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Research Article

PROSPECTIVE STUDY IN TREATMENT OF LONG BONE FRACTURE IN CHILDREN BY TITANIUM ELASTIC NAILING STABILIZATION

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ABSTRACT

To evaluate the results of operative treatment - outcome, safety and efficacy of Titanium Elastic Nailing for the treatment of diaphyseal fractures of long bones in children in the age group between 5 to 16 years.
Titanium elastic nail (TEN) fixation was originally meant as an ideal treatment method for femoral fractures, but was gradually applied to other long bone fractures in children, as it represents a compromise between conservative and surgical therapeutic approaches with satisfactory results and minimal complications.
Keywords: Titanium Elastic Nail, Children, Stabilization, Orthopaedists, Immobilisation.

INTRODUCTION

Over the past 20 years, paediatric orthopaedists have tried a variety of methods to treat paediatric long bone fractures to avoid prolonged immobilisation and complications.
Ender's nails are stainless steel implants that proved to be inadequate for adult femoral and tibial fractures but may be effective for paediatric fractures although they may be not elastic enough as their modulus of elasticity is higher than titanium nails.
TENs are more elastic, thus limiting the amount of permanent deformation during nail insertion, they promote healing by limiting stress shielding in addition to their biocompatibility without metal sensitivity reactions.

METHODOLOGY

All children and adolescent patients between 5-16 years of age with diaphyseal fractures of long bones admitted at Mamata General hospital, Khammam, meeting the inclusion and the exclusion criteria (as given below) during the study period from oct-2011 to oct-2013 were the subjects for study .

Inclusion criteria:
1. 5-16 years of age
2. Diaphyseal fractures
3. Simple fractures (closed fractures)
4. Ipsilatertal fractures
5. Fracture with head injury

Exclusion criteria:
1. Metaphyseal fractures
2. Compound fractures
3. Pathological fractures

As soon as the patient was brought to casualty, patient's airway, breathing and circulation were assessed. Then a complete survey was carried out to rule out other significant injuries. Plain radiographs of AP and lateral views of – the involved extremity including one joint above and one joint below was taken to asses the extent and geometry of fracture.
On admission to ward, a detailed history was taken, relating to the age, sex, and occupation, mode of injury, past and associated medical illness Routine blood investigations were done for all patients. Patients were operated as early as possible once the general condition of the patient was stable and patient was fit for surgery.

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

Flynn et al's formula
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.

Pre-operative planning of Nail size

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.
- The whole of the extremity below the umbilicus, including the genitalia was prepared appropriately.
- A systemic antibiotic, usually a 3rd generation cephalosporin was administered 1 hour before surgery.

Under anaesthesia, closed reduction and internal fixation with TENS nails done under c-arm guidance.

Figure: 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:

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

Postoperative Care:

- Patients were kept nil orally 4 to 6 hours post operatively
- IV fluids / blood transfusions were given as needed
- Analgesics were given according to the needs of the patient
- The limb was kept elevated over a pillow.
- IV antibiotics were continued for 5 days and switched over to oral antibiotics on the 5th day and continued till the 10th day.
- Sutures were removed on the 10th postoperative day and patients were discharged.

Post-operatively, patients are immobilized with long leg cast with a pelvic band for femur fracture or with above knee POP cast for tibia fracture for 6 weeks and such immobilization was continued for another 2-3 weeks based on radiological assesment.

The period of immobilization was followed by active hip and knee / knee and ankle mobilization with non-weight bearing crutch walking for lower limb fractures, active shoulder and elbow/elbow and wrist mobilization for upper limb fractures. Full weight bearing is started by 8 - 12 weeks depending on the fracture configuration and callus response.

In patients with humerus fracture and an ipsilateral radius or ulna fracture, the forearm fracture was stabilized with either Kirschner wire fixation or titanium flexible nails and placed into a posterior elbow splint. Patients without ipsilateral upper extremity fracture were either splinted or placed into a soft dressing and given a sling for comfort for 10–14 days.

No routine physical therapy was prescribed. Mobilization out of bed without restriction was permitted for patients with isolated injuries. Patients with lower extremity fractures were permitted to bear weight on the upper extremity as tolerated.

In case of forearm bone fractures we immobilized the patient for 3wks in a posterior slab followed by allowing ROM exercises for elbow and wrist, sling for another 3more wks.

