Study of the outcome of titanium elastic nail system (Tens) in diaphyseal fractures of femur and tibia in children

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DOI: https://doi.org/10.22271/ortho.2019.v5.i3k.1599

Abstract
Elastic stable intramedullary nailing for the treatment of Pediatric long bone fractures was introduced by Prevost and colleagues in 1979. Stabilization follows the three-point fixation principle that provides internal elastic support in the presence of cortical contact and an intact soft-tissue envelope. The technique offers several advantages including better reduction, dynamic axial stabilization, shorter hospitalization with early rehabilitation and low rate of complications.

All children and adolescent patients between 5-16 years of age with diaphyseal fractures of femur and/or tibia admitted at Institute of Medical Sciences And Research, meeting the inclusion and the exclusion criteria during the study period were the subjects for the study. Totally, 30 cases were studied without any sampling procedure. Patients were followed up at 6, 12 and 24 weeks after surgery and assessed clinically and radio-logically. The final outcome is assessed as per Flynn’s criteria as excellent/satisfactory/poor.

The final outcome was excellent in 18 (60%) cases, satisfactory in 12 (40%) cases and there were no poor outcome cases.

Titanium elastic nail fixation is a simple, easy, rapid, reliable and effective method for management of pediatric femoral and tibial fractures between the age of 5 to 16 years, with shorter operative time, lesser blood loss, lesser radiation exposure, shorter hospital stay and reasonable time to bone healing. Hence we conclude that flexible intramedullary nailing is an excellent technique for the treatment of diaphyseal fractures of the femur and tibia in children and adolescents aged 5 to 16 years.

Keywords: Titanium elastic nail system (tens), diaphyseal fractures, femur and tibia

1. Introduction
Treatment of pediatric fractures dramatically changed in 1982, when Métaizeau and the team from Nancy, France, developed the technique of elastic stable intramedullary nailing (ESIN) using titanium nails.

In the last two decades there was an increased interest in the operative treatment of pediatric fractures, although debate persisted over its indications (1). There is a little disagreement concerning the treatment of long bone fractures in children less than 6 years (POP cast) and adolescents older than 16 years (locked intramedullary nailing) (1). Controversy persists regarding the age between 6 to 16 years, with several available options: traction followed by hip Spica, external fixation, flexible stable intramedullary nails, plate fixation, and locked intramedullary nailing.

Whatever the method of treatment, the goals should be to stabilize the fracture, to control length and alignment, to promote bone healing, and to minimize the morbidity and complications for the child and his/her family (2).

Orthopedic surgeons will continue to be challenged to treat this age group with less morbidity at a lower cost, as no clear guidelines have been available until now despite efforts done initially by French surgeons, later on by European surgeons. 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 (3).

The decision regarding the best line of treatment of pediatric lower limb fractures is based on several factors: age of the patients, nature of the injury (Isolated or combined), fracture type...
(open or closed), fracture pattern (stable or unstable), patient and family compliance, social, psychological and economic status, and finally the surgeon’s preference. External fixation had resulted in pin-tract infection, loss of knee range of motion, delayed union, non-union, and re-fracture after fixator removal. Solid ante-grade intramedullary nailing had resulted in avascular necrosis of the femoral head, trochanteric epiphysiodesis, and coxa valga. The ideal device to treat pediatric femoral and/or tibial fractures should be a simple, load sharing internal splint, allowing early mobilization while maintaining length and alignment for several weeks until bridging callus forms, without endangering the blood supply to the epiphysis. Ender nails are stainless steel implants that proved to be inadequate for adult femoral and tibial fractures but may be effective for pediatric 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 bio-compatibility without metal sensitivity reactions.

The principle of Ender nail fixation is canal filling with the nails, while TENs work by balancing the forces between the two opposing flexible implants. To achieve this balance, the nail diameter should be 40% of the narrowest canal diameter; the nails should assume a double C construct. They should have similar smooth curve and same level entry points.

**Methodology**

An outcome surgical study with 30 patients with Diaphyseal fractures was undertaken to study the outcome of Titanium elastic nails fixation in Lower limb, All children and adolescent patients between 5-16 years of age with diaphyseal fractures of femur and / or tibia admitted and meeting the inclusion and exclusion criteria (As given below) during the study period were the subjects for the study.

