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A prospective study of titanium nailing system in tibia fractures in children

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Abstract
Introduction: Tibia fractures in children are third most long bone fractures after forearm and femoral fractures, Titanium elastic nailing system (TENS) are good option for surgical treatment of pediatric tibia fractures due to their advantage of having quicker recovery, shorter rehabilitation period, less immobilization, lack of stiffness of adjoining joints and less psychological impact to the children The study had aim and objective to determine the demographic (age and sex distribution) of pediatric diaphyseal fractures of tibia, study the advantages of TENS., study the union rates and functional outcome of closed reduction and internal fixation of pediatric widely displaced diaphyseal fractures of tibia with. TENS and compare the results with those in literature.
Methods: We included children and adolescents between the age group of 5-16 years with tibial shaft fractures were admitted to Vijayanagar Institute of Medical Sciences, Bellary from November 2020 to September 2022. All patients with displaced unstable fractures of diaphyseal fractures of tibia underwent elastic stable intra medullary nailing fixation for the sustained fracture. Surgery carried out after thorough clinical examination, radiography and routine investigations. Patients were followed up from 3 weeks to 6 months after surgery.
Results: The study comprised 17 male patients and 13 female patients aged from 5 to 16 years with mean of 9.76years with time for union, in 13.3% it was 8 weeks, in 53.3% it was 10 weeks, in 33.3% it was 12 weeks.
Conclusion: TENS is easy, simple, rapid, reliable and effective method for management of fractures between the age group of 5 to 14 years. This method has a short hospital stay, less operative time, minimal blood loss and reasonable time for bone healing. Complications associated with this method are minimal and can be minimized with effective management and precautions during surgery.

Keywords: Titanium elastic nailing system, TENS, tibia fractures, children, effective method

Introduction

Tibia fractures in children are third most long bone fractures after forearm and femoral fractures. Closed reduction and cast application is still regarded as the first line treatment for pediatric tibial fractures provided the appropriate indications are present [1]. Historically operative treatment has rarely been indicated in tibial fractures in children [2].

Over the past few decades management of pediatric tibia fracture has shifted more towards operative intervention because of quicker recovery, shorter rehabilitation period, less immobilization, lack of stiffness of adjoining joints and less psychological impact to the children [3] Elastic stable intra- medullary nailing (ESIN) or Titanium elastic nailing system (TENS) is a recent technique which allows stable reduction, maintenance of reduction and early mobilization [4]. It aims to develop early bridging callus and contributes to rapid restoration of bone continuity. It works on the basic principle of -three point fixation - providing flexural, axial, translational and rotational stability [5].

Titanium elastic nail is advantageous over other surgical methods particularly in this age group because it is simple, is a load sharing internal splint that doesn't violate open physis, allows early mobilization and maintains alignment [6]

TENS has been reported to be successful in stabilizing severely communitied tibial fractures so that union is obtained without angular deformity [7].

2 ante grade nails with a diameter of approximately 40% of the width of the medullary canal are used8 Micro-motion conferred by the elasticity of the fixation promotes faster external bridging callus formation. This study was intended to assess the results following treatment of fracture shaft of tibia by flexible intra medullary nail or elastic stable intramedullary technique.

Methodology

Source of Data

The children admitted to the Department of Orthopedics at Vijayanagar Institute of Medical Sciences, Bellary with diaphyseal fractures of tibia during the period from NOVEMBER 2020 to SEPTEMBER 2022 are selected. All the children who will be Operated during this period are included in the study. Those children between age 5 to 16 year and managed surgically are included in the study.

Method of collection of Data (including sampling procedures if any)

The study will be conducted at the Department of Orthopedics, VIMS, Bellary during the period from NOVEMBER 2020 to September 2022. The Complete data is collected from the children in a specially designed Case Record Form (CRF) by taking history of illness and by doing detailed clinical examination

And relevant investigations. Finally after the diagnosis the children are selected for the study depending on the Inclusion and exclusion criteria. Post operatively all the cases are followed until Fracture union occurred for the minimum period of 6 months to 18 months. Results Wereanalyzed both clinically & radiologically.

