Evaluation of functional outcome of closed intramedullary fixation with titanium elastic nails in paediatrics femoral diaphyseal fractures

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Abstract

Background: Femoral diaphyseal fractures account for 1.6% of all paediatric fractures. In children younger than 5 years nonoperative treatment is ideal as they have good remodeling ability; however, in children aged 6-11 years, accurate reduction is necessary to correct angular deformity. Titanium elastic nailing of femoral diaphyseal fractures in children between 6–11 years has gained widespread popularity because of its clinical effectiveness and low risk of complications. Several studies have evaluated the functional outcome of the use of Titanium Elastic Nails (TENS) in length-stable paediatric femoral shaft fractures in other parts of the world; however, there is a paucity of data in our environment. Objectives: The aim of the study is to evaluate the functional outcome of the use of Titanium Elastic Nails in managing paediatric femoral diaphyseal fractures in children aged 6-11 years using the Flynn scoring criteria. Methods: Thirty patients with paediatric femoral diaphyseal fractures were recruited for this prospective, interventional study. Two nails of equal diameter were used for each fracture fixation. The patients were followed up at the 3rd, 6th and 24th week by clinical and radiographic assessment for union, pain, mal-alignment, irritation at nail entry site, surgical site infection and limb length discrepancy. The outcomes were assessed at the end of 24 weeks using the Flynn outcome scoring criteria into excellent, satisfactory or poor outcome. Data collected were analysed using Chi-square with fishers' exact corrections. Results were compared with statistical significance set at $P < 0.05$. Results: Thirty patients within the age range of 6-11 years with a mean age of 8.6 years were studied. All patients achieved union at a mean time of 9.4+ 1.1 weeks (9 - 16 weeks), full weight bearing was achieved at a mean time of 9 + 0.8 weeks (9-16 weeks). At last follow-up all the patients had full range of knee motion with an excellent outcome in 90% of patients, satisfactory outcome in 10% of patients, no patient had a poor outcome. Conclusion: The use of Titanium Elastic Nails in treating length - stable paediatric femoral shaft fractures in children 6 - 11 years is associated with excellent to satisfactory outcome. It allows for early fracture healing, early return to function with minimal complications.

***Keywords**: Paediatric femoral diaphyseal fracture, Operative treatment, Titanium Elastic Nails, Flynn outcome scoring criteria.*

Introduction

Fractures in the femoral shaft are the most incapacitating fractures in the paediatric age group, accounting for approximately 1.6% of fractures in children. It accounts for 20% of children hospitalizations for fractures[1–3].

Most of the lower limb fractures in children younger than 5 years of age can be treated nonoperatively using cast and traction but for children above 6 years of age nonoperative treatment could lead to mal-union, shortening, intolerance to use of traction and complications associated with plaster or traction use. In children approaching skeletal maturity accurate reduction is necessary as angular deformity is no longer correctable by growth[1–5].

There has been increased interest in operative treatment of femoral fractures of school age children over the past two decades using external fixator, sub muscular standard compression plates, intramedullary nails and elastic stable intramedullary nails[6], because in children near skeletal maturity, accurate reduction is necessary as angular deformity is no longer correctable by growth[5].

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Flexible intramedullary nailing is considered a good method of choice in management of femoral shaft fractures in children due to various benefits such as earlier return to function, less joint stiffness, less wound complication, less mal-union or non-union, reduction in duration of hospitalization, early mobilization and cost effectiveness[7]. However, various methods of operative fixation which have been in use include the following:

1. The use of External fixators

External fixators were one of the earliest forms of operative treatment of femoral diaphyseal fractures with associated soft tissue injury, open fractures and the management of a polytraumatized child due to its speed and simplicity of application[8]. Some of the advantages of external fixation include minimal invasiveness, low blood loss, and shorter operating time[9]. It is however associated with the risk of pin tract infections, temporary loss of knee movement, refracture after removal of external fixator, malunion and loss of days from school, delayed union, and unacceptability to the child as well as their caregivers[10]. These complications limit its use.

2. Open reduction and internal fixation with plate and screw fixation

Plates and screws is a treatment option for treatment of femoral diaphyseal fracture in older children and adolescents and it provides excellent stability, allowing management of proximal and distal fractures which are difficult to manage with intramedullary nails. It however requires bigger surgical incisions, blood loss, stripping of periosteum with disruption of fracture haematoma which increases the risk of infection, delayed union, fracture below the hardware, stress fracture and hardware failure[8–11].

3. The use of rigid intramedullary nailing

Rigid intramedullary nailing is one of the treatment options in managing paediatric femoral diaphyseal fractures in older children and adolescents with length unstable fractures weighing > 49kg as it has the advantage of providing control of length, angulation and rotation. Its use is however restricted due to concerns over avascular necrosis of the femoral head and growth arrest in the proximal femur secondary to the nail entry at the piriformis fossa and trochanteric tip. The use of the lateral entry point prevents incidence of avascular necrosis by avoiding potential disruption of the blood supply and promotes ease of insertion, especially in overweight patients[12]. A study by Martus[13] showed better functional outcome and lower risk of osteonecrosis and growth disturbance with lateral trochanteric entry compared to the piriformis and trochanteric tip entry.

4. Flexible intramedullary nail

These Flexible intramedullary nailing can be done using either, Ender nails (stainless steel) or Titanium Elastic nails.

a. Ender nails

These are stainless steel implant, which were introduced in 1970 and were initially used for trochanteric femoral fractures with some successes[14].

It is made of 316L stainless steel with a modulus of elasticity of 196 GPa making it 80% stiffer, which provides a rigidity and bending compared to titanium alloy which has a lower modulus of elasticity making it less stiff[7].

