

# Associated injury complicated by pediatric lower limb shaft fractures and clinical efficacy of flexible stainless-steel intramedullary nailing in children less than 15 years old

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## Abstract

Although pediatric lower limb shaft fractures are common, little is known about associated injuries. The purpose of this study was to examine associated injuries complicated by pediatric lower limb shaft fractures and the efficacy of surgical treatment using a flexible stainless-steel intramedullary Ender nail in children less than 15 years old. This is a retrospective review of 29 children younger than 15 years old who were diagnosed with femoral or tibial shaft fractures and treated using Ender nails from 2005 to 2016. Baseline data, etiology, associated injuries, fracture site and patterns, operative and post-operative assessment were evaluated. The average age of the patients was 9.0 years, and mean follow-up was 18.2 months. Eleven patients (79%) had associated injury. At the final follow up, six patients (43%) sustained complications associated with the insertion area of the nail. There was no evidence of deep infection or nonunion at either fracture site. The clinical results were excellent in 10 (67%) fractures, and good in 5 (33%) fractures, based on the modified Flynn criteria. Almost all patients with a femoral fracture had an associated injury including abdominal visceral injury, cerebral contusion or other fractures. This study indicated good clinical and functional outcomes. On the other hand, the minor complications rate was high. Nevertheless, elastic stable intramedullary nailing recently has become available in Japan, and a prospective and comparative study is needed.

## Introduction

Femoral and tibial shaft fractures are common in pediatric orthopedic trauma. Epidemiological population-based studies in the United States have found that femoral shaft fractures account for about 62.5% of femoral fractures, with an incidence of 19 fractures per 100,000 children between 1998 – 2000 and these frequently occur in males aged 0-3 years old.<sup>1</sup> Tibial shaft fractures represent 15% of pediatric long-bone fractures in the United States, the second most common pediatric trauma injury.<sup>2,3</sup>

These fractures are generally treated by closed reduction and cast immobilization.<sup>4</sup> However, in the case of fractures which are open, unstable, and associated with multiple or neurovascular injuries, either open or closed surgical treatment may be required to achieve stable internal and external fixation. We were confronted by this situation in an adult patient, and supported the rigid fixation using an intramedullary nail. However, in pediatric patients this treatment may be counter-indicated because it exposes the epiphyseal plate to a potential risk for injury and subsequent growth impairment. Considering available surgical options,<sup>5</sup> intramedullary nailing has been used widely in pediatric lower limb shaft fractures.<sup>6,7</sup> Furthermore, the association of injury in children with femoral fracture has been reported in epidemiological population-based studies.<sup>1</sup> If life threatening complications that should be given priority treatment are encountered with these fractures, pre-operative treatment may have important implications.

This study investigates associated injuries complicated by pediatric lower limb shaft fractures and the efficacy of surgical treatment using flexible stainless steel intramedullary Ender nails in children less than 15 years old for femoral and tibial shaft fractures.

## Materials and Methods

The medical records of 29 children under 15 years old who were diagnosed with femoral or tibial shaft fractures at Kimitsu Central Hospital (Kisarazu city, Chiba, Japan) between January 2005 and December 2016 were analyzed retrospectively. All procedures performed in studies involving human participants were in accordance with the ethical standards approval of the institutional review board and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Informed consent was obtained from

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all patients who took part in this study and from their parents. Exclusion criteria for this study included patients who were 15

years old or older, were not followed until removing the nail, received surgical procedures other than Ender nailing or non-operative treatment, were transferred to our hospital post-operatively from a different institution with the aim of rehabilitation, or had pathologic fractures. Finally, a total of 14 patients (11 femoral, 2 tibial and 1 combined) were treated with Ender nailing. The definitive indication for surgical intervention using Ender nailing was difficulty with adequate alignment in cast immobilization. Baseline data were obtained retrospectively from the medical records and radiographs. All patients were screened for age at the time of injury, sex, height (cm), weight (kg), affected side, etiology, associated injuries, fracture site, fracture patterns and presence of an open fracture. Fracture patterns were classified based on principles of the AO pediatric comprehensive classification,<sup>8</sup> and open fractures were classified based on criteria from Gustilo and Anderson.<sup>9</sup>