Calculation of sample size
Formula for sample size calculation [8]
Source for formula
Source: Patrikar S. In Text book of Community Medicine. 1st Ed, 2009. Ed. Bhalwar R. Dept of Community Medicine. AFMC Pune. Publ. WHO

India Office, New Delhi) n= n= (〖Z1〗 ^2 {P (1-P))/d^2)

Variable considered for calculation of sample size
Excellent union rate of 70% using titanium elastic nailing system in tibia fractures in children wounds is considered here for sample size calculation

Table1

P	Your guess of Population P (any value<1)	0.70
1-α	Confidence level set by you	0.95
Z	Z value associated with confidence	1.96
d	Absolute precision (Value less than P)	0.21
n	Minimum sample size	19

By using above formula and putting the values in it, minimum sample size came to 19, but we planned to include total 30 cases fulfilling the eligibility criteria of the study

Statistical analysis and methods
Data will be collected by using a structure proforma. Data entered in MS excel sheet and analyzed by using SPSS 24.0 version IBM USA.
Qualitative data will be expressed in terms of proportions Quantitative data will be expressed in terms of Mean and Standard deviation.
Association between two qualitative variables will be seen by using Chi square/ Fischer's exact test Descriptive statistics of each variable will be presented in terms of Mean, standard deviation, standard error of mean.
A p value of <0.05 will be considered as statistically significant whereas a p value <0.001 will be considered as highly significant.

Interventional procedure
The patients with diaphyseal fractures of tibia are admitted and examined according to protocol. Associated injuries are noted. Clinical and radiological investigations will be carried out to get fitness for surgery. Patients will undergo Titanium elastic nail fixation of tibia diaphyseal fractures. Patients will be followed up at 6 weeks, 3 months, and 6 months, intervals till fracture union and once at 1 year after surgery.

Outcomes
1. Primary outcomes
To determine the demographic (age and sex distribution) of pediatric diaphyseal fractures of tibia. To study the advantages of TENS.

2. Secondary outcomes
To study the union rates and functional outcome of closed reduction and internal fixation of pediatric widely displaced diaphyseal fractures of tibia with TENS. To compare the results with those in literature.

Inclusion criteria
a. Children and adolescent patients from 5 to 16 year with diaphyseal tibia fracture.
b. Children of both the sexes are included in the study
c. Children with diaphyseal fractures of tibia
d. Patient fit for surgery

Exclusion criteria
1. Patients less than 5 years of age and more than 16 years of age.
2. Patients unfit for surgery
3. Comminuted and segmental fractures
4. Patients not willing for surgery
5. Patients medically unfit for surgery
6. Fracture involving the distal 1/3rd of femoral shaft.