The stainless-steel nails are stronger with higher tensile strength making it difficult to deform as such it does not conform to the canal wall or dissipate input stress associated with increased gap closure and nail slippage[15–19]. To improve the fixation when using stainless steel, the nails are stacked to improve canal fill[16].

b. Titanium Elastic Nails System

Titanium Elastic Nails System (TENS) has revolutionized the treatment of paediatric femoral diaphyseal fractures because it acts as a load sharing “internal splint” maintaining reduction for a few weeks until callus forms[17].

It was first developed and used by Metaizeau and colleagues[7] in Nancy, France in 1982 for treatment of femoral diaphyseal fractures stating the inadequacies of Enders nails (stainless steel) in managing femoral diaphyseal fractures in children.

The use of titanium elastic nail system has gained widespread popularity because of its clinical effectiveness, better reduction, dynamic stabilization, excellent result and low risk of complications, short hospital-stay with early functional recovery[2]. A study by Pradeep et al found a mean hospital stay of 5 days (range 3 -16 days) in children who had fixation of their femoral shaft fractures with Titanium Elastic Nails System (TENS)[16]. Ligier et al also had a similar duration of hospital stay of 4.5 – 8 days[18].

Titanium Elastic Nails System (TENS) exploits a child’s denser bone, immediate fracture stabilization, minimal soft tissue disruption, preservation of the fracture haematoma, rapid healing and ability to remodel without risking the blood supply to the femoral head or damaging the physes[19].

It is formed from an alloy of Titanium (89%), Aluminium (6%), Vanadium (4%) which forms a biphasic structure giving it the advantage of improved fatigue resistance. The titanium alloy has a modulus of elasticity of 115GPa, making it less stiff with higher yield strength and tensile strength making it more ideal for use in paediatric fractures. Titanium elastic nail has an excellent biocompatibility, magnetic resonance imaging compatibility, better osteo-integration as well as a remarkable resistance to corrosion compared to stainless steel[20].

The biomechanical principle of the Titanium elastic nailing is based on the symmetrical bracing action of two elastic nails inserted into the metaphysis, each of which bears against the inner bone at three points. This produces four properties that are essential for achieving optimal results: flexural, axial, translational and rotational stability[21]. The insertion of a pre-bent nail in a straight medullary canal impacts a bending moment which tends to angulate the fracture, as such insertion of a second nail of similar diameter from opposite side balances this moment leading to good stability against bending and torsional forces as each nail occupies 40% of the narrowest canal diameter with the apex of the bent surface lying at the fracture site to resist compressive, angular and rotational forces while in the medullary canal[18].

Lascombes et al observed a low incidence of postoperative complications when the nails filled 80% of the medullary canal as it gives a double C or S type configuration which is three times the diameter of the intramedullary canal ensuring maximum cortical contact at the fracture site in opposite direction[22].

The elasticity and stress distribution of Titanium Elastic Nails System facilitates callus formation due to cyclical micro-motion at fracture site which leads to early union, early mobilization, early weight bearing and high patient satisfaction rate as they are able to return to their normal activities with very low complication rate. Additionally, it has aesthetic postoperative scars, fast removal, shortening of the inpatient period, good cost-effectiveness ratio, and less psychological impact on the patient[23].

Titanium Elastic Nails System typicaly used for length -stable fracture patterns (transverse and short oblique fractures), however, it has been used in length -unstable fractures (long oblique, spiral and comminuted) with no difference in complications or outcome[24].

Antegrade Vs retrograde insertion of Titanium elastic nails

The insertion of elastic nails in an antegrade or retrograde manner is influenced by the site of the fracture. The indication for antegrade insertion are fractures to the distal third of the femur while for retrograde insertion are fractures of the proximal and midshaft of the femur.

Frick et al noted that retrograde insertion has significantly less axial range of motion and greater torsional stiffness compared to the antegrade insertion of the nail which was seen to have a greater resistance to shortening. He also noted that the retrograde double-C shaped design of the nails provides greater resistance to deformation than antegrade double C or S pattern[25]. The antegrade insertion, however, has the advantage of proximal elimination of knee irritation from the nail tip (which is the most common complaint in children treated with the retrograde technique). This Approach however lacks safe medial and lateral starting points, resulting in unbalanced, asymmetric implants.

Stainless steel Vs Titanium Elastic Nail Fixation

Wall et al[26] compared stainless steel to titanium elastic nails and found that the cheaper stainless-steel nails were superior to titanium nails owing to a lesser rate of mal union (6.3% vs. 23.2%). Perez et al[27] noted in their study that stainless steel nails were stiffer and did not conform to the shape of the medullary canal which increase average slip out at insertion, with more gap closure as well as a greater propensity of pathological limb shortening while Titanium Elastic Nails System is flexible with greater bone- implant contact which dissipates stress and increases stability, with less gap closure associated with improved fracture healing.

Removal of Implants

The nails are removed from the femoral diaphysis when there is radiological evidence of consolidation which is about 6-8 months from the time of injury as removal earlier than 6 months is associated with refracture[28]. Simanovsky et al[29] had an average removal time of 7 months for femoral shaft fractures in 143 children with Titanium Elastic Nails, with one of them having a re-fracture 2 months after radiographic healing of the fracture. Pradeep C et al[16] in their study, had all the Titanium Elastic Nails removed at an average duration of 27.2 weeks (22-35 weeks).

Complications of Titanium Elastic Nail Fixation

Although the use of titanium elastic nails is associated with excellent and satisfactory results, it is however associated with few complications which have been noticed to rise significantly when used in bigger or older children.

