The optimal choice for length unstable femoral shaft fracture in school-aged children
A comparative study of elastic stable intramedullary nail and submuscular plate

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Abstract
The utilization of elastic stable intramedullary nail (ESIN) in length unstable femoral shaft fractures in children remains controversial, and the results in different studies vary a lot. This study aims to investigate the clinical outcomes of ESINs versus submuscular plate (SMP) in length unstable femoral shaft fractures.

Patients aged 5 to 11 years old with length unstable femoral shaft fractures treated at our institute from January 2008 to January 2018 were included and categorized into ESIN and SMP group. The preoperative data and operative variables were collected from the hospital database, and postoperative data including complications were collected at follow-up visits.

In all, 77 patients (8.1 ± 1.9 years old, male 45, female 32) in ESIN group and 45 patients (8.0 ± 2.2 years old, male 26, female 19) in SMP group were included in this study. Comparing operative variables, there was significantly less operative time, reduced estimated blood loss (EBL) and shortened hospital stay for ESINs as compared with SMP (P < .001). However, the fluoroscopy frequency was not significantly different between these 2 fixation methods (P = .42). As for elective removal surgery, there was significantly reduced operative time, EBL and shortened hospital stay for ESINs as compared with SMP (P < .001).

Both ESIN and SMP are safe and effective choices for length unstable femoral shaft fractures in children aged 5 to 11 years. In ESIN, extra care is required to provide additional immobilization using spica cast or brace. Compared with SMP, ESIN is able to deliver comparable clinical outcomes with less EBL, operative time and shorter hospital stay.

Abbreviations: EBL = estimated blood loss, ESIN = elastic stable intramedullary nail, SMP = submuscular plate.

Keywords: elastic stable intramedullary nail, length unstable femoral shaft fracture, submuscular plate

1. Introduction
The concept of treating pediatric femoral shaft fractures has been evolving in skeletally immature children, and surgical intervention has gained popularity among orthopedic surgeons.[1] Operative fixations including external fixator, rigid antegrade intramedullary nailing, submuscular plating (SMP) and elastic stable intramedullary nail (ESIN) have been reported.[2–6] ESIN is a preferred choice in length stable femoral shaft fracture because of its advantages in early mobilization, shorter hospitalization, less dissection compared with plating.[7,8] Besides, it avoids the potential of serious complications such as fracture or pin tract infection (PTI) in external fixation, avascular necrosis in antegrade intramedullary nailing.[1,4,8] However, the utilization of ESINs in length unstable femoral shaft fractures remains controversial, and the results in different studies vary a lot.[7–9] This study aims to investigate the clinical outcomes of ESINs versus SMP in length unstable femoral shaft fractures.

2. Material and methods
This study was approved by the Ethics Committee of Tongji Medical College, Huazhong University of Science and Technology (IORG no: IORG0003572) on June 1, 2016. Written consent was obtained from the patient’s legal guardians.
Patients aged 5 to 11 years old with length unstable femoral shaft fractures treated at our institute from January 2008 to January 2018 were included and categorized into ESIN (n = 77) and SMP (n = 45) group. Exclusion criteria were age 12 years or above, body weight over 50 kg, pathological fracture, neuromuscular disorder, open fracture, metabolic disease, and previous femoral fracture or instrumentation. Patients with follow up less than 24 months or incomplete medical history were also excluded.

The preoperative data, including baseline information of the patients, radiographic parameters, and types of surgical procedure were collected from the hospital database, and postoperative data including complications were collected during the follow-up visit. Full-length anteroposterior radiograph was used to determine the total length of the femur, which was defined as the distance between the most superior aspect of the femoral head and the most inferior aspect of medial femoral condyle. Limb length discrepancy was defined as a difference at least 1 cm between limbs. Angulation was measured as angle between the anatomic axes of the proximal and distal fragments, and angular deformity was defined as coronal angulation > 10 degrees or sagittal angulation > 15 degrees.

Length unstable was defined as spiral, comminuted, or long oblique. According to AO pediatric comprehensive classification of long bone fractures,[10] the fracture in our study should be classified as 32-D/5.1 and 32-D/5.2. Radiographic union was defined as the bridging callus across the fracture site on at least 3 out of 4 corticles on anteroposterior and lateral radiograph. The final functional outcome was evaluated according to Flynn scoring system.[11] Complications were categorized into major and minor ones. Major complications included nonunion or loss of reduction, which required revision before fracture union. Minor complications included moderate limb length discrepancy or angular deformity, implant prominence, and superficial infection.