**Inclusion Criteria**
- Children and adolescent patients from 5 to 16 years with diaphyseal closed fractures of femur and tibia.
- Both the sexes are included in the study.

**Exclusion Criteria**
- Patients unfit or not willing for surgery
- Open fractures
- Old fractures

**Results**

**Table 1:** Time interval between trauma and surgery

| Time of interval | Number of Patients | % |
|------------------|--------------------|---|
| < 2days          | 10                 | 33.3 |
| 3-4 days         | 8                  | 26.7 |
| 5-7 days         | 10                 | 33.3 |
| >7 days          | 2                  | 6.7  |
| Total            | 30                 | 100.0 |

**Table 2:** 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 3:** Post-operative Immobilization

| Post-op | Number of Patients | % |
|---------|--------------------|---|
| Immobilization | | |
| 6 weeks  | 21                 | 70  |
| 9 weeks  | 9                  | 30  |
| Total    | 30                 | 100.0 |

**Table 4:** Duration of stay in hospital stay in days

| Duration of stay (days) | Number of Patients | % |
|-------------------------|--------------------|---|
| ≤7                      | 8                  | 26.7 |
| 8-10                    | 7                  | 23.3 |
| 11-15                   | 11                 | 36.7 |
| >15                     | 4                  | 13.3 |
| Total                   | 30                 | 100.0 |

**Table 5:** 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 6:** Range of movements at 24 weeks (Degrees)

| Range of movements (degrees) | Number of Patients | % |
|------------------------------|--------------------|---|
| Full range                   | 28                 | 93.3 |
| Mild restriction             | 2                  | 6.66 |
| Moderate restriction         | 0                  | 0    |
| Severe restriction           | 0                  | 0    |
| Total                        | 30                 | 100  |

**Table 7:** Time of full weight bearing

| Time of full weight bearing | Number of Patients | % |
|-----------------------------|--------------------|---|
| ≤12 weeks                   | 24                 | 80.0 |
| >12 – 18 weeks              | 5                  | 16.7 |
| >18 – 24 weeks              | 1                  | 3.3  |
| Total                       | 30                 | 100  |

**Table 8:** Complications

| Complications | Minor | Major | Nil | Total |
|---------------|-------|-------|-----|-------|
| No. of Patients | 12 | 0 | 18 | 100 |
| Percentage | 40 | - | 60 | 100 |

**Table 9:** Outcome

| Outcome | Number of patients (n=20) | % |
|---------|---------------------------|---|
| Excellent | 18 | 60.0 |
| Satisfactory | 12 | 40.0 |
| Poor | 0 | 0.0 |

**Discussion**

In the present series, 10 (33.3%) patients underwent surgery within 2 days after trauma, 8(26.7%) in 3 – 4 days, 10 (33.3%) in 5 – 7 days and 2 (6.7%) patients after 7 days. Among 2 cases in which duration was more than 7 days – one was case no.3 (Femur)--operated 8 days after trauma (admission) as they belong to lower socio economic status and took time to arrange for the expenses of the surgery. Another case was case no. 29 - operated 10 days after trauma (admission) as the patient had abrasions at the incision site and we waited for it to heal. Average duration between trauma and surgery was 3.9 days in the study Gamal el adl operated 56.1% of cases between 3-4 days after injury, 21.2% cases between 3 -4 days and 22.7%
cases after 7 days [7].

K C Saika et al. operated 77.27% patients within 7 days of injury [8].

In the present study, duration of surgery was < 30 mins in 1(3.3%) case, 30-60 mins in 13 (43.3%) cases, 61-90 mins in another 14 (46.7%) cases and 91-120 mins in 2 (6.7%) of the cases. Among the 2 cases in which duration was more than 90 minutes—one was case no.6 (femur) which was proximal third fracture which took 96 minutes and other was case no 10 (femur) which was comminuted fracture at the middle third which took 93 minutes. The extended duration of surgery in these cases was due to difficulty in reduction and passage of nail across the fracture site. The average duration of surgery in our study was 59.9 minutes.

In Khurram Barlas et al. study, the average duration of surgery was 70 mins [9].

In a study by K C Saikia et al., the duration of surgery ranged from 50 – 120 mins with a median of 70 mines.

In our study, 21 (70%) cases were immobilized (long leg cast with a pelvic band for femur fracture / above knee POP cast for tibia fracture) post operatively for 6 weeks and such immobilization was for 9 weeks in rest of the 9 (30%) of the cases.

