication. Irritation at the insertion site was present in 10 (40%) of the patients. No infection was detected in any of the patients. Radiographically, coronal and sagittal planar diaphyseal angulation was measured. No Angulation was seen in any of the patients post-operatively. Limb length discrepancy was assessed for clinically and none of the patients had clinically significant LLD. The mean follow-up period was 18.3 weeks.

Final Results

In addition, patients were evaluated according to Flynn's criteria. According to this, 13 (52%) of the patients' results were excellent, 10(40%) were good, and 2(8%) were poor [Table 3]. Flynn score was correlated to site of fracture and no statistically significant difference was observed. Complications that we observed in 2 patients were delayed union in one case and severe skin irritation with bursitis in another that required early nail removal at 6 weeks. Both patients came under Poor Flynn score. Knee Range of movements was comparable to opposite side at final follow-up.

TENS was removed for all patients after the fracture was considered healed at 8.24 weeks (range 6-16) without major intra-op complications. Flynn's Score was correlated with fracture level and there was no statistically significant difference.

Table 3: Flynn's outcome

Results	Number of cases	Percentage
Excellent	13	52
Satisfactory	10	40
Poor	2	8

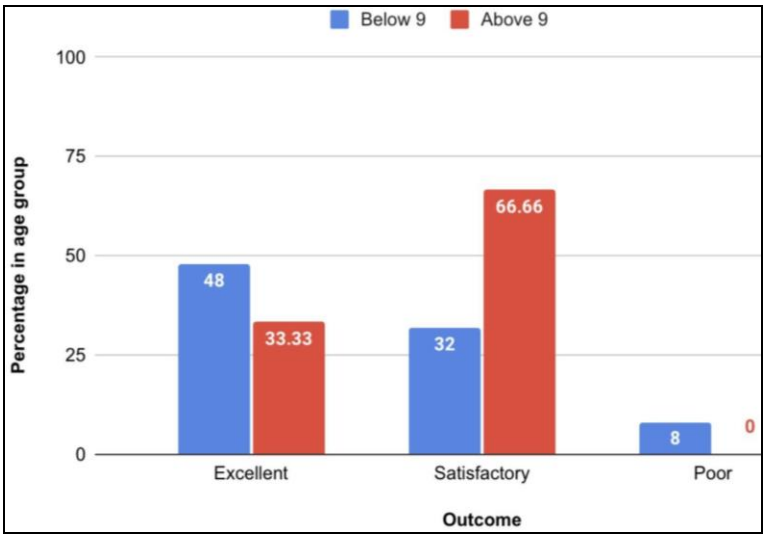

Fig 1: Percentage in age group

Discussion

In the last two decades pediatric femoral shaft in patients older than six years fractures are being treated operatively because of the benefit of reduced duration of hospitalization and immobilization, shorter rehabilitation period and importantly less psychological impact to child [19]. Studies that compare operative versus conservative methods reflects the trend towards operative management of these fractures [20, 21]. TENS has only recently emerged to be the implant of choice for treating pediatric femur shaft fractures. TENS works on the principle of three point fixation providing axial, translational, rotational stability at fracture site. TENS additionally has a very short learning curve and is associated minimal complications when performed properly. It allows for abundant callus formation, early union due to nails permitting micromotion at fracture site and avoids disrupting the fracture hematoma as it is a closed procedure [22].

Ligier JN *et al.* at Nancy Hospitals in their study first reported the outcome of TENS nailing in 123 pediatric femur fractures [9]. They reported one case of bone infection treated with drainage and removal of the infected nail. None of their patients suffered with a limp or gait abnormality post-operatively. They additionally calculated the cost reduction by over 70% by using TENS nailing instead of conservative treatment. Similar studies in other series using TENS, infection has been uncommon [11, 12, 15]. The present study does

not report any case of deep infection.

The most commonly reported complication associated with TENS is skin irritation at entry site due to prominent nail tips. Ligier JN *et al.* reported an incidence of 10% for skin ulcerations that occurs secondary to prominent nail tip. They settled the skin ulceration by trimming of the nails, while Salonen A *et al.* in his series of 32 patients reported five cases of skin irritation at entry site [9, 23]. They attributed this for not having bent the nail tips towards the side of femur. Flynn's series also reported four cases of skin irritation after bending the nail tip away from bone for easy removal [11]. Narayanan *et al*. however advocated the nail tip be kept flush with metaphyseal flare without bending to prevent skin ulceration after noticing it in their series 41 out of 79 patients [24]. Our series had 10 (40%) cases of similar symptoms with pain and bursa formation around distal nail tip with problems in knee motion. The literature is still unclear on whether the nails should be bent or kept flush with metaphyseal bone. However we agree with Narayanan *et al*., that nail tip should be kept flush with metaphyseal flare without bending to avoid skin irritation. One subject in the present study, owing to excessive nail irritation had to undergo early nail removal.

Reeves *et al.* did comparative study between conservative and operative methods of treatment for pediatric femur shaft fractures they found more complications and increased hospital stay duration with conservative method as opposed to operative group (26 vs 9 days) [21]. They concluded operative treatment is associated with shorter hospital stay and has financial, psychosocial and economic advantages allowing for early return to school. The mean duration of hospital stay in our study was 7.3 days which is comparable to other studies of Kapil Mani *et al.* (4 days), Luhmann *et al.* (3.4 days) and others [12, 15, 25].

