

1 **ELASTIC STABLE INTRAMEDULLARY NAILING OF FEMORAL SHAFT**
2 **FRACTURE-EXPERIENCE IN 48 CHILDREN**

3 **ABSTRACT**

4 **Introduction:** Femoral shaft fractures are an incapacitating paediatric injury accounting for 1.6%
5 of all paediatric bony injuries. Management of these fractures is largely directed by age, fracture
6 pattern, associated injuries, built of the child and socioeconomic status of the family. We
7 retrospectively evaluated the use of elastic stable intramedullary nail (ESIN) in surgical
8 management of femoral shaft fractures in children and its complications.

9 **Materials and Methods:** Fifty two children were treated with titanium elastic nails (TEN) from
10 June 2009 to June 2014 at our institution. At the end of the study there were 48 children.
11 Fractures were classified according to Winquist and Hansen's as Grade I(n=32),Grade
12 II(n=10),Grade III(n=6) and compound fractures by Gustilo and Anderson's classification,
13 Grade I (n=5), Grade II (n=3). There were 36 mid-shaft fractures, 7 proximal third shaft
14 fractures, 5 distal third shaft fractures. The final results were clinically evaluated by using
15 Flynn's criteria and radiologically by Anthony et al's criteria.

16 **Results:** The mean duration of follow-up was 20 months(range 12 – 40 months). All fractures
17 healed radiologically with grade III callus formation at 9 – 12 weeks (mean 9.7 weeks) . The
18 results were analysed using Flynn's criteria and were excellent in 40 children (83%) and
19 satisfactory in 8 children (17%). The soft tissue discomfort near the knee produced by nail ends
20 was the most common problem in our study (25%). Other complications include limb shortening
21 (n=5), varus malunion (n=4), Nail protruding site infection (n=4) and nail migration (n=2). There
22 was no delayed union,non-union or refractures.

- 23 **Conclusion:** TEN is minimally invasive, safe, relatively easy to use and an effective treatment
- 24 for fracture shaft of femur in properly selected children.
- 25 **Keywords:** Femur, Intramedullary fracture fixation, bone nailing, malunited fracture

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26 **INTRODUCTION:**

27 Femoral shaft fractures are the most common paediatric injuries treated by orthopaedic
28 surgeons resulting in high direct and indirect medical costs¹. The incidence of femoral fractures
29 is 20 – 25 per lakh children per year². The treatment of such fractures range from closed
30 reduction with hip spica, Bryant's traction and surgical stabilization with devices like plate and
31 screws, nails, ESIN and external fixators¹. Each method has its own set of advantages and
32 disadvantages.

33 Most paediatric fractures are treated conservatively, as nonsurgical management has been the
34 standard care of treatment for most young children historically, because of rapid healing and
35 spontaneous correction of angulation. The results were usually satisfactory in the long term¹. The
36 cost of care is low and the outcome is generally good. In older children, conservative treatment
37 results in loss of reduction, malunion, psychological intolerance to both the child as well as the
38 family and complications associated with plaster, hence, in the last two decades there has been a
39 growing tendency towards a more operative approach in children over six years of age.

40 Ideally in children between 6-16 years, the fracture needs an internal splint that shares load,
41 maintains reduction and does not endanger the growth areas or blood supply of the femoral head
42 and minimizes morbidity as well as complications³.

43 Plating offers rigid fixation and it needs a larger exposure with increased blood loss, resurgery
44 for implant removal and scarring. It is a load bearing device and refracture is a risk⁴. Antegrade
45 nailing is used in children near skeletal maturity⁵. External fixators are mainly used in open
46 fractures⁶.

47 ESIN was introduced for femoral fractures by Nancy group in 1979³. Titanium implants are
48 increasingly used for ESIN as titanium has an excellent biocompatibility and its elasticity limits
49 the amount that the nail is permanently deformed during insertion and also promotes callus
50 formation by limiting stress shielding. TEN acts as an internal splint, maintains length and
51 alignment that allows rapid mobilization while permitting enough fracture site motion for callus
52 formation and potentially has low risk of osteonecrosis, physeal injury and refracture⁷. Due to its
53 favourable results and lack of serious complications it remains the ideal treatment of choice for
54 stabilization of paediatric femoral fractures. We did a retrospective analysis of our results using
55 TEN in femoral shaft fractures at our institute.

