Evaluation of outcome of titanium elastic nailing (TEN) versus hip spica cast in the treatment of femoral shaft fractures in children

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Abstract
Femoral shaft fractures are among the most common pediatric injury and treatment of them carries a lot of controversies. The aim of this study was to compare the outcome of titanium elastic nailing versus hip spica cast in femoral shaft fractures in children. This prospective study was conducted on 40 children of 5 to 15 years of age treated with titanium elastic nail or early hip spica cast for the fracture shaft of femur during July 2016 to October 2017 in the Department of Orthopaedics, R.I.M.S., Ranchi, Jharkhand. Majority of patients in both treatment group were male child with overall boy to girl ratio was 1.85:1. Mean age in titanium elastic nailing group was 9.82 ± 2.99 years and in spica group was 8.35 ± 2.53 years. RTA was most common mechanism of injury and right limb was more commonly involved in both groups. Union time was less in titanium elastic nailing group (8.80 ± 1.76 week) than spica group (10.20 ± 2.33 week) (p = 0.039). Patients in titanium elastic nailing group walked with and without support earlier than the spica cast group (p = 0.000). Most common complication in titanium elastic nailing group was limb lengthening (50%) followed by mal alignment (40%) while in spica group it was limb shortening (65%) followed by mal alignment (55%). Overall complication was higher in spica group. At final analysis, Flynn score was better in titanium elastic nailing group than in hip spica group (p = 0.365). Titanium elastic nailing is better method for the management of femoral shaft fractures in children as it results in higher rate of excellent functional outcome with lower incidence of complications.

Keywords: Children, femoral-shaft fracture, hip spica cast, titanium elastic nailing (TEN), flynn score

Introduction
The femur (thigh bone) is the longest, strongest, largest and heaviest tubular bone in the human body [1, 2], and one of the principal load-bearing bones in the lower extremity [2]. Femoral shaft fractures, typically caused by blunt trauma, are the most common major pediatric injuries treated by the orthopedic surgeon [3] and representing about 1.6% of all fractures in the pediatric population [4].

Multiple treatment options are available for femoral shaft fractures but controversy remains over which method is superior in a given situation [5]. Until recently conservative treatment was the preferred method for the treatment of diaphyseal fractures in children and young adolescents. However, to avoid the effects of prolonged immobilization, to reduce the loss of school days and for better nursing care, the operative approach has been gaining popularity for the last two decades. The results of a recent survey of the members of the Pediatric Orthopaedic Society of North America indicate that surgery is the preferred treatment for older children, particularly those with high-energy injuries [6, 7]. Options for operative fixation include flexible and locked intramedullary nails, external fixators, and compression and bridge plating [8].

Plate osteosynthesis is still widely used. It is associated with a large exposure, relatively longer duration of immobilization and the risks of delayed union, infection and a large dissection for plate removal [9]. The external fixator provides good stability and early mobilization, but is associated with the risk of pin tract infections and it takes a longer time for weight bearing [9]. Intramedullary K-wire fixation has also been used for pediatric femoral fracture. But stability and fracture angulation is a disadvantage to be taken care of. Interlocking nail is ideal for skeletally matured children.
Reports of avascular necrosis of femoral head, coxa valga have been reported with interlocking nail when attempted in skeletally immature patients [9].

Early hip spica cast application of femoral shaft fracture in children is a useful alternative to the traditional method of treatment. It allows for a short hospital stay thereby avoiding all the problems associated with prolonged hospitalization. When the patients are selected appropriately, early spica casting has very good overall results with high rates of healing. Spica casting also has an excellent safety profile, with low rates of infection or major complications [10].

Titanium elastic nail seems advantageous over other surgical methods because it is simple, is a load-sharing internal splint that doesn't violate open physis, allows early mobilization and maintains alignment. Micromotion conferred by the elasticity of the fixation promotes faster external bridging callus formation. The periosteum is not disturbed and being a closed procedure there is no disturbance of the fracture hematoma, thereby less risk of infection [9]. It also has psychological, social, educational and economic advantage over conservative treatment [9].