### Operative procedure and assessment

All patients placed in the supine position on a standard table under general anesthesia. The affected limbs were cleaned and draped without a tourniquet. Adequate debridement surgery and cleaning with saline solution were performed for open

fractures. We demonstrated whether the fracture was reducible or not under fluoroscopic monitoring. If a closed reduction was not possible, an open reduction was indicated. A 2.0 cm incision was made on the medial and lateral sides proximal to the distal femoral growth plate or proximal tibial growth plate to the entry points marked under fluoroscopic monitoring. A cortical hole was made with a 2.0 mm K-wire and a drill bit 3.2 to 4.5 mm in diameter. Fractures were fixed with two nails (flexible stainless steel intramedullary nail, Ender nails, MIZUHO Medical Innovation, Japan) bending to fit the intramedullary cavity with appropriate length and diameter using fluoroscopic monitoring. They were inserted in retrograde fashion across the femoral fracture, and in anterograde fashion for the tib-

ial fractures. Finally, the nail tips were seated on the bone surface after the nail positions and total alignment of the fracture were confirmed. After hemostasis, layered closure was performed. Pre-operative treatment and surgery waiting periods were evaluated from the medical records. Operative records were used to estimate the reduction type to be performed during surgery and the diameter and length of the Ender nail.

### Post-operative management and assessment

Post-operatively, plaster splints were applied immediately. However, they were removed as soon as the local swelling and pain subsided. Partial weight bearing was started 4 weeks postoperatively after evi-

**Table 1. Acceptable angulation in children with femoral and tibia fracture.**

	Age (years)	Varus (deg)	Valgus (deg)	Anterior (deg)	Posterior (deg)
Femur	6 to 10	10	10	15	15
	11 to maturity	5	5	10	10
Tibia	< 8	10	5	10	5
	≥ 8	5	5	5	0

deg: degrees.

**Table 2. Baseline characteristics of the patients.**

	Sex	Age yrs	Ht cm	Wt kg	Femur/Tibia	Etiology	Side	Site	G-A class	AO class	Associated injury
1	M	11	150	45	Femur	Motor vehicle accident	R	Mid 1/3	Closed	32D/5.1	Ipsilateral radius Fx, Contralateral forearm Fx
2	M	7	115	22	Femur	Motor vehicle accident	R	Mid 1/3	Closed	32D/5.1	Ipsilateral tibia Fx
3	M	10	140	53	Femur	Motor vehicle accident	L	Pro 1/3	Closed	32D/4.1	Lung injury, Liver injury
4	M	7	119	24	Femur	Motor vehicle accident	L	Pro 1/3	Closed	32D/5.1	None
5	M	9	130	27	Femur	Motor vehicle accident	L	Dis 1/3	Closed	32D/4.2	Ipsilateral humerus and fibulaFx, Contralateral distal femoral epiphyseal injury Liver injury
6	M	10	139	49	Femur	Motor vehicle accident	R	Mid 1/3	Closed	32D/4.2	Brain injury, Lung injury
7	M	8	125	21	Femur	Motor vehicle accident	R	Mid 1/3	I	32D/4.1	R humerus Fx and Radial nerve palsy, Liver injury, Traumatic pancreatitis
							L	Pro 1/3	I	32D/4.2	
8	F	8	130	22	Femur	Motor vehicle accident	L	Dis 1/3	Closed	32D/5.1	Ascites
9	M	8	121	20	Femur	Motor vehicle accident	R	Mid 1/3	Closed	32D/5.1	Ipsilateral rib Fx, Subdural hematomas of frontal lobe, Traumatic pneumothorax, Lung injury, Liver injury
10	M	13	155	40	Femur	Motor vehicle accident	R	Mid 1/3	Closed	32D/4.2	Skull Fx, Lung injury
11	M	10	146	58	Femur	Fall from a height	L	Mid 1/3	Closed	32D/4.2	Bilateral distal radial Fx
12	M	8	118	23	Femur Tibia	Motor vehicle accident	R	Pro 1/3	Closed	32D/5.1	Ipsilateral rib and olecranon Fx Liver injury
							R	Mid 1/3	Closed	42D/5.1	
13	M	7	125	26	Tibia	Motor vehicle accident	L	Mid 1/3	II	42t-D/4.1, 42f-D/1.1	None
14	F	10	130	30	Tibia	Motor vehicle accident	R	Dis 1/3	Closed	42D/4.2	None