Spica casting or brace was used in the ESIN group for 4 to 6 weeks, whereas long-leg slab was used in SMP group for 2 to 3 weeks after surgery. Non-weight bearing exercises were encouraged after cast removal. In ESIN group, toe-touch weight was initiated when the radiological union was noticed at clinical visit, and progression to full weight bearing was allowed according to the radiographic and clinical manifestation. In SMP group, toe touch weight was initiated when the radiological union was noticed at clinical visit, and progression to full weight bearing was allowed according to the radiographic and clinical manifestation (see Figs. 1 and 2).

All descriptive data were presented as the mean ± SD. Statistical analysis was performed using SPSS (SPSS Inc, Chicago, IL). P value of < .05 is regarded as statistical significance.

3. Results

As shown in Table 1, 77 patients (8.1 ± 1.9 years old, male 45, female 32) in ESIN group and 45 patients (8.0 ± 2.2 years old, male 26, female 19) in SMP group were included in this study. Patients in both groups were followed up for more than 24 months. There was no significant difference between 2 groups concerning the patients demographic parameters including sex, age, and weight.

Comparing operative variables (Table 2), there was significantly less operative time, reduced estimated blood loss (EBL) and shortened hospital stay for ESINs as compared with SMP (P < .001). However, the fluoroscopy time was not significantly different between these 2 fixation methods (P = .42). As in Table 3, according to Flynn scoring system, excellent rate was (42/77, 54.5%), excellent + satisfactory rate was (76/77, 98.7%) in ESIN group. When applied to SMP, excellent rate was (40/45, 88%), excellent + satisfactory rate was (44/45, 97.8%).

We performed elective hardware removal about 6 to 14 months after the primary surgery. As in Table 4, there was significantly reduced operative time, EBL and shortened hospital stay for ESINs as compared with SMP (P < .001). However, the fluoroscopy frequency was not significantly different between these 2 fixation methods (P = .78).

4. Discussion

ESIN was not advocated in the treatment of complex length unstable femoral fractures in pediatric population, because it might result in high rates of major complications and revision surgery.[7,8] Whereas, SMP has been demonstrated as a successful option for these challenging fractures in children.[12-14] This study demonstrated that length unstable femoral shaft fractures can be successfully managed with ESIN, and it showed comparable clinical outcomes with regard to SMP. Besides, the removal of ESIN was easier than SMP with less operative time and EBL.

The known advantages of ESIN for length stable femoral fracture include early mobilization, shorter hospitalization, and less invasive dissection. However, it was not recommended for the length unstable femoral fracture.[7,8] Sink et al found that intramedullary canal fill over 80% resulted in better clinical outcomes,[14] which was validated by other authors.[15,16] In our study, according to the Flynn scoring system the excellent rate was 54.5%, but overall excellent + satisfactory rate was 98.7%. The implant prominence rate was 40.3% in ESIN group, mostly because we opted for technically easy removal of hardware.

There was no case of major complication that required revision surgery, probably due to 4 to 6 weeks immobilization in spica cast. In 1 patient, loss of reduction was caused by accidental fall onto the ground, and was treated with closed reduction and additional casting for 4 weeks. Our findings suggested ESIN is a safe and effective choice for stabilization of length unstable pediatric femoral fractures, consistent with a previous report.[19]

According to certain authors, ESIN cannot adequately prevent shortening or control rotation in unstable fractures.[12,17,18] In certain studies,[12,19] no postoperative immobilization was necessary for patients following SMP surgeries. However, in our institute, 2 to 3 weeks of long leg slab protection after surgery was routine. It is helpful for the pain and swelling, and the duration was not long to encumber rehabilitation exercises. There was no case of major complications that required revision surgery partially due to strict execution of less invasive dissection on the fracture site. One patient suffering refracture at the same femur without significant displacement was treated with immobilization and the healing was uneventful. In all, SMP is a successful option for length unstable femoral shaft fractures.

