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Clinical study of surgical management of paediatric diaphyseal fractures of femur by Titanium Elastic Nailing System (TENS)

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Abstract
Femoral shaft fractures are the most common major paediatric injuries managed by the orthopedic surgeon. Non-surgical management usually with early spica cast application is preferred in younger children. In the older child, traction followed by casting, external fixation, flexible IM Nails and plate fixation have specific indications. Potential complications of treatment include shortening, angular or rotational deformity, delayed union, Nonunion, over growth, skin problems and scarring. Risks of surgical management includes re-fractures after external fixator or plate removal, osteonecrosis after rigid IM nails fixation and soft tissue irritation caused by ends of flexible nails.

Keywords: Paediatric diaphyseal fractures of femur, TENS

Introduction
There was an increased interest in the operative treatment of paediatric fractures in the past two decades, although debate persisted over its indications. There is a little disagreement concerning the treatment of femur fractures in children less than 5 years (POP cast) and adolescents older than 15 years (locked intramedullary nailing) [1]. Controversy persists regarding the age between 5 to 15 years. Several treatment options for femoral shaft fractures in children and adolescents have been described. Children below the age of 3 can be treated with cast or extensional devices. In the past two decades the management of displaced femoral shaft fractures in older children has gradually evolved toward a more operative approach due to a more rapid recovery, faster reintegration of the patients and possible negative effects of immobilization even in children [2]. Orthopaedic surgeons will continue to face the challenge to treat this age group with less morbidity at a lower cost, as no clear guidelines have been available until now despite efforts done initially by French surgeons, later on by European surgeons and recently by the Paediatric Orthopaedic Society of North America (POSNA) [3]. Titanium elastic nail (TEN) fixation was originally meant as an ideal treatment method for femoral fractures as it represents a compromise between conservative and surgical therapeutic approaches with satisfactory results and minimal complications [3].

Aim and objective of the study: To study the various aspects of managing diaphyseal fractures of femur in children aged between 5-15 years by using Titanium Elastic Nailing System. Subjective and objective study of clinical parameters like pain, comfort to the patients, early mobilization, operative techniques, radiological evaluation for union, stages of weight bearing till complete recovery and any associated complications by using Titanium Elastic Nailing System.

Methodology: All children and adolescent patients between 5-15 years of age with diaphyseal fractures of femur admitted at Mamata General Hospital, Khammam, meeting the inclusion and the exclusion criteria during the study period from October 2018 to September 2020 were the subjects for the study.

Patients

Inclusion Criteria: Children and adolescents between the age of 5 to 15 years having THE following type of diaphyseal fractures of femur:

1. Fresh closed displaced/UN displaced diaphyseal fractures.
2. Fresh Type I and Type II open fractures.
3. Closed comminuted fractures.
4. Segmental fractures.

Exclusion criteria

- All open fractures having secondary infections or suspected deep infections or late presentations (>10 days)
- All type III open fractures
- Closed fractures more than two weeks old
- All metaphyseal fractures with/ without the involvement of epiphysis
- All pathological fractures

As soon as the patient was brought to casualty, patient's airway, breathing and circulation were assessed. Following this, a complete survey was carried out to rule out any other significant injuries. Plain radiographs of AP and lateral views of the involved extremity, including one joint above and one joint below were taken to assess the extent and geometry of fracture.

Collection of data from children admitted with diaphyseal fractures of the femur was the history (relating to the age, sex, and occupation, mode of injury, time of injury and place of injury, past and associated present medical illnesses) taken by verbal communication from the child and/ or parents/ guardians.

The following were thereafter performed

- Clinical examination, both local and systemic
- Baseline haematological investigations
- Radiological Examination-X Rays of involved limbs with one joint above and one joint below the fracture and Chest X Rays.
- Pre-anaesthetic check-up
- Informed & written consent before surgery.
- Surgery
- Postoperatively after 24 hours - Check X-ray to assess reduction.
- Active static exercises/ passive exercises / active neighbouring joint movement at the earliest.
- Wound inspection on 5th POD.
- Between 10 to 12 days - wound inspection and subsequent suture removal.

