Early complications with flexible intramedullary nailing in childhood fracture: 100 cases managed with precurved tip and shaft nails

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Summary
Background and purpose: Diaphyseal and metaphyseal fractures in children are frequently treated with the flexible intramedullary nailing (FIN) method. The aim of this study was to record postoperative complications and outcome in consecutive fracture patients treated with the new precurved tip and shaft nails and dedicated ergonomic instrumentation.

\textbf{Methods:} We report the analysis of 100 consecutive fractures followed up for a minimum of 6 months. Ninety-seven children were included, comprising 77 shaft and 23 metaphyseal fractures. Demographic data, duration of surgery, nail and medullary canal diameter, date of nail removal, clinical assessment, follow-up radiographs and all complications were recorded.

\textbf{Results:} Mean age was 9.7 years, and mean body weight 35.1 kg. Twenty-one fractures had associated lesions. Mean duration of surgery was 42.4 minutes. Nail removal was at a mean 6.1 months. Twelve percent of patients had complications, with six insufficient reductions, one delayed union, one non-union, one iterative fracture, and three skin impingements. Unexpected surgical revision was required in seven cases. At follow-up, only one patient showed functional impairment, with 20° pronation loss, and three showed more than 10° axial deviation on X-ray.

\textbf{Conclusion:} The low rate of skin impingement compared with the literature may be due to the new dedicated instruments. We believe that other complications can be avoided if one follows the FIN principles, avoiding weak assembly due to an insufficient nail/medullary canal diameter ratio, which is a limiting factor for indications in adolescents. The surgeons reported that precurved shaft nails facilitated the FIN procedure, although this subjective judgment may be due simply to the novelty of the nails.

\textbf{Level of evidence:} Level IV. Retrospective study.

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Introduction

Flexible intramedullary nailing (FIN) was first described in Spain for the management of forearm fracture in children [1]. The technique and its applications were subsequently widely developed in France [2–7]. It is applied in diaphyseal and certain metaphyseal long-bone fractures in children. Initially, fractures were osteosynthesized using straight stainless steel nails of various diameters, with the surgeon having to curve the tip and shaft. Several manufacturers then developed nails with the tips precurved to facilitate introduction in the medullary canal; the shaft still had — and still has — to be curved by the surgeon so that the summit of the curve is at the fracture site at the end of assembly [8–12]. In shaft fracture, blunt nails can slip into the medullary canal, whereas in metaphyseal fracture sharp nails provide better penetration into the metaphyseal-epiphyseal cancellous bone.

Novel nails have recently been developed (T2 Kids®, Stryker Trauma, 24232 Schönkirchen, Germany), with a "classic" precurved tip, tapered so as to combine the properties of a blunt nail with effective cancellous penetration, adapted to both diaphyseal and metaphyseal fractures. The proximal part is also precurved, enabling the surgeon simply to continue the curvature so as to position the summit at the level of the fracture (Fig. 1) [13].

New ergonomic instruments have also been developed:

- a nail-bending instrument, used for altering the curvature of large-diameter nails;
- a slotted hammer that can slide along the nail when it is fixed to the T-handle;
- and two cannulated impactors to push the nail at the end of the operation so as to leave a sufficiently long end above the bone surface for later removal but without inducing skin impingement.

The present prospective observational study concerned 100 consecutive fractures managed using these T2 Kids® titanium nails. Patients were followed up for at least 6 months. The objective was to inventory postoperative complications and assess outcome using these novel nails.

Patients and methods

Study design

One hundred consecutive diaphyseal and metaphyseal fractures in 97 children were managed by FIN. Five surgeons, with experience ranging from resident to senior surgeon level, operated these cases in our center between January 2009 and December 2010, following the technique described in the manuals [14,15]. There was no postoperative immobilization.

Inclusion criteria were: femoral (Fig. 2), forearm (Fig. 3), tibial or humeral shaft fracture, or proximal humeral, supracondylar humeral, radial neck and subtrochanteric femoral metaphyseal fracture. Presence of growth plate was a further necessary inclusion criterion.

Exclusion criteria were: pathologic fracture associated with bone tumor, cerebral palsy, neuromuscular disorder, or osteoporosis.

Preoperative data were: age, gender, weight, fracture site, trauma mechanism, associated lesions and fracture level and type. Peroperative data were: nail insertion direction (anterograde or retrograde), medullary canal diameter at the isthmus, nail diameter, duration of surgery from skin incision to closure, and need to approach the fracture site. Any departure from FIN principles was also noted. Assembly factors such as nail intersection at fracture level or nail orientation causing angulation were judged defective. According to recommendations, the nail/medullary canal diameter ratio (ND/MCD) was meant to be greater than 40% for the femur, tibia and forearm and greater than 33% for the humerus.