However, the data on efficacy and functional outcome of TENS or hip spica cast in India is scanty and no such study was undertaken in our hospital setting. Hence, this study was planned to assess the efficacy and the functional outcome following titanium elastic nail system (TENS) vs hip spica cast for shaft femur fracture among the children aged 5 to 15 years.

**Materials and methods**

This one year & three month prospective study was carried out from July 2016 to October 2017 in the Department of Orthopaedics, Rajendra Institute of Medical Sciences (R.I.M.S.), Ranchi, Jharkhand. A total of 40 children (divided in two equal groups) with fracture shaft femur were studied. Group A including 20 children were treated with titanium elastic nail and group B including 20 children were treated with early hip spica cast. Approval for the study was obtained from the Institutional Ethics Committee, R.I.M.S., Ranchi, Jharkhand.

Patients were diagnosed on the clinical and radiological basis including anteroposterior and lateral radiographs. The consent for surgery and anaesthesia was taken from the parent/attendant after explaining the procedure and possible complications in their own vernacular language.

**Inclusion criteria**

1. Femoral diaphyseal fractures in patients between 5 to 15 years of age.
2. Closed fractures.
3. Children with either sex.
4. Attendant of patients willing to give informed consent.

**Exclusion criteria**

1. Patient with pathologic fractures, previously diagnosed neuromuscular disease (e.g., cerebral palsy), metabolic bone disorders (e.g., osteomalacia).
2. Patients with associated injuries (head/pelvic/abdominal injuries).
3. Patients who were not medically fit for surgery (for TENS) or anaesthesia.
4. Segmental or type III & IV comminuted fractures according to the Winquist classification.
5. Fractures involving femoral condyles or cervicotrechanteric area.
6. Solid malunion requiring open correction.

Every patient included in this study was managed initially with below knee skin traction for controlling pain and preventing deformities. The selection of mode of treatment whether TENS or hip spica cast was based on the choice of parents or attendants, after explaining advantages and disadvantages of each option. All patients were treated with appropriate antibiotics, analgesics & anti-inflammatory medications pre & post operatively.

For patients in TENS group, the standard technique described by Flynn & colleagues [11] was applied with some modification. Operation was done under general or spinal anesthesia on a radiolucent table. After a linear incision, opening the fascia and passing muscle fibres, a hole was made in lateral & medial side of distal femur about one fingerbreadth proximal to upper pole patella. Then each nail was placed retrogradely. Each nail was about 40% of the canal diameter at the narrowest site of femoral shaft. Fracture was reduced by open technique. Using the inserter, hammer guide and locking slide hammer, two nails were advanced proximally one after the other into the proximal fragment to diverge laterally and medially within the femoral neck and trochanteric region for proper rotational stability. Proximal extent of nail tip was guided by a nail from outside. About 1 cm of the end of the nail was left distal to the insertion hole to allow ease in later removal. The incised wounds were closed in layers, compression bandage were applied & high groin slab was applied for two weeks postoperatively. Quadriceps strengthening and active assisted range of motion exercises were began after slab & stitch removal. Knee bending exercises were started according to the patients' pain tolerance.

Partial weight-bearing was allowed after 4 weeks, according to the stability of reduction, type of fracture, weight, and compliance of the child. Full weight-bearing was allowed after union was achieved. Spica cast was applied under general anaesthesia. Child was placed on spica cast table in supine position and closed reduction was achieved under fluoroscopy. Keeping the reduced position, cotton wrap placed from lower level of chest to toes on the injured leg. Assistant held the patient's limbs in appropriate position. Folded towel (up to 2 inches in thickness) was placed over chest and abdominal area to allow full respiratory excursion. Extra cotton wrap placed on bony prominences (iliac crest, greater trochanter, patella, fibular head) to avoid maceration and sores. First a long leg cast was applied with the knee at about 10 to 15 degree of flexion & ankle in neutral position. Then hip spica cast was completed while maintaining the alignment of the shaft of femur and hip in 30 to 45 degree flexion, 20 to 30 degree abduction and 10 to 15 degree external rotation. Additional POP slab was placed across hip and casting done to strengthen the cast. Cast was molded appropriately during application to maintain the alignment. Lastly reduction was checked using c-arm fluoroscopy. Window was trimmed for perineal care, towel removed over chest and abdomen and it was ensured that cast edges were not sharp. Spica cast was kept for 6 to 14 weeks depending upon the age of patient and fracture union. After removal of spica cast, hip, knee and ankle mobilizing exercises and gradual partial and full weight bear were advised.