dence of a bridging callus was detected on radiographs. Full weight bearing was allowed 6-8 weeks post-operatively when there was evidence of increasing bridging callus. The disappearance of the fracture line on the radiographs was considered a sign of union. The nail was routinely removed in a subsequent operation after achieving radiographic evidence of bone union. Residual deformity of the femur or tibia was assessed on anteroposterior and lateral radiographs at the final follow-up based on the guidelines set by Rockwood and Wilkins' fractures in children,<sup>10,11</sup> and is presented in Table 1. Post-operative time until bone union, implant removal, final follow-up, any complications (superficial or deep infection, nail migration, skin irritation, keloid scars, mal-union  $\geq 5^\circ$ , nonunion, and limb length discrepancy (LLD)  $\geq 10$ mm) and clinical results were documented. LLD was assessed by measuring side to side differences from the anterior superior iliac spine to the medial malleolus in the supine position at the final follow-up. Clinical results were evaluated at the final follow-up, using the criteria defined by Flynn *et al.*<sup>12</sup> These criteria were modified and complications classified based on previous reports<sup>13,14</sup> as follows: minor complications were skin-tissue irritations, keloid scars, superficial infections, and any other complications that did not disturb walking or lead to long-term morbidity; major complications were deep infections, nonunion, and any other complication not classified as minor that led to long-term morbidity.

### Statistical analysis

Student's t-tests were used to compare the time to bone union or implant removal between patients less than 10 years old and those 10-14 years old. The Fisher exact probability test was used for dichotomous data. A value of  $P < 0.05$  was considered significant. All calculations were made using R software, version 3.4.1 (R Development Core Team).

## Results

A total of 14 patients (12 boys and 2 girls) met the criteria for inclusion in this study. The baseline characteristics of the patients enrolled are summarized in Table 2. The mean age at injury was 9.0 years (range, 7 to 13 years). The mean height and weight were 131.6 cm (range, 115 to 155 cm) and 32.9 kg (range, 20 to 58 kg), respectively. The most common cause of injury was a motor vehicle accident. Eleven patients (79%) had associated injury, including seven (50%) ipsilateral fractures,

five (36%) abdominal visceral injuries, five (36%) lung injuries or rib fractures and two (14%) brain injuries or subdural hematomas. Eleven patients (92%) with a femoral shaft fracture had associated abdominal visceral injury, cerebral contusion or other fractures. The locations of femoral fractures included the middle third (54%), proximal third (31%) and distal third (15%), and for tibial fractures included the middle third (67%) and distal third (33%). Thirteen (81%) fractures were closed and three (19%) were open fractures. In the latter, two were graded as type I in the femur, and one was graded as type II in the tibia based on the Gustilo and Anderson classification.<sup>9</sup> According to the AO pediatric comprehensive classification, the types of fractures were as follow: 32D/5.1 in 6 fractures

(38%), 32D/4.2 in 5 fractures (31%), 32D/4.1 in 2 fractures (13%), 42D/4.2 in 1 fracture (6%), 42D/5.1 in 1 fracture (6%), and 42t-D/4.1, 42f-D/1.1 in 1 fracture (6%).

Table 3 summarizes the pre-operative and intra-operative treatments including the characteristics of the nail. The mean surgical waiting time for all fractures was 3.2 (range, 0-9) days. Open reduction using K-wire or Schanz screw during the operation was required in 33% of femoral fractures.

Post-operative assessments are summarized in Table 4. The mean duration of follow-up was 18.2 (range, 8 to 36) months (Figures 1 and 2). There was no significant difference between patients less than 10 years old and those 10 years and older in time to union ( $P=0.125$ ) or to implant removal ( $P=0.714$ ). Radiographic evalua-

**Table 3. Pre-operative and intra-operative outcomes with the characteristics of the nail.**

Parameters	Femur (n = 12)	Tibia (n = 3)
Preoperative type of treatment (n (%))		
Direct traction	8 (66.7)	0 (0)
Indirect traction	3 (25.0)	1 (33.3)
External fixation	1 (8.3)	0 (0)
Plaster slab	0 (0)	2 (66.7)
Surgical waiting time (days)	3.8 $\pm$ 2.6	1.0 $\pm$ 1.0
Nail diameter (mm)		
3.0	13 (54.2)	6 (100)
3.5	9 (37.5)	0 (0)
4.0	2 (8.3)	0 (0)
Mean	3.2 $\pm$ 0.3	3.0 $\pm$ 0
Nail length (mm)	266.2 $\pm$ 41.3	226.7 $\pm$ 25.8
Reduction type (n (%))		
Closed	8 (66.7)	3 (100)
K-wire	3 (25.0)	0 (0)
Schanz screw	1 (8.3)	0 (0)

Mean values  $\pm$  the standard deviation.