Materials

Nail Size [8]

Nail width: The diameter of the individual nail is selected as per Flynn *et al*. formula.

Flynn *et al.*'s formula

The diameter of nail = width of the narrowest point of the medullary canal on AP and lateral view X 0.4mm.

In case of single nail usage, it's diameter should be more than 60% of the narrowest diameter of the medullary canal.

Nail length:

Lay one of the selected nails over the thigh/leg, and determine that it is of the appropriate length by fluoroscopy.

Preoperative preparation of patients

Patients were kept nil by mouth overnight before surgery.

Adequate amount of compatible blood was kept ready for any eventuality.

1. The whole of the extremity below the umbilicus, including the genitalia was prepared appropriately.
2. A systemic antibiotic, usually a third-generation cephalosporin was administered one hour before surgery.
3. Under anaesthesia, closed reduction and internal fixation with TENS nails done under c-arm guidance.

Fig 1: Titanium Elastic Nail System Instrumentation Set

1. Titanium elastic nails
2. Bone awl
3. Inserter
4. Beveled tamp
5. Hammer
6. Steffe cutter

Pre-requisites for ESIN for stable internal fixation

1. *Nail diameter* should measure 40% of the narrowest diameter of the diaphysis.
2. Nails should be contoured with a long bend such that *apex of the convexity* will be at the level of fracture to provide optimal three-point fixation.
3. Both the nails should be *bent symmetrically to the same extent.*
4. The nails are pre-bent so that the *height of the curve* is three times greater than the diameter of the medullary canal.
5. Always use *same diameter* nails to prevent loss of reduction towards the side of stronger nail.
6. The *entry point* of both nails should be at the same level.
7. When inserted, nails should have *maximum cortical contact at the fracture site* in the opposite directions.

4. Procedure for TENS nailing of diaphyseal fracture of femur retrograde fixation [43, 44, 45, 46]

Step I: Positioning and draping

The patient may be placed supine on a fracture table with a traction boot. If fracture reduction can be accomplished with manual reduction, we can use a standard radiolucent table. Position the image intensifier on the lateral side of the affected femur for AP and lateral view of the thigh from the hip to knee. The setup must allow the surgeon to access both medial and lateral aspects of the distal femur. Reduce the fracture and confirm alignment with c-arm both AP and lateral views. Prepare and drape the leg from hip to knee.

Fig 2: Surgical procedure of femur TENS nailing

Step II: Contouring the Nail

Contour both nails into a bow shape with nail tip pointing towards the concave side of the bowed nail. The apex of the bend should be a fracture site and at a distance, three times the diameter of bone, usually it requires about 300 bend.

Fig 3: Surgical procedure of femur TENS nailing Step

III: Nail Entry Point

The selection of entry point for nails in medial and lateral at the top of the flare of the femoral condyles, so that after insertion, they will tend to bind against the flare of the condyle. If the nail insertion is too low, it will tend to back out. An incision is made on the lateral side of leg 2.5 c.m above the physis and extending distally for 2.5 cm. Use drill sleeves to protect the soft tissues. Start the drill bit perpendicular to the bone surface to penetrate the cortex. Use a curved bone-awl, enlarge the hole in 45° angulations. Similarly, make a medial entry point in the same manner.

Fig 4: Surgical procedure of femur TENS nailing

Step IV: Nail insertion and fracture reduction:

Both the nails are inserted through entry points one after the other and are driven up to the fracture site. Using C-arm align the nail tip so the convex side will glance off from far cortex. It is very essential that sufficient reduction of the fragment in achieved so that about half of the medullary canal overlap.