Postoperative data were: duration of hospital stay and date of nail removal (which was performed in all the patients followed-up). Other routinely recorded data were range of motion in neighboring joints and radiologic axes of the fractured bones at a minimum 6 months' follow-up.

All complications were inventoried: skin impingement, insufficient reduction, stiffness, angulation, recurrent fracture, infection, non-union or any need for surgical revision. Insufficient reduction was defined as greater than 10° alignment defect in the coronal, sagittal or horizontal plane before onset of malunion; joint stiffness, as greater than 5° elbow or knee extension deficit or greater than 20° loss of shoulder, wrist, hip or ankle range of motion; malalignment, as greater than 10° angulation in any plane after bone consolidation; recurrent fracture, as a new fracture during follow-up at the same level as the primary; and surgical revision, as any fracture-related surgical procedure following FIN, other than to remove material.

Patient data

Table 1 presents patient data according to fracture type. Sixty-five boys and 32 girls presented with 100 fractures: 77 diaphyseal and 23 metaphyseal. Mean age at trauma was 9.7 years (SD, 3.2), median 9.6 years, range 3.5–15.2 years. Mean body weight was 35.1 kg (SD, 15.6), median 30 kg, range 15–77 kg. The right side was involved in 49 and the left in 51 cases.

Trauma mechanism was a fall in 69 patients, a motor-vehicle accident in 25, and direct trauma in three.

Seventy-nine of the 97 patients presented with isolated fracture, seven with multiple trauma, six with associated cranial lesion and five with another associated long-bone fracture. One boy with multiple trauma had four fractures...
Complications with FIN in childhood fracture

Figure 2  Transverse left femur fracture in a girl aged 10.8 years, 30 kg (a). Retrograde FIN, 3.5 mm nails, ND/MCD ratio 39% (b). Lateral radiograph (c). 1-month X-ray (d). 10-month X-rays (e, f).

Figure 3  Open Gustilo I mid-shaft fracture of both forearm bones, in a 13 year-old girl, 48 kg. Anterograde ulnar and retrograde radial FIN, 2.5 mm nails, ND/MCD ratio 63% for radius and 71% for ulna (a, b). Two-month X-ray (c). Nine-month X-ray (d).

managed by FIN: right humerus and left femur, tibia and forearm.

Ten of the 100 fractures were open: six forearm, four tibial (six Gustilo I, four Gustilo II). In five distal humeral shaft or supracondylar humeral fractures there was associated transitory nerve lesion. Two tibial fractures required immediate fasciotomy for associated compartment syndrome. Four forearm fractures were iterative.

Statistics

Descriptive statistics comprised mean, standard deviation (SD), median and range for patient data, osteosynthesis and operative data, and date of material ablation.

Ethics

The study conformed to the French national recommendations of the ethics committees for human clinical research, in line with the 1975 Declaration of Helsinki as revised in 2000.

Results

Results according to fracture type are shown in Table 2. FIN insertion techniques for anterograde, retrograde and mixed nails were respected. One hundred and ninety two titanium nails were inserted. Diameters were: 1.5 mm
Table 1  Patient data according to fracture type.

<table>
<thead>
<tr>
<th>Fracture</th>
<th>Number</th>
<th>Sex ratioM/F</th>
<th>Age (yrs)m ± SD</th>
<th>Weight (kg)m ± SD</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Shaft</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Humerus</td>
<td>11</td>
<td>4.5</td>
<td>9.7 ± 3.2</td>
<td>34.7 ± 12.6</td>
</tr>
<tr>
<td>Radius and Ulna</td>
<td>30</td>
<td>4.3</td>
<td>10.7 ± 2.9</td>
<td>38.0 ± 15.3</td>
</tr>
<tr>
<td>Radius</td>
<td>3</td>
<td>3M</td>
<td>11.2 ± 5.7</td>
<td>47.0 ± 30.5</td>
</tr>
<tr>
<td>Ulna</td>
<td>2</td>
<td>2F</td>
<td>9.5 ± 2.1</td>
<td>25.5 ± 7.8</td>
</tr>
<tr>
<td>Femur</td>
<td>16</td>
<td>1.0</td>
<td>7.9 ± 2.4</td>
<td>28.5 ± 14.4</td>
</tr>
<tr>
<td>Tibia</td>
<td>15</td>
<td>4.0</td>
<td>10.6 ± 3.7</td>
<td>39.6 ± 18.4</td>
</tr>
<tr>
<td><strong>Metaphysis</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proximal humerus</td>
<td>9</td>
<td>0.5</td>
<td>10.8 ± 3.4</td>
<td>37.5 ± 16.5</td>
</tr>
<tr>
<td>SC humerus</td>
<td>10</td>
<td>1.5</td>
<td>7.1 ± 2.4</td>
<td>25.8 ± 6.9</td>
</tr>
<tr>
<td>Radius neck</td>
<td>3</td>
<td>2.0</td>
<td>8.3 ± 3.9</td>
<td>31.3 ± 17.0</td>
</tr>
<tr>
<td>ST femur</td>
<td>1</td>
<td>1F</td>
<td>9.1</td>
<td>25.0</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>100</td>
<td>2.1</td>
<td>9.7 ± 3.2</td>
<td>35.1 ± 15.6</td>
</tr>
</tbody>
</table>

