

# “Unstable” Pediatric Femoral Shaft Fractures Treated With Flexible Elastic Nails Have Few Complications

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**Objectives:** To determine our complication rate in pediatric femoral shaft fractures treated with flexible elastic nailing and to determine fracture characteristics that may predict complications.

**Design:** Retrospective cohort study.

**Setting:** One Level 1 and One Level 2 academic trauma centers.

**Patients/Participants:** One hundred one pediatric femoral shaft fractures treated from 2006 to 2018.

**Main Outcome Measurement:** Major and minor complications.

**Results:** One hundred one femurs met inclusion criteria. The average age was 7 years (range 3–12 years). The average weight was 29.0 kg (range 16–55 kg). The average follow-up was 11 months (6–36 months). Ninety-three patients underwent elective implant removal at our institution. Fifty-one of the 101 (50%) fractures were “unstable” patterns. Ninety-three percent had implants that filled >80% of the canal (69 titanium and 32 stainless steel). Seventeen percent (18) had cast immobilization. All fractures went on to union. No patient required revision surgery for malunion as follows: 6 had coronal/sagittal malalignment >10 degrees, 3 had malrotation >15 degrees, and none had a leg length inequality >1 cm. Three patients had an unplanned surgery as follows: 2 for prominent implants and 1 for refracture after a second injury. There were no patient, fracture, or treatment characteristics that were predictive of complications or unplanned surgery, including “unstable” fractures ( $P = 0.78$ ).

**Conclusion:** Our study demonstrates that flexible elastic nailing can be safely used in most pediatric femoral shaft fractures, including those previously described as “unstable.”

**Key Words:** pediatric femur fracture, flexible elastic nail, pediatric femoral shaft fracture, pediatric femur fracture, flexible elastic nail, submuscular plate

**Level of Evidence:** Therapeutic Level IV. See Instructions to Authors for a complete description of levels of evidence.

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## INTRODUCTION

The group in Nancy, France, first described the successful use of flexible elastic nailing (FEN) of pediatric femoral shaft fractures in 1979.<sup>1</sup> The original series demonstrated good results in patients 5–14 years of age with all fracture patterns, including segmental, comminuted, oblique, spiral, and transverse. Later series have demonstrated increased complications after FEN in older and or heavier children.<sup>2–4</sup> Other studies have cited increased pin migration, leg length discrepancy, and malunion after FEN in “unstable” fracture patterns.<sup>2,3,5,6,17,18</sup> Currently, the American Academy of Orthopaedic Surgery (AAOS) guidelines recommend FEN in children 5–11 years of age with “length stable” femoral shaft fractures, citing comminution or shortening >2 cm as instability.<sup>7</sup> In many centers, FEN has been replaced by other implants, including external fixation, locked stainless steel nails, and submuscular plates in “length unstable” patterns.<sup>8–16</sup>

Despite the concerns with unstable femoral shaft fractures, the term “unstable” is poorly defined from fracture location, cortical comminution, obliquity of the fracture, or a combination.<sup>5,6,15,17</sup> As a result, reported outcomes are inconsistent.<sup>2,3,5,18–21</sup> Ultimately, much of the decision behind implant choice in “unstable” femoral shaft fractures is dependent on institutional preference and surgeon experience.

It has been our practice to use FEN for nearly all pediatric femoral shaft fractures based on age and weight, even in “unstable” fractures. The purpose of this study was to examine our results in pediatric femoral shaft fractures treated with FEN and to determine factors that may predict complications. We hypothesized that using FEN in “length unstable” fractures would not lead to adverse outcomes, including malunion, nonunion, and unplanned reoperation.

## PATIENTS AND METHODS

We conducted an institutional review board–approved retrospective review of skeletally immature patients 2–12 years of age with femoral shaft fractures treated with flexible

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elastic nails or submuscular plates between 2006 and 2018. All patients were treated by fellowship-trained orthopaedic trauma surgeons and underwent surgery at one of 2 trauma centers. Patients were followed until the fracture had healed or implant removal. Pathologic fractures, follow-up <6 months, and those treated nonoperatively or with rigid locked nails were excluded. Patients treated with submuscular plates were included for subgroup analysis to help mitigate any selection bias. Specifically, we wanted to determine if there was any difference in the fracture pattern in those patients treated with FEN.