Fig 5: Surgical procedure of femur TENS nailing

Step V: Nail advancement and cutting:

Viewing with an image intensifier, note which nail will be the easiest to drive across the fracture site. This nail is advanced 2cm into a proximal fragment and then rotated. The motion of the proximal fragment demonstrates that the nail is in the proximal fragment. At this point, it is advanced further. By rotating this nail, further reduction of fracture can be accomplished, and then the second nail is inserted. Don't advance the first nail so far until the second nail crossed the fracture site. If the first nail is advanced too far, it will shift the fragments and make the passing of the second nail difficult. The traction is released, and both the nails are advanced to their full length.

Both nails should reach at least up to the level of the base of the femoral neck. Both the nails should be cut to appropriate length leaving around half to one cm of each nail away from the bone margins so that removal will be easy. The nails should not be too proud or bent as it may cause skin irritation.

Step VI: Closure

The wound is closed in layers, and an aseptic dressing applied.

i) Post -Op Protocol

For lower limb fractures, weight-bearing will depend on the fracture pattern and stability. Progression of weight-bearing should be at the discretion of the surgeon and stability of fixation. When early callus formation is observed weight bearing can be increased, external support can be discontinued when radiographic healing is complete.

Observations and results

Results of the present study

An outcome surgical study of 20 patients with Diaphyseal fractures of the femur was undertaken to study the outcome of Titanium elastic nail fixation for femur fractures in children and adolescents aged 5-15 years.

Table 1: Distribution of patients based on duration of surgery

Duration of surgery (min)	Number of patients	Percentage (%)
<30	0	0
30-60	2	10.0
61-90	14	70.0
91-120	4	20.0
Total	20	100.0

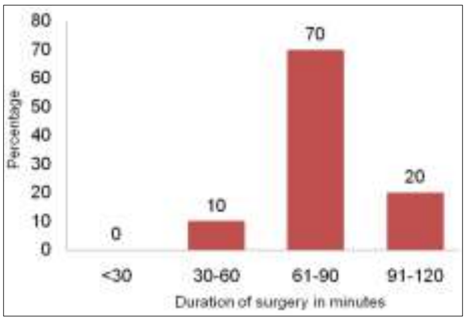


Fig 6: Distribution of patients based on duration of surgery

Table 2: Distribution of patients based on post-operative Immobilization

Post-op Immobilisation	Number of patients	Percentage (%)
4 weeks	8	40.0
6 weeks	9	45.0
8 weeks	3	15.0
Total	20	100.0

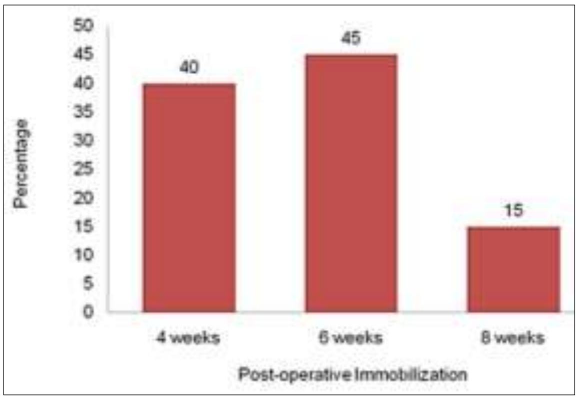


Fig 7: Distribution of patients based on post-operative Immobilization

Table 3: Distribution of patients based on duration of stay in hospital stay

Duration of stay (days)	Number of patients	Percentage (%)
≤7	0	0
8-10	1	5.0
11-15	13	65.0
>15	6	30.0
Total	**20**	**100.0**

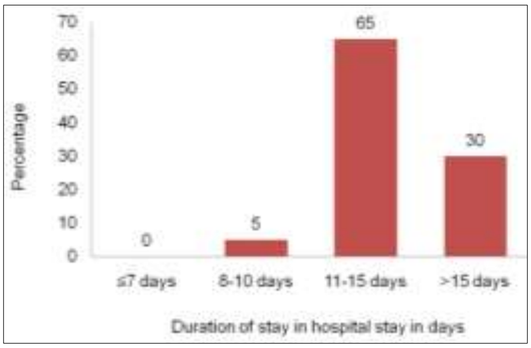


Fig 8: Distribution of patients based on duration of stay in hospital stay

Table 4: Distribution of patients based on time taken for union

Time for union	Number of patients	Percentage (%)
< 12 weeks	6	30.0
12 –18 weeks	14	70.0
18–24 weeks	0	0
Total	20	100.0