m: mean; SD: standard deviation; SC: supracondylar; ST: subtrochanteric.

(n = 1), 1.75 mm (n = 4), 2 mm (n = 32), 2.25 mm (n = 39), 2.5 mm (n = 44), 3 mm (n = 34), 3.5 mm (n = 26) and 4 mm (n = 12). Table 2 shows mean ND/MCD ratio per fracture type. Surgery time varied between fracture types; mean duration was 42.4 (SD, 16.0) min, median 40 min, range 15–80 min.

Median hospital stay was 2 days (range, 1–13 days); mean stay was 3.7 days (SD, 3.1) for fractures in general, and 2.5 days (SD, 1.4) for the 77 isolated fractures.

Three patients were lost to follow-up. All 94 patients followed-up had revision for material ablation, at a median 6.3 months (range, 1.5–14 months; mean, 6.6 months [SD, 3.0]).

Complications

Six shaft fractures showed reduction defect: in one femoral fracture, in a girl aged 10.8 years and weighing 30 kg, the two nails were in varus; and in two distal humerus, two tibial and one femoral fracture, the ND/MCD ratio was too small (Table 3).

There was delayed union in one forearm fracture in a 15 year-old boy weighing 64 kg operated on via an approach at the level of the radial fracture site.

There was non-union in a girl aged 13.6 years and weighing 40 kg, with open (Gustilo II) tibial fracture; 5-months’ X-ray showed no signs of bone consolidation.

Malunion or delayed or defective consolidation exclusively involved diaphyseal and never metaphyseal fractures.

There were no postoperative infectious complications.

One boy, aged 5.8 years and weighing 20 kg, had recurrent fracture: he initially presented with four shaft fractures (humerus, forearm, femur and tibia) due to a car crash, managed by FIN; 6 months later, he again sustained a tibial fracture in a second accident.

Table 2  Results according to fracture type.

<table>
<thead>
<tr>
<th>Fracture</th>
<th>ND/MCD (%)</th>
<th>Surgery time (minutes)</th>
<th>Hospital stay (days)</th>
<th>Time to ablation (months)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Shaft</strong></td>
<td>m ± SD</td>
<td>m ± SD</td>
<td>m ± SD</td>
<td>m ± SD</td>
</tr>
<tr>
<td>Humerus</td>
<td>30 ± 6</td>
<td>42.0 ± 7.9</td>
<td>2.9 ± 3.1</td>
<td>4.6 ± 1.2</td>
</tr>
<tr>
<td>Radius and Ulna</td>
<td>51 ± 15</td>
<td>44.4 ± 17.8</td>
<td>2.5 ± 2.0</td>
<td>8.2 ± 2.1</td>
</tr>
<tr>
<td>Radius</td>
<td>52 ± 21</td>
<td>26.7 ± 5.8</td>
<td>3.0 ± 3.5</td>
<td>7.7 ± 1.9</td>
</tr>
<tr>
<td>Ulna</td>
<td>50 ± 7</td>
<td>25.0 ± 7.1</td>
<td>2.0 ± 0.0</td>
<td>7.4 ± 1.8</td>
</tr>
<tr>
<td>Femur</td>
<td>37 ± 5</td>
<td>44.7 ± 13.4</td>
<td>6.6 ± 3.5</td>
<td>6.1 ± 1.4</td>
</tr>
<tr>
<td>Tibia</td>
<td>33 ± 6</td>
<td>40.0 ± 14.8</td>
<td>5.1 ± 4.1</td>
<td>7.1 ± 3.2</td>
</tr>
<tr>
<td><strong>Metaphysis</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proximal humerus</td>
<td>34 ± 6</td>
<td>47.3 ± 19.9</td>
<td>2.8 ± 2.4</td>
<td>4.7 ± 2.3</td>
</tr>
<tr>
<td>SC humerus</td>
<td>29 ± 5</td>
<td>38.0 ± 11.6</td>
<td>3.0 ± 1.2</td>
<td>4.0 ± 1.1</td>
</tr>
<tr>
<td>Radius neck</td>
<td>49 ± 8</td>
<td>25.0 ± 13.2</td>
<td>2.0 ± 0.0</td>
<td>2.5 ± 1.0</td>
</tr>
<tr>
<td>ST femur</td>
<td>37</td>
<td>30.0</td>
<td>3.0</td>
<td>8.4</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>39 ± 13</td>
<td>42.4 ± 16.0</td>
<td>3.7 ± 3.1</td>
<td>6.4 ± 2.6</td>
</tr>
</tbody>
</table>