56

57 **MATERIALS AND METHODS:**

58 On a retrospective search of hospital records, We found 52 children between the age group of
59 6-16 years were treated at our institution from June 2009 to June 2014 among which 48 were
60 available for follow-up. Data collected included details of the patient (age, gender), description of
61 the fracture (type, location, pattern), surgery (open/closed), presence of fracture angulation or
62 rotational malalignment, details of fracture union with initial X-ray to final follow-up X-ray and
63 rehabilitation milestones (non-weight bearing, partial and full weight bearing, return to school)
64 along with presence of any complications. There were 30 boys and 18 girls in our study with an
65 average age of 9.5 years (range 6 – 16) at the time of injury.

66 The most common mechanism of injury was road traffic accident (n=34, 70%) followed by fall
67 from height (n=14, 30%). 36 fractures were in the middle third followed by, seven proximal one-
68 third and five distal-third fractures in which 28 right sided fractures (58%) and 20 left sided

69 fractures(42%) were noted. Fracture patterns according to AO classification included 32 – A3
70 (n=24), 32 – A2 (n=12), 32 – A1 (n=6) and 32 – B3 (n=6) types. Fractures were classified
71 according to Winquest and Hansen’s classification as Grade I(n=32),Grade II(n=10) and Grade
72 III(n=6). Associated injuries were present in 7 patients, 3 had minor head injury and 4 had
73 associated upper limb fractures, two had fracture both bone forearm right side, one had type I
74 epiphyseal injury distal radius right side and last one had type I monteggia fracture left side. We
75 had five grade I open fractures and three grade II open fracture. All cases after complete pre-op
76 evaluation were taken up for surgery within 10 days (mean 3.6 days). We had inclusion and
77 exclusion criteria for our study.

78

79 **Inclusion criteria:**

80 Children between 6-16 years with closed fractures and grade I and II open fractures.

81 **Exclusion criteria:**

82 Children <6 and >16 years, grade III open fractures, pathological fractures, metabolic bone
83 disease, non-ambulatory children, children with neuromuscular disorders, segmental and severely
84 communitated fractures grade IV.

85 **Technique:**

86 Under regional anesthesia after prophylactic antibiotic, the child was placed supine on fracture
87 table with adduction of the affected limb by 10^0 . Closed reduction was performed by manual
88 traction and gentle rotation along with use of F-tool (a radiolucent device), the arms of the F-tool
89 were re-adjusted depending upon the fracture configuration and bulk of thigh, alignment was

90 confirmed in both planes by an image intensifier and was used to make an entry for the
91 placement of skin incision and dividing the fascia-lata in most cases. We used antegrade entry
92 only in cases where the fracture was in distal third or the cortex distally found communito to
93 hold the distal nail entry site. No nail caps were implemented during the surgery.

94 We used 2 nails of same diameter, which was calculated by pre-operative radiograph by:

- 95 1. Flynn et al's formula⁸, diameter of nail=width of narrowest point of the medullary canal
96 on AP and LATERAL view X 0.4 mm.
- 97 2. Kasser and Beaty formula⁹, nail size=internal diameter/2-0.5 mm.

98 Nails come in five diameters from 2.5mm to 4.5mm in fixed length. The nails are color coded
99 for identification. The drill was inclined at an angle of 10 degree, the nail tip was also bent to
100 facilitate placement and to allow the nail to bounce of the opposite cortex at the time of insertion.

101 Two nails were introduced upto the fracture site and both nails should pass the fracture site
102 nearly simultaneous to prevent angulation at the fracture site. In ten cases we did minimal open
103 reduction. The nails were put in double 'C' construct to ensure three point fixation and for proper
104 rotational stability nails were further advanced into the proximal fragment to diverge laterally
105 towards the greater trochanter and medially within the femoral neck so that early mobilization
106 was possible⁷. Care was taken to see the nails did not cross the growth plate proximally and
107 distally. The nail was cut at the entry site so that 1 cm of nail protrudes outside of the cortex. Too
108 much bending was avoided to prevent impingement and bursa problems. There was cock
109 screwing of nails in two cases (4%), we revised it intraoperatively.

110 Post operatively IV antibiotics continued for three days. Suture removal was done at tenth day.

111 No postoperative external immobilization was used and gradual mobilization was started. The

112 children were followed up at 1,2,3,6 month's interval until fracture union. At each visit,
113 progression of union at fracture site was assessed radiologically, tenderness at the fracture site
114 was determined by clinical examination along with limb alignment, rotation, length discrepancy,
115 range of motion of hip and knee and any other complications. Full weight bearing was started
116 when radiograph revealed soft callus at the fracture site. The children were evaluated clinically
117 by Flynn's criteria⁸(table 1) and radiologically by Anthony et al criteria¹⁰(table 2) at the end of
118 six months and at the end of one year.