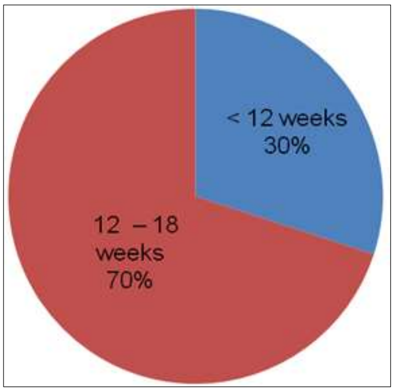


Fig 9: Distribution of patients based on time taken for union

Table 5: Distribution of patients based on range of movements at 24 weeks (degrees)

Range of Movements (degrees)	Number of patients	Percentage (%)
Full range	19	95.0
Mild restriction	1	5.0
Moderate restriction	0	0
Severe restriction	0	0
Total	20	100.0

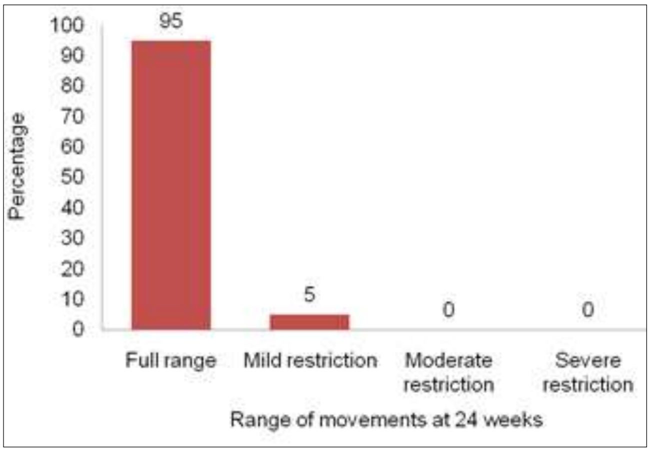


Fig 10: Distribution of patients based on range of movements at 24 weeks

Table 6: Distribution of patients based on time for full weight bearing

Time of full weight bearing	Number of patients	Percentage (%)
< 12 weeks	6	30.0
12 –18 weeks	14	70.0
18–24 weeks	0	0
Total	**20**	**100.0**

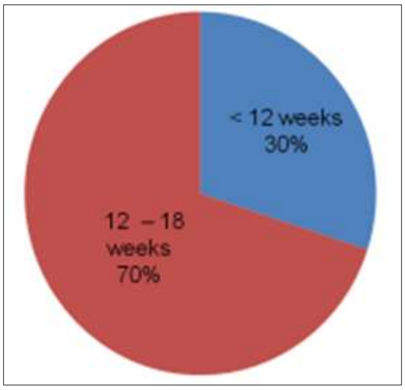


Fig 11: Distribution of patients based on time for full weight bearing

Table 7: Distribution of complications among the patients

	Minor	Major	Nil	Total
Number of patients	6	0	14	20
Percentage (%)	30.0	0	70.0	100.0

Table 8: Distribution of specific complications among the patients

Complications	No. of cases	Percentage (%)
Pain	6	30.0
Infection		
• Superficial	0	0
• Deep	0	0
Inflammatory reaction	0	0
Delayed union and nonunion	0	0
Limb lengthening		
• < 2 cm	0	0
• > 2 cm	0	0
Limb shortening		
• < 2 cm	0	0
• > 2 cm	0	0
Nail back out	0	0
Malalignment		
• Varus angulation	0	0
• Valgus angulation	0	0
• Anterior angulation	0	0
• Posterior angulation	0	0
• Rotational malalignment	0	0
Bursa at the tip of the nail	0	0
Sinking of the nail into the medullary cavity	0	0