Data were collected using medical records and imaging studies. Demographic data were collected, including sex, age, and weight. Injury characteristics included mechanism of injury, presence of open injury, or concomitant injury. Fracture characteristics were analyzed with imaging, including Winquist classification, OTA/AO fracture classification, location (proximal, middle, or distal third), and the novel use of a fracture instability ratio.<sup>22,23</sup> Murphy et al first described the ratio to correlate fracture obliquity with nonaccidental trauma. The numerator is the length of the fracture drawn from the most proximal and distal point. The denominator is the narrowest width of the shaft at the fracture site. A ratio 2.0 or greater was considered "unstable." Parameters considered "unstable" included proximal/distal, spiral fractures, butterfly segments, fracture ratio 2.0 or greater, or comminution with <50% cortical contact (Fig. 1).<sup>2,5,6,15,17</sup>

Two titanium or stainless steel elastic nails were placed using standard techniques.<sup>20,22</sup> The metallurgy was determined at the surgeon's discretion. Radiographic measurements were made preoperatively to choose implants that would fill 80% of the canal.<sup>18</sup> Postoperative weight-bearing status and immobilization varied on surgeon's discretion.

Information collected at follow-up included presence of pain, time until weight-bearing, gait pattern, hip and knee range of motion, clinical signs of leg length inequality or rotational inequality, and signs of implant irritation or infection. Standard physical examination techniques are performed in our clinics. Leg length discrepancy is evaluated clinically with progressive examination beginning with observing gait and standing pelvic tilt. This can be followed by leg length measurements from the anterior superior iliac spine to the medial malleolus, standing blocks, and a supine Galeazzi test to assess femoral length discrepancy. Rotational alignment is determined with foot progression angle and the differences in hip rotation with the hip flexed to 90 degrees

when compared with the contralateral hip. A scanogram is not used unless clinically suspicious, to limit radiation exposure.

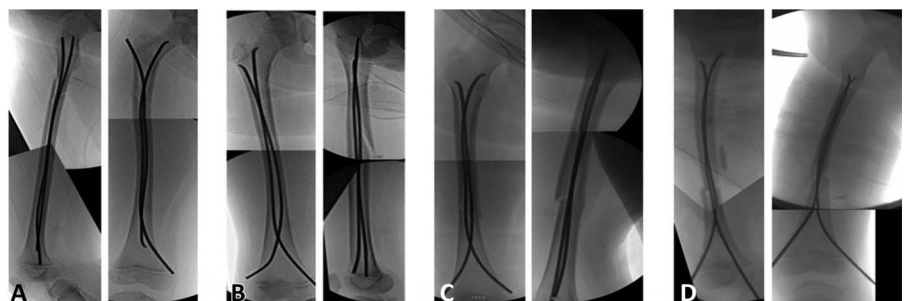
Anteroposterior and lateral radiographs of the femur were obtained at each follow-up visit. Final radiographic evaluation included frontal and sagittal alignment and union. Varus and valgus angulation was measured from the anatomic axis. Flexion and extension was measured with consideration of the normal anterior bow of the femur.

Complications were recorded if there was an unplanned return to the operating room, superficial or deep infection, symptomatic nail migration, malunion (sagittal or coronal >10 degrees, malrotation >15 degrees, and leg length discrepancy >1 cm), delayed union, or nonunion (t). Delayed union was defined as persistent pain with incomplete healing on radiographs 3 months after the index procedure.

### STATISTICAL METHODS

The primary outcome was defined as a composite indicator for major complications (yes/no) and was considered present if a patient experienced any of the following: unplanned return to operating room, nonunion, malunion, leg length discrepancy, or clinical malrotation. The primary predictor was unstable (yes/no), which was considered present if a patient had any of the following: proximal third fracture, distal third fracture, spiral fractures, butterfly segments, or fracture ratio 2.0 or greater, and comminution with <50% cortical contact. In addition, demographic characteristics (age, sex, and weight), injury characteristics (mechanism, high/low energy, open/closed, presence of additional injuries to head, chest, abdomen, upper extremity, ipsilateral, contralateral, or spine), fracture characteristics (Winquist category, OTA/AO classification, fracture location, and fracture length ratio), and treatment characteristics (treatment, nail diameter, metal [titanium vs. stainless steel], retrograde/antegrade, open/closed reduction, and immobilization) were also evaluated as potential predictors of complications. Categorical variables were required to have at least 10 patients per evaluated category, to be included in subsequent analyses.

