Original Research Article

A Clinical Study on Titanium Elastic Nail System in the Treatment of Diaphyseal Tibial Fractures in Paediatric Age Group

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Abstract

Background: TEN is a relatively new technique used in tibia fractures, which has had an increased popularity in the last decades, and there are few publications on this technique. These nails facilitate callus production by decreasing shear forces and allowing micro movements. They stimulate union by converting their traction forces to compression forces through the three points fixation that is provided. **Materials & Methods:** A total of 36 patients, twenty five (25) male and eleven (11) female patients (M : F = 2.3 : 1) ranging in age from 6–15 years and a mean age of 9.11 ± 2.44 years with diaphyseal fracture of tibia & road traffic accidents accounted for majority of fractures (69.44% cases) and the remaining comprises fall from height and injuries while playing etc. that met the inclusion criteria underwent treatment with Titanium elastic nails in the Department of Orthopaedics, Fakhruddin Ali Ahmed Medical College & Hospital, Barpeta Assam, between February 2019 to January 2020. **Results:** The fracture of both tibia and fibula was found in 25 (69.44 %) cases and among those, in 17/25 (47.22%) cases the fracture of tibia and fibula were in the same level. Close reduction was achieved in 35 (97.22%) cases. A slab was applied for immobilization in 9 cases post operatively. The results were evaluated as per Flynn criteria, 29 (80.56%) had excellent outcome, 6 patients showed good results and 1 case had fair result.**Conclusion:**TENs is a relatively simple and effective way to stabilize open and close fractures of the tibia in children with few complications allowing early mobilisation and an excellent functional outcome.

Key words: Paediatric age group, Tibia fracture, Titanium elastic nails.

Introduction

Tibial diaphysis fractures are one of the most common cause of post traumatic hospital admissions in paediatric age group and accounts for about 15% of pediatric long-bone fractures[1-6].In tibia fractures during childhood, closed reduction and casting are the most common, safe and efficient method of treatment[7-10] and due to unique remodeling potential many deformities may heal spontaneously[1].Surgical treatment is also needed in open fracture, polytrauma,compartment syndrome, neurovascular injuries, or severe soft tissue compromise Earlier, operative fixation for these unstable tibial shaft fractures includes external fixation and plate and screw fixation. These techniques were associated with complications like, infection, over-growth, and refracture[11].Fixation with TEN is an easy, effective, and safe method that can be used in tibia fractures that are open, irreducible, or associated with loss of reduction and in cases with accompanying trauma, such as floating knee[1,12,13]. It is a minimally invasive technique. TENS provides stable and elastic fixation that allows for controlled micro motion at the fracture site which results in healing by external callus[14].

An adult or adolescent patient may be treated with a rigid intramedullary nail for cases with diaphyseal fractures of Tibia. However in paediatrics patients with growing physis this is not acceptable due to potential complications of limb length discrepancies[15].Minimal soft tissue disturbance with small scars, early mobilisation, low infection rates, ease of management

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and shorter hospital stays has made the use of TENs more advantageous over other procedures. Possible complications such as malunion and refracture remain as they would with conservative treatment[15-18].The tibia has been divided into 3 zones – Zone I, II and III where TENS is indicated for Zone II and some cases of Zone III[19].The aim of this study is to evaluate the efficacy and safety of fixation using Titanium elastic nails (TEN) in Paediatric diaphyseal fractures of tibia Zone II and Zone III.The purpose of the present study was to evaluate the radiological union in treated patients and the short and medium term complications.

Material and methods

This was prospective and single centre study.The study was reviewed and approved by the Internal ethics committee of FAAMCH.From February 2019 to January 2020 consecutive patients with fracture tibia, who were admitted either through the outpatient department (OPD) or the emergency department (Casualty) of orthopaedics and meeting the inclusion and exclusion criteria mentioned below were the subject for the study. The sample comprises of 36 patient.Out of total 36 patients in the study, 25 were males and 11 were females with a meam age of 9.11(6 to 15 years).right tibia was involved in 17 cases and left was in 19 cases.cause of injury in majority was road traffic accidents.

Inclusion criteria

Patients with age group 6- 15 years.

All closed tbia fracture

Open fractures with Gustilo Anderson type I and type II,diaphyseal fractures of tibia involving zone II and zone III and time of presentation < 3 weeks was included in the study.

Exclusion criteria

Patients unfit or not willing to undergo surgery.