These complications can be grouped into; Minor and Major Complications [30]

Minor complications

These are complications which are resolved without additional surgery. They include a) Pain at the site of nail insertion, b) Minor angulation (< 10° – sagittal/coronal; < 10° rotational malalignment) at final follow up, c) Minor leg length discrepancy (< 2cm – shortening/lengthening) at final follow-up (24 weeks), d) Inflammatory reaction to nails, e) Superficial infection at site of nail insertion. f) Delayed union and g) Nail backout. Most of the complications are minor and many of them preventable.

Major complications

These are complications which (i) require further operation and (ii) resulting in long term morbidity. These include: a) Angulation exceeding the guidelines (<10° – sagittal/coronal or >10° rotational malalignment) at final follow-up, b) Leg length discrepancy exceeding the guidelines (>2cm –shortening/lengthening) at final follow-up, c) Deep infection, d) Loss of reduction requiring repeat reduction or surgery, e) Surgery to revise nail placement, f) Compartment syndrome requiring surgery, g) Neurological damage after nailing and h) Delayed or non-union leading to revision. The most common among them includes:

1. Pain at entry point[31]
This is one of the most common complications. It occurs because of inflammatory reaction due to the nails projecting beyond the cortices at the entry points. It is assessed as the presence of unresolved pain at follow up which is scheduled at 3 weeks, 6 weeks and 24 weeks as in the Flynn outcome criteria. This can be minimized by keeping the ends of the cut nails flush with the cortices avoiding a bend at the end[31].

2. Varus/valgus angulation
This occurs due to fixation with dissimilar nails. The varus and valgus angles were measured from the anatomical axis. This can be minimized by avoiding nails that are mismatched in terms of size and pre-bending, paying close attention to the location of the fracture[31].

3. Limb length discrepancy

Limb length discrepancy usually resulting from shortening or overgrowth of the injured limb due to improper reduction, significant dissociation of the fracture fragments, loss of the normal femoral antecurvatum or stimulation of growth of the fractured bone[32]. Ligier postulated that early resumption of weight bearing stimulated growth due to an increase of blood flow to the adjacent growth areas in response to the fracture healing process with lengthening in transverse fractures and shortening in spiral fractures assessed both clinically and radiologically[18].

4. Reoperation before union

This usually becomes necessary due to nail migration/skin perforation, loss of reduction, refracture, neurologic deficit[1].

Other complications include:
5. Protruding nails with or without skin erosion
6. Knee stiffness
7. Septic arthritis
Functional outcome measures

The outcome measures following fixation of femoral diaphyseal fractures with titanium elastic nails can be assessed using the Flynn scoring criteria[7] which has the following assessment criteria: limb length discrepancy, rotational deformity, angulation, pain and complications; and is interpreted as:

Excellent: When there is anatomical or near anatomical alignment, no leg length discrepancy.

Satisfactory: When there is acceptable alignment and leg length with minor complications.

Poor: When there is presence of unacceptable alignment or leg length with major complications.

A study by Munzur et al had an excellent outcome in 86% ,14% satisfactory outcome with no poor outcome[33], Komlatse' et al also had similar result with an excellent outcome of 90.63%, satisfactory outcome of 9.37% with no poor outcome[2] which is in keeping with most studies. Bahinipati J et al however had 67% excellent outcome, 16% satisfactory outcome and 8% poor outcome[19]. A study by Moroz et al found that patients with weight >49kg were five times likely to have poor outcome than patients with weight < 49kg[34].

The use of elastic stable intramedullary nails (Titanium Elastic Nails) for paediatric long bone fractures in skeletally immature population has gained widespread popularity due to its clinical effectiveness, low risk of complications, closed insertion, preservation of the fracture hematoma, and a physeal sparing entry point[17]. The aim of this study is to evaluate the functional outcome of the use of Titanium Elastic Nails in managing paediatric femoral diaphyseal fractures in children 6-11 years using the Flynn scoring criteria.

Materials and Method

Study center

This study was carried out at the National Orthopaedic Hospital, Dala, Kano, North-west Nigeria. The hospital was established in 1959 and is a major Orthopaedic referral hospital in Northern Nigeria. It is a 300 bedded hospital which provides training and services for Orthopaedics in the entire Northern part of Nigeria and part of Niger, Chad and Cameroun. The Paediatric unit is a 36 bedded ward and divided into the mother and child (neonates and infant segment), pre-school aged segment and the adolescent segment.

Study designs

This study was a hospital based prospective interventional study. It was aimed at evaluating the functional outcome of closed intramedullary fixation of paediatric femoral diaphyseal fractures with Titanium Elastic Nails.

Study duration

The study was conducted over a period of 12 months (1 year).

Study population

The population included all patients with femoral diaphyseal fractures within the age range of 6-11 years who satisfied the inclusion criteria.

Inclusion criteria

1. Males and Females within the age group of 6-11 years who sustained closed femoral diaphyseal fractures.
2. Length - stable closed isolated femoral diaphyseal fractures.
3. Patients who sustained closed femoral diaphyseal fractures and presented within a week from the injury.
4. Patients whose parent(s) /guardian have consented to participate in the study.

Exclusion criteria

1. Children < 6 years and >11 years of age.
2. Metaphyseal femoral fractures.
3. Children with floating knee.
4. Open femoral shaft fractures.
5. Patients in whom closed fracture reduction cannot be achieved.
6. Patient who presented to the hospital beyond a week from injury.
7. Patients with pathological fractures.
8. Patients on immunosuppressive therapy.
9. Patients whose parent(s) /guardians decline consent to participate in the study.
10. Patients who weigh greater than 49kg.