The period of immobilization was followed by active hip and knee/knee and ankle mobilization with non-weight crutch walking. The average duration of immobilization was 6.9 weeks.

The average length of immobilization in plaster was 9.6 weeks in Gross R.H et al. study [10].

John Ferguson et al. treated 101 children with immediate hip spica casting. They immobilized children for an average duration of 10 -12 weeks with spica casting [11].

The advantage of the present study was early mobilization of the patients.

The duration of stay in the hospital ≤ 7 days for 8 (26.7%) patients, 8-10 days for 7 (23.3%), 11-15 days for 11 (36.7%) and 4 (13.3%) patients stayed for more than 15 days. Among the 4 patients who stayed for more than 15 days, 2 were case no 3 and case no 29 for whom time interval between trauma (admission) and surgery was more, therefore they stayed for 18 and 20 days respectively. Case no 4 though operated within 3 days of injury, developed superficial infection which had to be dressed regularly, so stayed for 18 days. Another was case no 25 who was operated 5 days after injury (admission), stayed for 22 days waiting for his insurance scheme to be sanctioned.

The average duration of hospital stay in the present study is 11.6 days.

The mean hospital stay was 12 days in Kalenderer O et al. study [12]. Average hospitalization time was 11.4 days in the study conducted by Mann DC, et al. [13]

Gross RH, et al. conducted a study on cast brace management of the femoral shaft fractures in children and young adults. The average length of hospitalization in their study was 18.7 days [10].

Compared to the above studies conducted on conservative methods and cast bracing, the average duration of hospital stay was less in our study i.e. 11.6 days. The reduced hospital stay in our series is because of proper selection of Patients, stable fixation and less incidence of complications.

In our study union was achieved in <3 months in 24 (80%) of the patients and 3–4.5 months in 6 (20%). Average time to union was 12.1 weeks.

Oh C.W et al. reported average time for union as 10.5 weeks [14]. Aksoy C, et al. compared the results of compression plate fixation and flexible intramedullary nail insertion. Average time to union was 7.7 (4 to 10) months in the plating group and 4 (3 to 7) months for flexible intramedullary nailing. In our study, closed reduction of the fracture, leading to preservation of fracture hematoma, improved biomechanical stability and minimal soft tissue dissection led to rapid union of the fracture compared to compression plate fixation.

In the present study, unsupported full weight bearing walking was started in <12 weeks for 24 (80%) of the patients, between 12 and 18 weeks in 5 (16.7%) and at 20 weeks in 1 (3.3%) patient. The average time of full weight bearing was 11.5 weeks.

Wudbhav N. Sankar et al. in their study allowed full weight bearing between 5.7–11.6 weeks an average of 8.65 weeks. In the present study, 7 (23.3%) patients had developed pain at site of nail insertion during initial follow up evaluation which resolved completely in all of them by the end of 16 weeks.

J.M. Flynn et al. reported 38 (16.2%) cases of pain at site of nail insertion out of 234 fractures treated with titanium elastic nails. Superficial infection was seen in 1(3.3%) case in our study which was controlled by antibiotics.

J.M. Flynn et al. reported 4 (1.7%) cases of superficial infection at the site of nail insertion out of 234 fractures treated with titanium elastic nails. All patients 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, but normal range of knee flexion was achieved at 8 months.

J.M. Flynn et al. reported 2 (0.9%) cases of knee stiffness out of 234 fractures treated with titanium elastic nails. This is the most common sequel after femoral shaft fractures in children and adolescents. 2(6.66%) patients had shortening (femur–1cm and tibia–0.7cm) and 1(3.33%) had lengthening (femur–1.2cm). No patient in our study had major limb length discrepancy (i.e.> ± 2cm).

**Conclusion**

Based on our experience and results, we conclude that Elastic Stable Intramedullary Nailing technique is an ideal method for treatment of pediatric femoral and tibial diaphyseal fractures. It gives elastic mobility promoting rapid union at fractures site and stability which is ideal for early mobilization. It gives lower complication rate, good outcome when compared with other methods of treatment.

It is a simple, easy, rapid, reliable and effective method for management of Pediatric femoral and tibial fractures between the age of 5 to 16 years, with shorter operative time, lesser blood loss, 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.

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