


CLINICAL ARTICLE

Elastic Stable Titanium Flexible Intramedullary Nails Versus Plates in Treating Low Grade Comminuted Femur Shaft Fractures in Children

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Objectives: To review the experience at our center with elastic stable titanium flexible intramedullary nails (ESIN) for pediatric femoral shaft unstable fractures.

Methods: From January 2015 to January 2017, 56 consecutive patients with femur shaft fractures were treated in our hospital. History and radiologic parameters were retrospectively reviewed. The inclusion criteria were: femur shaft fractures treated by ESIN or locking compressing plates (LCP); more than 2 years' follow-up care; and complete clinical information. A total of 51 patients were included according to the criteria: 16 girls and 35 boys. Ages at operation averaged 5.9 ± 2.8 years. Outcome: anteroposterior (AP) and lateral X-ray radiographs were performed every 2 weeks before the fracture healing, every 3 months until 1 year, then once a year after the surgery. Clinical examinations were recorded for any clinical deformity, hardware prominence, pain, and infection. ESIN were applied in either a retrograde or an antegrade fashion for 29 patients. For 22 patients, LCP were implanted. For the remaining 5 cases, instruments other than ESIN and LCP were applied.

Results: The average follow-up time was 29 months (range, 24–37 months). The average operation time was 78.2 min (range, 25–155 mins). The average blood loss in surgery was 69.6 mL (range, 3–700 mL). The average healing of fracture time was 2.2 month (range, 1–6 months). The average removal of implants time was 7.8 months (range, 3–20 months). The average expense for index operation was CNY 31 100 (CNY 17 500–142 200). Comminution grades were strongly correlated with time to fracture union ($P < 0.001$, $r = 0.53$) and time to implant removal ($P = 0.006$, $r = 0.38$). For comminuted pattern, the operation time and blood loss during operation in LCP were significantly higher than those in ESIN ($P = 0.037$ and $P = 0.006$, respectively). Other clinical parameters were similar between the two groups. No clinically detectable LLD, rotational or angular deformity was found. All patients recovered full knee range of motion. In this series, 30 patients (59%) had complications; 26 minor complications (51%) did not require unplanned surgery, most of which were prominence of hardware; 4 patients (8%) had a major complication and underwent an unplanned surgery. Of these, 2 were refractures distal to primary fracture and 2 were intolerable prominence of ESIN.

Conclusions: Elastic stable intramedullary nails provide equivalent outcomes but decreased operative time and blood loss during surgery, and lower hospitalization cost in treating low-grade comminuted femur shaft fracture compared with plating techniques. The results of this study support the use of ESIN over plates in low-grade comminuted femur shaft fractures despite the fact that both options are indicated.

Key words: comminuted fracture; femoral fracture; flexible intramedullary fixation; pediatric

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Introduction

Femoral shaft fractures account for <2% of all fractures in children¹. The mechanism is typically high-energy trauma, such as a fall from a height or motor vehicle collision. The fractures are located in the diaphysis, and surgical intervention is typically necessary². A variety of methods have been introduced to treat pediatric femur fractures, including spica casting, traction followed by spica casting, internal fixation with plate, intramedullary nailing, and external fixation. Little controversy exists in the immediate hip spica casting of femur fractures in patients under 3 years old, while no consensus has been reached in other age groups. Controversy exists regarding the most optimal surgical treatment for femoral shaft fractures in children³. The treatment should be decided based on age, fracture location and pattern, associated injuries, socioeconomic situation, as well as the preference of surgeons⁴.

The appropriate management of length-unstable femoral fractures is still a debatable issue. Skeletal traction followed by spica casting is a viable choice. However, this procedure has been largely abandoned because of excessive hospital stay and unfavorable quality of life⁵. External fixation is a simple way to maintain anatomic alignment for a femur fracture, but complications are quite common, such as refracture, increased time to union, and pin tract infections⁶.