All of these patients were operated under general anaesthesia. The appropriate size of the nail was calculated by using the Flynn's formula, i.e., nail diameter = 0.4 x narrowest diameter of the medullary canal. The nails were manually pre-contoured into C shape to achieve intramedullary three-point fixation. A45 degrees bent was given to the nails' tip for easy negotiation across the fracture site.
An incision of size around 2 cm was given either lateral or medial side of the proximal leg and entry point was made 1.5 to 2 cm distal to the physis using an owl. Now the pre-countered nail tip was introduced into the medullary canal and advanced up to the fracture site. Once the nail was at the fracture site, we performed closed reduction and then advanced the nail across the fracture site. The proper nail positioning was confirmed under C-arm both in antero-posterior and the lateral views. Then the second nail was inserted by similar method as described above. We advanced the nails distally till the tips were just proximal to the distal tibial physis. Proximally, around 1 cm of the nails was left outside the cortex for removal; however unburied portion of nail was not bent to prevent skin irritation and bursitis at the entry site of the nail. Special attention is to be paid to ensure that both the nails are of the same size to avoid differential loading over opposite cortices which may lead to angular deformity. An above knee posterior slab was applied at the end of the surgery. The posterior slab was removed after three weeks post-operatively and the patients were asked to walk with partial weight bearing over the affected leg.
Patients were evaluated at three weeks, six weeks, three months, six months and one year post surgery to assess the alignment at the fracture site, limb length discrepancy, any infection, knee range of motion, delayed union, non-union and the fracture union time. Final fracture alignment, limb length discrepancy and the knee range of motion were calculated when the fracture was noted to have united. We assessed the alignment at the fracture site by drawing lines on X-ray films and measuring with a goniometer. The limb length discrepancy was calculated by measuring the length of both the limbs from anterior superior iliac spine to the medial malleolus in supine position. Any difference of length in the affected limb as compared to the normal limb was considered as limb length discrepancy. As far as the knee range of motion is concerned, we assessed it by passive flexion and extension of the knee joint and the angle was measured with the help of a goniometer. The delayed union and nonunion were assessed based on the clinical and radiological union. The fracture is considered to be clinically united when there is no pain on movement of the fracture ends. On the other hand, radiological union is

defined as the appearance of a mature callus over at least 3 out of the 4 planes. All of the data were tabulated in Microsoft Excel Programme and the results were interpreted as mean ± standard deviation and simple percentage also.

Results

The mean age in our study is 9.76 ± 3.11, 95% CI [2.84, 4.19], aged between 5 to 16 years based on age in years, 33.3% belong to 5-8 years, 46.7% belong to 9-12 years, 20% belong to 13-16 years.

Based on gender, it was seen that 56.7% (17) are male and 43.3% (13) are female.

based on nature of trauma, majority of the trauma was due to road traffic accident (RTA) seen in 66.7% followed by fall while playing in 16.7% and by fall from height in 16.7%.as depicted in table number 1

Nature of trauma

Table 2: Based on nature of trauma

	Frequency	Percentage
RTA	20	66.7%
Fall while playing	5	16.7%
Fall from height	5	16.7%
Total	30	100%

Based on the side affected it was observed majority of patients in our study, 63.3 % (19) were affected on right side and 36.7 % (11) were affected on left side. Depending on type of fracture it was seen that 50 %(15) had transverse fracture followed by 26.7% (8) having oblique fracture and 23.3% (7) having spiral fracture as depicted in figure 1