Ethical considerations

The study was carried out following approval from the Hospital Research Ethical Committee.

Consent

Consent for inclusion into the study was obtained from parents/guardians.

Sample size estimation

The sample size for the study was calculated from the results of the pilot study using the Yamane formula [35] for estimating sample size.

$$n = \frac{N}{1 + N(e)^2}$$

where: n= minimum sample size

N =Value obtained from the pilot study done at National Orthopaedic Hospital, Dala =30

e = Margin of error at 5% (standard value of 0.05) and a confidence level of 95%

$$n = \frac{30}{1 + 30(0.05)^2} = \frac{30}{1 + 30(0.0025)}$$

$$= \frac{30}{1 + 0.075} = \frac{30}{1.075}$$

$$= 27.9$$

Approximately =28

10% Attrition rate =2.8 ≈ 3

Sample size N = 28+3 = 31

Therefore, the minimum sample size for this study was 31 closed femoral diaphyseal fractures.

Study protocols

Patients were recruited in a consecutive manner as they presented via the accident and emergency (A & E) unit and Surgical Outpatient Department (SOPD).

Pre-operative Protocol

As soon as the patients were brought to the Accident and Emergency room, ATLS protocol was instituted for resuscitation, however, this step was skipped in patients admitted via the Surgical Outpatient Department (SOPD) as they were usually haemodynamically stable. The affected limb was rested in a splint prior to definitive management.

Orthogonal plain radiographs of the thigh in Antero-Posterior (AP) and lateral views including the hip and knee joints were taken. The diameter of the isthmus was measured on the PACS and the appropriate nail diameter was determined using Flynn et al's formula (diameter of nail = Width of the narrowest point of the medullary canal on Antero-Posterior and lateral view x 0.4mm) [1].

The fractures were classified based on the AO classification into length - stable (32-D/4.1, 32-D/5.1).

Patients' weight was obtained by weighing the patient along with their guardian and then the guardians were weighed separately, the difference in their weight was calculated and recorded. Patients were optimized for surgery.

Detailed Consent for surgery was taken from parent/guardian.

Intraoperative Protocol

All surgeries were performed in the hospital's main operating theatre suites and strict aseptic technique was adhered to. Prophylactic antibiotics were given at induction of anaesthesia using intravenous ceftriaxone 25mg/kg which was calculated based on the patient's weight.

Patient positioning was supine on a radiolucent operating table. Anaesthesia as deemed fit by the procedural anaesthetist was given, skin preparation was done extending from the umbilicus to the ankle using cetrimide then prepared skin area was dried, 70% alcohol was applied followed by 7.5% Povidone iodine paint. The prepared skin was draped appropriately. The fluoroscopy machine was covered with sterile drape and placed on the contralateral side of the limb.

Two titanium elastic nails of identical diameter as obtained from the plain radiographs of the respective patients. The nails were pre-bent using a bender with the apex of the bowed nails resting at the fracture site which was predetermined fluoroscopically. The depth of the nail curvature being three times the diameter of the femoral canal and each nail occupied about 40% of the medullary cavity.

The Retrograde approach was used for the fixation of all the fractures. A skin incision 2.5 - 3.5cm above the lateral aspect of the distal femoral physis as determined under fluoroscopic guidance. The soft tissues were retracted until the distal femoral metaphysis was exposed. Entry into the bone was achieved using a bone awl or a drill bit with a drill sleeve through the near cortex at 45^{O} relative to the femoral shaft axis after ensuring the entry point is at the middle of the width of lateral cortex. The selected pre-bent nails was inserted with curved tip into the medullary cavity using a T-insertion handle until resistance was met indicating contact with the far cortex and then the nails were gently hammered with the curved tip sliding on the inner cortex until the fracture site was reached. A medial incision was made at the same level with the first nail and the second nail was inserted in a similar manner up to the fracture site. The fracture was reduced by traction or external manipulation with a mini-F–tool under fluoroscopic guidance and the nails were tapped across the fracture site in an alternating manner for 1-2 cm into the far segment until it spans the entire length of the bone. The convex part of the pre- bent portion of the nail will be ascertained to be situated at the fracture site and the ends crossing each other at its proximal ends with the medial nail extending to the level of the calcar region while the lateral nail extends to the level of the trochanteric apophysis. These give the nails a double C' shape under fluoroscopic view.

The fracture site was impacted by applying a gentle tap to the flexed knee with the palm.

Distally the nails were cut 1 cm outside the cortex on both the lateral and medial side. The extraosseous portion of the nails were bent slightly away from the bone for easy removal after fracture union.

Intra operative fluoroscopic image of entire femur were done to assess fracture reduction and alignment.

Entry site was irrigated with Normal saline and closed with Nylon suture.

Sterile dressings were applied to the entry sites.

Postoperative Protocol

Nursing of patients was in supine position with the limb elevated on a pillow.

All patients received the same parenteral analgesics (Paracetamol at 15mg/kg/dose, pentazocine at 0.5mg/kg/dose) for 48 hours after which oral analgesics were commenced.

Vital signs were monitored hourly for the first 6 hours and subsequently 4 hourly.

Post operative radiograph was done and saved on the PACS for documentation purposes and to serve as baseline for assessments during follow up.

Patients commenced on static quadriceps exercises, hip and knee exercises within 48 hours post operatively as tolerated.

Patients were ambulated Non-Weight Bearing with bilateral axillary crutches on post operative day 1, and physiotherapy was continued and they were discharged when confident on ambulation as ascertained by physiotherapist. Stitches were removed on day 14 at the Surgical Outpatient Department (SOPD).