**Table 4. Post-operative outcomes.**

Parameters	Femur (n = 12)	Tibia (n = 3)
Bone union (weeks)	27.9 $\pm$ 5.7	29.2 $\pm$ 9.7
Implant removal (months)	10.3 $\pm$ 2.8	9.0 $\pm$ 2.6
Follow-up (months)	19.5 $\pm$ 7.6	13.0 $\pm$ 4.6
Complications (n (%))		
Superficial infection	1 (8.3)	0 (0)
Deep infection	0 (0)	0 (0)
Nail migration	1 (8.3)	0 (0)
Skin irritation	1 (8.3)	1 (33.3)
Keloid scars	1 (8.3)	1 (33.3)
Mal-union $\geq 5^\circ$	4 (33.3)	2 (66.7)
LLD $\geq 10$ mm	1 (8.3)	0 (0)
Result (n (%))		
Excellent	9 (75.0)	1 (33.3)
Good	3 (25.0)	2 (66.7)
Poor	0 (0)	0 (0)

Mean values  $\pm$  the standard deviation, LLD: limb length discrepancy.



tion for femoral fractures at the last follow-up included 7 fractures (54%) with varus angulation and a mean angle of 2.0 (range, 1 to 3) degrees, and 3 patients (23%) with valgus angulation and a mean angle of 3.3 (range, 1 to 6) degrees in the anteroposterior plane. Eleven (84%) fractures had anterior angulation with a mean angle of 4.2 (range, 2 to 8) degrees. One (8%) fracture had neutral angulation and one (8%) had a posterior angulation of 4.0 degrees in the lateral plane. All tibial fractures had valgus angulations, with a mean angle of 4.0 (range, 3 to 5) degrees in the anteroposterior plane. One (33%) fracture had neutral angulation, and 2 (67%) fractures had posterior angulation with a mean angle of 3.0 (range, 1 to 5) degrees in the lateral plane.

Four (33%) patients with femoral fractures and 2 (67%) with tibial fractures had complications associated with the insertion area of the nail (Figure 3). One (8.3%) patient had tibiofibular synostosis in a fracture in the distal third of the tibia (Figure 4). No deep infections or non-unions were reported for any fracture.

Based on the modified Flynn criteria, excellent clinical results were obtained in 10 (67%) fractures, and good results in 5 (33%) fractures. There was no significant difference between patients younger than 10 years old and those 10 years of age or older ( $P=0.329$ ).

## Discussion

To the best of our knowledge, there are few previous reports in Japan about the efficacy of using Ender nails for femoral and tibial shaft fractures in children less than 15 years old. This study suggests that the outcome of treatment using Ender nails in children younger than 15 years old is favorable. Interestingly, almost all patients with a femoral fracture had associated injury included abdominal visceral injury, cerebral contusion and other fractures. These findings suggest that life threatening complications may be encountered and should be given priority treatment. The incidence of minor complications such as skin-tissue irritation, keloid scars or superficial infection in the present series was higher than previous reports of treatment using intramedullary nailing.<sup>13,15-17</sup> On the other hand, we observed no major complications in this study. Pre-operative treatment to prevent shortening of limbs, to improve soft tissue conditions, and to maintain alignment may have important implications for subsequent internal fixation using an intramedullary nail.

Standard treatment strategy for pediatric lower limb shaft fractures traditionally has involved non-operative treatment with closed reduction and cast immobilization.<sup>4</sup> However, in cases of open fractures, unstable fractures that are difficult to maintain adequate alignment, or those associated with multiple or neurovascular injuries, the surgical strategy should be to achieve stable fixation. In accordance with the considerations above, operative treatments using various fixation methods have been performed. Although internal fixation with a plate<sup>18</sup> and external fixation<sup>19</sup> have been popular procedures, flexible intramedullary nailing recently has been a commonly used fixation technique for long bone fractures in children<sup>12,20</sup> because flexible intramedullary nailing has advantages for more rapid healing, low refracture rate and low infection rate.<sup>7</sup> Ender, an Austrian surgeon from the