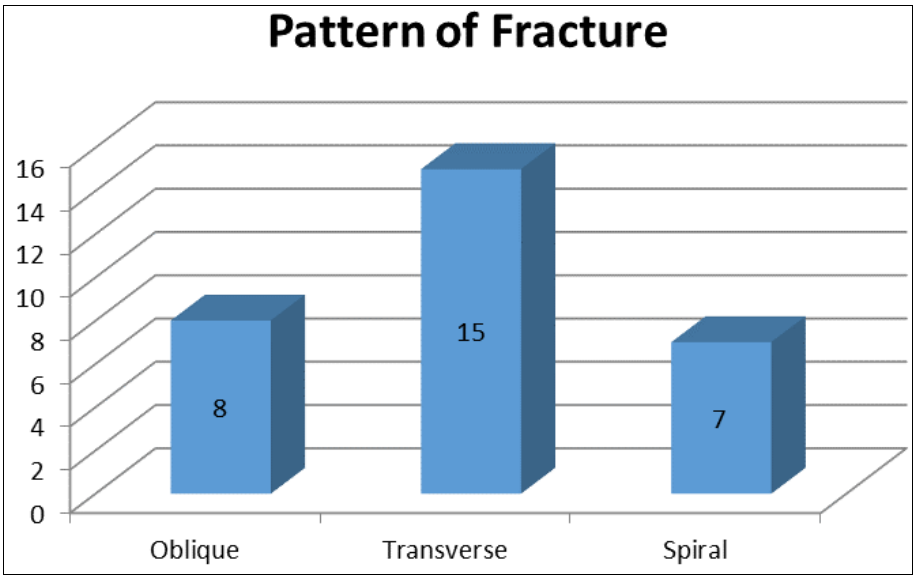

Fig 1: Pattern of fracture

Based on the level of fracture it was seen that most of them 70% (21) hadmid shaftfracture, and 30% (9) had distal fracture. Based on type of fracture, 20% (6) it was open fracture and in 80% (24) it was closed fracture.

Depending on time interval between trauma and surgery, <24 hours' time interval in16.7%, 2-4 days in 70%, 5-7 days in 6.7% and >8 days in 6.7% depicted in figure 2.

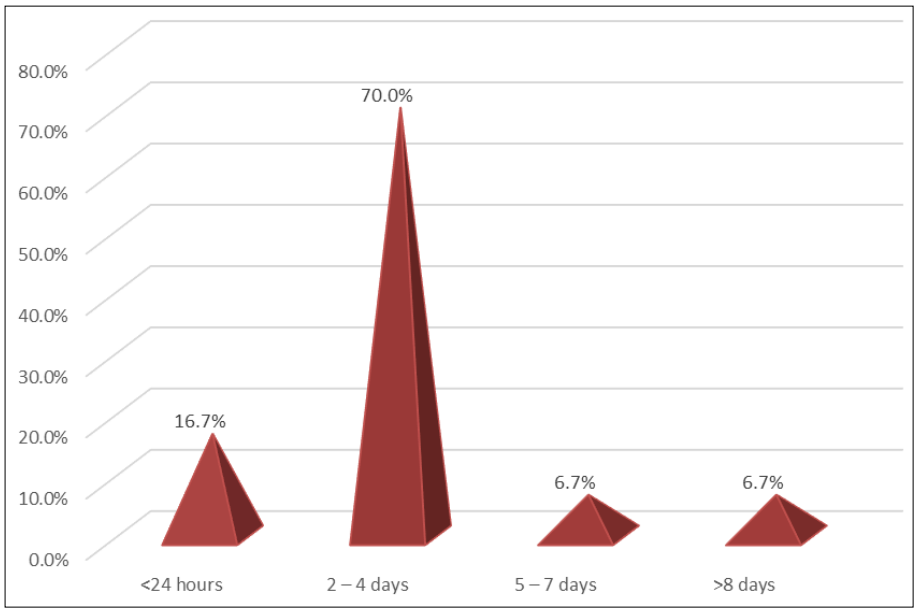

Fig 2: Depending on time interval between trauma and surgery

Depending on type of reduction it is observed open reduction was done in 10% (3) and closed reduction in 90%. (27). distribution based on size of nail, in 10% (3) it was 2mm size, in 43.3% (13) it was 2.5mm, in 36.7% (11) it was 3mm, in 10% (3) it was 3.5mm as depicted in figure 3.

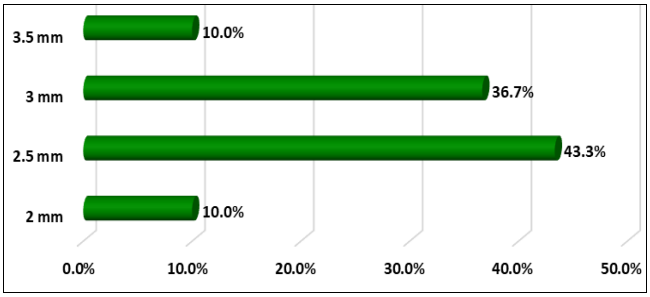

Fig 3: Distribution based on size of nail

Based on duration of hospital stay, in 46.7% it was <5 days, in 33.3% it was 6-12 days, in 20% it was >13 days. Depending on time for union, in 13.3 % (4) it was 8 weeks, in 53.3 % (16) it was 10 weeks, in 33.3 %(10) it was 12 weeks Figure 4 and table 2 shows distribution based on complications, limb lengthening of >5mm in 3.3 % (1) and <5 mm in 3.3 % (1) limb shortening by >5mm in 3.3 %(1) and <5 mm in 3.3 %(1) 16.7 % (5) observed to have surgical site infection and 6.7% (2) had Nail impingement.