119 **RESULTS:**

120 The median duration of surgery was 65 minutes (range 40-90 minutes). The mean hospital stay
121 was 7.3 days (5 - 15 days), the hospital stay was longer in children with head injury and
122 associated other injuries, there was no post-operative infection in our study even in open
123 fractures. The mean age was 9 years (range 6 -16 years) and median body weight was 27.5kg
124 (range 14 – 65) as well as average BMI was 27.2 (range 24.4 to 31.0). Minimum nail size used
125 was 2.5mm while maximum nail size used was 4mm according to Flynn's and Beaty's formula.

126 Out of 48 children available for evaluation, within a mean follow-up of 20 months (range 12 –
127 40 months) callus was first noted on follow-up radiograph at mean of 3.6 weeks (range 3.2-6.4
128 weeks). All fractures in our study united with grade III callus in average of 9.7 weeks (9-12
129 weeks) and full weight bearing was started at the same time and was initiated to attend school as
130 well (Table 4). Functional range of movement of knee was achieved in an average of 8.6 weeks
131 (6 – 14 weeks).Clinical evaluation revealed full range of motion of hip, knee and ankle in all
132 patients at final follow-up.

133 Radiological evaluation was done by Anthony et al criteria. All children had grade III callus at
134 the end of 12 weeks. Two children with head injury had large sized and very early callus
135 formation which decreased with passage of time and the final result was excellent. There was no
136 nonunion or delayed union in our study. Clinical evaluation was done using Flynn's criteria. The
137 results were excellent in 40 children (83%)(Case 1- Figures 1-4) and satisfactory in eight
138 children (17%)(Case 2-Figures 5-10). No child had poor result.

139 The most common problem encountered in our present study was skin irritation and
140 impingement due to the distal nail ends in 12 cases (25%)(Table 3). We had asymptomatic nail
141 migration in two cases (4%)(Case 3- Figures 11-14). All these problems settled upon nail
142 removal. Out of 48 cases, 5 cases (10%) had limb length shortening, out of which, four children
143 had shortening of less than 5 mm which was insignificant. In one child, with comminuted
144 fracture, who weighed 65 kg at age 14 had shortening of 15 mm. Angular mal alignment was
145 defined as an angulation of $> 10^{\circ}$ in the coronal plane or $>15^{\circ}$ in sagittal plane¹¹. In our study we
146 had varus malunion of >5 degree in coronal plane in four children(8%).Rotational malalignment
147 was termed as "excessive" if it was more than 10 degree¹². We did not have any children with
148 rotational malalignment. Four children (8%) had nail protruding site infection which settled with
149 regular dressing and oral antibiotics.

150 Nails were routinely removed (Not mandatory) at the end of one year after good fracture union.
151 In two cases we had had asymptomatic proximal migration of the nail which penetrated the
152 proximal cortex. So we removed the nail from the other side. No complications were associated
153 with the nail removal procedure and no refractures was observed after nail removal till date.

154

155 **DISCUSSION:**

156 The ideal choice in treatment of femoral shaft fractures has remained a constant challenge to
157 the orthopaedics fraternity. Non- operative management results in complication such as
158 malunion, joint stiffness and delay in functional recovery in older children and also results in
159 prolonged hospitalization causing financial loss to the family as well as increased hospital bed
160 occupancy ratio has lead to the emergence of operative fixation for these kind of fractures^{13,14}.

161 TEN is elastic stable intramedullary nail which works on the principle of symmetric bracing
162 action of two nails with same modulus of elasticity which gives three point fixation, rotational,
163 axial, transitional and bending stability by counteracting the distraction and compression forces
164 working at the fracture site^{15,16}.

165 In the present series, all fractures were united within 12 weeks of fixation with no non-union
166 or delayed union. Children who had transverse fracture pattern had a shorter union time and was
167 found to be heavier when compared to others. Male children had earlier union rate when
168 compared to females. Oh et al observed that all 31 fractures in his series healed within 12weeks
169 without delayed union¹⁷. Buechsenchuetz et al reported that in 42 patients treated with ESIN all
170 fractures healed at a mean of 88 days from injury¹⁸.

171 Hospitalization time has been considerably decreased with TEN. In present series it was 7.3 days
172 on average and return to school was initiated on 9.7 weeks on average causing less disturbance in
173 the continuation of the studies in children. The partial and complete weight bearing in the series
174 averaged 4.5 and 9.7 weeks respectively. In children with comminuted fracture, head injury and
175 associated other injuries affected the mobility of the patients in turn delaying the weight bearing.
176 Oh et al used ender nails and observed walking without assistive devices at an average of 9.7

177 weeks¹⁷. Flynn et al and Mazda et al observed walking without assistive devices at an average of
178 8.5 and 9.5 weeks respectively in patients using TENs^{1,19}.