University of Vienna first introduced Ender nails for fixation of peri-trochanteric fractures in 1969.<sup>21</sup> Accumulating clinical evidence reported the successful use of Ender nails in children with femoral and tibial shaft fractures.<sup>16,22</sup> The advantages of a flexible stainless steel intramedullary nail like an Ender nail lie in the fact that adequate internal fixation can be obtained, decreasing the potential risk of injuring the epiphyseal plate, and stimulating bone healing and callus formation at the fracture site by allowing micromotion. Second, this technique is minimally invasive, preserving the biological environment in case open reduction is not necessary. Hence, operative scarring is minimized, and early cast removal and mobilization are generally accepted.<sup>16,22</sup> On the other hand, the disadvantages are skin irritation including superficial infection, implant migration and the necessity for



**Figure 1** A 7-year-old boy with closed femoral shaft fracture (AO classification: 32D/5.1). (A) Preoperative anteroposterior and lateral radiographs. (B) Immediately postoperative anteroposterior and lateral radiographs. (C) 6 months after surgery, anteroposterior and lateral radiographs. (D) 3 years after surgery, final follow up, anteroposterior and lateral radiographs.

additional surgery for implant removal.

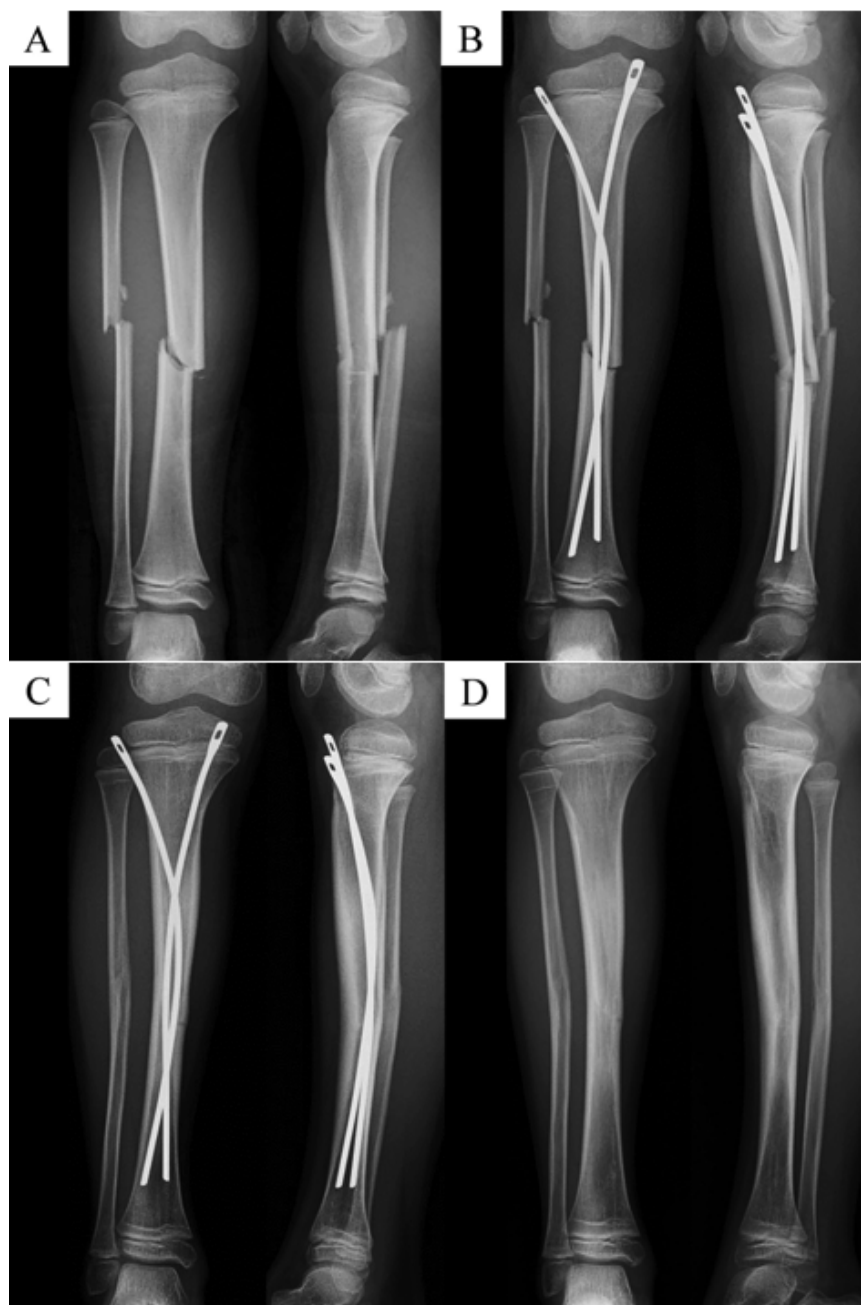
Little is known about associated injuries in pediatric lower limb shaft fractures. According to epidemiological population-based studies, associated injuries complicated by pediatric femoral fracture occur in 28.6% of cases, and are present in nearly 70% of cases as a result of motor vehicle accidents.<sup>1</sup> In addition, Heo *et al.* reported an incidence of 37.5% for associated injuries complicated by tibial shaft fractures in children up to 10 years.<sup>14</sup> Our findings demonstrate that the rate of associated injuries is higher than previously reported because our study examined only patients who underwent operations in which injuries were caused by high-energy trauma. If life threatening complications that should be given priority treatment are encountered with these fractures caused by high-energy trauma, pre-operative treatment and management may have important implications.