During the past two decades, flexible intramedullary nailing has become a popular choice for the fixation of femoral shaft fractures in children⁷. This technique, adapted from existing flexible rodding techniques, was developed in Nancy, France⁸. Flexible nailing offers many advantages, including minimal invasiveness, short hospital stays, early mobilization, and fewer complications. The elastic stable intramedullary nails (ESIN) have been distinguished from other flexible nail systems such as Ender nails. The latter are not sufficiently elastic for children's fractures, and tend to straighten the normal bony curvature. For length-stable (transverse and short oblique patterns) femoral fracture patterns, ESIN has been widely accepted as an appropriate choice. Moreover, ESINs avoid femoral head osteonecrosis and premature greater trochanteric epiphysiodesis secondary to rigid intramedullary techniques. The use of ESINs in unstable fractures remains somewhat controversial. Some authors have advocated that titanium elastic nail stabilization of unstable fracture patterns in children is correlated with high rates of angular and rotational deformity⁹. Ellis asserts that Ender nails are one of the only flexible implants in which screws can be used to control implant backout and prevent shortening of the fracture site¹⁰. Some other authors support submuscular bridge plating in the management of length-unstable femur fractures¹¹.

There are basically two types of ESIN techniques: the retrograde technique and the antegrade technique. The former involves one medial and one lateral incision just above the distal femoral physis. The entry points are created, medially and laterally, by drilling a hole in the distal metaphysis of the femur. The nails are then driven through the canal of

the femur until the proximal metaphysis and the femoral neck. The nails are bent into a double C pattern. Most reported complications are problems with skin irritation due to the distal ends of the nails protruding. The antegrade technique involves a single incision around the level of the greater trochanter of the femur. This approach obviates the complications around the knee. The entry portals can be either through the greater trochanter apophysis or just inferior to the greater trochanter. The flexible nails are introduced downwards in the femoral canal until just proximal to the distal epiphysis. Nails are bent into C and S patterns.

Plating techniques have been a popular alternative to ESIN and were primarily indicated in length-unstable fracture patterns or patients weighing over 49 kg. The benefits of plates include a lower incidence of malunion, stronger axial and torsional stability in loading, and the limited exposure of the submuscular technique¹². In addition, plate osteosynthesis allows stable fixation with good results in the pediatric population¹³. Traditional plates require extensive exposure with soft tissue disruption. Minimally invasive plating and submuscular techniques have evolved to reduce soft tissue dissection.

Comminuted long bone fractures are unstable and require surgery even in children. Reconstruction of these fractures is usually difficult. Winquist introduced the classification of comminuted femoral fractures¹⁴. In this classification, lower grades mean more intact cortex and less fragmentation. Our hypothesis was that in lower grade comminution, ESIN were capable of maintaining angular and rotational stability by virtue of a more intact cortex.

Up till now, no studies have directly compared the use of plating and ESIN in the setting of length-unstable femur fractures in children, especially the comminuted type. This study aimed: (i) to review the experience at our center with elastic stable intramedullary nailing of pediatric femoral shaft unstable fractures; (ii) to compare the efficacy and outcomes between ESIN and plates in treating length-unstable fractures of the femur; and (iii) to evaluate the cost-effectiveness of ESIN in the index surgery of fracture reduction. With the results of this study, we expect to add valuable evidence to decision-making when treating children with length-unstable femur fractures.

Methods

A total of 56 consecutive patients with femur shaft fractures were treated in our hospital from January 2015 to January 2017. History and radiologic parameters were retrospectively reviewed. The inclusion criteria followed the PICOS principle: (i) patients with femur shaft fractures treated in our center; (ii) the fracture was treated by ESIN and LCP; (iii) comparison, with the operation time, blood loss, outcome, and expense compared between the ESIN group and the LCP group; (iv) outcome (similar results of long-term outcome between the ESIN and LCP groups should be expected); and (v) study design (retrospective study). Exclusion criteria: (i) pathologic fractures and

fractures second to metabolic conditions; (ii) open fractures; and (iii) patients treated with other internal fixation techniques.

Fractures were classified as transverse, comminuted, or oblique. Transverse fractures were regarded as stable type. Comminuted or oblique fractures were regarded as unstable type. Oblique fractures were identified if the length of the fracture line was more than twice the diameter of the femur. Spiral fractures were recorded as oblique fractures. The diameter of the femoral diaphysis measured by computer on the digital radiographs was also recorded. Comminuted fractures were graded according to the Winquist classification. Grade 0 was defined as no fragmentation at the fracture site, grade I as fragmentation less than 25%, grade II as 25% to 50%, grade III as 50% to <75%, and grade IV as 75% to 100%.