Follow up

Follow up was done at weeks 3, 6 and 24 weeks post operatively. During each follow-up visit, patients were assessed as follows:

Clinical Assessment

1. Pain (Present or Absent)
2. Measurement of limb length and
3. Range of movement which was graded as below:

Range of motion of knee [36]

Joint movement	Extension (degree)	Flexion(degree)
Full range	0-10	0-140
Mild restriction	0-10	0-120
Moderate restriction	0-10	0-100
Severe restriction	-	<100

Radiological Assessment

All the radiologic assessments and measurements were done using PACS at 3 weeks, 6 weeks and 24 weeks post operatively to check for angular deformities and evidence of bridging callus in both the antero-posterior and lateral views. Patients were commenced on Partial Weight Bearing (PWB) when callus was noticed and then progressed to Full Weight Bearing (FWB) when bridging callus appeared and fracture line not visible on plain radiograph as depicted by Anthony et al scale to be Grade 3[17].

At 24 weeks post operatively both clinical and radiologic outcomes were assessed using the Flynn's TENS scoring criteria[7].

Flynn's TENS scoring criteria

Variables at 24 weeks	Poor results	Satisfactory results	Excellent results
Limb length discrepancy malalignment	>2.0cm	1.0-2.0cm	<1.0cm
	>10 degrees	5-10 degrees	<5 degrees
Unresolved pain	Present	None	None
Complications	Major and lasting morbidities	Minor and resolved	None

Removal of implants

After achieving fracture union as evidenced by the presence of bridging callus in 3 or more cortices and satisfied the Anthony et al criteria, patients were prepared for nail removal. At the point of removal, incisions were made at sites of surgical scars and surrounding soft tissues were retracted till the tip of the nails were seen. A plier was used to grab the nail tip, and the nails were extracted by longitudinal traction and rotational movement.

Outcome measures

Primary outcome measures

Primary outcome measures were time to achieve fracture union after surgery and presence of associated complications.

Secondary outcome measure

Secondary outcome measures were ascertaining time to full weight bearing and return to full function

Data analysis

Data obtained from the study were entered and analysed using Microsoft excel and statistical package for the social sciences (SPSS) version 26.0 [IBM Corp. Released 2019. IBM SPSS Statistics for Windows, Version 26.0. Armonk, NY: IBM Corp] [37] software. Tables and charts were used for the data presentation appropriately.

Numerical variables (Age, duration of fracture union,) were presented using percentages and mean. Categorical data (Gender, mechanism of injury, fracture pattern, complications) were presented in tables and charts as percentages. Test for relationship between the clinical variables and rate of complications was done using Chi – square test with fishers' exact corrections where necessary. The level of statistical significance was set at $P<0.05$.

Results

A total of thirty-one patients with paediatric femoral diaphyseal fractures were enrolled into the study after fulfilling the inclusion criteria. The study duration was 12 months (October 2022 to September 2023). One patient (3.2%) was lost to follow up. Thirty patients were available for final analysis at the end of the study. Data was collected and each patient was followed for a duration of 6 months. Union achieved in 9.4 ± 1.1 weeks. Three patients had limb overgrowth of less than 2cm, 4 patients had pain at entry site, 2 patients had irritation at entry site. Using the Flynn et al outcome scores 90% of the patients had excellent outcomes, 10% had satisfactory outcomes, none had poor outcome.

Table 1: Age distribution

Age Range(years)	Number of patients	Percentage %
6-8yrs	20	66.7
9-11yrs	10	33.3
Total	**30**	**100**

Mean = 8.5 ± 1.5 years

The age range of the patients was between 6-11 years with a mean age of 8.5 ± 1.5 years in the study. Twenty out of the 30 participants (66.7%) were within the ages 6- 8 years while the remaining 10 patients were within the ages 9-11 years as shown in Table 1.

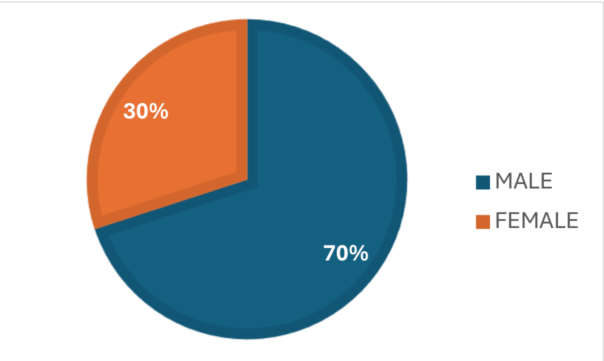

Figure 1: Gender distribution

There were 21 males (70%) and 9 females (30%) with a 2.3:1 ratio with Paediatric femoral diaphyseal fractures were in this study (Fig. 1).

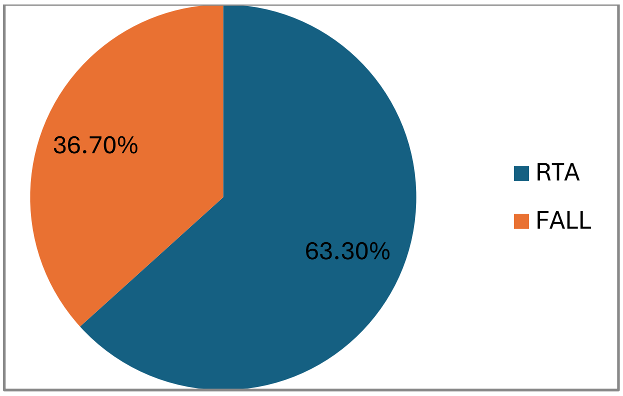

Figure 2: Mechanism of injury

Road traffic Accident was the commonest mechanism of injury in the study accounting for 63% of the injuries while fall accounted for 37% of injuries (Fig. 2).

