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ORIGINAL STUDY

Randomized controlled trial comparing stabilization of fresh close femoral shaft fractures in children with titanium elastic nail system versus stainless steel elastic nail system

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In vitro mechanical studies have demonstrated equal or superior fixation of pediatric femoral fractures with use of titanium elastic nails (TENS) as compared with stainless steel elastic nails (SSEN). SSEN are less expensive as compared to TENS. However, there are only two studies in the English literature which have compared the results of TENS and SSEN in paediatric femoral shaft fracture. The present study compares the clinical and radiological outcomes of femoral shaft fracture in patients 6-12 years of age, operatively stabilised either by TENS or SSEN.

35 children (6-12 years) with closed, post traumatic femoral shaft fractures were randomized into two treatment groups. Both groups underwent closed reduction internal fixation (CRIF) by either of the implants (TENS OR SSENS) as per randomization protocol and followed up for six months. Comparison of clinical and radiological outcomes in both the groups was done in terms of time to union of fracture and radiological angulations in coronal and sagittal plane.

There was no significant difference in both groups with respect to fracture site tenderness and presence of bridging callus at fracture site at 3 weeks, 6 weeks and 6 months follow up (p-value = 1.000). There was no significant difference in radiological angulation rate in both groups in the sagittal (p-value = 0.661) as well as in the coronal plane (p-value = 0.219) at six month follow up. Both groups showed a similar rate of complication, most common being prominent hardware.

TENS and SSENS are equally effective treatment modalities for paediatric femoral shaft fracture with similar rate of complications. However, SSENS is less costly as compared to TENS and can be considered as an alternative in a resource constrained setup.

INTRODUCTION

Femoral shaft fractures including subtrochanteric and supracondylar fractures represent approximately 1.6% of all fractures in children (*25*). In children of 6 to 12 years of age, due to problems associated with non-operative treatment including spica cast and the care provideris demand for early mobilization, a variety of therapeutic alternatives, such as intramedullary stabilization, compression plate fixation, sub muscular bridge plates and external fixator have become available, thereby decreasing impairment, increasing convenience, and decreasing hospital cost (*5,10,12,13,14,17,18,20,25*). The Titanium elastic nailing system (TENS) has gained

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popularity as the choice of fixation in paediatric femoral shaft fracture as they allow early mobilization and good functional outcome (*3,15*). However, in resource constrained hospitals, titanium elastic nails are not an economically viable option. Compared to TENS, stainless steel elastic nail (SSEN) is an equally effective and a more economical treatment modality for these fractures. Hence we envisaged this study to compare the feasibility, clinical and radiological outcome of intramedullary nailing in fractures of the shaft of the femur in children 6-12 years of age, using TENS and SSEN systems.

MATERIALS AND METHODS

A randomized controlled trial was conducted in the department of Orthopaedics of a tertiary care hospital in Northern India. Forty children (age 6-12 years) with closed femoral shaft fractures were included in the study. Fractures that were located 3 cm below the lesser trochanter and 5 cm above the distal femoral physis were included in the study. Patients with an injury hospital duration of more than 10 days, Winquist type 3 & 4 comminuted fracture, pathological fracture, patients with other ipsilateral or contralateral major limb injury or polytraumatized patients, patient on drugs which affects fracture healing like steroid, anticancer drugs were excluded from the study. After clinical assessment and appropriate stabilisation of the patient, radiographs of the affected thigh including hip and knee joint (AP and Lateral view) were taken. After informed consent from parents/ guardians, the enrolled patients were randomized into two groups as per plan generated by www.randomization.com. Group 1 patients were treated by closed reduction and stabilisation with TENS and group 2 patients were treated by closed reduction and stabilisation with SSEN. Standard operative technique for flexible intramedullary nailing was used for both groups (*19, 24*). Patients were followed up at 3, 6, 12, 24 weeks for assessment of union and complications, if any. Clinically the fracture was labelled as united when there was absence of pain / tenderness at the fracture site. Radiologically, the fracture was labelled as united if there was presence of bridging callus in at least three of the four cortices in two orthogonal views. The complications were classified as major or minor. Major complications were defined as conditions leading to unscheduled nail removal or operative treatment, including deep infection, implant irritation, or pain and nail breakage (*31*). Malunion, delayed union and non union were considered to be major complications. Delayed union was defined as the persistence of bone pain and tenderness three months after the fracture without complete union radiographically (*21*). Non union was defined as the absence of radiological signs of osseous union more than six months after the injury (*21*). Malunion was defined as an angulation of > 10 degree in the coronal plane or >15 degree in the sagittal plane (*21*). Minor complications were defined as nail irritation or infection that was treated nonoperatively (*31*).