Old fracture with pathological and skelletal dysplasia like osteogenesis imperfectadiaphyseal, pseudoarthosis tibia.

Associated systemic injury ,contralateral limb fracture and neurovascular injury.

undisplaced fracture.

Method

Workup Protocol

- ❑ General, Systemic as well as Local examination of the patient.
- ❑ Thorough clinical examination was done to rule out other systemic injuries as mentioned in the proforma (Annexure III)
- ❑ Resuscitation of the hemo-dynamically unstable patients. To address associated injuries and consultation of other departments whenever indicated.
- ❑ Careful assessment of injured limb as regard to neuro-vascular status
- ❑ Primary immobilisation with Posterior POP slab was applied to the fracture for pain relief and allow for soft tissue oedema to reduce.
- ❑ Radiological assessment by Antero-posterior and Lateral radiographs of the affected limb.
- ❑ Fracture was classified according to the AO classification system

Pre-operative preparation

- ❑ Prophylactic IV antibiotic (ceftriaxone plus sulbactam), given in the night before the day of surgery and 30 minutes before the skin incision.
- ❑ Patient were taken for surgery once declared fit for anaesthesia and surgery.
- ❑ All patients will receive a prophylactic IV antibiotic i.e Cefoperazone or ceftriaxone immediate before the surgery.
- ❑ Shaving of the limb wherever necessary.
- ❑ The operating field was washed with savlon, povidone iodine and was draped separately.
- ❑ IITV was placed on opposite side.
- ❑ Anaesthesia : GA /SA as per choice of anaesthesia team

Patient positioning

- ❑ Supine position on a radiolucent operating table
- ❑ Orthopaedic surgery table was used
- ❑ Tourniquets were not applied on any patient
- ❑ Wound debridement was performed on open fractures and the accompanying soft tissue injuries

Operative technique

- ❑ The fracture line was visualized under fluoroscopy.
- ❑ Close reduction of the fracture achieved under IITV guidance in most of the cases.
- ❑ The entry site was determined to be 2 cm distal to the proximal physis of the tibia and caution was exerted not to injure the tibial apophysis
- ❑ Two longitudinal incisions measuring 2 cm on the medial and lateral sites of the tibia were performed.
- ❑ Two TEN's of equal thickness were selected to occupy 40% of the medulla that was defined preoperatively.

- The cortex was penetrated with an AWL
- Both wires were forwarded until they reached the fracture line.
- Reduction was checked, which was performed under fluoroscopy, the first wire was forwarded to pass beyond the fracture line.
- After checking the distal tibia by fluoroscopy in the lateral and anteroposterior plane for the first wire, the second wire was introduced similarly if the position of the first one was deemed appropriate.
- Afterwards, fluoroscopy controls were performed in both planes again.
- Open reduction was performed on one patient as close reduction could not be achieved.
- Wires were cut 1.5 cm away from the bone surface.
- Long leg splints were applied in some patients depending upon fracture configuration, which stayed in place for 2-4 weeks postoperatively.

Post operative care

- After wound closure, antiseptic dressing done.
- Wound inspected on 3rd post-operative day or earlier if there was soakage.
- Supportive medical treatment were instituted as per requirements of the patient.
- Sutures were removed after 10 days.

Statistical analysis

Data are expressed as mean ± SD for continuous variables, and as frequencies for categorical variables.Data were analyzed with Microsoft office Excel 2010. The significance testing was performed using the 2-tailed Student t-test and, Fisher's exact and chi-squared (χ^2) test in Graph Pad Prism software. *p-value*<0.05 was considered as statistically significant.

Results & Observations

A total of 36 patients with fracture tibia were recruited in this study, who met the inclusion study. The patients were followed up at 3weeks, 6 weeks, 12 weeks and 6 months after surgery. The results and observation were as follows:

Table 1: Showing the age distribution

	MEAN	± S.D.	MINIMUM	MAXIMUM
AGE (in years)	9.11	± 2.44	6	15

The age in the study population ranged from 6-15 years. The mean age was 9.11±2.44 years.