Potential predictors of complications were evaluated with Fisher exact tests for categorical variables and *t* test or Wilcoxon Rank Sum for continuous variables. Stepwise logistic regression with backward selection was performed to identify independent predictors of poor outcomes. Variables with a *P* value of <0.20 in univariate analysis were



**FIGURE 1.** Unstable fracture patterns: (A) Proximal third, (B) spiral fracture, (C) butterfly fragment (OTA/AO B2/B3), and (D) comminution with <50% cortical contact (Winquist III/IV).

chosen as candidates for the logistic model. Significance was set at  $P < 0.05$ .

### RESULTS

There were 179 femur fractures that were initially reviewed. Forty-four were excluded because of intramedullary fixation with a rigid nail, 17 had less than 6 months of follow-up, 6 had pathologic fractures, and 2 had external fixation. There were 108 patients with 110 femur fractures that met all inclusions criteria. One hundred one fractures were treated with FEN and comprised our primary study group, and 9 were treated with submuscular plating and underwent separate subgroup analysis. Demographic and injury characteristics can be seen in **Supplemental Digital Content 1** (see **Table**, <http://links.lww.com/JOT/B134>). The average age was 7 years old (range 3–12 years) with an average weight of 29.0 kg (range 16–55 kg). The average follow-up was 11 months (6–36 months).

Approximately half of the fractures (51/101) were considered “unstable” patterns according to previously mentioned literature (Table 1). After surgery, 18 patients were supplemented with cast immobilization at surgeon’s discretion (12 long leg and 6 spica), with the remainder (N = 83) without cast immobilization (Table 2).

All fractures had union at final follow-up (see **Figures**, **Supplemental Digital Contents 2 and 3**, <http://links.lww.com/JOT/B135> and <http://links.lww.com/JOT/B136>, respectively). Ninety-three patients underwent planned, elective implant removal at our institution. The average coronal alignment was 1.11 degrees valgus (range 5 degrees varus to 10 degrees valgus), and the average sagittal alignment was 6.10 degrees procurvatum (range 5 degrees recurvatum to 25 degrees procurvatum). The average coronal alignment was 1.05 degrees valgus (range 0 degrees varus to 9 degrees valgus) for the stable group and 1.12 degrees valgus (range 5 degrees varus to 10 degrees valgus) for the unstable group. The average sagittal alignment was 6.73 degrees procurvatum (range 5 degrees recurvatum to 25 degrees procurvatum) for

the stable group and 7.18 degrees procurvatum (range 0–25 degrees procurvatum) for the unstable group. No patient required revision surgery for malunion as follows: 6 had coronal or sagittal malalignment >10 degrees, 3 had malrotation >15 degrees, and none had a leg length inequality >1 cm. Three patients (2.9%) had unplanned reoperations as follows: 2 for prominent implants and 1 for refracture after a second injury (Table 3).

There were no patient, fracture, or treatment characteristics that were predictive of complications or unplanned reoperation, including “unstable” fractures ( $P = 0.78$ , Table 4). The radiographic fracture length ratio was unable to predict which fractures would be more likely to have major complications after FEN ( $P = 1.00$ ).

Fracture characteristics of the 9 patients treated with submuscular plating is demonstrated in **Supplemental Digital Content 4** (see **Table**, <http://links.lww.com/JOT/B137>), and the complications are demonstrated **Supplemental Digital Content 5** (see **Table**, <http://links.lww.com/JOT/B138>).