Three senior surgeons performed the operations in the same fashion. The choices of implants were based on the preference of the operators. ESIN (Synthes USA, Paoli, PA) were applied in either a retrograde or an antegrade fashion for 29 patients. For the remaining 22 patients, LCP (Dabo China, Xiamen, China) was implanted. Details including operation duration, blood loss, and nail diameters were recorded.

The operations were performed under general anesthesia. The fracture was reduced by fluoroscopy guidance. Basically, close reduction was attempted at first. When close reduction was unsuccessful, a small incision at the level of the fracture would be made to assist reduction. Two nails of the widest diameter that could pass the narrowest width of the medullary canal were introduced. The nail ends were cut short and left adjacent to the supracondylar flare of the distal femur.

A single leg spica was used for immobilization for all patients until healing of the fracture could be confirmed at follow-up. AP and lateral X-ray radiographs were performed every 2 weeks before the fracture healing, every 3 months up to 1 year, then once a year after the surgery. Sagittal angulation, coronal valgus, and lower limb discrepancy were measured. Clinical examinations were recorded for any clinical deformity, hardware prominence, pain, and infection.

Surgical Technique

The operations were performed under general anesthesia. The patient was placed on an orthopaedic table in supine position. The senior surgeon chose the implants according to his preference and the type of femur fracture. ESIN (Synthes USA, Paoli, PA) were applied in either a retrograde or an antegrade fashion for 29 patients. For the rest of the 22 patients, LCP (Dabo China, Xiamen, China) was implanted.

When using ESIN, the fracture was reduced by traction with fluoroscopy guidance. Basically, close reduction was attempted at first. When close reduction was unsuccessful, a small incision at the level of fracture would be made to assist reduction. For the retrograde technique, two nails of the widest diameter that could pass the narrowest width of the

medullary canal were introduced from the distal femur metaphysis with small incision approaches bilaterally. The nail ends were cut short and left adjacent to the supracondylar flare of the distal femur. For antegrade fashion, a small incision was made at the level of the great trochanter and two nails were introduced just below the great trochanter.

When using LCP, a lateral approach was used. After exposure and reduction of the fracture, LCP was placed with at least 2 screws both above and below the fracture line. Once the internal fixator was placed, reduction was confirmed by fluoroscopy.

Outcome

A single leg spica was used for immobilization for all patients until heal of fracture could be confirmed at follow-up. AP and lateral X-ray radiographs were performed every 2 weeks before the fracture healing, every 3 months up to 1 year, then once a year after the surgery. Sagittal angulation, coronal valgus, and lower limb discrepancy were measured. Clinical examinations were recorded for any clinical deformity, hardware prominence, pain, and infection.

Fracture Healing

Fracture healing is a recapitulation of bone development, which involves a complex interaction of multiple cell types and cellular processes. Fracture healing was confirmed by both standard of clinical healing and radiologic healing. Clinically, tenderness and longitudinal percussion pain should be absent, with full weight bearing on the limb without pain. Radiologically, X-ray should show that the fracture line is vague or absent and there is a continuous callus through the fracture line and bridging callus in at least three cortices. Delayed union was defined as the persistence of bone pain and tenderness 3 months after the fracture without complete radiological union. Nonunion was defined as the absence of osseous union more than 6 months after the injury.

Sagittal and Coronal Angulation

Angulation was defined as the formation of an abnormal angle or bend on the femur. The angle between two lines was measured on lateral view and accepted as sagittal angulation, and anterior angulation was regarded as positive. Line A was from the internal point to the greater trochanter to the midshaft point and line B was from the intercondylar fossa to the midshaft point. Coronal angulation was measured in a similar way on the AP view and lateral angulation was regarded as positive. Angular malalignment was defined as an angulation of $>10^\circ$ in the coronal plane or $>15^\circ$ in the sagittal plane.

