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Clinical profile and recovery of patients with open fracture of long bones treated with tens nail

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Abstract
Background: Open fracture of long bones is still one of the difficult fractures to manage. It needs regular wound care, dressing and soft tissue cover which many a times become difficult due to external fixators. TENS nail provides excellent opportunity to temporarily stabilize the fracture as well as allows for wound care.
Aim: To study clinical profile and recovery of patients with open fracture of long bones treated with TENS nail.
Material and Methods: A total of 30 patients with Grade 2 and 3a open trauma, grade I fractures of long bones where internal fixation could not be done immediately and Grade 3b open trauma without gross contamination were treated with TENS nails and definitive surgery once wound heals. Patients were followed up for complications and recovery.
Results: The average trauma-wound healing duration was 3.5±1.36 months. The average primary fixation to wound closure procedure duration was 18.4±3.82 days. No patient required realignment of fixation for Wound closure procedure of patient. No patients had infection after definitive surgery. 4 (13.3%) patients had union on TENS nail while majority of the patients (86.7%) required a definitive surgery.
Conclusion: Better wound management, patient compliance, decreased hospitalization, low cost of implant and operative time with comparable wound healing time suggest that titanium elastic nailing can be a viable option in early management of open fracture long bone with some merit over other procedures.

Keywords: open fracture of long bones, tens nails, hospital stay, healing, complications

Introduction

It has been estimated that between 3. 5 to 6 million fractures occur in the United States annually [1, 2]. Extrapolating from European data, we can estimate that more than 3%, i.e., 150,000, of these are open fractures [3, 4]. When adjusting for population differences, we predict that more than 4.5 million open fractures occur per year in India. This figure may be an underestimation, given the high population density in the large urban centers in India.

Goals of open fracture management are well known and include the prevention of infection, achievement of bony union, and the restoration of function. Surgical stabilization may be necessary in open fractures, fractures accompanied by neurovascular injuries, multi-trauma, and serious soft tissue injuries, the presence of the inability to keep reduction and fractures with rotational deformities in spite of successful results achieved with conservative treatment [5, 6].

The popularity of TENS (Titanium Elastic nailing system) has been gradually increasing due to its ease of use, better wound management, compatible with wound cover procedure if required and low complication rate. TENS has been used successfully primarily in femur fractures and in various long bone fractures with many published reports in the literature [3, 7, 9]. Hence, the present study was conducted to study clinical profile and recovery of patients with open fracture of long bones treated with TENS nail.

Material and Methods

A hospital based single centre, prospective study was done with 30 patients to study the benefits of using TENS Nail as a primary procedure in open trauma long bone.

Sample size

Considering a confidence level of 95% and confidence interval of 18 the number of patients in our study to achieve statistical significance is 30. This was calculated by Survey System (http://www.surveysystem.com/sscalc.htm#one). The Survey System ignores the population size when it is "large" or unknown. Population size is only likely to be a factor when you work with a relatively small and known group of people (e.g., the members of an association). Hence, a sample size of 30 was considered adequate for our study.

Inclusion criteria

All patients with presenting with

- Closed fractures where internal fixation could not be done due to poor local condition, etc.
- Grade 1 open fracture where internal fixation could not be done due to poor local condition, poor general condition, etc.
- Grade 2 and 3a open trauma

- Grade 3b open trauma without gross contamination (Gross contamination was taken as those cases of grade 3b open fracture which came to the hospital after 24 hours of trauma and Road Traffic Accident (RTA) cases with crushed bone, bone loss or massive i.e., >1/2 circumference, soft tissue loss
- Age 8-80 years
- Upper and Lower limb long bones fractures

Exclusion criteria

Patients, otherwise meeting the inclusion criteria were ineligible in case of any of the following criteria:

- Gross bone loss - more than 1 cm or more than 2/3 of circumference
- Gross contamination (grade 3b and 3c)
- Individuals unable to give consent.
- Any comorbidity affecting result outcome

Methodology

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 assess 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.

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

Pre-requisites for stable internal fixation

Nail diameter should measure 40% of the narrowest diameter. Nails were contoured with long bend such that apex of the convexity were 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.