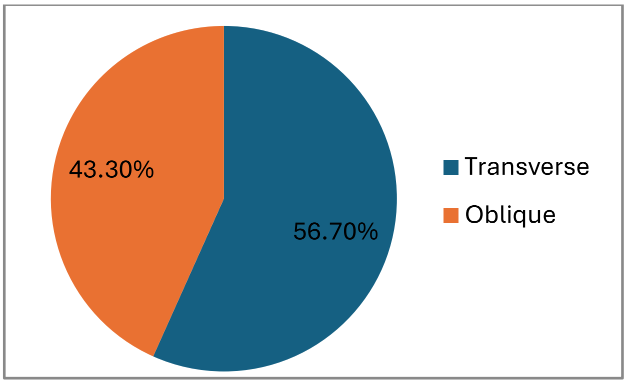

Figure 3: Fracture pattern

Seventeen(56.7%) patients had transverse fracture while 13 patients (43.3%) had short oblique fracture pattern (Fig. 3).

Table 2: Level of Fracture

Level of fracture	Number of patients	Percentage %
Proximal 1/3rd	7	26.3
Middle 1/3rd	23	73.7
Distal 1/3rd	0	0
TOTAL	30	100

Twenty-three patients (73.7%) had middle 1/3rd fractures ,7 patients (26.3%) had proximal 1/3rd fractures. No patient had distal 1/3rd fractures as shown in Table 2.

Table 3: Time to union

DURATION	NUMBER OF CASES	PERCENTAGE%
0-8weeks	11	36.7
9-16weeks	19	63.3
17-24weeks	0	0
Total	30	100

Mean± SD = 9.4 ±1.1 weeks

Nineteen patients (63.3%) attained radiological union within 9-16 weeks with a mean time to union of 9.4 ± 1.1 weeks while 11 patients (36.7%) attained radiologic union within 8 weeks. All patients achieved union before 16 weeks as shown in Table 3.

Table 4 : Time of full weight bearing

Time of full weight bearing	No of patients	Percentage %
0-8weeks	12	40
9-16weeks	18	60
17-24weeks	0	0
TOTAL	30	100

Mean ± SD = 9 ± 0.8 weeks

Eighteen patients attained full weight within 9-16 weeks with a mean time of 9 ± 0.8 weeks, while 12 patients attained full weight within 8 weeks. All patients attained full weight bearing 17 weeks before as shown in Table 4.

Range of knee movements at 24 weeks

Table 5: Range of Knee movement

Range of movement	At 3weeks	At 6 weeks	At 24 weeks
Full range of movement	29(96.7%)	30(100%)	30(100%)
Mild restriction	1(3.3%)	0	0
Moderate restriction	0	0	0
Severe restriction	0	0	0
Total	**30(100%)**	**30(100%)**	**30(100%)**

One (3.3%) patient had mild restriction in knee movement at first follow up of 3 weeks due to pain at entry site which resolved with ingestion of non-steroidal anti-inflammatory drugs. At 6 weeks and final follow-up visit all patients were noted to have full range of knee movement as shown in Table 5.

Table 6: Summary of complications

Complications	Number of patients	Percentage%
Minor	9	30
Major	0	0
Nil	21	70

Nine patients had minor complications (30%) ; pains at entry site, irritation at entry site which resolved and limb lengthening of less than 2cm) while no patient had major complications ,21 patients (70%) had no complications as shown in Table 6.

Table 7: Common Complications associated with TENS

Complications	At 3weeks	At 6 weeks	At 24 weeks
Pain at entry site	4(13.3%)	0	0
-Superficial surgical site infection	0	0	0
-deep surgical site infection	0	0	0
Limb Overgrowth:			
<2cm	3(10%)	3(10%)	3(10%)
>2cm	0	0	0
Limb shortening	0	0	0
Malalignment			
-Varus Angulation	0	0	0
-Valgus Angulation	0	0	0
-Anterior Angulation	0	0	0
-Posterior Angulation	0	0	0
Entry site irritation	2(6.6%)	0	0
Delayed union	0	0	0
Nail back out	0	0	0

In this study, the complications recorded are summarized in Table 7. At 3 weeks follow up: 4 patients (13.3%) had pains, 2 patients (6.6%) had entry site irritation which resolved with ingestion of non-steroidal anti-inflammatory medications while 3 patients (10%) had limb overgrowth of less than 2cm which persisted at 6 weeks and 24 weeks final follow up visit. No patient had superficial or deep surgical site infection, mal-alignment, delayed union, nail back- out or limb shortening.

Table 8: Relationship between clinical variables and development of Complication

Variables	Total number of patients	Complications present	Complications absent	p-value
Age				0.67
6-8YRS	20	5	15	
9-11YRS	10	4	6	
Gender				0.68
Male	21	7	14	
Female	9	2	7	
Mechanism of injury				0.44
RTA	19	3	16	
Fall	11	6	5	
Fracture Pattern				0.69
Transverse	17	5	12	
Oblique	13	4	9	

The relationship between different variables and complications observed are shown in Table 8. There was 5 minor complications in children ages 6 -8 years, while there was 4 complications in children 9-11 years with a P-value of 0.67 which was not statistically significant. Seven males and 2 females had complications with a P-value of 0.68 which was not statistically significant.

In comparison of the mechanism of injury 3 patients whose injury were from fall and 6 patients whose injury were from Road traffic accident had complications with a P-value of 0.44 which was not statistically significant. 5 patients with transverse fractures and 4 patients with oblique fracture pattern developed complications with a P-value of 0.69 which was not statistically significant.