FOLLOW UP

Assessment done at 6, 12 and 24 weeks and at 1yr. At each follow up patients are assessed clinically, radiologically and the complications are noted

CLINICAL ASSESMENT

Range of movements

Table: Measurement of limb length – noted for shortening / lengthening

JOINTS MOVEMENTS	HIP		KNEE		ANKLE	
	FLEXION	EXTENSION	FLEXION	EXTENSION	DORSI - FLEXION	PLANTAR-FLEXION
FULL RANGE	0 -160	0-10	0 -140	-	0 -35	0 -45
MILD RESTRICTION	0 -140	0-10	0 -120	-	0 -30	0 -35
MODERATE RESTRICTION	0 -100	0-10	0 -100	-	0 -20	0 -25
SEVERE RESTRICTION	<100	-	<100	-	< 20	< 25

COMPLICATIONS

Minor complications –

a) when they resolved without additional surgery

b) not resulting in long term morbidity.

Major complications –

a)when further operation was required

b)long term morbidity ensued.

Minor complications[7]:

1. Pain at the site of nail insertion
2. Minor angulation (< 10^0 – saggital/coronal; <10^0 rotational malallignment) at final follow-up (24 weeks)
3. Minor leg length discrepancy(< 2cm – shortening/lengthening) at final follow-up (24 weeks)
4. Inflammatory reaction to nails
5. Superficial infection at site of nail insertion
6. Delayed union

Major complications[7]

1. Angulation exceeding the guidelines (>10^0 – saggital/coronal; or > 10^0 rotational malallignment) at final follow-up
2. Leg length discrepancy exceeding the guidelines (>2cm – shortening/lengthening) at final follow-up
3. Deep infection
4. Loss of reduction requiring new reduction or surgery
5. Surgery to revise nail placement
6. Compartment syndrome requiring surgery
7. Neurological damage after nailing
8. Delayed or nonunion leading to revision

The final outcome based on the above observations is done as per Flynn's criteria.

TENS outcome score (Flynn *et al*)[2,7,8]

RESULTS VARIABLES at 24 weeks	Excellent	Satisfactory	Poor
Limb-length inequality	< 1.0 cm	< 2.0 cm	> 2.0 cm
Mal alignment	5 degrees	10 degrees	>10 degrees
Unresolved pain	Absent	Absent	Present
Other complications	None	Minor and Resolved	Major and lasting morbidity

ADDITIONAL VARIABLES: included in our study

Variables Outcome	Excellent	Satisfactory	Poor
Range of movements	Full range	Mild restriction	Moderate – severe restriction
Time for union	8– 12 weeks	13– 18 weeks	>18 weeks
Unsupported weight Bearing	8– 12 weeks	13– 18 weeks	>18 weeks

Excellent: When there was anatomical or near anatomical alignment, no leg length discrepancy with no preoperative problems.

Satisfactory: When there was acceptable alignment and leg length with resolution of preoperative problems.

Poor: In the presence of unacceptable alignment or leg length with unresolved preoperative problems[2].

Statistical Analysis:

Descriptive statistics like numbers , percentages , average , standard deviations ,were used. Data was presented in the form of tables and graphs wherever necessary.Inferential statistical tests like Chi- square and Fisher's exact probability test were applied to know the association between incidence of complications and clinical variables.

OBSERVATIONS AND RESULTS

Study design: An outcome surgical study of 30 patients with Diaphyseal fractures of long bones is undertaken to study the outcome of Titalnium elastic nail fixation for long bone fractures in children.

Table 1: Age distribution of patients studied

Age in years	Number of patients	%
5-8	13	43.3
9-12	7	23.4
13-16	10	33.3
Total	**30**	**100.0**

Table 2: Gender distribution of patients studied

Gender	Number of patients	%
Male	21	70.0
Female	9	30.0
Total	**30**	**100.0**

Table 4: Mode of Injury of patients studied

Mode of injury	Number of patients	%
RTA	16	53.3
Fall due to stumbling	11	36.7
Fall from height	3	10.0
Total	**30**	**100.0**

Table 5: Bone affected

Bone affected	Number of Patients	%
Femur	12	40
Tibia	10	33.34
Humerus	4	13.33
Forearm bone	4	13.33
Total	**30**	**100.0**

Table 6: Side affected

Side affected	Number of patients	%
Right	13	43.3
Left	17	56.7
Total	**30**	**100.0**