Postoperative X-ray of the involved femur with hip and knee was taken in both treatment group. First follow up was done at 2 week for assessment of spica cast or stitch removal. Further follow up was done at every two weeks interval till fracture consolidation and then at monthly intervals and at every visit patients were clinically and radiologically monitored.
evaluated and at 6 months the final results were evaluated using criteria of Flynn et al. [11]

**Statistical analysis**

The data was inserted into Excel and then analyzed in the program STATA/SE version 13.0. Mean values and standard deviations were calculated for the collected variables. To compare the variables of the conservative and surgical treatment, Pearson’s Chi square test was used to see statistic significance. A ‘p’ value of less than or equal to 0.05 was considered as statistically significant.

**Results and discussion**

Femoral shaft fractures are a common and disabling injury in children. Recent advances in adult orthopaedic traumatology have led to a more aggressive approach to the child with a femur fracture. Multiple treatment options are available, and controversy remains over which method is superior in a given situation. Although spica casting is traditionally used for femoral shaft fractures in children, recent studies have shown its possible effects on social, economic, educational and emotional cost. In contrast, TEN has gained extensive popularity because of its better clinical and psychosocioeconomic outcomes with lower risk of complications. Hence, this study was undertaken to compare the outcome of titanium elastic nail versus early hip spica cast in femoral shaft fracture in children of 5 to 15 years of age.

**Sex distribution**

It is reported that, pediatric femoral shaft fractures are more common in males with approximately a 2.5:1 male to female ratio [12]. In the present study 65% of the patients were boys and 35% were girls. The overall boy to girl ratio was 1.85:1.

**Age distribution**

Studies have reported bimodal age distribution in children with fractures of the femoral shaft, with peaks in the younger than 5 years and mid-teenage groups. In this study 27 (67.5%) children were aged between 5 to 10 years and 13 (32.5%) were between 11 to 15 years. The mean age in TEN group was 9.82 ± 2.99 years and in spica group was 8.35 ± 2.53 years. Mean age in TEN group was higher than in spica group.

**Mode of Injury**

Our study shows (Graph 1) that most common mode of injury in both group was RTA (60% in TEN vs 65% in spica group) followed by fall from height. These findings are consistent with other studies [14, 15]. However, Mohammed Ibrahim et al. [16] reported 100% cases due to RTA but sample size was small (total 10 cases) in their study.

**Duration of hospital stay**

In this study, spica cast group was found to have a shorter duration of hospital stay (4.85±1.22 day) compared with elastic nail group (9.30±1.80 day) which is highly significant (p value = 0.000) finding. A longer stay in hospital increases costs.

**Side and location of fracture:** In our study, right limb involvement was common than left in both study group. Also femur fracture was most common in middle third followed by proximal third and distal third. In Ferhat Say et al. [14] femur fracture was most common in middle third followed by distal third and proximal third.

**Type or pattern of fracture:** In this study (Graph 2) most of the patients presented with transverse fracture in both treatment groups. In TEN group 45% patients had transverse fracture followed by oblique (30%) and spiral type (25%) fracture. In spica group 40% patients had transverse fracture followed by spiral (35%) and oblique type (25%) fracture. In Khaffaf R.M.N et al. [15] study, in TEN group oblique fracture (46.7%) was most common followed by equal number of transverse & spiral fracture while in spica group transverse fracture (46.6%) was most common followed by oblique and spiral fracture.
Union time: In our study, all fractures were united but 2 (10%) fractures in spica group had delayed union. Mean union time was less in TEN group (8.8 ± 1.7 week in TEN group versus 10.2 ± 2.3 week in spica group) which is statistically significant (p value = 0.039). It is probably because of better contact of the fracture surfaces and anatomical reduction in patients who underwent TEN surgery. These findings are similar to that of Harish Kumar Jain study [17] who found mean union time of 10.2 weeks and 8.4 weeks in spica and TENS group respectively. In 6.67% patients of spica group delayed union was noted. Ghulam Rasool et al. [18] study had shorter union time in both groups than our study.