Table 2: Distribution based on complications

		Frequency	Percentage
Limb lengthening	>5 mm	1	3.3%
	<5 mm	1	3.3%
Limb shortening	>5 mm	1	3.3%
	<5 mm	1	3.3%
Infection	Yes	5	16.7%
	No	25	83.3%
Delayed union and Non union	Yes	0	0.0%
	No	30	100.0%
Nail impingement	Yes	2	6.7%
	No	28	93.3%
Misalignment	Yes	0	0.0%
	No	30	100.0%

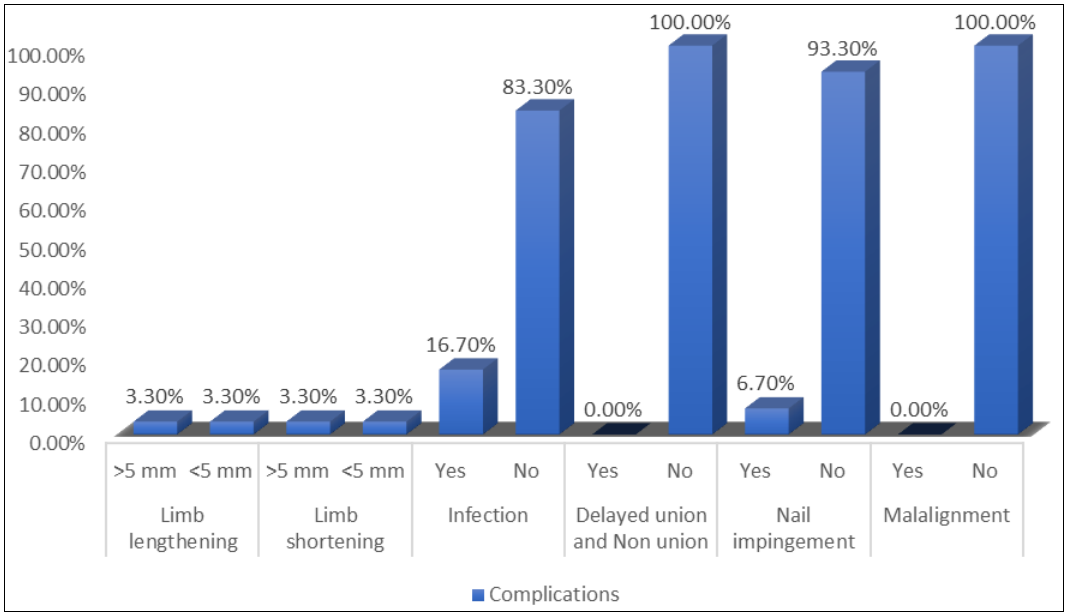

Fig 4: Distribution based on complications

Discussion

Age distribution

In this present study, 33.3% belong to 5-8 years, 46.7% belong to 9-12 years, and 20% belong to 13-16 years.

Wudbhav N. Sankar *et al*. [9] The mean age of the study population is 12.2 years with the age range of 7.2 to 16 years. JeongHeo *et al* (2016) [10] included 16 tibia shaft fractures with the mean age at operation was 7 years (range from 5 to 10 years). Kapil Mani *et al* [11] reported that the mean age of the study population in their study was 9.48±2.17 years

Gender distribution

In this present study based on gender distribution 56.7% are male and 43.3% are female

Wudbhav N. Sankar *et al* [9] included 19 study participants were 14 were boys and 5 were girls. Jeong Heo *et al* (2016)[10] included 9 boys and 7 girls. Kapil Mani *et al*[11] 62.2% were male and 37.8% were female.