ND/MCD: nail diameter/medullary canal diameter; m: mean; SD: standard deviation; SC: supracondylar; ST: subtrochanteric.
Complications

There were three skin lesions implicating the nail; in two of these, the dedicated impactors had not been used and the end of the nail was too long.

There were no tendon tears.

To sum up, unexpected surgery was required in seven cases of ‘major’ or ‘minor’ revision. The four major revisions comprised two FIN substitutions by intramedullary locking nail and two FIN replacements. Two of the three minor revisions were for excessively long subcutaneous nail ends, and the other for repeat fracture requiring closed manipulation.

Outcomes

Material was removed at a mean 12.1 months’ follow-up (SD 4.6, median 12.2, range 6.0–28.3 months) in the 94 patients with FU. Neighboring joint ranges of motion were conserved and symmetrical in 93 patients; one patient with forearm fracture with delayed union showed 20° pronation loss at 1 year. All the fractures followed-up showed union, with less than 10° angulation on X-ray in 94 out of 97 fractures. There were three malunions: 10° and 20° varus in two humeral fractures and 10° recurvatum in one tibial fracture.

Discussion

The rate of complications in femoral [6,16–28], tibial [29–31] and forearm [4,32–40] shaft fracture can be as high as 50% in certain series. The present series showed 12 complications, mainly associated with less experienced surgeons, confirming the existence of a learning curve [16].

The sharp end of nails sectioned under the skin may induce different types of complication. Skin irritation at the nail end mainly concerns femoral fracture, at a rate of 3.3 to 50% [3,12,17–19,26]. There were three cases in the present series. Superficial or deep infection was reported in 3.4% of femoral and 8% of tibial fractures [31]. There were also reports of postoperative knee synovitis [41]. Tendon tear was reported in cases of a distal radial approach [42]. To avoid these problems, certain authors recommend using protective caps [43]. We recommend using a ‘guillotine’ nail cutter, to provide a clean and blunt cut. Cannulated impactors can be used to push the nail at the end of the operation while still leaving a long enough end beyond the bone surface for subsequent removal, without risking soft tissue irritation: the protruding nail should be 7–12 mm for the femur and tibia and 3–5 mm for the humerus, radius and ulna; the dedicated impactors enable this to be achieved.

Shaft fracture

Wall et al. reported 23.2% malunion in femoral fracture with titanium nails and 6.3% with stainless steel nails [25]. Other factors of malunion have been reported: body-weight [22], fracture type (stable or unstable) [17,19] and unsuitable nail diameter [19]. Failure to respect FIN principles is the main cause of reduction defect [28]. In the present study, one femoral fracture showed immediate postoperative varus deformity due to misalignment of the nails. It is essential at the end of the operation to check perfect reduction, horizontally as well as frontally and laterally, to avoid rotational deformity [23].

Another important cause of bone malalignment is failure to respect an optimal ND/MCD ratio, although the relation to reduction defect has never been properly assessed. In the present series, five cases of more than 10° reduction defect were associated with less than 30%ND/MCD ratio.