A Review of the previous literature indicates that flexible nailing for pediatric lower limb shaft fractures has yielded excellent bone union.<sup>16,23</sup> Several factors associated with bone union have been reported. Flynn *et al.* recommended that an appropriately sized nail diameter should be 40% of the diameter of the narrowest portion of the medullary canal.<sup>12</sup> Narayanan *et al.* further reported that using two nails of different diameters should be avoided.<sup>24</sup> A systematic review in management of pediatric femoral fractures shows that the relationship between material properties and time to union remains a controversial issue.<sup>25</sup> In our study, the mean time to union was about double compared to previous reports because union was defined as the disappearance of the fracture line on radiographs.<sup>16,20,23,24,26</sup> However, bone union using an Ender nail may allow a consistent and acceptable outcome regardless of age in children. Several studies have shown that the incidence of complications associated with skin or soft tissue irritation at entry points ranges between 10% and 38%.<sup>13,15-17</sup> In our study, 6 (43%) of 14 patients experienced a high incidence of complications that included superficial infection, skin irritation, keloid scars and nail migration. One patient had a second surgery to remove the nail. No patients had symptoms associated with superficial infection or skin irritation immediately after surgery. Post-surgically, minor complications may be influenced by gait training and range of motion exercises that were started with a goal to improve activity level after reducing painful swelling. Furthermore, the design of the end of the nail plays an important role in these complications.<sup>16,24</sup> Current elastic stable intramedullary nailing (ESIN) is designed

with an end cup to prevent pull out of the nail. The Ender nail has an eye (hole) at its end to facilitate nail removal but not to prevent pull out. Therefore, it is important that the surgeons choose the optimal nail length and minimize the prominence of nail protrusion.

Malunion is another important complication. Acceptable alignment at the time of union was based on the guideline in Table 1.<sup>10,11</sup> Our radiographic results show that the residual deformity of the femur and tibia

compare consistently and favorably with this guideline, except for the posterior angle in tibial fractures. A number of studies have examined clinical results following the criteria defined by Flynn and reported good clinical results for both femoral and tibial fractures.<sup>14,16,17,26</sup> Goyal *et al.* reported that the clinical outcome using stainless steel elastic nails (SEN) was significantly better than outcomes with titanium elastic nails (TEN); different material properties may account for this difference. In addition,



**Figure. 2** An 8-year-old boy with closed tibial shaft fracture (AO classification: 42D/5.1). (A) Preoperative anteroposterior and lateral radiographs. (B) Immediately postoperative anteroposterior and lateral radiographs. (C) 6 months after surgery, anteroposterior and lateral radiographs. (D) 10 months after surgery, anteroposterior and lateral radiographs.