In this study, the outcome of using Titanium Elastic Nails for paediatric femoral diaphyseal fractures over 24 weeks was analysed using the TENS outcome score by Flynn et al [7]. Twenty-seven patients (90%) had excellent outcome, 3 patients (10%) had satisfactory outcome, no patient had a poor outcome as shown in Table 9.

Table 9: TEN outcomes scoring by Flynn et al[7]

Variables at 24 weeks	Excellent result	Satisfactory result	Poor result
Limb length discrepancy(cm)	27	3	0
Mal-alignment (deg)	0	0	0
Unresolved pain	0	0	0
Complication	0	0	0
Total	**27(90%)**	**3(10%)**	**0**

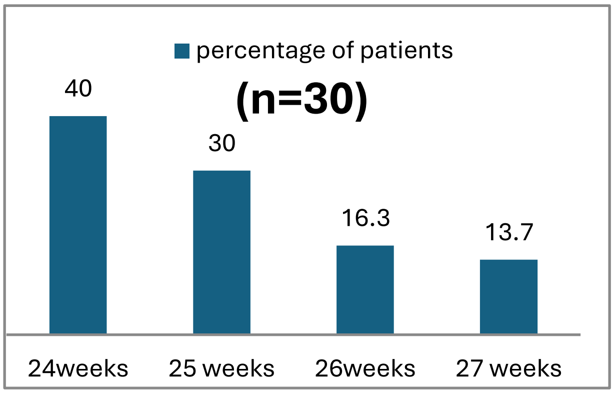

Figure 4: Time of nail removal

After achieving union both clinically and radiologically, the implants were removed at a mean time of 25 $\pm$ 1 week, with 12(40%) patients having their nails removed at 24 weeks, 9(30%) patients at 25 weeks, 5(16.3%) and 4(13.7%) patients at 26 and 27 weeks respectively (Fig. 4).

Discussion

The management of femoral diaphyseal fractures in paediatric age group especially in 6-11 years age groups has been controversial. The use of Titanium Elastic Nails is a good surgical choice in managing paediatric femoral diaphyseal fractures in children ages 6-11 years as it is associated with fewer complications early union and early return to function as deduced by several studies. This study was set to assess the time to union, complications associated with the use of Titanium Elastic Nails (TENS) and functional outcomes using Flynn et al scoring criteria. Union achieved in 9.4 $\pm$ 1.1 weeks. The functional outcome using the Flynn scoring criteria had 90% Excellent outcome, 10% Satisfactory outcome with no poor outcome. The complications associated with the procedure included; pain at entry site, limb overgrowth of less than 2cm and entry site irritation.

Nineteen patients,19 (63.3%) achieved union within 9 – 16 weeks with a mean time of union of 9.4 $\pm$ 1.1 week, while eleven patients 11(36.7%) achieving union within 8 weeks. Munzur R. et al [33] had a similar result with the index study as he recorded an average time to union of 9.1 weeks (ranges 8 -10 weeks). Flynn JM et al[7] recorded an average time to union of 9 weeks. In a study by Panchal P et al [38] who studied 41 patients, 29.2% of the patients achieved union at 6 weeks and by 12 weeks all the patients had achieved union which was similar to that obtained by Jalan D. et al [39] who achieved union at a mean time of 6.83 weeks in 56.75% of the patients. Bahinipati J et al[19] in their study achieved union at a mean time of 7.9 weeks with about 56% of the cases achieving union within 6-8 weeks while Shaunak P. et al[30] noted a time to union of < 3 months in 80% of their patients while 20% of the patients achieved union within 3 - 4.5 months with a mean time to union of 12.1 weeks. The rate of early union may be associated with patients age while the delay in time to union may be due to the disruption of fracture haematoma as well as surgical site infection noted in those studies.

In this study, eighteen patients 18(60%) commenced full weight within 9-16 weeks with an average time of 9 $\pm$ 0.8 weeks, while 12 patients (40%) commenced full weight bearing between 0-8 weeks. In a similar study, Munzur R. et al [33] recorded a mean time of commencing full weight bearing of 8.6 (range 7-10) weeks. Flynn J.M. et al[7] in their study recorded an average time of full weight bearing of 8.5 weeks. Jalan D et al [39] noted an average of 6.83 weeks for commencing full weight bearing in their study while Bahinipati J et al[19] achieved full weight bearing at 7.9 weeks. The time of commencing full weight bearing coincided with time of union as noted by the various studies.

Nine patients, 9(30%) had minor complications with 6 patients having resolution of their symptoms before the final follow up. The complications included; pain at entry site, entry site irritation with limb overgrowth less than 2cm. There were no patients with major complications like unresolved pain, bursitis, re-fracture or limb overgrowth of greater than 2cm. This is like the findings by Furlan D. et al[21] who noted 6.3% minor complications with no major complications. The complications they noticed included: skin infection, entry site skin irritation, nail protrusion. However, Sink et al[39] in their study recorded a total of 62% complications with 41% minor complications which resolved before the final follow-up visit and 21% major complications requiring additional surgeries. This variation may be as a result of both length - stable and length - unstable fractures in their study.

Four patients, 4(13.3%) had pain at entry site at 3 weeks follow up visit, which was treated with non-steroidal anti-inflammatory medications and noted to have completely resolved on subsequent follow up visits. Sarkar S. et al [31], in their study recorded 20% (14 out of 70 patients in their study had pain which resolved with removal of the nails. Flynn J.M.et al [7], in their study had 0.9% cases with pain at entry site. This may be due to prominence of the ends of the nails and fact that caps were not used in this study as well as other studies with similar findings leading to soft tissue irritation resulting in pain and discomfort.