Lower Limb Discrepancy

Leg length discrepancy, or anisomelia, is defined as a condition in which the paired lower extremity limbs have a noticeably unequal length. On the AP view of the pelvis, the LLD was measured as

TABLE 1 Demographics of patients

Parameters	Values
Gender (male/female)	35/16
Age (years)	5.90 ± 2.77 (3–14)
Weight (kg)	23.95 ± 11.12 (12–67)
Height (cm)	119.10 ± 18.40 (90–168)
Body mass index (kg/m ²)	16.49 ± 5.52 (10.8–39.5)

the perpendicular distance between a line passing through both teardrop points medial to the acetabula to the corresponding tip of the lesser trochanter. A positive LLD value was used when the operated limb was longer than the contralateral side, while a negative value indicated the opposite. LLD greater than 2 to 2.5 cm can potentially have an adverse effect on our walking and standing mechanisms and requires proper correction involving surgical treatment. In children's femur fractures, slight LLD secondary to overgrowth of the fracture site is common.

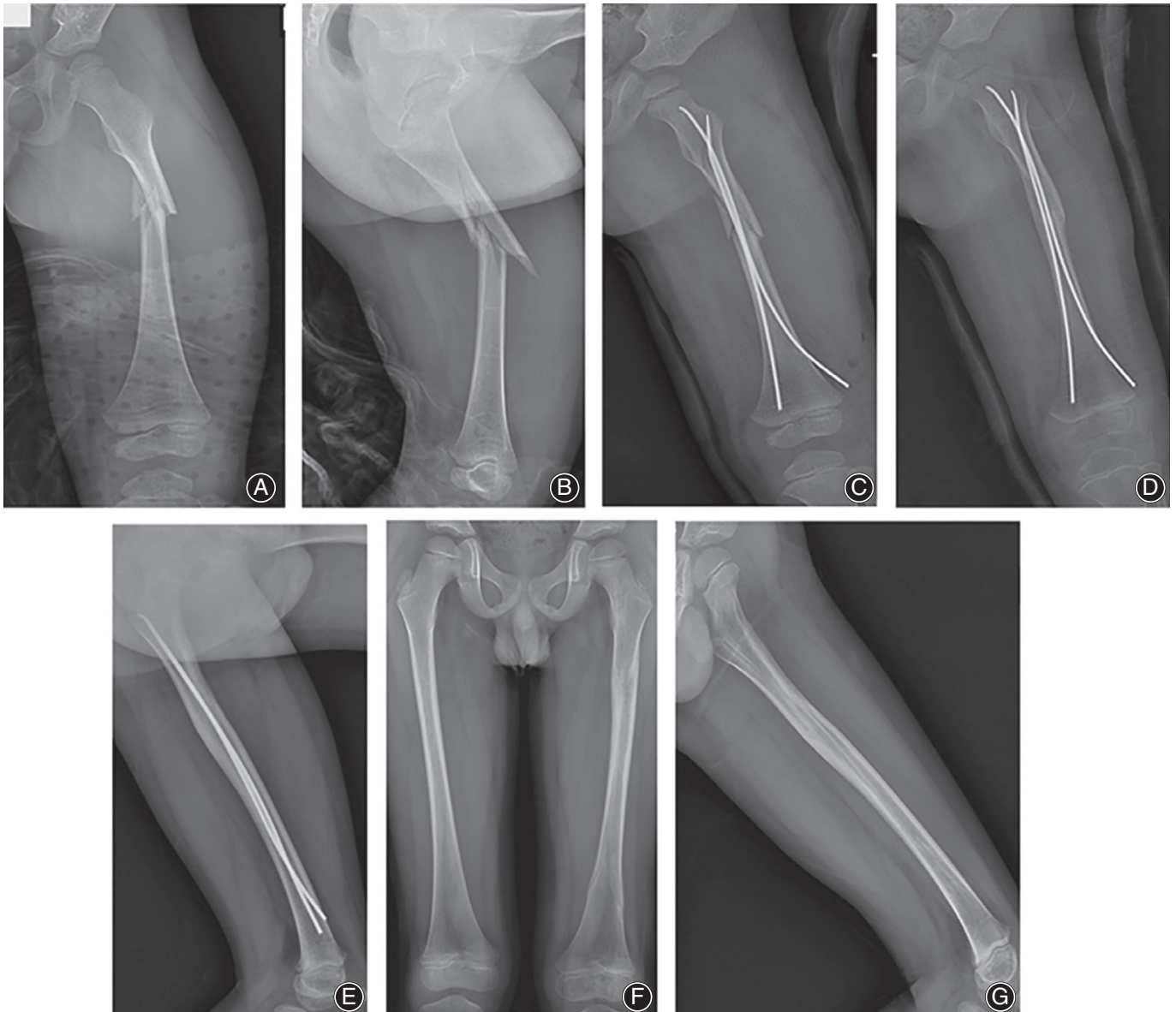


Fig. 1 A case of Winquist type II femoral fracture. A 4-year-old boy, diagnosed with Winquist type II fracture of left femur shaft due to trip and fall, underwent close reduction with ESIN. (A and B) Anteroposterior (AP) and