179 The indication of TEN is expanding, as their advantages are realized and complications are
180 very less compared to other methods of fixation. The main advantages are: they are readily
181 available in different diameters and inexpensive.

182 Similar functional outcomes are noted in cases of both open and closed femoral shaft fractures as
183 we included only children with intact periosteum in our series and TENS don't disturb the
184 fracture hematoma when done as closed procedure, so chance of infection is very less. When
185 applied in retrograde manner there is little chance of avascular necrosis of femoral head^{20,21}.

186 Through thorough nail size evaluation using the formula implemented, our results were outlined
187 to be excellent as compared to other studies. In Narayanan et al series, smaller and mis-matched
188 nail diameter used in three cases was associated with increased incidence of varus or valgus
189 angulation and mal-rotation.

190 Fracture geometry and the location is an important determinant for surgical outcome. In our
191 study, TEN gave excellent results in transverse, short oblique fractures. Transverse, short oblique
192 and minimally comminuted fractures are suitable for TEN as stated by Flynn et al and Narayanan
193 et al^{1,22}.

194 The chance of entry site irritation was the most common problem (25%) encountered in our
195 study as compared to other studies. Ligier et al observed 13 cases of skin ulceration or local
196 inflammatory reaction due to nail protrusion out of 123 cases²³. In our series, it could have been
197 avoided with proper selection of insertion site and proper advancement of the nail to lie against
198 the supracondylar flare. We had two cases of nail migration in the present series that probably

199 was caused due to the poor technique. Two cases of proximal migration were observed by
200 Karaoglu et al in the series of 31 femoral fractures stabilized with ender nails²⁴.

201 As we used two nails of same thickness after proper pre-bending we had varus angulation in
202 only four cases which would have been avoided with adequate bracing. This enlightens us that a
203 cautious approach is always needed in treating unstable fracture patterns and fractures in obese
204 children^{25,26,27}. So this mal-alignment can be overcome by additional plaster stabilization or by
205 traction or a brief period of bed rest or use of femoral brace. Limb length discrepancy was seen
206 in five cases in which three had angulation at the fracture site. Few more years of follow up will
207 be required before precise difference in lower limb extremities can be determined.

208 In our study, there was superficial infection at nail protruding site in four cases which would
209 have been accounted due to the poor hygienic activities. We had per-operative technical
210 difficulties in 10 cases where we had to open the fracture site due to failure of closed reduction
211 due to soft tissue interposition. This might be due to improper traction or splintage or due to
212 delayed surgery by associated injuries. In two cases we had cork screw phenomenon which was
213 deduced by image intensifier and replaced in correct manner.

214 We evaluated our clinical results using Flynn's criteria in our study. We had excellent results
215 in 40 children (83%) and satisfactory results in 8 children (17%). we did not have any poor
216 results. Our results were comparable to other studies which were done in similar manner viz,
217 Flynn et al, Narayanan et al^{1,22}. In our study nails were removed at end of one year as an
218 outpatient procedure under anesthesia, without any complication during or after the procedure.

219 This study had certain limitations as it was single centered, so the results should be generalized
220 with caution. We didn't compare other modalities of fixation with TEN. Long term results of the
221 treatment were not analyzed.

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223

224 **CONCLUSION:**

225 TEN is minimally invasive, safe, physal protective, relatively easy to use and an effective
226 treatment for fracture femur in properly selected children with minimal complications. Most of
227 the complications are in fact due to improper technique which can be eliminated by strictly
228 adhering to the basic principles and technical aspects. TENS used in children at 6 – 16 years of
229 age for femoral shaft fractures hastens fracture union, reduced amount of shortening and mal-
230 union as well as allows earlier rehabilitation along with return to school life with successive
231 functional outcome. We recommend TEN for pediatric femoral shaft fractures in children.

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233 **FOOT NOTES:**

234 Source of support: Nil

235 Conflict of interest: None

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237 **AUTHOR'S CONTRIBUTION:**

238 RG¹ and JJM wrote the paper. RG²,RG¹,SK reviewed the literature. RG¹ and SK were the main
239 operating surgeons in the whole series and critically reviewed the paper. JJM and SI maintained
240 all records of the patients and followed them. All authors read and approved the final manuscript.

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