The data from our study affirmed longer operative time, greater EBL and longer hospital stay in SMP group and similar results of fluoroscopy frequency and clinical outcomes in both groups. The operative time in ESIN (54.5 ± 8.1 minutes) was shorter than SMP (73.7 ± 9.7 minutes). The reported operative times for ESIN are 0.9 hours for ESIN, and 1.5 to 1.9 hours for SMP. Thus, our operative times are in good agreement with
reports in the literature.\textsuperscript{20–22} The EBL in ESIN (51.7 ± 18.9 mL) was notably less than SMP (106.4 ± 26.6 mL). Abdelgawad et al reported an EBL about 121 mL in a study of SMP.\textsuperscript{22} The data in our study show that EBL was higher in SMP when compared to ESIN. The fluoroscopy duration was not meticulously measured as in literature,\textsuperscript{23} because we have C-arms of different brands and different operators for each surgery. Therefore, the frequency of fluoroscopy was recorded and compared. Concerning the fluoroscopy frequency, there was no significant difference between ESIN (20.9 ± 5.0) and SMP (21.7 ± 5.0) for the primary surgery ($P = .42$).

Implant removal is routinely performed at our institute. ESIN had superior operative parameters at 21.1 ± 5.6 versus 49.3 ± 6.3 minutes of operative time, 19.6 ± 6.6 versus 50.9 ± 6.9 mL of EBL, 2.9 ± 0.9 versus 3.8 ± 0.8 days of hospital stay. However, the fluoroscopy frequency showed no significant difference between these 2 groups. In the ESIN, fluoroscopy was used sometimes to ascertain the tail of ESIN; in the SMP, the screws that were inserted in percutaneous fashion might require fluoroscopy to ascertain the location. Sink et al reported mean operative time of 0.9 hours for hardware removal,\textsuperscript{24} consistent with our data. Sometimes, extensive exposure was required to

\begin{figure}[h]
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\caption{Six-year-old boy of right femoral shaft fracture treated with ESIN. A. Anteroposterior (AP) view of femur before surgery. B. Lateral view of femur before surgery. C. AP view of femur after surgery. D. Lateral view of femur after surgery. E. AP view of femur at 2\textsuperscript{nd} month follow-up. F. Lateral view of femur at 2\textsuperscript{nd} month follow-up. G. AP view of femur after hardware removal. H. Lateral view of femur after hardware removal. AP = anteroposterior.}
\end{figure}
Figure 2. Eight-year-old girl of right femoral shaft fracture treated with SMP. A. Anteroposterior (AP) view of femur before surgery. B. Lateral view of femur after surgery. C. AP view of femur at 2nd month follow-up. D. Lateral view of femur at 2nd month follow-up. E. AP view of femur after plate removal. F. Lateral view of femur after plate removal. AP = anteroposterior.

| Table 1          | ESIN (N = 77) | SMP (N = 45) | P value |
|------------------|---------------|--------------|---------|
| Sex              | Male          | 45           | 26      | .95     |
|                  | Female        | 32           | 19      |         |
| Age              | 8.1 ± 1.9     | 8.0 ± 2.2    | .81     |
| Weight           | 27.0 ± 5.4    | 27.0 ± 6.1   | .97     |

ESIN = elastic stable intramedullary nail, SMP = submuscular plate.

| Table 2          | ESIN (N = 77) | SMP (N = 45) | P value |
|------------------|---------------|--------------|---------|
| Operative time (min) | 54.5 ± 8.1   | 73.7 ± 9.7   | <.001   |
| EBL (mL)          | 51.7 ± 18.9   | 106.4 ± 26.6 | <.001   |
| Fluoroscopy (times) | 20.9 ± 5.0    | 21.7 ± 5.0   | .42     |
| Length of stay (d) | 4.0 ± 0.9     | 5.9 ± 0.8    | <.001   |

EBL = estimated blood loss.
remove ingrown bone from around the plate, possibly due to the periosteal stripping at primary surgery. Therefore, ESIN was easier to be removed than SMP in the elective removal surgery. There were several limitations in our study. We undertook a retrospective investigation therefore our findings should be interpreted with caution. The allocation process of patients to either ESIN group or SMP group depended on the preference of the surgeon in charge and this strategy may cause allocation bias. The follow-up was not long enough, and the long-term impact upon growth remains unclear. Besides, the mechanism of injury such as fall, motor vehicle accident, was not included in the data collection and analysis. Furthermore, the rotation malalignment was not thoroughly investigated, and Dunn images might be helpful.\cite{18}

Moreover, although all the operations were performed by senior surgeons in our department, but the experience and preference varied among them.

### 5. Conclusion

Both ESIN and SMP are safe and effective choices for length unstable femoral shaft fractures in children aged 5 to 11 years. In ESIN, extra care is required to provide additional immobilization using spica cast or brace. Compared with SMP, ESIN is able to deliver comparable clinical outcomes with less EBL, operative time and shorter hospital stay.

### Author contributions

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