lateral view of the left femur before operation. (C and D) AP view of the left femur fracture instantly and 2 months postoperatively. (E) Six months after index operation just before ESIN were removed. (F and G) Shows nice remodeling without LLD or angular deformity 1 year postoperatively.

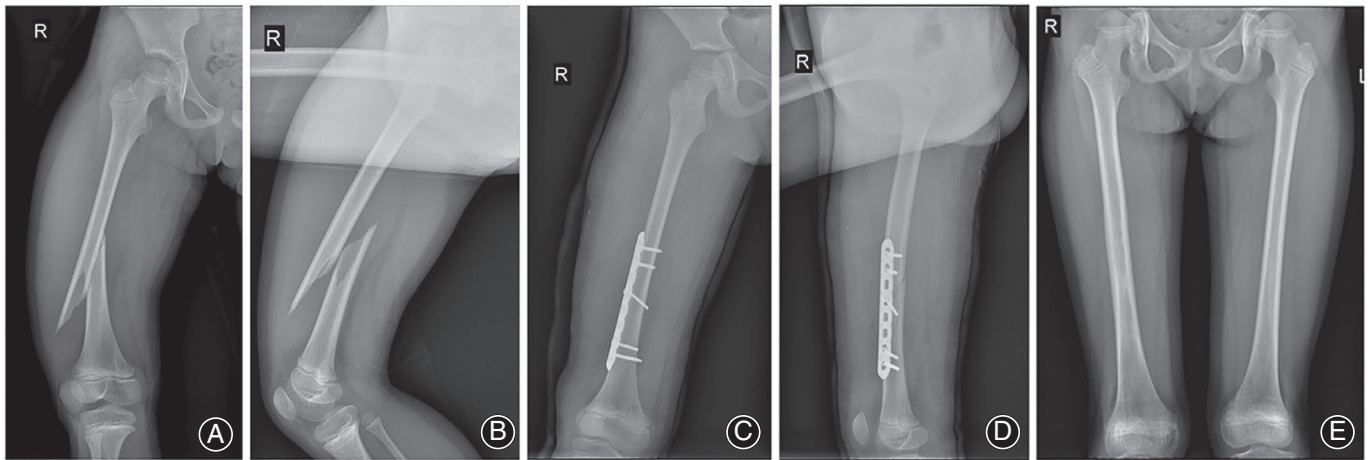


Fig. 2 A 7-year-old boy who fell to the ground and injured his right femur was diagnosed as having a long oblique fracture of the right femur. (A and B) Preoperative anteroposterior and lateral radiograph of the right femur. (C and D) Anteroposterior (AP) and lateral radiographs showing a well-healed femur at half-year follow-up just before the removal of implants. (E) Anteroposterior radiographs at 2 years' follow-up showed nice remodeling and a slight overgrowth of 0.8 cm of the right femur.

Statistics

Data analysis was performed with SPSS 25 (IBM Co, USA). The significance was set at $P < 0.05$ with a 95% confidence interval. Data were displayed as mean \pm SD (standard deviation). Bivariate Pearson correlation was used to evaluate the connection between Winquist comminution grades and clinical parameters. Independent sample t -test was applied to evaluate differences in operational data and clinical outcomes between the groups.