Consolidation delay was reported in tibial [29] and ulnar [37,39] fracture. In the present study, a 14 year-old girl, weighing 40 kg, with open comminutive grade II tibial

<table>
<thead>
<tr>
<th>Fracture</th>
<th>Age (yrs)</th>
<th>Weight (kg)</th>
<th>ND/MCD (%)</th>
<th>Treatment</th>
<th>Evolution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Femur</td>
<td>10.8</td>
<td>30</td>
<td>39</td>
<td>Nail change at d1</td>
<td>Very favorable</td>
</tr>
<tr>
<td>Femur</td>
<td>8.1</td>
<td>26</td>
<td>30</td>
<td>Nail change at d30</td>
<td>Very favorable</td>
</tr>
<tr>
<td>Tibia</td>
<td>14.8</td>
<td>70</td>
<td>24</td>
<td>IMLN</td>
<td>Very favorable</td>
</tr>
<tr>
<td>Tibia</td>
<td>6.4</td>
<td>21</td>
<td>24</td>
<td>None</td>
<td>Recurvatum 10°</td>
</tr>
<tr>
<td>Humerus</td>
<td>6.9</td>
<td>27</td>
<td>22</td>
<td>None</td>
<td>Varus 10°</td>
</tr>
<tr>
<td>Humerus</td>
<td>13</td>
<td>30</td>
<td>22</td>
<td>None</td>
<td>Varus 20°</td>
</tr>
<tr>
<td>Delayed consolidation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Forearm</td>
<td>15</td>
<td>64</td>
<td>32–36</td>
<td>None</td>
<td>Consol @ 9 mo</td>
</tr>
<tr>
<td>Non-union</td>
<td>13.6</td>
<td>40</td>
<td>38</td>
<td>IMLN</td>
<td>Very favorable</td>
</tr>
<tr>
<td>Iterative fracture</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tibia</td>
<td>5.8</td>
<td>20</td>
<td>29</td>
<td>Manip. under GA</td>
<td>Very favorable</td>
</tr>
<tr>
<td>Skin lesion</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ulna</td>
<td>11.9</td>
<td>62</td>
<td>61</td>
<td>Early abl.</td>
<td>Very favorable</td>
</tr>
<tr>
<td>Humerus</td>
<td>6.8</td>
<td>21</td>
<td>35</td>
<td>Scheduled abl.</td>
<td>Very favorable</td>
</tr>
<tr>
<td>Tibia</td>
<td>12.9</td>
<td>52</td>
<td>32</td>
<td>Nail recut</td>
<td>Very favorable</td>
</tr>
</tbody>
</table>

IMLN: intramedullary locking nail; consol: consolidation; manip: manipulation; abl: nail ablation.
fracture showed delayed union. This type of fracture should be considered to be a contraindication for FIN [30]. Another case of delayed union was observed in the forearm, associated with 36% ND/MCD ratio in the radius and 32% in the ulna. In the present series, there were no cases of delayed union associated with a ratio exceeding 40%; we therefore recommend a 40% threshold for the femur, tibia, radius and ulna and 33% for the humerus [44]. There may be iterative fracture before nail ablation in case of renewed trauma. In one such case in the present series, the new fracture was treated by closed reduction under general anesthesia, to straighten the deformed nails.

Metaphyseal fracture

FIN has often shown excellent results in proximal humeral [45], supracondylar humeral [46], radial neck [47,48] and subtrochanteric femoral [49] fracture. In the present series, the tapered end of the nail provided easier insertion into the metaphysis. Unlike in shaft fracture, there were no cases of defective or delayed union or of non-union in the metaphyseal fractures.

Surgical technique

The surgeons involved in the study reported that precurving facilitated the procedure. In metaphyseal fracture, nail curvature did not need altering as the nails were positioned divergently in the shaft or epiphysis. In shaft fracture, the summit of the curve was adapted by the surgeon so as to be positioned at the level of the fracture site. The regular shaft curvature radius set by the precurving was continued along the nail. Assessment of shaft precurvature, however, remains totally subjective and studies with various types of nail will be needed to assess the associated complications and surgery durations.

Conclusion

The present preliminary study reports results using precurved nails in long-bone fracture in children. Dedicated instrumentation facilitated surgery, providing a low rate of skin impingement. Reduction defects, consolidation problems and malunions were mainly secondary to an inadequate nail/medullary canal diameter ratio. Further studies will be needed to confirm the relation between such consolidation defects and low ND/MCD ratios.

In shaft fracture, we would stress strict respect of recommendations in positioning the nails and selecting their diameters. Thus, too great a medullary canal diameter may contraindicate the FIN technique. It is especially important to improve the quality of results as the incidence of surgery for pediatric fracture is on the rise [50,51].

Disclosure of interest

PL: Conferences: invitations as a presenter for Stryker.

The other authors have not supplied their declaration of conflict of interest.

References

Complications

Weinberg
Garg
Mittal
Luhmann
Srivastava
Kubiak
Gordon
Sagan
Khazzam
Salem