In this study, three patients, 3(10%) had limb overgrowth of less than 2cm, no patient had lengthening of greater than 2cm or limb shortening. This is like the findings of Komlatse' A. et al[2] in Togo, who studied 32 patients and reported limb overgrowth of 1.5cm in 2 patients. Similarly, Sarkar et al[31] noted a limb overgrowth of 1.5cm in 2 (2.85%) patients. However, Kaiser S.et al[42] in Ghana, noted shortening of less than 1.5cm in their study, Bahanipati J. et al[19] recorded an average limb overgrowth of 1.1cm (0.9-1.3cm) in 4 cases and average limb shortening of 0.6cm (0.5-0.7cm) in 2 cases 6 months after surgery, while Kumar N. et al[41] recorded 1m shortening in their patients . This variation could be due to the inclusion of both length stable and length unstable fractures in their study which was not part of this study.

Two patients, 2 (6.6%) had entry site irritation/bursitis in this study, but no infection recorded. This is like the findings of Munzur R.et al[33] who recorded entry site irritation with no bursitis or infection. However, Bahanipati J. et al[19] in their study noted entry site irritation in 5 (20%) cases with associated bursitis resulting in infection in 2 cases. This is due to friction by the cut ends of the nail.

In this study, no patient had infection, mal-alignment, nail back-out or re-fracture.

In analysing the relationship between Age, gender, mechanism of injury, fracture pattern with rate of complications following treatment of paediatric femoral diaphyseal fractures with TENS there was no statistically significant findings as the P- values were 0.67, 0.68, 0.44 and 0.69 respectively. Similar findings were noted by Patil C. et al[36] who noted no statistically significant findings between age, gender, mechanism of injury, fracture pattern and occurrence of complications. However, Ulici A. et[42] noted a statistically significant relationship between mechanism of injury, age and weight > 50kg and the occurrence of complications in their study. This could be due to the demography of their study population.

Functional Outcome

The assessment of functional outcome was based on clinical and radiological features gotten at follow up at 3 weeks, 6 weeks and 24 weeks.

At the end of 24 weeks the outcome was analysed using the TENS Outcome scores by Flynn et al[7] for all the 30 patients. Twenty-one of the patients (90%) had Excellent outcome, 9 patients (10%) had satisfactory outcome. No patient had a poor outcome. A similar study by Komlatse' et al[2] in Togo also recorded Excellent results in 90.63% cases, satisfactory in 9.37% with no patient that had a poor outcome. Munzur R. et al[33] in Bangladesh who studied 36 children who had Titanium Elastic Nails for femoral diaphyseal fractures, recorded excellent outcome in 31(86%) patients, satisfactory in 5(14%) with none of the patients having poor outcomes. On the other hand, the study by Moroz et al [34] reported excellent results in 150 (65%) cases, satisfactory in 57(25%) cases and poor in 23(10%) cases. Bahanipati J. et al[19] in their study recorded excellent outcome in 19(76%) cases, Satisfactory outcome in 4(16%) cases and poor outcome in 2(8%) cases which was similar to the result obtained by Flynn JM et al[7] who had excellent outcome in 67.3% of patients, satisfactory outcome in 31% of patients and poor outcome in 1.7% patient. This could be due to the inclusion of length stable and length unstable fracture patterns in their studies as well as inclusion of patients weighing greater than 49kg (which were excluded from this study).

Nail removal

Among the 30 patients in this study who had Titanium elastic nailing for the treatment of femoral diaphyseal fracture; nails were removed at an average time of 25 $\pm$ 1 weeks. Twelve 12(40%) patients had their nails removed at 24 weeks, 9(30%) had their nails removed at 25 weeks while 5(16.3%) and 4(13.7%) patients had their nails removed at 26 and 27 weeks respectively. No complications was associated with nail removal. Simanovsky N. et al[29], in Isreal, studied 94 children who had Titanium elastic nail fixation for femoral diaphyseal fractures and noted a mean time of removal of 4 – 8 months, Sarkar S. et al[43] also had the nnails of patients removed at 6 -14 months with a mean time of 8 months which was similar to the findings of Pradeep C. et al[16] who had all the nails in their study removed at an average duration of 27.2 weeks (22 – 35 weeks). These findings are similar to the findings of this study. However, Munzur R. et al[33] had a mean time of nail removal of 47 weeks (42 -54 weeks) which was different from the findings of this study. This variation was due to longer duration of follow-up in their study.

Conclusions

Treatment of Paediatric femoral diaphyseal fractures with Titanium Elastic Nail (TENS) in children ages 6-11 years has Excellent to Satisfactory outcome. We therefore recommend the use of Titanium elastic nails for treatment of length - stable paediatric femoral diaphyseal fractures, though a multicenter study and long term follow up is desirable to validate our findings.

Limitations

The sample size was small in a single centre study with a short duration of follow-up, though the outcome was excellent to satisfactory we are careful in recommending it to the public.

Contribution of research to knowledge

The Paediatric Orthopaedic Unit of the National Orthopaedics Hospital Dala –Kano is adopting the use of Titanium Elastic Nails (TENS) in management of length stable Paediatric diaphyseal fractures. Our instrument set, the length stable paediatric femoral fracture and outcome of treatment are shown in Fig. 5 and 6 below:

Fig. 5: The TENS instrument set use for the study

Fig. 6: (a) The length stable paediatric femoral fracture recruited for the study, b) the healed paediatric femoral fracture treated with TENS in situ and (c) after removal of TENS

Conflict of interest

There is no conflict of interest

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