### DISCUSSION

The definition of “unstable” as a descriptor for pediatric femoral shaft fractures varies in the literature. The AAOS guidelines define “length unstable” as comminuted fractures or spiral fractures with shortening >2 cm.<sup>7</sup> Allen et al reported similar outcomes between “length stable” and “length unstable” fractures, with “length unstable” defined as those with comminution or fracture length greater than shaft width.<sup>24</sup> To the contrary, Sink et al<sup>5</sup> found 66% of “length unstable” fractures required unplanned surgery. In Sink et al’s study, “length unstable” was defined as comminuted or fracture length greater than 2 times the diaphyseal width. Narayanan et al<sup>6</sup> reported an increased rate of malunion and

**TABLE 1.** Fracture Characteristics

Winquist Classification	
0 to 2 (>50% cortical contact)	94 (93%)
3 or 4 (<50% cortical contact)	7 (7%)
OTA/AO fracture classification	
A1	24 (25%)
A2	15 (16%)
A3	49 (51%)
B2	7 (7%)
B3	1 (1%)
Location	
Proximal	17 (17%)
Midshaft	76 (75%)
Distal	8 (8%)
Fracture obliquity ratio, mean (range)	1.9 (1–6)
Ratio >2.0	32 (32%)
Ratio 0–1	69 (68%)

**TABLE 2.** Treatment Characteristics

Implant Technique	
Nonlocked FEN	95 (99%)
Locked FEN	1 (1%)
Canal fit ratio	
<0.8	7 (7%)
>0.8	93 (93%)
Implant metallurgy	
Titanium	66 (69%)
Stainless steel	30 (31%)
Retrograde versus anterograde	
Retrograde alone	92 (96%)
1 retrograde, 1 anterograde	4 (4%)
Open versus closed reduction	
Open	3 (3%)
Closed	97 (97%)
Postoperative immobilization	
None	66 (69%)
Knee immobilizer	14 (15%)
Long leg cast	12 (12%)
Spica cast	4 (4%)

**TABLE 3. Complications**

Major Complications	12 (12%)
Coronal malalignment >10 degrees	1 (1%)
Sagittal malalignment >10 degrees	5 (5%)
Clinical malrotation >15 degrees	3 (3%)
LLD >1 cm	0 (0%)
Nonunion	0 (0%)
Unplanned reoperation	3 (3%)
Deep infection	0 (0%)
Minor complication	15 (15%)
Pin migration/symptomatic implant	14 (14%)
Superficial infection	1 (1%)
LLD, leg length discrepancy.	

unplanned surgeries with comminuted fractures but no increased risk with fracture location of obliquity. Others have identified proximal fracture patterns as "unstable" patterns.<sup>17,18</sup> Li et al<sup>18</sup> retrospectively compared proximal fractures treated with FEN versus submuscular plate and reported a 48% overall complication rate in the FEN group compared with 14% in the submuscular plate group.

Other studies have reported increased angular deformities and overgrowth with "length stable" transverse fracture patterns. Staheli et al in 1967 demonstrated the concept of accelerated growth of the fractured femoral shaft. In the series of 84 patients treated under closed means followed for on average 6 years, 48% of the anatomically reduced femur shafts demonstrated overgrowth of >1 cm, whereas only 11% of comminuted and oblique fractures with 0.5–1.5 cm of initial shortening went on to have a leg length discrepancy.<sup>20</sup> Ligier et al<sup>1</sup> in their original series describing FEN suggested that some shortening may be advantageous to compensate for the accelerated growth seen after femoral shaft fractures.

FEN is now the most common method of fixing pediatric femoral shaft fractures since its advent decades ago in Nancy, France. As a result, our understanding of the technical aspects and its limitations has been better defined. Weight has been reported as an independent predictor of malunion and unplanned surgery in children receiving FEN.<sup>2</sup> Canal fit less than 80% and nail mismatch are associated with complications after FEN.<sup>6,19</sup> We feel that our series offers an advantage to previously described studies whose results may have been confounded by inconsistent adherence to these