Table 9: Distribution of outcome among the patients

Outcome	Number of patients	Percentage (%)
Excellent	18	90.0
Satisfactory	2	10.0
Poor	0	0
Total	20	100.0

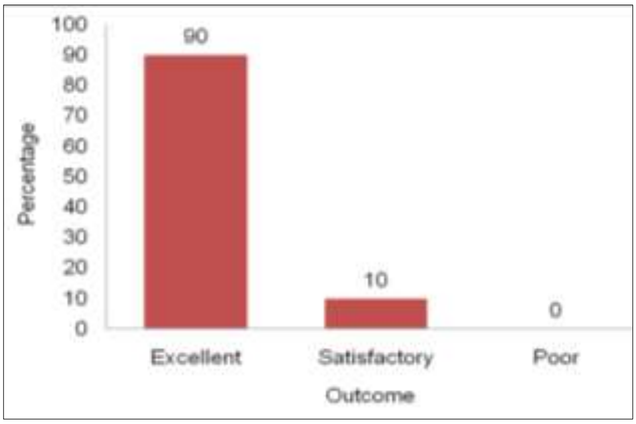


Fig 12: Distribution of outcome among the patients

Table 10: Distribution of outcome for additional variables in the present study

Outcome Variables	Excellent n (%)	Satisfactory n (%)	Poor n (%)
Range of movements	19 (95.0)	1 (5.0)	0
Time for union	14 (70.0)	6 (30.0)	0
Unsupported weight	14 (70.0)	6 (30.0)	0

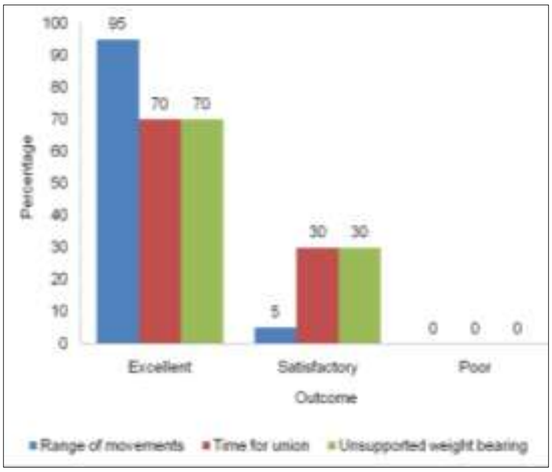


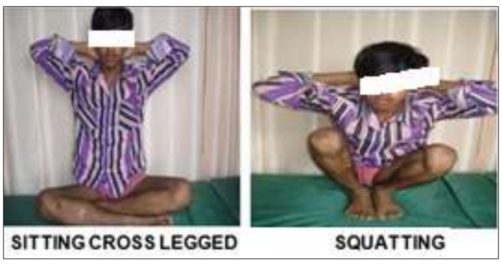
Fig 13: Distribution of outcome for additional variables in the present study

Table 11: Association of Incidence of complications with clinical variables studied among the patients

Clinical variables	Total number of patients (n=20)	Complication(Minor) Present (n=)	Absent (n=)	p value
Age in years				
5-8	9(45.0%)	1(11.1%)	8(88.9%)	0.24
9-12	7(35.0%)	3(42.9%)	4(57.1%)	
13-15	4(20.0%)	2(50.0%)	2(50.0%)	
Gender				
Males	17(85.0%)	5(29.4%)	16(70.6%)	0.89
Females	3(15.0%)	1(33.3%)	2(66.7%)	
Mode of Injury				
RTA	10(50.0%)	4(40.0%)	6(60.0%)	0.41
Self-fall	7(35.0%)	2(28.6%)	5(71.4%)	
Fall from height	3(15.0%)	0(0%)	3(100.0%)	
Pattern of fracture				
Transverse	9(45.0%)	2(22.2%)	7(77.8%)	0.27
Oblique	5(25.0%)	1(20.0%)	4(80.0%)	
Spiral	4(20.0%)	3(75.0%)	1(25.0%)	
Segmental	1(5.0%)	0(0%)	1(100.0%)	
Comminuted	1(5.0%)	0(0%)	1(100.0%)	
Time interval between trauma & surgery				
< 2days	10(50.0%)	4(40.0%)	6(60.0%)	0.62
3-4 days	7(35.0%)	2(28.6%)	5(71.4%)	
5-7 days	1(5.0%)	0(0%)	1(100.0%)	
>7 days	2(10.0%)	0(0%)	2(100.0%)	