Results

General Information

Five patients were excluded because they were treated with hardware other than ESIN and LCP. Three were treated with bone traction and cast, one with K wires, and one with the Orthofix external fixator. Consequently, 51 cases met the criteria, including 16 girls and 35 boys. Ages at operation averaged 5.9 ± 2.8 years. Demographic and clinical data are listed in Table 1. All fractures were followed up for at least 2 years. A number of injury mechanisms accounted for these fractures. Almost half of the injuries (45%, 23/51) were caused by high-energy trauma, including motor vehicle accidents and fall from a height. Trip and fall was another main mechanism, responsible for 41% cases (21/51). Other causes made up the rest, 14% (7/51). Moderate or severe head injuries (9.8%, 10/51) were the most common accompanied injuries.

Classification of the Fracture

A total of 27 fractures were left-sided and 24 were right-sided; 65% of the fractures (33/51) involved the mid-diaphysis of the

femur, 24% (12/51) involved the proximal third, and 11% (6/51) affected the distal third.

Regarding fracture pattern, transverse fractures were identified in 33% (17/51), oblique in 24% (12/51), and comminuted in 43% (22/51). A total of 12 fractures were grade I comminuted, grade II in 6 cases, grade III in 2 cases, and grade IV in 2 cases. Transverse and oblique fractures were, thus, both classified as grade 0 comminuted in 29 cases.

Correlation Between Comminution Grades and Clinical Parameters

Comminution grades were not correlated to height, weight, age, BMI, blood loss during operation, or hospital stay. Comminution grades were strongly correlated with time to fracture union ($P < 0.001$, $r = 0.53$) and time to implant removal ($P = 0.006$, $r = 0.38$). Comminution grades were also marginally correlated with operation time ($P = 0.05$, $r = 0.27$) and postoperative valgus ($P = 0.07$, $r = 0.26$). Comminution grades had no correlation with postoperational LLD or sagittal angulation.

Comparison Between Elastic Stable Intramedullary Nails and Locking Compressing Plates in Comminuted Femur Fractures

Elastic stable intramedullary nails were applied for 29 patients, 16 close reduced and 13 open reduced. Among comminuted fractures, 10 (Group A) were treated with ESIN, all of which were level I or II comminutions; 5 were open reduced and 5 close reduced, Fig. 1 showed the healing process of a 4-year-old boy with left femur shaft comminuted fracture using ESIN. The remaining 12 (Group B) were treated with LCP, Fig. 2 showed the healing process of a 7-year-old boy using LCP. The operation time and blood loss during surgery in Group B were significantly higher than those in Group A

TABLE 2 Comparison of the clinical data between the two groups

Variables	Expense (thousand yuan)	Operation time (min)	Blood loss in operation (ml)	Hospital stay (day)	Heal of Fracture (month)	Removal of implants (month)	LLD (cm)	Sagittal angulation (degree)	Coronal valgus (degree)
Group A (N = 10)	22.62 ± 3.47	69.40 ± 33.98	18.30 ± 29.74	5.8 ± 2.62	2.30 ± 1.34	8.40 ± 2.98	1.40 ± 3.66	0.60 ± 1.27	0.60 ± 0.97
Group B (N = 12)	48.11 ± 30.16	100.75 ± 31.59	163.33 ± 5.80	10.92 ± 11.89	2.63 ± 0.77	9.08 ± 4.23	1.50 ± 2.02	1.00 ± 2.66	1.36 ± 3.04
t	-2.65	-2.24	-3.31	-1.33	-0.71	-0.43	-0.08	-0.44	-0.79
P	0.015	0.037	0.006	0.200	0.484	0.673	0.936	0.668	0.445

Note: Group A includes 10 comminuted cases treated with ESIN, 5 open reduced and 5 close reduced. Group B included 12 comminuted cases treated with LCP

($P = 0.04$ and $P = 0.006$, respectively). There was no difference in any other clinical parameters between the two groups.

The hospitalization expense of Group A and Group B averaged CNY 22 600 ± 3500 and CNY 48 100 ± 30 200, respectively. The expense of Group A was significantly lower than that of Group B ($P = 0.02$) (Table 2). There was no difference between Group A and Group C as far as expense was concerned.