In both groups, the angulation at the fracture site in the coronal and sagittal plane was measured after radiological union in postoperative anteroposterior and lateral radiographs taken at 6 month. The long axis of the proximal and distal fragments was drawn by joining the two mid points of width of the femoral shaft at two different levels in each proximal and distal fragment. The angle between the two segments was measured in degrees by a goniometer to get the angulation in coronal and sagittal plane (Fig. 1a, b) (*27*). These measurements were done by two surgeons (ANA and NG) independently at different times. Both surgeons were blinded to the group to which that particular radiograph belonged. The mean of these values obtained by these observers for a particular radiograph was used for statistical analysis. This analysis was done by using standard unpaired t-test and using Windows SSPS (version 14) software.

Fig. 1A and 1B. – Measurement of angulation in AP and Lateral view.

RESULTS

A total of 40 patients were included in the study. Out of these, three patients were lost to follow up and two others were excluded from the study because open reduction was done in these two patients as a rescue treatment. 35 patients successfully completed six month follow up and were included in the final analysis. Eighteen patients were managed with titanium nails and seventeen patients were managed with stainless steel nails. The mean age of the patients in Group-1 (TENS) was 8.7 years while in Group-2 (SSENS) it was 8.5 years. There were 13 males (72.2%) and 5 females (27.8%) in Group-1 (n = 18) while in Group-2 (n = 17) there were 11 males (64.7%) and 6 female (35.3%) patients. There were no significant differences in both the study groups regarding age and sex.

Progression of union at fracture site

Postoperatively, at 6 weeks, bridging callus was seen across 3 or more cortices in all patients in both groups. Hence there was no statistically significant difference between two groups regarding time of union with p- value of 1 on applying chi-square test. Finally, at 6 months all patients (n = 35) in both groups showed mature callus across all 4 cortices as seen on two orthogonal views of the femur.

Angulation in coronal plane

In the coronal plane, the angulation at the fracture site ranged from 2 to 18 degrees in Group-1 (TENS). The mean angle was 4.2 degree (SD = 3.97). In Group-2 (SSENS) the range was 2 to 13 degree. The mean angle was 4.7 degree (SD = 3.21) (Table I).

Table I. – Angulation at fracture site

	GROUP	N	Mean	Std. Deviation	Std. Error Mean
Angulation in sagittal plane	1	18	4.22	3.979	0.938
	2	17	4.76	3.212	0.779
Angulation in coronal plane	1	18	7.72	3.908	0.921
	2	17	6.12	3.655	0.887

Angulation in sagittal plane

In sagittal plane the angulation at the fracture site ranged from 3 to 16 degrees in Group-1 (TENS). The mean angle was 7.7 degree (SD = 3.90). In Group-2 (SSENS) the range was 1 to 13 degree. The mean angle was 6.1 degree (SD = 3.65). There was no significant difference in fracture site angulation in both groups in the sagittal (p-value = 0.661) as well as in the coronal plane (p-value = 0.219). Deformity in the coronal plane was varus in all patients and in the sagittal plane it was procurvatum in all patients (Table I). The patient outcome was measured by the Flynn criteria (*8*) (Table II).