There was no significant association observed between clinical variables (age, gender, mode of injury, pattern of fracture and time interval between trauma and surgery) and incidence of complications.

Radiological & clinical photographs



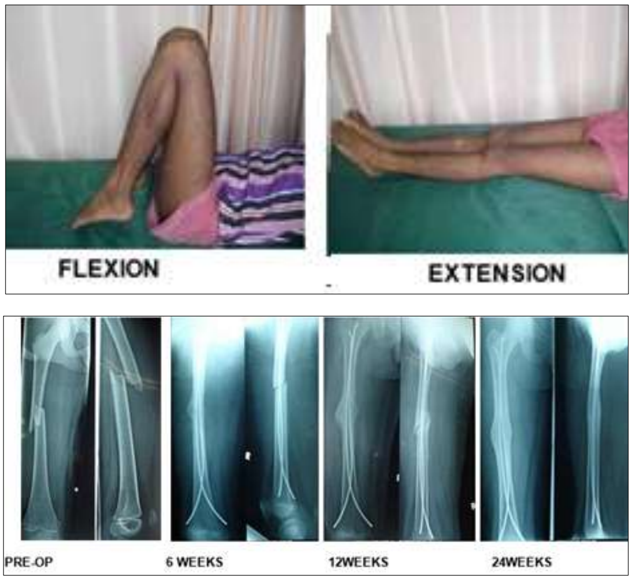


Fig 14: Radiological & Clinical Photographs of Case No: 1

Discussion

Distribution of Age: In the present study [9], (45.0%) of the patients were 5-8 years, 7 (35.0%) were 9 to 12 years, and 4 (20.0%) were 13 to 15 years age group with the mean age being 9.1 years. J. N. Ligier *et al*. studied children ranged from 5-16 years with a mean of 10.2 years [8]. Wudbhav N Sankar *et al*. studied children ranged from 7.2-16 years with a mean of 12.2 years [28].

Table 12: Studies comparing the duration of immobilization among the patients

Studies	Average duration of Immobilization
Present study	**6.0**
Gross R.H. *et al.*	9.6

John Ferguson *et al*. treated 101 children with immediate hip spica casting. They immobilized children on an average duration of 10 -12 weeks with spica casting [30].

The advantage of the present study was early mobilisation of the patients.

Duration of stay in the hospital: The duration of stay in the hospital: 8-10 days for 1 (5.0%), 11-15 days for 13 (65.0%) and 6 (30.0%) patients stayed for more than 15 days.

Among the 6 patients who stayed for more than 15 days, 3 were for whom time interval between trauma (admission) and surgery was more, therefore they stayed for 30, 20 and 17 days.

Other cases, though operated within 3 days of injury, developed complaints of pain and so stayed for 25 days.

Other 2 cases stayed for 16 days each, waiting for their insurance scheme to be sanctioned.

The average duration (mean) of hospital stay in the present study is 13.5 days. The mean hospital stay was 12 days in Kalenderer O *et al*. study [31]. Average hospitalization time was 11.4 days in the study conducted by Mann DC, *et al.* [32]

Table 13: Studies comparing the duration of stay among the patients

Studies	Average duration of stay in hospital (in days)
Present study	13.5
Kalenderer O *et al.*	12
Mann DC *et al.*	11.4

Gross RH, *et al*. conducted a study on cast brace management of the femoral shaft fractures in children and young adults. The average length of hospitalization in their study was 18.7 days [29].