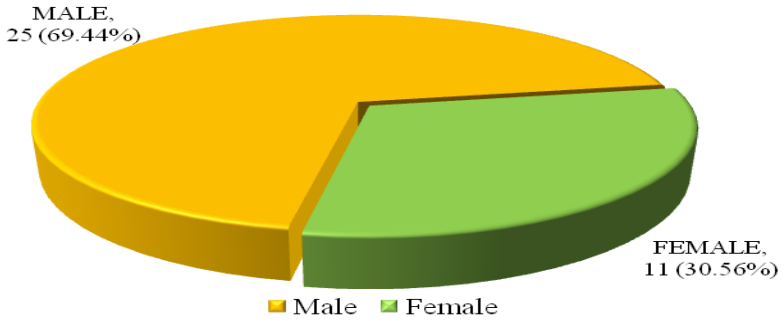

Fig 1:Sex distribution

Out of total 36 patients in the study, 25 were males and 11 were females with male to female ratio of 2.27:1

Side of Injury

In our study, Right tibia was involved in 17 cases (47.22%) and Left tibia was involved in 19 cases (52.78 %).

Mode of injury

Out of total 36 patients, RTA was the cause in 25 (69.44%) cases, 7 (19.44%) patients sustained fracture due to Simple fall and 4 (11.11%) after Sports related injuries.

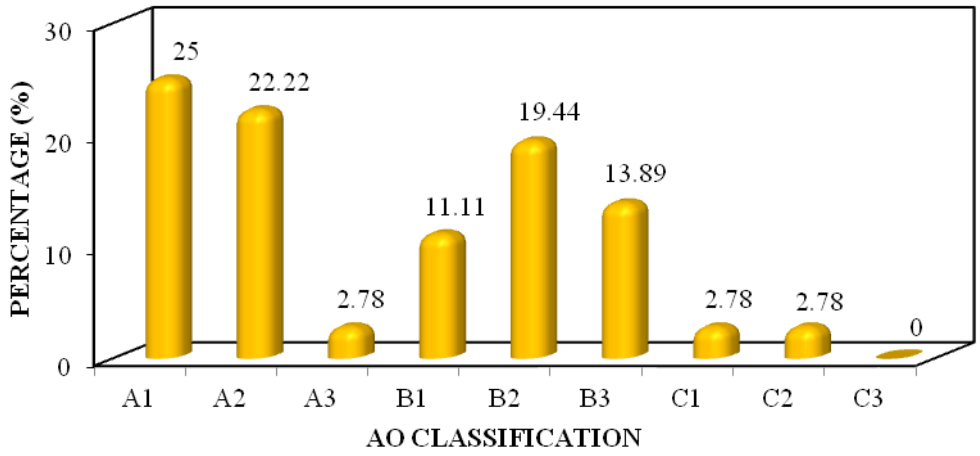

Fig 2:AO Classification

The fracture pattern was Spiral in 9 (25 %) cases, Oblique in 8 (22.22%) cases, Transverse in 1 case. Wedge fracture pattern (B1-B3) was noted in 16 cases (44.44%). Complex spiral and complex segmental fracture pattern was noted in one case each.

Location of fracture:The fracture was located in the Zone II in 21 children (58.33 %) and in the Zone III in 15 children (41.67 %). Fracture in Zone I of Tibial shaft are not included in the study.

Gustilo-Anderson type:7 cases were Type 1 open fracture and 3 cases were of Type 2 fracture.

Fibula:The Fibula was intact in 11 cases (30.56 %) and fractured in 25 cases (69.44%).

Angulation : Sagittal angulation was seen in 1 case and coronal angulation was seen in 5 cases.

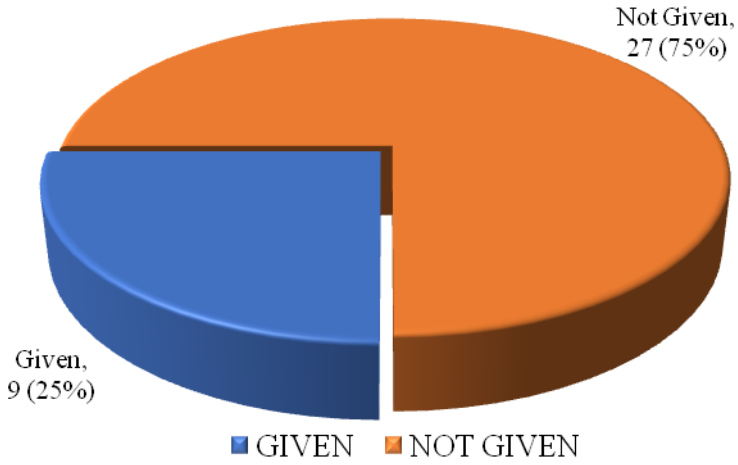

Fig 3:Immobilisation

Immobilisation in the form of PoP slab has been given in 9 (25%) cases. No immobilization was given in 27 (75 %) patients.