Nature of trauma

In the present study, RTA in 66.7%, fall while playing in 16.7%, fall from height in 16.7%.

Similar findings were observed by the study conducted by where Wudbhav N. Sankar *et al* [9] fractures resulted from motor vehicle accidents were predominant (four vehicle versus pedestrian, two vehicle versus bicyclist, and four vehicle versus vehicle); six patients fractured their tibias from sports-related injuries. In 16 patients, the tibia fracture was an isolated injury; two had associated femur fractures, and one patient had an ipsilateral clavicle fracture. Six fractures were open (four Gustilo grade 1, two Gustilo grade 2). Goodwin *et al* [12] reported that high energy injuries due to motor vehicle accidents are the most common nature of trauma observed in the study. Jeong Heo *et al* (2016) [10] reported that the most common mode of trauma is pedestrian injuries and in car accidents and all the injuries were acute traumatic fractures. Kapil Mani *et al* [11] pedestrian injury in 26.7%, motor vehicle injury in 20%, fall

from height in 17.8%, sports related injury in 15.5%, motorbike injury in 20%.

Side affected

In the present study based on side affected, right side in 63.3% and left side in 36.7%.

Kapil Mani *et al* [11] reported that44.4% right side involvement and 55.6% it was left sided involvement

Pattern of Fracture

In the present study distribution based on pattern of fracture shows, oblique fracture in 26.7%, transverse fracture in 50%, spiral fracture in 23.3%.

Similar findings were observed in the study conducted by Wudbhav N. Sankar *et al* [9] where Nine fractures were either transverse or short oblique in nature, seven were long oblique, two were spiral and one was comminuted. Fourteen patients had concomitant fibula fractures.

Kapil Mani *et al* [11] transverse fractures in 46.7%, oblique fracture in 24.4%, spiral fractures in 15.6% and comminuted fractures in 13.3%

Level of fracture

In the present study based on level of fracture, Middle level in 70% and distal in 30%.

Wudbhav N. Sankar *et al* [9] reported that 5 midshaft, two proximal shaft, and two distal shaft fractures.

Type of Fracture

In the present study based on type of fracture, 20% it was open fracture and in 80% it was closed fracture.

Time interval between trauma and Surgery

In the present study based on time interval between trauma and surgery, <24 hours' time interval in 16.7%, 2-4 days in 70%, 5-7 days in 6.7% and >8 days in 6.7%.

Type of Reduction

In the present study, open reduction in 10% and closed reduction in 90%.

Size of nail

In the present study based on size of nail, in 10% it was 2mm size, in 43.3% it was 2.5mm, in 36.7% it was 3mm, in 10% it was 3.5mm. Jeong Heo *et al* (2016) [10] reported that nail diameter included, 3.5, 3.0, and2.5 mm nails used in one, 12, and three patients, respectively. Wudbhav N. Sankar *et al* [9] observed 26% patients complained of pain over the proximal insertion sites. Luhman *et al* [13], observed that leaving less than 2 cm of nail protruding from the cortex with minimal bending of the nail away from the cortex to facilitate cutting. It is perhaps even more important to minimize hardware prominence in the tibia compared with the femur, due to the more subcutaneous location of the nail insertion site.

Duration of hospital stay

Based on duration of hospital stay, in 46.7% it was <5 days, in 33.3% it was 6-12 days, in 20% it was >13 days.

Time for union

In the present study based on time for union, in 13.3% it was 8 weeks, in 53.3% it was 10 weeks, in 33.3% it was 12 weeks. Kubiak *et al*reported superior functional outcomes and patient satisfaction in the cohort treated with TENs. In addition, the time to union was significantly shorter in the TEN group (mean 7 weeks) compared to the external fixation group (mean 18 weeks) [14, 15].