Table 7: Pattern of fracture

Pattern of fracture	Number of patients	%
Transverse	10	33.3
Oblique	7	23.3
Spiral	5	16.7
Segmental	0	0.0
Communited	8	26.7
Total	**30**	**100.0**

Table 8: Level of fracture

Bone fractured	Level of fracture	No of patients	%
Femur (12)	Proximal 1/3rd	3	25
	Middle 1/3rd	6	50
	Distal 1/3rd	3	25
Tibia (10)	Proximal 1/3rd	2	20
	Middle 1/3rd	6	60
	Distal 1/3rd	2	20
Humerus (4)	Proximal 1/3rd	1	25
	Middle 1/3rd	2	50
	Distal 1/3rd	1	25
Fore arm bones (4)	Proximal 1/3rd	1	25
	Middle 1/3rd	2	50
	Distal 1/3rd	1	25

Table 9: Time interval between trauma and surgery

Time of interval between trauma & surgery	Number of patients	%
< 2days	6	20%
3-4 days	16	53.33%
5-7 days	6	20%
>7 days	2	6.67%
Total	**30**	**100.0**

Table 10: Duration of surgery in minutes

Duration of surgery (min)	Number of patients	%
<30	1	3.3
30-60	13	43.3
61-90	14	46.7
91-120	2	6.7
Total	**30**	**100.0**

Table 11: Post-operative Immobilization

Post-op immobilization	Number of patients	%
6 weeks	21	70
9 weeks	9	30
Total	**30**	**100.0**

Table 12: Duration of stay in hospital stay in days

Duration of stay (days)	Number of patients	%
≤7	3	10
8-10	12	40
11-15	11	36.67
>15	4	13.33
Total	**30**	**100.0**

Table 13: Time for union

Time for union	Number of patients	%
< / = 12 weeks	24	80.0
>12 – 18 weeks	5	16.7
>18 – 24 weeks	1	3.3
Total	**30**	**100.0**

Table 14: Range of movements at 24 weeks(degress)

Range of movements(degrees)	Number of patients	%
Full range	28	93.33
Mild restriction	2	6.66
Moderate restriction	0	0
Severe restriction	0	0
Total	**30**	**100**

Table 15: Time of full weight bearing

Time of full weight bearing	Number of patients (n=30)	%
≤ 12 weeks	24	80.0
>12 – 18 weeks	5	16.7
>18 – 24 weeks	1	3.3

Table 15 A: Complications

	Minor	Major	Nil	Total
No.of Patients	8	0	22	100
Percentage	26.67	-	73.33	100

Table 15 B: Complications

Complications	No. of cases	Percentage
Pain	**2**	6.6
Infection	1	3.3
Superficial	1	3.3
Deep	-	-
Inflammatory reaction	1	3.3
Delayed union and non union	-	-
Limb lengthening	1	3.3
< 2 cm	1	3.3
> 2 cm		
Limb shortening	2	6.6
< 2 cm	1	3.3
> 2 cm		
Nail back out	-	-
Mal alignment		
a. Varus angulation	1	3.3
b. Valgus angulation	1	3.3
c. Anterior angulation	-	-

d. Posterior angulation	-	-
e. Rotational malalignment	-	-
Bursa at the tip of the nail	-	-
Sinking of the nail into the medullary cavity	-	-

Table 16: Outcome

Outcome	Number of patients (n=30)	%
Excellent	22	73.33
Satisfactory	8	26.67
Poor	0	0.0

Table 17: Outcome for additional variables in the present study

OUTCOME VARIABLES	XCELLENT (%)	SATISFACTORY (%)	POOR (%)
Range of movements	93.3	6.7	-
Time for union	80	20	-
Unsupported weight bearing	80	16.7	3.3

Table 18: Association of Incidence of complications with clinical variables studied