Compared to the above studies conducted on conservative methods and cast bracing, the average duration of hospital stay was less in our study i.e., 13.5 days. The reduced hospital stay in our series is because of the proper selection of patients, stable fixation and less incidence of complications.

Time for union

In our study union was achieved in <12 weeks in 6 (30%) of the patients and 12 –18 weeks in 14 (70%). Average time to union was 12 weeks. Oh C.W *et al*. reported average time for the union as 10.5 weeks [33].

Aksoy C *et al*. compared the results of compression plate fixation and flexible intramedullary nail insertion. Average time to union was 7.7 (4 to 10) months in the plating group and 4 (3 to 7) months for flexible intramedullary nailing [34].

Table 14: Studies comparing the time taken for reunion among the patients

Studies	Time of Union (in weeks)
Present study	**12.0**
Oh C.W, *et al.*	10.5
Aksoy C, *et al.*	16

In our study, closed reduction of the fracture, leading to preservation of fracture hematoma, improved biomechanical stability and minimal soft tissue dissection led to the rapid union of the fracture compared to compression plate fixation.

Time of full weight bearing

In the present study, unsupported full weight- bearing walking was started in <12 weeks for 6 (30.0%) of the patients, and between 12 and 18 weeks in 14 (70.0%). The average time of full weight-bearing was 12.0 weeks. Wudbhav. N. Sankar *et al*. in their study allowed full weight bearing between 5.7-11.6 weeks an average of 8.65 weeks [28].

Table 15: Studies comparing the time taken for full weight bearing among the patients

Studies	Average time of full Weight bearing (in weeks)
Present study	12.0
Wudbhav. N. Sankar.	8.65

Complications

Pain at the site of nail insertion

In the present study, 6 (30.0%) patients had developed pain at the site of nail insertion during initial follow up evaluation which resolved completely in all of them by the end of 4 months. J.M. Flynn *et al*. reported 38 (16.2%) cases of pain at the site of nail insertion out of 234 fractures treated with titanium elastic nails [7].

Infection: Superficial infection was not seen in any patients.

J.M.Flynn *et al*. reported 4 (1.7%) cases of superficial infection at the site of nail insertion out of 234 fractures treated with titanium elastic nails [7].

Pin tract infection is a significant disadvantage of external fixation application. Bar- on E *et al*. reported 2 cases of deep pin tract infection in their patients treated with external fixation [35].

Range of motion: All patients had full range of hip motion in the present study and only 1 (5.0%) patient had mild restriction in knee flexion at 12 weeks, but normal range of knee flexion was achieved at 8 months. J.M. Flynn *et al.* reported 2 (0.9%) cases of knee stiffness out of 234 fractures treated with titanium elastic nails [7].

Limb length discrepancy: No patient in our study had limb length discrepancy.

Beaty *et al*. reported, two patients had an overgrowth of more than 2.5 cm necessitating epiphysiodesis, after conservative treatment [36].

Ozturkman Y *et al*. observed mean leg-lengthening of 7mm in 4 (5%) patients and mean shortening of 6mm in 2 (2.5%) children [37]. Cramer KE *et al*. noted average limb lengthening of 7mm (range 1-19mm) in their study. Clinically significant limb discrepancy (> 2cm) did not occur in any patient in their study [38].

Wudbhav. N.Sankar, in their study of 19 tibial shaft fractures reported no leg length discrepancy [28].

John Ferguson *et al*. noted more than 2cm shortening in 4 children after spica treatment of pediatric femoral shaft fracture. In the present study, limb length discrepancy of more than 10mm was present in 2 (10%) cases [39].

Comparing to limb length discrepancy in conservative methods, limb length discrepancy in our study was within the acceptable limits.

Nail back out

In the present series, nail back out was not seen in any of the cases. Carrey T.P. *et al* out of 38 cases, noted nail back out in one case in their study, which necessitated early removal [40].

Malalignment: No patients had malalignment in the present study**.**

Varus/valgus malalignment: No patients presented with varus (40) angulation or valgus (50) angulation. J.M. Flynn *et al*. reported 10 (4.3%) cases of minor angulation out of 234 fractures treated with titanium elastic nails [7].