Luhman *et al* [13] and Morz *et al* [16] in their study observed that TENs in the farmer have shown a greater risk of malunion in patients with a weight of more than 49 kgs. This can be reduced by post operative immobilization in tibia compared with femur which allows adequate maintenance of reduction in heavier patients. Jeong Heo *et al* (2016) [10] reported that all fractures achieved union at a mean of 16.1 weeks after surgery (range, 11–26 weeks), including a case of delayed union that united at 26 weeks. At the last follow-up, there were no angular or rotational deformities over 108 in either sagittal or coronal planes.

Economedes *et al* [17] also reported a longer time to union in over 50% of open tibia fractures in children who received elastic nailing. They also experienced three non-unions which required a change in the instruments and removal of the elastic nails.

Baldwin [18] reported that grade II and III open fractures might have a higher risk of complications than grade I fractures. However, those studies included older children or adolescents. The biology of these fractures in young children might result in increased healing potential, perhaps due to a thick periosteum, better vascularity, and better healing ability. From this viewpoint, elastic nailing is a safe method in open tibia fractures of young children, with minimal complication rates.

Complications

In the present study based on complications, limb lengthening of >5mm in 3.3% and <5 mm in 3.3%. limb shortening by >5mm in 3.3% and <5 mm in 3.3%. 16.7% observed to have surgical site infection and 6.7% had Nail impingement.

A recent systemic literature review [18], reported an overall infection rate for open tibia fractures in children ranging from 3.6 to 30.4%. Severe wounds from grade III open fractures may have a higher incidence of infection compared to lower-grade injuries. However, recent reports[17,19] showed that immediate or early elastic nailing of open pediatric tibia shaft fractures could be safely performed with minimal risk of wound or infectious complications

Wudbhav N. Sankar *et al* [9] reported that Irritation at the nail entry site was the most common complications following nail insertion, occurring in five patients (26%). One child required early removal of the nails for this complaint. No patients developed obvious rotational abnormalities, leg length discrepancies, or physeal arrests as a result of treatment. One child developed full thickness skin necrosis from the second postoperative cast, well away from the nail entry sites, which required a free flap. Two patients required repeat manipulation under anesthesia to maintain adequate reduction following the index operation.

Several studies have described irritation at the nail entry site as the most common complication following the use of TENs in the femur, ranging in incidence from 7 to 40%. [13, 20, 21]

Goodwin *et al* [13] reported that incidence of compartment syndrome in their study was 32%

Jeong Heo *et al* (2016) [10] observed out of 16 patients included in the study, four minor complications. A superficial wound infection in a patient with a type III open

fracture resolved with oral antibiotic administration. No deep infections or osteomyelitis were reported. The other three patients experienced soft tissue irritation due to prominent nail tips at the proximal/medial entries. All three required additional procedures; two to cut the tips at 6 and 10 weeks respectively, and one for nail removal at 14 weeks Wudbhav N. Sankar *et al* [9] reported 12 excellent results, six satisfactory results, and one poor result (Table 2). Satisfactory results were due to either irritation at the nail entry site or need for repeat manipulation. The poor result was due to the full-thickness skin necrosis that occurred between cast changes in one patient following treatment with TENs

JeongHeo *et al* (2016) [10] observed assessment of final outcomes using modified Flynn criteria revealed 15 excellent and 1 satisfactory outcome. Kapil Mani *et al* [11] reported that malunion observed in 4.4%, delayed union in 8.8%, limb shortening in 6.6% and limb lengthening in 4.4%, nail prominence and skin irritation in 13.3% superficial infection pet entry site in 4.4%.

Conclusion

TENS is easy, simple, rapid, reliable and effective method for management of fractures between the age group of 5 to 14 years. This method has a short hospital stay, less operative time, minimal blood loss and a reasonable time for bone healing. Complications associated with this method are minimal and can be minimised with effective management and precautions during surgery.

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