Complications

All fractures united uneventfully 2.2 ± 0.9 months postoperatively. No clinically detectable LLD, rotational or angular deformity was found. All patients recovered full knee range of motion. In this series, 30 patients (59%) had complications. A total of 26 minor complications (51%) did not require unplanned surgery, most of which were prominence of hardware. A total of 4 patients (8%) had a major complication and underwent an unplanned surgery. Two were refractures distal to primary fracture and two were intolerable prominence of ESIN. All hardware was removed 7.8 ± 2.9 months after initial reduction.

Discussion

The purpose of this study was to evaluate operative parameters, postoperative outcomes, and the hospitalization cost of ESIN in treating pediatric comminuted femur shaft fractures in comparison with traditional plating techniques. The data from our study showed shorter operative time, lower blood loss during operation, and lower hospitalization cost with ESIN techniques and similar results for postoperative outcome.

For length-stable fracture patterns, ESIN are widely accepted to have high rates of union, short time before ambulation, limited surgical dissection, and shorter hospitalization as compared with other operative techniques¹⁵. Nevertheless, the use of ESIN for length-unstable fracture patterns is still controversial. In addition, ESIN are limited by higher reported complication rates, LLD, and malunion, especially for patients heavier than 49 kg^{16,17}. Plating techniques are an important alternative to ESIN, indicated in length-unstable fracture patterns or patients weighing >49 kg. The submuscular plate technique has gained popularity for limited exposure^{18,19}.

This study was focused on comminuted pattern of femur fractures. In this series of patients, higher comminution grades lead to longer time to fracture union ($P < 0.001$, $r = 0.53$) and implant removal ($P = 0.006$, $r = 0.38$) as well as notably longer operation time ($P = 0.05$, $r = 0.27$). Generally speaking, comminution grades did not affect long-term outcomes. Sagittal angulation, coronal valgus, and lower limb discrepancy were radiological measurements we used for lower limb alignment evaluation. Femoral torsional difference is an important rotational parameter and has been measured in other studies²⁰. We did not choose femoral torsional difference in our study because CT would be needed for the measurement, which meant excessive radiation exposure. Another

reason was that no LLD, rotational or angular deformity was clinically observed.

In this study, ESIN and plates were applied in length-unstable fracture patterns mostly based on personal preference of the surgeon with similar outcomes. Operation time and blood loss were obviously lower for ESIN than plates, which is consistent with the literature. No difference in any other clinical or radiological parameters between the two groups was identified. A stringent spica cast plan was routinely used for immobilization after surgery until union of the bone. We only chose to implant with ESIN for grade I or grade II comminuted fractures. For low-grade comminution, at least 50% of the cortex is intact and probably able to sustain longitudinal and axial stability. The above might explain why angular and rotational malunion rates were relatively lower in this study than in the literature. We do suggest implants other than ESIN be considered for Grade III or Grade IV comminuted femur fractures.

Reported ranges of 54 min for ESIN²¹ and 114 mins for open plating¹² have been documented. Our results were 69mins for ESIN and 100 min for plates in comminuted pattern, in consistent with the literature.

Elastic stable intramedullary nails performed better in regard to blood loss. The blood loss for ESIN averaged 18 mL as compared with plating at 163 mL in the current

study. In some cases, open reduction was not necessary and this minimized blood loss dramatically. Currently, the non-invasiveness of ESIN cannot be matched by any other implants, including submuscular bridge plates.

In the aspect of cost effectiveness, ESIN are also better choices. The hospitalization expense of ESIN averaged CNY22 600 ± 35 000, almost half the price for plates. It was mostly due to lower prices of ESIN than that of plates. In our center, the expense is independent of the operation duration. However, in Allen's study, implant cost was not significantly different between ESIN and plates²².

The present study had several limitations. First, it was a retrospective study. The operative technique was based on surgeon's preference. A prospective randomized trial in the future will enhance the conclusions of this study. Second, although the total number of patients reached 51, the numbers for each subgroup were not so big and the period of follow-up was not very long relatively.

In conclusion, in treating low-grade comminuted femur shaft fractures, ESIN provide equivalent outcomes but decreased operative time and blood loss during surgery, and lower hospitalization cost compared with plating techniques. The results of this study support the use of ESIN over plates in low-grade comminuted femur shaft fractures, despite the fact that both options are indicated.

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