Full weight bearing was started by 8 - 12 weeks depending on the fracture configuration and callus response. 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 were immobilized the patient for 3wks in a posterior slab followed by allowing ROM exercises for elbow and wrist, sling for another 3 more wks.

Routine follow up was done. At each follow up patients are assessed clinically, radiologically and the complications were noted.

Wound was considered to be healed when white blood cell counts, erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP) were within normal limits, no clinical evidence of fever and no discharge from wound. Patients were evaluated on the basis of rate of wound healing, post-op soft tissue healing, bone infection, Patient compliance for post op mobilization.

Statistical analysis

Appropriate statistical software, including but not restricted to MS Excel, SPSS ver. 20 were used for statistical analysis. Quantitative data is presented with the help of Mean and Standard deviation. Qualitative data is presented with the help of frequency and percentage table.

Results

Majority of the patients (30%) were in the age group of 31-40years followed by 16.7% in the age groups of 21-30 years, 41-50years and 51-60 years.10% patients were in the age group of 11-20 years while 6.7% patients were in the age group of 61-70years.3.3% patients were in the age group of 71-80 years. The mean age of the patients was 39.6±14.49years. There was male preponderance (76.7%) in the study while female patients constituted 23.3% of the study group.

Table 1: Distribution of patients according to Age and sex

Age and sex	No. of cases	Percentage
Age		
11-20 years	03	10%
21-30 years	05	16.7%
31-40 years	09	30%
41-50 years	05	16.7%
51-60 years	05	16.7%
61-70 years	02	6.7%
71-80 years	01	3.3%
Sex		
Male	23	76.7%
Female	07	23.3%

In the study, there was left sided predominance compared to the right side (56.7% vs. 43.3%). Road Traffic Accident was observed to be the main cause of fracture (56.7%) whereas 23.3% fractures were due to fall. The cause of fracture in 16.7% and 3.3% cases were Assault and Seizure respectively. Four (13.3%) patients had diabetes mellitus while 2 (6.7%) and one (3.30%) patients had hypertension and epilepsy respectively.

In our study, 30 patients with fracture of tibia (50%), radius Ulna (26.6%), femur (16.7%), and humerus (6.7%) were treated. It was observed that 12 (40%) fractures were Gustilo Grade 2 while 8 (26.7%) and 10(33.3%) fractures were Gustilo Grade 3a and Gustilo Grade 3b. The study included only those Gustilo Grade 3b cases which were not grossly contaminated.

Table 2: Characteristics of the fractures

Fracture characteristics	No. of cases	Percentage
Laterality		
Right	13	43.3%
Left	17	56.7%
Mode of injury		
RTA	17	56.7%
Fall	07	23.3%
Assault	05	16.7%
Seizure	01	3.3%
Co-morbidities		
Diabetes	04	13.3%
Hypertension	02	6.7%
Epilepsy	01	3.3%
Bone affected		
Tibia	15	50%
Radius ulna	08	26.6%
Femur	05	16.7%
Humerus	02	6.7%
Gustilo-Anderson grading		
Grade 2	12	40%
Grade 3a	08	26.7%
Grade 3b	10	33.3%

The hospital stay of all patients ranged between 8 to 34 days. 5 (16.7%) patients were admitted in the hospital for ≤10 days while 43.3% and 36.7% patients were admitted in the hospital for 11-20 and 21-30 days respectively. 1 (3.3%) patients were admitted in the hospital for >30 days. The mean hospital stay was 18.3±7.24 days.

Table 3: Postoperative characteristics of the patients

Postoperative characters	No. of cases	Percentage
Hospital stay		
<10 days	05	16.7%
11-20 days	13	43.3%
21-30 days	11	36.7%
>30 days	01	3.3%
Trauma wound healing		
≤2 months	10	33.3%
2-4 months	09	30%
4-6 months	11	36.7%
Mobilization		
1-3 weeks	05	16.7%
3-6 weeks	21	70%
6-9 weeks	04	13.3%

The trauma to wound healing duration for 10 (33.3%) patients was ≤2 months, while it was 2-4 months and 4-6 months for 9 (30%) and 11 (36.7%) patients respectively. The average trauma – wound healing duration was 3.5±1.36 months.