Clinical variables	Total number of patients (n=30)	Complications(Minor)		P value
		Absent (n=22)	Present (n=8)	
Age in years				
• 5-8	13(43.3%)	9(69.23%)	4(30.77%)	
• 9-12	7(23.3%)	5(71.43%)	2(28.57%)	
• 13-16	10(33.3%)	8(80%)	2(20%)	0.617
Gender				
• Male	21(70%)	15(75%)	6(60%)	
• Female	9(30%)	5(25%)	4(40%)	0.431
Mode of Injury				
• RTA	16(53.3%)	8(40%)	7(70%)	
• Self fall	11(36.7%)	9(45%)	2(20%)	0.340
Fall from height	3(10%)	2(10%)	1(10%)	
Bone affected				
• Femur	12(40%)	8(66.67%)	4(33.33%)	
• Tibia	10(33.34%)	8(80%)	2(20%)	0.705
. Humerus	4(13.33%)	3(75%)	1(25%)	
. Forearm	4(13.33%)	3(75%)	1(25%)	
Pattern of fracture				
• Transverse	10(33.3%)	6(30%)	4(40%)	
• Oblique	5(16.7%)	6(30%)	1(10%)	
• Spiral	7(23.3%)	3(15%)	2(20%)	
• Segmental	0(0%)	0(0%)	0(0%)	
• Communited	8(26.7%)	5(25%)	3(30%)	0.700
Time interval between trauma & surgery				
• < 2days	6(20%)	5(22.72%)	1(12.50%)	
• 3-4 days	16(53.33%)	12(54.55%)	4(50%)	
• 5-7 days	6(20%)	4(18.18%)	2(25%)	
• >7 days	2(6.67%)	1(4.55%)	1(12.50%)	0.717

There was no significant association observed between clinical Variables (Age,Gender, Mode of injury, Bone affected, Pattern of Fracture and Time Interval between trauma and surgery) and Incidence of complications.

DISCUSSION

Age incidence:

In the present study 13(43.3%) of the patients were 5-8 years, 7 (23.3%)were 9 to 12 years and 10(33.3%) were 13 to 16 years age group with the average age being 9.8 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[17].

STUDIES	AGE INCIDENCE (average) in years
Present study	**9.8**
J.N.Ligier et al.	10.2
Wudbhav N Sankar et al.	12.2

Sex incidence:
There were 9(30%) girls and 21 (70%) boys in the present study. The sex incidence is comparable to other studies in the literature girls[8].

In their study J. N. Ligier et al. out of 118 cases, had 80 (67.7%) boys and 38
In their study, Gamal El-Adl et al. out of 66 patients, there were 48 (72.7%) male and 18 (27.3%) females[2].

STUDIES	SEX INCIDENCE (%)	
	MALE	FEMALE
Present study	**70**	**30**
J. N. Ligier et al	67.7	32.3
Gamal El-Adl et al.	72.7	27.3

Mode of Injury:
In the present study RTA was the most common mode of injury accounting for 16 (53.3%) cases, self fall accounted for 11 (36.7%) cases and fall from height accounted for 3 (10%) of the cases.

J. M .Flynn et. al, in their study assessing 234 cases, 136(58.1%) were following RTAs, 46(19.6%) were following self fall and remaining 43(28.8%) were as a result of fall from height[7,8].

STUDIES	MODE OF INJURY (%)		
	RTA	FALL DUE TO STUMBLING	FALL FROM HEIGHT
Present study	**53.3**	**36.7**	**10**
J. M .Flynn et. al	58.1	19.6	28.8

Bone affected
We studied 12(40%) femoral, 10(33.34%) tibial fractures, 4(13.33%) humeral and 4(13.33%) forearm bone fractures.

In D.FURLAN & Z. POGORELIC STUDY had 42(24.28%) femoral, 36(20.80%) tibial, 53(30.64%) humeral and 42(24.28%) forearm bone fractures.

STUDIES	BONE EFFECTED			
	FEMUR	TIBIA	HUMERUS	FOREARM BONES
PRESENT STUDY	40	33.34	13.33	13.33
D.FURLAN & Z. POGORELIC STUDY	24.28	20.80	30.64	24.28

COMPLICATIONS:

COMPLICATIONS	PRESENT STUDY (% incidence)	PREVIOUS STUDIES (% incidence)	
Pain at the site of nail insertion	6.6	16.2	J.M.Flynn et al.
Superficial infection	3.3	1.7	J.M.Flynn et al.
Range of motion	6.6	0.9	J.M.Flynn et al.
LIMB LENGTH DISCREPANCY (minor)			
Lengthening	3.3	5.0	Ozturkman Y. et al
Shortening	3.3	2.5	Ozturkman Y. et al
Nail back out	-	2.6	Carrey T.P. et al
MALALIGNMENT(minor)			
Varus / Valgus	6.6	4.3	J.M.Flynn et al
Anteroposterior	-	8	Heinrich SD, et al
Rotational deformities	-	3.2	Heinrich SD, et al
Nail back out	-	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[16].