Heinrich SD *et al*. reported 5° of varus angulation in one child in their study and 11 % of fractures had an average varus or valgus malalignment of 6°.41 Herndon WA *et al*. compared the results of femoral shaft fractures by spica casting and intramedullary nailing in adolescents. They noticed varus angulation ranging from 7 to 25° in 4 patients treated with spica casting and no varus angulation in surgical group [42].

Anteroposterior angulation

In the present study, no patients had anteroposterior angulation. Ozturkman Y *et al*. noted an anterior angulation of 7° and a posterior angulation of 6° in 2 patients respectively.37 Herndon WA *et al*. noticed anterior angulation ranging from 8° to 35° in patients treated with traction and spica casting.42 8% of the patients had an average anterior or posterior angulation of 8° in Heinrich SD, *et al* study [41].

Rotational deformities

A difference of more than 10° has been the criterion of significant deformity. No patient in our study had significant rotational deformity. Heinrich SD *et al*. out of 183 fractures studied, reported 80 out toeing in 4 children and two children with 50 in toeing following flexible intramedullary nailing. No patient in our study had significant rotational deformity [41].

Table 16: Studies comparing the occurrence of complications among the patients

Complications	Present study (% Incidence)	Previous studies (%incidence)	
Pain at the site of nail	30.0	16.2	J.M. Flynn *et al.*
Superficial infection	0	1.7	J.M. Flynn *et al.*
Range of motion	0	0.9	J.M. Flynn *et al.*
LIMB Length Discrepancy			
Lengthening	0	5.0	Ozturkman Y. *et al.*
Shortening	0	2.5	Ozturkman Y. *et al.*
Nail back out	0	2.6	Carrey T.P. *et al.*
Malalignment			
Varus / Valgus	0	4.3	J.M. Flynn *et al*
Anteroposterior	0	8	Heinrich SD, *et al.*
Rotational deformities	0	3.2	Heinrich SD, *et al.*
Nail back out	0	2.6	Carrey T.P. *et al.*

Other complications

Proximal migration of the medial nail was noticed in one case in our study; During removal, a cortical window was made, and the nail was removed. Bar-on E *et al*. noticed proximal migration of the nail in one case [35].

Assessment of Outcome

In the present study, the outcome was excellent in 18 (90.0%) cases, satisfactory in 2 (10.0%) cases and there were no poor outcome cases. In D. Furlan and Z. Pogorelic study, the final out-come was excellent in 89% cases, satisfactory in 11% cases and there were no cases showing the poor outcome.

Table 17: Studies comparing the outcome among the patients

Studies	Out come		
	Excellent	**Satisfactory**	**Poor**
Present study	90.0%	10.0%	0%
D. Furlan & Z. Pogorelic study	89.0%	11.0%	0%

Conclusion

Based on our experience and results, we conclude that elastic stable intramedullary nailing technique is an ideal method for the treatment of pediatric diaphyseal fractures of the femur. It gives elastic mobility promoting rapid union at fracture site and stability, which is ideal for early mobilization. It gives a lower complication rate, good outcome when compared with other methods of treatment.

It is a simple, easy, rapid, reliable and effective method for management of paediatric long bone fractures between the age of 5 to 15 years, with shorter operative time, lesser blood less, lesser radiation exposure, shorter hospital stay, and reasonable time to bone healing.

Because of early weight bearing, rapid healing and minimal disturbance of bone growth, ESIN may be considered to be a physiological method of treatment.

Use of TENS for definitive stabilization of diaphyseal fractures of femur in children is a reliable, minimally invasive, and physeal-protective treatment method. In many respects, flexible intramedullary nailing is safe, minimally invasive, appears to have few complications, does not interfere with growth, and is associated with short hospital stays and a rapid return to daily activity [51]. Our study results provide new evidence that expands the inclusion criteria for this treatment and shows that TENS can be successfully used regardless of fracture location and fracture pattern.

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