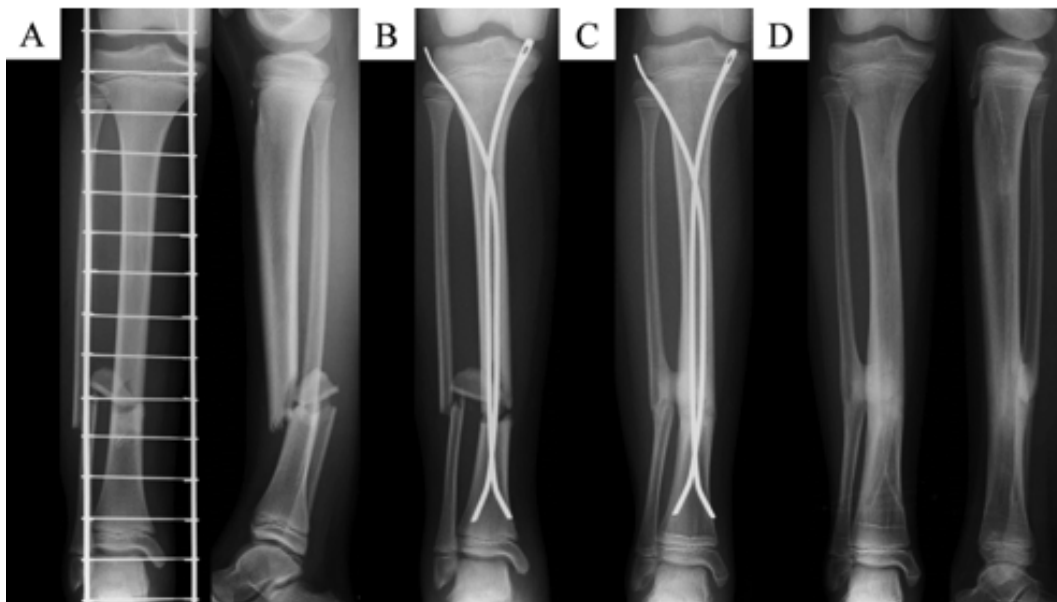
Gyaneshwar *et al.* reported a high incidence of puncture of the opposite cortex intraoperatively and low costs of stainless-steel nails compared with titanium nails.<sup>27</sup> The clinical results have been influenced greatly by major complications including excessive LLD, nonunion and deep infection. An LLD of 17 mm was measured at the final follow-

up in one 10-year-old patient, probably due to hyperactivity around the fracture and bone remodeling. Although this is not acceptable considering the guidelines set by Rockwood and Wilkins' fractures in children,<sup>10</sup> this patient had few clinical symptoms, and did not limp. Moroz *et al.* suggested children older than 11 years and

heavier than 49 kg are more likely to have complications or a poor outcome.<sup>13</sup> Mini-review of treatment options and outcome showed higher age and higher weight were associated potential risk factors for poor outcomes of treatment for displaced long bone fractures and lead us to conclude that there is insufficient data regarding treat-



**Figure. 3** A 10-year-old boy with closed femoral shaft fracture (AO classification: 32D/4.2). (A) Pre-operative anteroposterior radiographs. (B) Immediately post-operative anteroposterior radiographs. (C) 3 months after surgery, the medial nail had backed out and (D) then was removed. (E) Anteroposterior radiographs 15 months after surgery.



**Figure. 4** A 10-year-old girl with closed tibial shaft fracture (AO classification: 42D/4.2). (A) Preoperative anteroposterior and lateral radiographs. (B) Immediately postoperative anteroposterior radiographs. (C) 6 months after surgery, tibiofibular synostosis was detected with union. (D) Anteroposterior radiographs 14 months after surgery.



ment for children weighing 50 kg or more.<sup>28</sup> Our study indicated that clinical and functional outcomes were satisfactory for both femoral and tibial fractures regardless of age. However, the incidence of minor complications defined more broadly than the original Flynn criteria was higher than previous reports.

Our findings should be interpreted in the context of several limitations. First, the design was a retrospective case study in which we did not compare a control treatment with other intramedullary fixation devices or techniques such as ESIN, or immobilization alone. Further prospective studies are necessary to compare with ESIN, which has become available recently in Japan. Furthermore, we cannot exclude selection bias because fixation was decided by individual physicians. Second, because the study was limited to a single-center in Chiba prefecture, the sample size was relatively small and the study may be underpowered. Finally, mal-rotation in radiography was not evaluated. The acceptable mal-rotation angle based on the guideline set by Rockwood and Wilkins' fractures in children is narrower than varus and valgus angles in children.

## Conclusions

In conclusion, there are associated injuries with fracture that need priority treatment. The results of this study indicate good clinical and functional outcomes in pediatric femoral and tibial shaft fracture. On the other hand, the minor complications rate with Ender nails was high and careful post-operative follow-up should be considered. Nevertheless, because ESIN has become available only recently in Japan, a prospective and comparative study is needed to confirm the results of our study.

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