The commencement of mobilization in 5 (16.7%) patients was 1-3 weeks while it was 3-6 weeks and 6-9 weeks for 21 (70%) and 4 (13.3%) patients respectively. 28 (93.4%) patients had radiological alignment while 1(3.3%) patient each presented with Sagittal plane angulation (>10° procurvatum) and Coronal plane angulation (>10° valgus).

Table 4: Distribution of Patients according to Radiological Alignment

Radiological Alignment	No. of cases	%
Radiological Alignment Achieved	28	93.4%
Sagittal plane angulation (>10° procurvatum)	01	3.3%
Coronal plane angulation (>10° valgus)	01	3.3%
Total	30	100%

The primary fixation to wound closure procedure duration for 2 (16.7%) patients was 10-15 days, while it was 16-20 days for 6 (50%) and 21-30 days for 4 (33.3%) patients. The average primary fixation to wound closure procedure duration was 18.4±3.82 days.

Table 5: Primary Fixation - wound closure procedure duration of patients

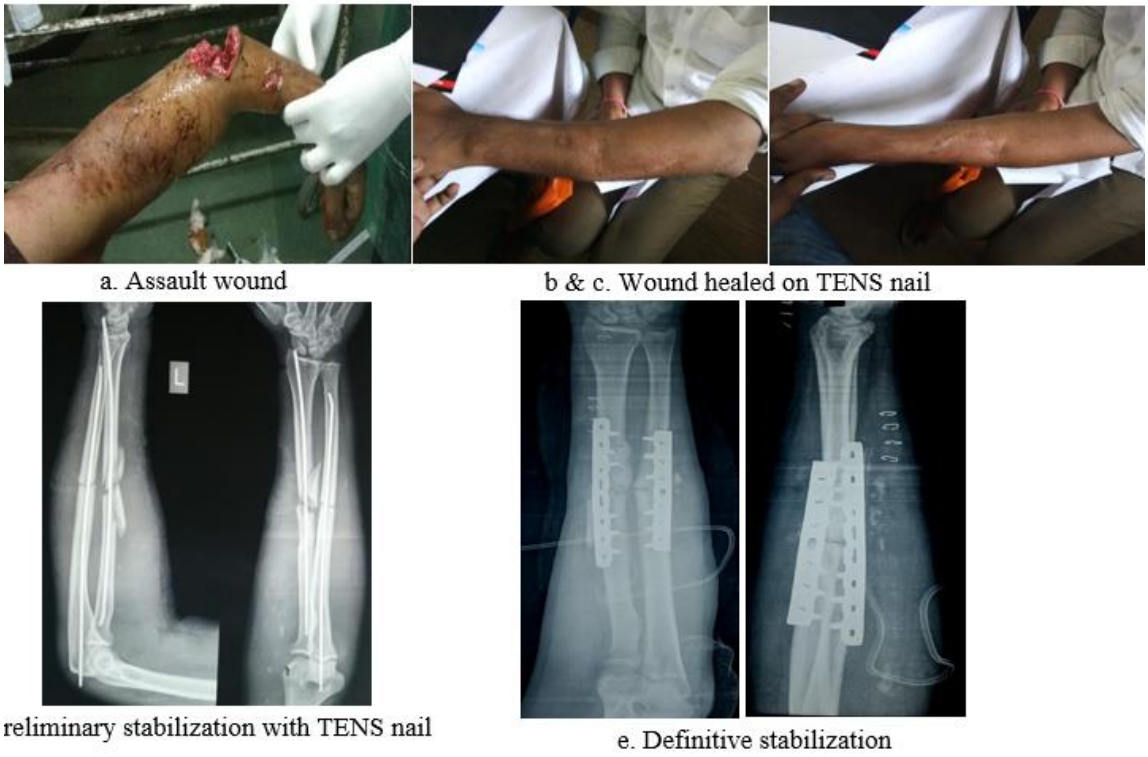
Primary Fixation –Wound closure procedure (days)	N	%
10-15	2	16.7%
16-20	6	50%
21-30	4	33.3%
Total	12	100%
Mean±SD	18.4±3.82 days	

It was observed that no patient required realignment of fixation for Wound closure procedure of patient. The removal of primary fixation was done in the same sitting as definitive surgery for all the patients. It was observed that no patients had infection after definitive surgery. 4 (13.3%) patients had union on TENS nail while majority of the patients (86.7%) had no union on TENS nail.