Partial and full weight bearing: In our study, mean time for partial weight bear in TENS group was 5.90 ± 1.37 week and in spica group it was 11.10 ± 2.02 week; and mean time for full weight bear in TEN group was 8.00 ± 1.29 week and in spica group it was 12 ± 1.95 week. So, patients in TEN group walked with and without support earlier than the spica cast group (p value = 0.000), which conforms with the literature [11, 19]. In Ferhat Say et al. [14] study, patients of both group started partial weight bearing earlier than our study. Allowing early movement by providing sufficient fixation is a primary advantage of elastic nailing.

Range of motion of knee: At final evaluation in this study, knee range of motion of the spica cast group (133.60° ± 3.21°) was found to be better compared with the TEN group (131.40° ± 4.15°) but difference was not significant (p value = 0.069). Goniometer was used to measure range of motion. This minimal difference between groups could be explained by measurement error. In R. Chandra Sekhar et al. [20] study, knee range of motion of the spica cast group was 137.4° ± 5.4° and of elastic nailing group was 127.3° ± 9.6°).

Associated injury: In TEN group, 4 (20%) patients had concomitant injury i.e., clavicle fracture in 2 patients, humerus and contraletal tibia fracture one in each patient. In spica group, 2 (10%) cases had concomitant injury i.e., radius and contraletal tibia fracture one in each patient. These fractures were treated accordingly.

Complications: In this study, most common complication in TEN group was limb lengthening followed by mal alignment while in spica group it was limb shortening followed by mal alignment. Overall complication was higher in spica group. In TEN group, pain & discomfort was seen in 3 (15%) cases, entry site bursitis in 3 (15%), infection in 2 (10%), mal alignment in 8 (40%) and limb lengthening in 10 (50%) cases. Mal alignment can be prevented by choosing correct nail diameter and placing anterograde nail for distal shaft. Infection was cured with oral antibiotics. In spica group, pain & discomfort was seen in 7 (35%) cases, pressure sore in 2 (10%) cases, delayed union in 2 (10%) cases, mal alignment in 11 (55%) and limb shortening in 13 (65%) cases. Mal alignment in the cast group can be avoided by passing a Steinmann pin from the femoral metaphysis and incorporating into the spica cast.

Verma DP et al. [21] study found pressure sore in 8.8%, delayed union in 4.4%, malunion in 22.22%, limb length discrepancy in 26.66% cases in spica group while infection & inflammation in 10%, malunion in 6.66%, limb length discrepancy in 8.88% cases of TEN group.

Final outcome (based on Flynn criteria): Flynn score (Graph 3) was better in TEN group than in hip spica group but difference between two groups was not significant (p value = 0.365). In TEN group, 15 (75%) cases had excellent outcome, 4 (20%) had satisfactory and 1 (5%) case had poor final outcome while in spica group, 11 (55%) cases had excellent, 6 (30%) had satisfactory and 3 (15%) cases had poor outcome. Common causes of poor Flynn score in spica group may be malunion and limb length discrepancy. These findings are comparable with other studies [17, 18, 20]. All these studies showed better Flynn score in TEN group.

Graph 3: showing final outcome (Flynn criteria) in both treatment groups.
Limitations of This Study: Treatment cost, time to return school, parents satisfaction were not measured in either group. Lack of long term follow-up & small sample size could result in falsely high complication rates.

Conclusion
We found that both hip spica cast and titanium elastic nail (TEN) are effective method of treatment for femoral shaft fractures in children. However, TEN takes lesser time for union, has less limb length discrepancy and mal alignment, allows earlier rehabilitation and return to activities of day to day life than spica cast treatment. Convenience of micturition & defecation in TEN group, also make it better than spica treatment. Thus, TEN proved to be superior than spica cast treatment for diaphyseal femoral fractures in children. Further, our study may be the basis for randomized controlled trials with long term follow up and large sample size to determine the optimal treatment strategy for these fractures with more accuracy.

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