In our study, two patients in group 1 and three patients in group 2 had prominent hardware at the nail insertion site. This prominent hardware was the cause of persistent knee pain and tenderness. Amongst these five patients one patient in group 2

Table II. – Outcome according to Flynn's Criteria

Flynn's Criteria			
	Excellent	Satisfactory	Poor
Length discrepancy	< 1.0 cm	< 2.0 cm	> 2.0 cm
Malalignment	5 grades/degrees	10 grades/degrees	> 10 grades/degrees
Pain	No	No	Yes
Complications	None	Minor & solved	Major and/or residual morbidity
Our study	26 (74.3%)	5 (14.3%)	4 (11.4%)

Fig. 2. — Union at fracture site despite inadequate length of nail.

had skin breakdown due to prominent hardware for which trimming of the prominent part of the nail was done under local anesthesia. The wound healed and the patient was pain free in two weeks time and subsequent follow up was uneventful. In one patient, due to technical errors, the second nail got stuck halfway just after passing across the fracture site into the proximal fragment. The nail could not be extracted and was kept in situ. On subsequent follow up the fracture united uneventfully. The nails were removed after 1 year follow up without any difficulty (Fig. 2). In two cases there was a medial cortex perforation at the superior end of the femur but they were symptomless. These fractures united uneventfully. In two cases there was an opposite cortex perforation while inserting the lateral nail, one in the titanium group and one in the SSENS group. However,the nail was reintroduced and was made to cross the fracture site. In three cases there was intertwining of nails seen intraoperatively, one in group 1 and two in group 2. The nails were reintroduced and the fractures united uneventfully (Fig. 3a, b, c, d).

Fig. 3A. — Pre operative anteroposterior view showing fracture shaft of the femur.

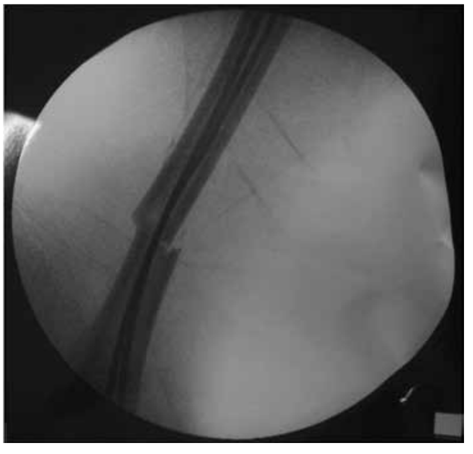

Fig. 3B. — Intertwining of the nails intraoperatively.

Fig. 3C. — 3 weeks post operative radiograph showing bridging callus across the fracture site.

Fig. 3D. — 6 months follow up radiographs showing sound union.

DISCUSSION

The ideal device for the treatment of most femoral fractures in children should be a simple, load sharing internal splint that allows mobilization and maintenance of alignment and limb length until bridging callus forms (*8*). The implant should neither endanger the physis nor the blood supply to the femoral head. It should promote, rapid healing and should provide for ability to remodel (*8*). Over the past few years, there are an increasing number of reports in literature describing flexible intramedullary nailing as a safe method in paediatric shaft femur fractures (*4,6,7,9,19,20,22,26,28*). Anastasopoulos *et al* reported in their study that although radiographs revealed that 44% of the children had malalignment at the fracture site in one or both planes, none of the children presented with clinical malalignment of the fractured limb (*1*). Luhmann *et al* reported that technical pitfalls with titanium nails exist and can be minimized by leaving less than 2.5 cm of the nail out of the femur and by using the largest nail sizes possible (*21*). Patients over 10 years of age, due to their larger size, may be better treated with other fixation systems, such as a rigid femoral nail inserted through the greater trochanter (*21*). Sagan *et al* studied residual deformity after treatment of paediatric shaft of femur fracture with flexible titanium nails (n = 70) and reported anterior bowing > 15° as the most common malunion (16%) in these cases (*30*). It was more frequently observed in older children with middle third of femur fracture and more in transverse fractures. They also suggested that it can be decreased if one of the nails is positioned to resist procurvatum (*30*).