a. Per-op X-rays b. Post-op X-rays

c. Post-op X-rays after definitive surgery

Case 1: Tibia shaft fracture with grade 2 open wound



Case 2: Grade 3a open fracture associated with assault

Discussion

In the present study, majority of the patients (30%) were in the age group of 31-40 years followed by 16.7% in the age groups of 21-30 years. The mean age of the patients was 39.6±14.49 years. There was male preponderance (76.7%) in the study while female patients constituted 23.3% of the study group. Upadhyay AS *et al*. [10] found age range of patients was from 18 years to 65 years with an average of 39.08 years. The majority of patients 17 (68%) were males and only 8 (32%) were females. In Luo Z *et al* study [11], 9 (75%) were males and 3 (25%) were female patients. According to the Gustilo Classification, there were 2 cases of type II, 5 of type IIIA and 5 of type IIIB. There were 2 cases of upper-tibia fracture, 3 of middle-tibia and 7 of middle-lower. Patil S *et al* study [12] found 9(30%) girls and 21 (70%) boys in the present study.

In our study, there was left sided predominance compared to the right side (56.7% vs. 43.3%). In Wang Q *et al*. [13] left side was involved in 11 cases and the right side was involved in 12 cases. Anjum R *et al* [14] found Right side (60%) was more frequently involved than left (40%).

Road Traffic Accident was observed to be the main cause of fracture (56.7%) in our study whereas 23.3% fractures were due to fall. The cause of fracture in 16.7% and 3.3% cases were Assault and Seizure respectively. Upadhyay AS *et al*. [10] reported Road traffic accident was the commonest mode of injury accounting for 18 (72%) patients, the remaining six (24%) patients presented with the history of fall and one (4%) gave a history of assault. Luo Z *et al*. [11] investigated 12 cases among them, 8 cases were caused by traffic accidents, 2 crush, 1 falling and 1 mechanical accident. Patil S [12] reported RTA was the most Common mode of injury accounting for 16 (53.3%) cases followed by fall in 11 (36.7%). Anjum R *et al*. [14] reported RTA was the most common cause of injury accounting for 80%, other common cause was fall from height which accounted for 20% of the cases.

It was observed in our study that 4 (13.3%) patients had diabetes mellitus while 2 (6.7%) and 1 (3.30%) patients had hypertension and epilepsy respectively. Also 30 patients with fracture of tibia (50%), radius Ulna (26.6%), femur (16.7%), and humerus (6.7%) were treated. Upadhyay AS *et al*. [10] reported 19 (76%) patients had fracture at middle third of shaft of humerus and six (24%) patients had fracture at proximal third of shaft of humerus. Sixteen (74%) patients had transverse fracture, seven (28%) had oblique fracture, and two (8%) had spiral fracture.

In the present study, 12 (40%) fractures were Gustilo Grade 2 while 8 (26.7%) and 10 (33.3%) fractures were Gustilo Grade 3a and Gustilo Grade 3b. The study included only those Gustilo Grade 3b cases which were not grossly contaminated. Luo Z *et al*[11] investigated 12 cases according to the Gustilo Classification, there were 2 cases of type II, 5 of type IIIA and 5 of type IIIB. Wang Q *et al*. [13] reported Seventeen cases were closed fractures and 6 cases were open fractures, all were Gustilo type I and II fractures.

In our study, the commencement of mobilization in 5 (16.7%) patients was 1-3 weeks while it was 3-6 weeks and 6-9 weeks for 21 (70%) and 4 (13.3%) patients respectively. Wang Q *et al*. [13] reported ankle and knee flexion and extension exercises immediately after surgery, and begun ambulation with crutches and non-weight bearing functional exercise of the affected limb 2 to 3 days after soft tissue swelling disappeared and full weight

bearing was allowed according to the status of fracture healing. Patil S *et al*. [12] study reported 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. Anjum R *et al*. [14] reported 84% fractures were united within 8 weeks and in 10 weeks 100% fractures were united.