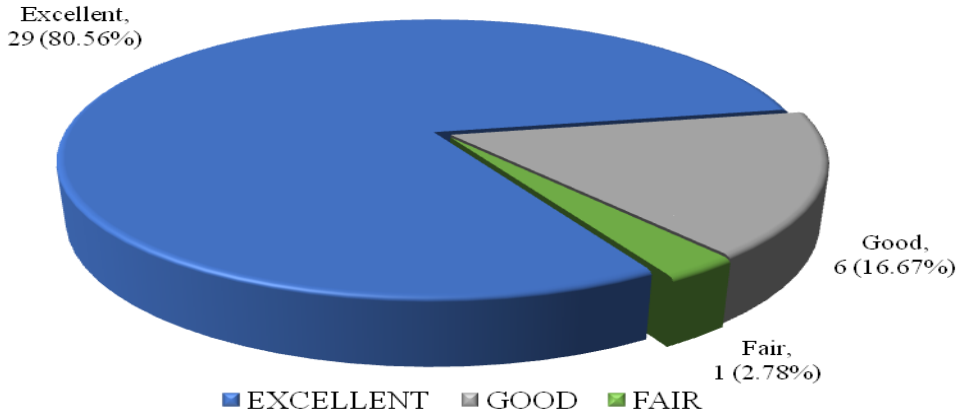

Fig 4:Results(Ten scoring system)

According to Flynn *et al.* criteria, 29 (80.56%) patients were evaluated as excellent, 6 (16.67%) patients showed good results and In 1 (2.78 %) patient the outcome was fair.

Table 2: Time of partial weight bearing in open and close fracture

	MEAN	± S.D.	MIN	MAX	*p value*
Close fracture (n = 26)	5.65	1.70	2	8	0.0399*(S)
Open fracture (n = 10)	7.10	2.13	3	10	

**Student t test*

There is statistically significant difference found in the time of partial weight bearing between close fracture and open fracture (p <0.05).

Table 3: Complications in open and close fracture

COMPLICATIONS	NUMBER (n)	CLOSE FRACTURE (n = 26)		OPEN FRACTURE (n = 10)		*p value*
		N	%	n	%	
Hardware Irritation	4	3	75.00	1	25.00	0.895333
Saggital Plane Angulation	1	0	0.00	1	100.00	0.123539
Coronal Plane Angulation	5	3	60.00	2	40.00	0.608503
Superficial Infections	2	1	50.00	1	50.00	0.057579
Limb Length Discrepancy	16	11	68.75	5	31.25	0.684498

**Chi-square test*

There is no statistical significant difference found when complications were compared between close fracture and open fracture (p>0.05).

Table 4: Outcome in open and close fracture

OUTCOME	NUMBER(n)	OPEN FRACTURE (n = 10)		CLOSE FRACTURE (n = 26)		*p value*
		N	%	N	%	
Excellent	29	7	24.14	22	75.86	0.5103 (NS)
Good	6	3	50.00	3	50.00	
Fair	1	0	0.00	1	100.00	

**Chi-square test*

There is no statistical significant difference found in outcome when compared between close fracture and open fracture (p>0.05).

Discussion

Although tibial diaphyseal fracture can be treated both conservatively and operatively, the choice of ideal treatment remains a constant challenge to the orthopedics fraternity. Conservative treatment has been one of the most preferred methods but has its own drawbacks. Operative method is gaining popularity to prevent prolonged immobilization, reduce the effects of loss of school days and for better nursing care. TEN fixations provide a three point bony fixation without damaging the epiphysis[20].TEN acts like an internal splint and the mechanical conduction is stress shared type and hence giving relative stabilization of the fracture. Due to this upon active and passive mobilization there is micromotion at the fracture site which helps in early union[14,21]The following variables of each patient were recorded and analysed: age, sex, fracture type and pattern, mode of injury, limb involved, duration of hospital stay in days, follow up in weeks and months, complication and final outcomes.During subsequent follow up the following variables viz. pain, complications such as infection, limb length discrepancies, alignment of the limb, symptoms and signs of union were recorded. The statistical analysis consisted of percentages, range, mean wherever applicable.

Age distribution

The age of the patients ranged between 6-15 years, with a mean of 9.11 ± 2.44 years. The mean age of the patients in our study is similar to a study by Ozkul *et al*. 2014[1].O'Brien *et al*. 2004[22]. In another prospective study by Ahmed *et al*[23] where the age group was 5-15 years with a mean age of 11.3 years is found to be similar to our study.However some studies[20,24-26]. have mentioned peak age for tibia fractures occurs on an average of 8 years.