TENS preserves the fracture biology due to physiological method of fixation as a result union rates have been excellent with FIN. Flynn *et al.*, Lohiya *et al.* and Narayanan *et al.* did not report any case of delayed/non-union [11, 15, 24]. Luhmann *et al.* however observed one case of hypertrophic nonunion and one case of delayed union [25]. Our average union time of 8.16 weeks is comparable to those in above series. Our study correlated compared level of fracture to time to union and observed no significant statistical difference. In our series, we had no case of nonunion and one case of delayed union, which finally united at 12 weeks.

Several authors have described malunion with TENS. Heinrich *et al.* in their study on 77 cases reported 8% sagittal malalignment and 11% coronal malalignment [26]. In Flynns series on 58 cases, six cases with malalignment of 5-10° were reported [11]. Nancy Hospital group reported 14 cases of 5-10° angulation out of their 123 subjects [9]. Ligier *et al.* in their study did not use any postoperative method of immobilsation or cast. On the contrary Flynn *et al.*, Luhmann *et al.*, Moroz *et al.* used selective spica cast or femoral braces in their series [9, 11, 25, 27]. In our series we did not observe any malalignment which is less as compared to other studies. In our series as we used long knee cast for 4 weeks post operatively. Weight bearing was allowed when grade 2 callus was achieved. TENS has been reported as an ideal implant for transverse and short oblique fractures of midshaft femur. In our study however we did not find statistically significant difference between level of fracture and Flynn's grading. The use of TENS must be avoided in patients weighing more than 45 kgs and above 14 years of age as it does not stabilize the fracture enough and fails when weight bearing is begun leading to implant failure or malunion [32]. In our study we do not report any case of malalignment and shortening perhaps because none of the children weighed greater than 40 kilos.

The availability of different diameters in nail sizes is an advantage in choosing the correct implant. We used two Titanium flexible nails of same size after pre-op calculations by Flynns formula [11]. In a series by Narayanan *et al.* there is a strong association between smaller nail sizes and angulations or malrotations in three patients [24]. We did not have any problems with medullary canal and nail mismatch owing to precise preoperative evaluation. While many series report lengthening after femoral fractures due to increased physeal blood supply, we report no case of lengthening. Lengthening/shortening in our study was assessed only clinically at the end of the follow-up period of 16 weeks. Kapil Mani *et al.* reported four cases of lengthening (average 7 mm) while Luhmann *et al.* reported lengthening in six patients (average 8 mm) and shortening in two patients (average 12.5 mm) [12, 25]. Long term follow-up is required to determine the final leg length discrepancy at skeletal maturity. Kemal *et al.* in their study observed bone length to have increased in 15 patients. They also observed that as the follow-up period prolonged, the LLD increased, the patients in their study were followed up for a period of 24 months [33]. Our study on the other hand had a relatively shorter follow-up. The problem of significant shortening was also not observed on short term follow-up because of the fact that we included only Winquist type-1 and 2 fractures.

Most authors recommend routine nail removal after union, there is no proper consensus in the literature with regarding's to timing of nail removal. Despite the chances of complications from early removal, many authors have reported good outcomes after removing nails at three months [9, 11]. Most authors have typically removed nails around one year after surgery with excellent outcomes [29]. We removed nails at 8 weeks for 23 cases. In 1 case owing to excessive nail site irritation and bursitis underwent an early nail removal at 6 weeks, the patient was subsequently put in a long knee cast. One patient with delayed union underwent nail removal at 16 weeks after achieving complete union.

Flynn *et al.* had one poor result in 58 cases, while Vransky *et al.* in a series of 141 fractures had extremely good results without a single complication [30]. Luhmann *et al.* reported a complication rate of 49%, but only two major postoperative complications [25]. Lohiya *et al.* reported a complication rate of 44% with only four poor results in 73 cases [15]. The current study had a complication rate of 48% with nail irritation as the most common complication seen in 10 (40%) subjects. Nail irritation however in 9 subjects qualified as only a minor complication. In one patient Nail irritation requiring early implant removal qualified as a major complication. Another major complication observed was delayed union resulting in two patients (n=2{8%}) falling under Poor Flynn's category. According to Flynn's criteria, the most common complication which caused satisfactory and poor results was the angulation. Similar results were obtained with recent studies in the literature [34].

In our study 13 subjects (52%) were assessed to fall under Excellent Flynn's criteria and 10 subjects under satisfactory Flynn's criteria. Sourabh *et al*. evaluated Functional outcome with Flynn's scoring system in a sample size of 53 and reported excellent outcome in 75.5% of cases, satisfactory outcome in 17% and poor outcome in 7.5% of cases [35]. Our study is in close agreement with Sourabh *et al.* Higher complication rates were initially observed with the use of TENS nail due to improper use in bigger, older and heavier

children [36. 37]. Careful patient selection is therefore paramount

Conclusion

Our study had various limitations as we had no control group and did not compare our results with that of other methods of treatment. Further, a larger sample size would have been more conclusive in determining factors that cause complications/failure in TENS. However, we consider this procedure to be worthwhile in developing countries. Our follow-up was short term. Long term follow-up is needed to determine the effects of this procedure on final limb length discrepancy.

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Author's Contribution

Not available

Conflict of Interest

Not available

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