Assessment of Outcome

In the present study, the final outcome was excellent in 22 (73.33%) cases, satisfactory in 8 (26.67%) cases and there were no poor outcome cases.

In D. Furlan and Z. Pogorelic study, the final outcome was excellent in 89% cases, satisfactory in 11% cases and there were no cases showing poor outcome.

Studies	Out come		
	Excellent	Satisfactory	Poor
Present study	73.33%	26.67%	0%
D.Furlan & Z.Pogorelic study	89%	11%	0%

OUTCOME FOR ADDITIONAL VARIABLES IN THE PRESENT STUDY

OUTCOME VARIABLES	EXCELLENT (%)	SATISFACTORY (%)	POOR (%)
Range of movements	93.3	6.7	-
Time for union	80	20	-
Unsupported weight bearing	80	16.7	3.3

SUMMARY

Thirty patients with diaphyseal fractures of the femur (12), tibia (10), humerus (4) and forearm bones (4) were treated with titanium elastic nailing in the period of October 2011 to October 2013 at Mamata General and Super speciality hospital, Khammam.

Out of 30 Children, aged between 5 to 16 years who were included in the study. 13 patients were between 5-8 years (43.3%),7 were between 9-12 yrs (23.33%) and 10 were between 13 to 16 years (33.3%) age group with the average age being 9.86 years.

70% of the patients were boys. RTA was the most common mode of injury accounting for 16 (53.3%) cases followed by self fall - 11 (36.7%). Transverse fractures accounted for 10(33.3%) cases, communited fractures-8(26.7%), oblique fractures - 7(23.3%) and spiral fractures – 5(16.7%). Fractures involving the middle $1/3^{rd}$ accounted for 16 (53.34%) cases, upper $1/3^{rd}$ accounted for 7 (23.33%) cases, lower $1/3^{rd}$ accounted for 7 (23.33%) cases.

All the patients were prepared and operated as early as possible once the general condition was stable and the patient was fit for surgery.

The average duration between trauma and surgery was 3.96 days and average duration of surgery is 59.9 minutes.

21 (70%) cases were immobilized postoperatively for 6 weeks and such immobilization was for 9 weeks in rest of the 9 (30%) of the cases with an average duration of stay in hospital was 11.6 days.

Union was achieved in <3 months in 24 (80%) of the patients with average time to union being 12.1 weeks.

Unsupported full weight bearing walking in case of lower limb fractures, carrying weights in case of upper limb fractures was started in < 3 months for 24 (80%) of the patients.

All patients with femur and tibia fractures had full range of hip and ankle motion in the present study and 2 (6.66%) patients had mild restriction in knee flexion at 12 weeks. Patients with humerus and forearm bone fractures had full range of motion at shoulder, elbow and wrist joints. 2 (6.67%) had developed pain at site of nail insertion during follow up evaluation, all of which resolved by the end of 12 weeks follow up.

Superficial infection was seen in 1(3.3%)case. 1(3.33%) patient had shortening(femur – 1cm) and 1(3.33%) patient had lengtheng (femur – 1.2cm).No patient in our study had major limb length discrepancy (i.e. > ± 2cm). Nail back out was not seen in any of the cases. 1(3.33%) patient presented with varus (4^0) angulation, 1(3.33%) patient presented with valgus(5^0) angulation and no patients had anteroposterior angulation or rotational malalignment.

The development of the TENs fixation method has put an end to criticism of the surgical treatment of paediatric long bone fractures, as it avoids any growth disturbance by preserving the epiphyseal growth plate, it avoids bone damage or weakening through the elasticity of the construct, which provides a load sharing, biocompatible internal splint, and finally it entails a minimal risk of bone infection

CONCLUSION

Based on our experience and results, we conclude that ELASTIC STABLE INTRAMEDULLARY NAILING technique is an ideal method for treatment of pediatric diaphyseal fractures of long bones. It gives elastic mobility promoting rapid union at fracture site and stability which is ideal for early mobilization. It gives lower complication rate, good outcome when compared with other methods of treatment**.**

Is a simple, easy, rapid, reliable and effective method for management of paediatric long bone fractures between the age of 5 to 16 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 long bones in children is a reliable, minimally invasive, and physeal-protective treatment method. 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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