Sex distribution

The study shows male preponderance which is in concordance with other similar studies. In our study we had 25 male and 11 female patients with a male: female ratio of 2.3:1. This is consistent with a study by Gordon *et al*[27]who reported 35 males and 15 females with a male: female ratio of 2.3:1. A study by Goodwin *et al*[28] reported 16 males and 3 females in their study and a study by Srivastava *et al*[13] reported 21 males and 3 females. Santili *et al*[2,29] in their study stated that the ratio of male: female is 2:1.

Side of involvement

In our study fracture of left tibia was found in 19 (52.78%) cases and right tibia in 17 (47.22%) cases. Vallamshetla *et al*[30] also reported similar pattern of involved side. Economedes *et al[8]*reported 22 right sided and 16 left sided fractures. However none of the cases in our study had bilateral Tibia fractures.Considering the mode of injuries, out of total 36 patients 25 cases were due to RTA (69.44%), 7 (19.44%) patients sustained fracture due to simple fall, and 4 (11.11%) patients after sports events related injuries.

Type of fracture

External fixation used in open fractures of tibia has associated problems of pintract infections and delayed weight bearing. Use of TEN has been well advocated in open fractures. In our study of 36 children, 26 (72.2%) cases comprised of close fracture and 10 (27.78 %) cases of open fractures. According to Gustilo Anderson [31] classification for open fracture, Type 1 and Type 2 fractures were included in our study with 7 (19.44%) cases of type 1 fracture and 3 (8.33 %) cases of type 2 fracture. Vallamshetla *et al*.[30] reported 23% cases of Open fractures with 62% type 1 (70% in our study) and 15% type 2 (30 % in our study) according to Gustilo and Anderson classification, which is almost similar to our study. Gordon *et al*[27] reported a series of 50 patients where 26 had open fracture and 24 close fractures while Srivastava *et al*[13] in their study reported 8 close and 16 open fractures

Bones involved

Griffet *et al*[16] in their study of 86 children reported 53 (61.63%) children with isolated tibia fracture and 33 (38.37%) with both tibia and fibula fracture. This is may be due to difference in the mechanism of injury involved.It has also been observed that, in our study 11 (30.56 %) children suffered from isolated tibia shaft fractures and 25 (69.44 %) children from both tibia and fibula shaft fractures.In cases with fracture both bone involving tibia and fibula, the fracture level was found to be same for both the bones in 17 (47.22%) cases and was different in the remaining 8 cases. In 3/8 cases, fracture was above the level of tibia fracture and 5/8 cases below the level of Tibia fracture.

Time of union

In our study the overall mean duration of partial weight bearing was found to be 6.06 ±1.91 weeks and the time of union was found to be 11.53±2.51 weeks. The mean duration of time of partial weight bearing and time of union has been calculated separately for open fractures and close fractures. The mean duration of time of partial weight bearing found to be 7.10 ±2.13 weeks in open fractures and 5.65± 1.70 weeks in close fracture. This difference is found to be statistically significant (*p* value =0.0399) The time of union for close fracture was found to be 10.81±2.12 weeks and open fracture was found to be 13.40±2.59 weeks and this difference in the time of union is found to be statistically significant (*p value*=0. 0040).No case had delayed union.Heo *et al*[32] in their study reported the mean duration for the time of union as 16.1 weeks (11-26 weeks). Ozkul *et al*[1]in their study reported the mean duration to union as 8 weeks after close fractures and 14 weeks after open fracture.Sankar *et al*[11] also reported the meantime to union as 11 weeks which is in concordance with our study.Limitations of the current study include use of a small sample size and lack of a control group treated with either external fixator or immobilization alone. Furthermore, because of time limitation follow up is of short duration.

Conclusion

Tibia fracture is one of the common fracture in paediatric age group which is prone to delayed union or non-union and hence every possible attempt should be made to treat these fractures in a close manner with preservation of the vascularity of the bone ends. TENs is a reliable stabilization method for long-bone fractures in children, provided that the important principles of biomechanics are respected. It is predominantly used for stabilization of diaphyseal fractures and less commonly used for metaphyseal fracture.Thus we have found, TENs is a relatively simple and effective way to stabilize open and close fractures of the tibia in children with few complications allowing early mobilisation and an excellent functional outcome.

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