There is no conclusive evidence in the literature that supports the superiority of titanium over steel; however some studies describe the superiority of titanium over stainless steel as a material when they are used as a plate (*32*). The titanium plates led to the appearance of a small amount of periosteal callus without any histological evidence of fracture instability, thus allowing the radiological assessment of fracture union. They also produce less bone loss during the remodelling phase. Titanium plates also produce less soft-tissue reaction than stainless steel plates (*32*). In an experimental study in rabbits under otherwise identical experimental conditions the rate of infection for steel plates (75%) was significantly higher than that for titanium plates (35%) ($p < 0.05$) (*2*). Thus differences between these two materials have been observed in laboratory tests, it is generally accepted that steel is stronger, yet less flexible (*16,23,28*). Titanium intramedullary nails were more stable than stainless steel nails in torsion and axial compression when tested in a synthetic femur model because increased deformation of titanium nails increases the contact area with the intramedullary canal wall thus increasing stability, but both materials stabilized the simulated fractures at levels beyond physiologic non-weight-bearing loads without permanent deformation (*28*).

In our study, there is no statistically significant difference between the two groups regarding time of union with p -value of 1 on applying chi-square test. At 6 months follow up all patients (n = 35) in both the groups showed bridging callus across all 4 cortices as seen on two orthogonal views of the femur. As the timing of appearance of bridging callus in both the groups was similar it can be reasonably inferred that both types of implants provided the required stability at the fracture site to promote healing. There were no cases of non union or delayed union in our study. Similar observation was found by studies conducted by Flynn *et al* (*8*), Crammer *et al* (*6*), and Galpin *et al* (*11*) when titanium elastic nails were used. In the study by Rios *et al* (*29*) where both titanium and steel nails were used there were no cases of delayed union or non union. However,in a similar study by Wall *et al* (*33*) there was one delayed union with a stainless steel nail (n = 48).

Contrary to our study Wall *et al* (*33*) reported that the malunion rate was significantly higher in the titanium group (23.2% ; thirteen out of fifty-six patients) than in the stainless steel group (6.3% ; three out of forty-eight patients) (p = 0.017). The risk of malunion was nearly four times higher in the titanium group than in the stainless steel group (odds ratio = 4.535 ; 95% confidence interval, 1.208 to 17.029). This difference may be due to the reason that the study done by Wall *et al* (*33*) was not randomized. However, Rios *et al* (*29*) have reported no statistically significant difference between the malalignment in coronal and sagittal plane when titanium and stainless steel nails were used. Similar results have been found in our present study. However, none of our patients with angulations in coronal/sagittal plane complained of any functional disability. It raises the question whether the angulation of these magnitude are clinically significant. The cost of the titanium elastic nail in our country is around 150 $ US dollars whereas stainless steel nails cost about 20 $ US dollars. The strength of the present study is that it is a prospective randomized controlled study. However the number of patients enrolled in the present single center study is small. A multicentric study with more number of patients is desirable.

CONCLUSIONS

We conclude that TENS and SSENS are equally effective treatment modalities for paediatric femoral shaft fractures in the age group of 6-12 years with similar rate of complications but SSENS is more cost effective as compared to TENS. Radiographic angulations in coronal and sagittal plane in both the study groups were comparable. Further none of our patients/parents complained of any deformity despite the presence of coronal and sagittal angulations in the radiographs. Hence it so seems that these angulations may not be clinically significant and are likely to remodel to a significant extent, which can be conclusively established only on longitudinal long term follow up of a larger number of such patients. Hence further studies in this regard are warranted in future to further define this aspect.

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