In the present study, 28 (93.4%) patients had radiological alignment while 1(3.3%) patient each presented with Sagittal plane angulation (>10° procurvatum) and Coronal plane angulation (>10° valgus). Wang Q *et al*. [13] study reported mean duration of fracture healing in the radiographs was 4.1 months (range, 3-8 months). Upadhyay AS *et al*. [10] reported union rate was 100% in the at the final follow-up. The period of fracture union ranged from 10weeks to 32 weeks, with an average period of 14.98±4.08weeks. There was a single case of delayed union which eventually healed at 32 weeks without any intervention. There were no cases of non-union.

In our study, the average primary fixation to wound closure procedure duration was 18.4±3.82 days. It was observed that none of the 12 patients required realignment of fixation for wound closure procedure of patient. The trauma to wound healing duration for 10 (33.3%) patients was ≤2 months, while it was 2-4 months and 4-6 months for 9 (30%) and 11 (36.7%) patients respectively. The average trauma -wound healing duration was 3.5 months. In Li SD *et al* study [15], fracture healing time was (12.79±2.52) weeks. The removal of primary fixation for 7 patients was done in the same sitting as definitive surgery for all the patients. The trauma to definitive surgery duration for 4 (57.1%) patients was 3-4 months while it ≤2 for 1 (14.3%) patient and >4 months for 2 (28.6%) patients each. The average trauma-definitive surgery duration was 3.7±1.11 months. It was observed that all the 7 patients had union after definitive surgery and none of them had infection after definitive surgery. Patil S *et al* study [12] reported superficial infection in 1(3.3%) case. 1 (3.33%) patient had shortening (femur-1cm) and 1 (3.33%) patient had lengthening (femur-1.2cm). No patient in study had major limb length discrepancy (i.e. >±2cm). 1(3.33%) patient presented with varus angulation, 1(3.33%) patient presented with valgus angulation and no patients had anteroposterior angulation or rotational malalignment. Anjum R *et al*. [14] reported overall complications in 2 (8%) of the cases. The most common complication with titanium nailing is a palpable implant & was present in 8% of the patients. Complications like wound infection, knee stiffness were not encountered. All of the cases returned to full power and range of motion at knee within 16 weeks. Excellent results were observed in 23 (92%) of the patients and good results in 2 (8%) of cases.

Upadhyay AS *et al*. [10] reported 2 (10%) patients had nail impingement at the proximal end as it was not buried completely into the bone. There was restriction of shoulder movement (terminal 20 degrees of abduction), and were considered to have moderate functional outcome. One (4%) patient ended up with shoulder stiffness mainly affecting abduction (0-60 degree) and internal rotation (up to lumbosacral junction) at end of 14 months. In our study, 4 (13.3%) patients had union on TENS nail while majority of the patients (86.7%) had no union on TENS nail. In Wang Q *et al*. [13] study, 21 patients were followed up for a mean follow-up period of 16.3 months (range, 12-26 months). No recurrent fracture dislocation and breakage of implant were observed. At the last follow-up visit, the lower-extremity alignment was excellent. Two degrees of varus deformity was found in 3 cases, and 2 degrees of valgus deformity was observed in 2 cases, but there were no serious varus or valgus deformity affecting the lower-extremity function or causing pain. Upadhyay AS *et al*. [10] study showed no incidence of iatrogenic fractures, as titanium has modular of elasticity nearer to the human bone, whereas Enders nail and interlocking nail which are made of stainless steel are stiffer. As a result, titanium nails are easier to negotiate through the bone. As they bend while passing through the bone tension is increased within the nail which improves the three-point fixation.

The key distress with respect to titanium elastic nail is its inability to provide suitable rotational stability. The rotational instability can be overcome to an extent with the pre-insertion "C" contouring of nail providing an efficient three- point fixation, distal fanning of nail tips and different entry points for nail insertion. The non-ferromagnetic property of titanium nail further enhances its advantage as it will never interfere with any future MRI (if required). It also reduces the need for a second surgery for implant removal.

Conclusion

The use of the TENS nail fixation method in compound fracture long bone has opened up an alternative method of management of these fractures. Better wound management, patient compliance, decreased hospitalization, low cost of implant and operative time with comparable wound healing time suggest that titanium elastic nailing can be a viable option in early management of open fracture long bone with some merit over other procedures.

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