**TABLE 4. Association of Major Complications With Unstable Fracture Patterns**

	No	Yes	P
Unstable fracture pattern	44	7	0.78
Fracture length ratio >2.0	27	3	1.00
Winquist 3 or 4	6	1	1.00
OTA/AO B or C	7	1	1.00
Proximal fracture	13	4	0.12
Distal fracture	7	1	1.00

parameters. All but 2 patients in our series who underwent FEN were <49 kg in adherence with the AAOS recommendations.<sup>6</sup> Both weighed <55 kg and both went on to union without unplanned reoperation. One developed a sagittal malalignment >10 degrees that did not require surgery. Riccio et al recently showed that stainless steel Ender's nails in patients >100 lbs does not result in significant differences in malunion, malalignment, or shortening when compared with a lighter cohort.<sup>25</sup> Six patients did not meet the goal of maximizing canal fit using the 0.8 ratio as previously described. Of these 6 patients, 3 had a symptomatic or migrating implant that did not require an unplanned surgery before union. Of these 3 patients, 1 had stainless steel FEN. A recent study of 261 children undergoing FEN with stainless steel nails showed no correlation between the >0.8 ratio and radiographic outcome, alignment, or complication.<sup>26</sup>

We were not able to predict major complications in "unstable" fractures treated with FEN with our fracture length ratio. Instead, the results of our study suggest most previously described "unstable" fractures can be successfully treated with FEN. FEN has several noted advantages over other implants used for pediatric femur fractures, including external fixation, submuscular plating, and rigid nails. External fixation has yielded good results with pediatric femur fractures but has its own complications, including knee stiffness, pin site infections, and an increased refracture rate after removal.<sup>27,28</sup> Rigid locked nailing is limited to children with canals wide enough for a rigid implant and those older than 10 years to increase the likelihood of separation of the trochanteric apophysis from the proximal femoral physis to prevent premature physeal arrest resulting in coxa valgus.<sup>29</sup> Submuscular plating has grown increasingly popular with good outcomes but is associated with increased costs, operative time, and blood loss.<sup>24</sup> When reviewing those patients in our series with submuscular plating, 5 of the 9 had open reduction of the fracture opposed to a true percutaneous submuscular technique. Sagittal deformity occurred in 3 patients but did not require revision surgery, and a symptomatic implant was present in 2 patients. Complication rates were similar between our submuscular plating subgroup and our patients treated with FEN. There was a trend for submuscular plating being used for very distal fractures near the physis.

There are several limitations to this study. Ideally, the patients would have been followed until skeletal maturity, but this is not the standard of care in our system. However, it has been reported that there is no significant change in leg length discrepancy once a fracture has healed.<sup>20</sup> We were unable to determine if patients went on to have additional or corrective surgery at another center, but given our regional practice pattern, this would have been unlikely. Postoperative immobilization varied by surgeon, and its influence on outcomes could not be determined. Routine full length standing scanograms would have been the most precise method of determining length discrepancies. However, its use was limited to when there was clinical suspicion to avoid unnecessary radiation exposure to the child. There is a selection bias given the retrospective nature of the study. To mitigate the selection bias we also analyzed the patients that underwent submuscular plating. Ten patients treated with FEN were younger than

5 years that is contrary to current AAOS guidelines—3 were polytrauma patients, and FEN was performed to limit casting; 5 patients had patterns that the surgeon felt could not be controlled with a cast, and 2 patients, both 4 years of age, had undocumented reasons.

There were also certain potential predictive variables that we were unable to evaluate due to inadequate sample sizes in at least one category. It is possible that we may have been underpowered to evaluate some of the other factors we did consider. In particular, sex (men vs. women), low/high energy, mechanism of injury, and potentially the canal filling ratio showed differences that may become significant with substantially larger sample sizes. For the primary question of whether there are differences in major complication rates between stable and unstable fractures, we observed a 5.6% difference between the groups (12% vs. 17.6%). In a post hoc power analysis, it was estimated that a total sample size of  $n = 1262$  patients ( $n = 631$  per group) would be necessary to find a significant difference in composite major complications between patients with “stable” and “unstable” fracture patterns based on this study sample. Given the low incidence of this type of injury, this would likely only be accomplished through a large, multisite study over a couple of decades.

## CONCLUSIONS

Our study demonstrates that FEN can be safely used in most pediatric femoral shaft fractures, including those previously described as “unstable.” The previously reported complications can be minimized with strict adherence to patient selection (weight <49 kg) and proper surgical technique. Although not all pediatric femoral shaft fractures may be amenable to FEN, we found no significant difference in patient, fracture, or treatment characteristics that were predictive of complications or unplanned reoperation, including previously described “unstable” fracture patterns.

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