


CLINICAL ARTICLE

Clinical Efficacy of Minimally Invasive Elastic Stable Intramedullary Nailing for Limb Long Bone Fractures in Children

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Objective: The aim of the present paper was to investigate the clinical efficacy of minimally invasive elastic stable intramedullary nailing (ESIN) for long bone fractures in children.

Methods: A total of 350 children with limb fractures from June 2012 to June 2018 were recruited and randomized into two groups: an ESIN group ($n = 175$) treated with elastic stable intramedullary nailing, and an MPIF group ($n = 175$), treated with metal plate internal fixation. Both groups received the same physical examination and routine medication. Operation related indexes, clinical efficacy, complications, and postoperative quality of life scores were analyzed and compared.

Results: The operation time, intraoperative blood loss, hospitalization time, and fracture healing time in the ESIN group were 43.74 ± 4.96 min, 8.14 ± 1.34 mL, 5.97 ± 1.88 days, and 55.89 ± 5.61 days, respectively, which were all significantly less than those in the MPIF group (all $P < 0.001$). In terms of common complications after limb fracture treatment, there were 6 cases of osteomyelitis, 5 cases of skin irritation response, and 7 cases of inflammatory granuloma in the MPIF group. There were 2 cases of skin irritation response and 5 cases of inflammatory granuloma in the ESIN group. The incidence of postoperative complications in the ESIN group was 4.00%, which was significantly lower than that in MPIF group (10.29%) ($P < 0.05$). The effective rate for recovery condition in the ESIN group (93.71%) was significantly higher than that in the MPIF group ($P < 0.001$). The quality of life scores after treatment in both groups were improved, while the score in the ESIN group was significantly higher than that in the MPIF group (79.43%) ($P < 0.001$). The postoperative satisfaction rate in the ESIN group (94.29%) was significantly higher than that in the MPIF group (86.29%) ($P < 0.05$). The quality of life scores after treatment in both groups were improved, while the score in the ESIN group was significantly higher than that in the MPIF group ($P < 0.001$). The postoperative satisfaction rate and the acceptance rate for adjacent joint function in the ESIN group (100%) were significantly higher than those in the MPIF group (92.00%) ($P < 0.0001$).

Conclusion: Elastic stable intramedullary nailing is a minimally invasive procedure for long bone fractures in children. It can effectively improve the operation-related indicators and postoperative quality of life and reduce the incidence of complications.

Key words: Bone fractures; Children; Clinical efficacy; Intramedullary nailing

Introduction

Limb fractures are common in the pediatric population and account for 10%–25% of childhood injuries, with its incidence demonstrating an upward trend^{1,2}. Pediatric limb

fractures are generally treated with non-invasive treatments, such as splint fixation, manual reduction, and skeletal traction. However, these treatments may cause complications, such as malformation and ankylosis, leading to poorer functional

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recovery. Traditional modalities may extend the length of stay and constitute a significant financial burden on families³⁻⁶. Traditional hip herringbone plaster fixation after skin traction requires pediatric patients to endure a prolonged hospitalization and bed rest at home. Although this treatment modality is relatively effective, pediatric patients may suffer psychologically due to the long recovery period and alienation from their usual lives. A lack of effective and appropriate guidance from medical staff for pediatric patients who live in remote mountainous areas or economically backward areas will result in more serious consequences for these patients.

An elastic stable intramedullary nail with a specific elastic and bending metal strip is a common fixation instrument for pediatric long bone fractures. Each elastic nail works by achieving good three-point contact within the fractured bone to ensure effective fixation. Due to its minimal invasion, good functional and cosmetic results, and the early mobilization and discharge it allows, this instrument has gradually gained the recognition of orthopaedists^{7,8}. Kubiak *et al.* adopted two treatment methods for children with tibial fractures: elastic stable intramedullary nailing (ESIN) and external fixation⁹. The results showed that ESIN could effectively promote fracture healing, with an average healing period of 7 weeks, while the children who underwent external fixation had an average healing period of 12 weeks, suggesting that ESIN is an advisable and favorable treatment modality for children's fractures. In addition, ESIN has sufficient fixing strength and can promote jiggling at the fracture site, which is conducive to fracture healing^{10,11}. Alberghina *et al.* retrospectively analyzed 24 patients who underwent ESIN and found that the treatment resulted in short hospitalization time and a favorable prognosis, and most cases (83.70%) showed good clinical results in radiology¹².

With the development of medical technology, the application of elastic stable intramedullary nails is providing advantages for the treatment of limb fractures in children, effectively preventing the occurrence of adverse events, such

as refracture after plate removal, and simultaneously avoiding serious damage to osteoepiphysis caused by common intramedullary nailing. Furthermore, ESIN has demonstrated better treatment effects over conservative therapy. Bone fractures differ in children and adults. Children's epiphyseal plates are still not closed; therefore, they have higher growth, stronger plasticity, and greater post-injury repair function but lower reshaping ability as compared with adults. Without timely and effective treatment, bone fractures in children may be accompanied by various degrees and types of complications, such as slow recovery of limb function, malunion, and joint stiffness. As a result, this study aimed to evaluate: (i) complications that occurred with ESIN, (ii) intraoperative treatment using clinical indicators, to standardize subsequent treatment protocols, and (iii) the postoperative quality of life score to better understand patient prognosis and to potentially provide a supporting reference for clinical practice and treatment.

Methods

Baseline Characteristics

A total of 350 patients with long bone fractures admitted from June 2012 to June 2018 were selected and randomized into two groups, an ESIN group and a metal plate internal fixation (MPIF) group, with 175 cases in each group. In the ESIN group, the average age was 9.46 ± 1.77 years, and there were 95 cases with upper limb fractures and 80 with lower limb fractures, belonging to 107 males and 68 females. Of the 175 patients in the MPIF group including 94 male and 81 female patients, 78 presented with upper limb fractures and 97 with lower limb fractures, with an average age of 9.76 ± 1.98 years. There were no statistical differences in the general data between the two groups, demonstrating comparability for this study (Table 1). The study was approved by the ethics committee of our hospital.

TABLE 1. Baseline characteristics

	MPIF group (n = 175)	ESIN group (n = 175)	t/ χ^2	P
Sex (male/female)	94/81	107/68	1.975	0.160
Age (years)	9.76 ± 1.98	9.46 ± 1.77	1.544	0.123
Body mass index (kg/m ²)	23.55 ± 4.33	23.48 ± 4.30	0.167	0.867
Limb fracture (upper/lower)	78/97	95/80	3.303	0.069
Site of fracture (distal/proximal/middle)	53/72/50	60/76/39	1.901	0.386
Cause of injury			2.010	0.570
Traffic accident	80	85		
High falling	15	21		
Accidental falling	38	34		
Crash by heavy stuff	42	35		
Hemoglobin (g/dL)	13.22 ± 0.98	13.35 ± 1.05	1.234	0.218
Platelet count ($\times 10^9/L$)	218.90 ± 18.81	222.62 ± 18.28	1.880	0.061

Measurement data were expressed as mean \pm standard deviation and enumeration data were expressed as cases; ESIN, elastic stable intramedullary nailing; MPIF, metal plate internal fixation.

Inclusion and Exclusion Criteria

The included patients: (i) were diagnosed with long bone fractures through X-ray and diagnostic criteria from *Clinical Osteology*¹³; (ii) underwent ESIN or MPIF and had good expression and normal cognition without serious congenital diseases; and (iii) had operation-related indicators, clinical efficacy, complications, and postoperative scoring of quality of life taken into consideration in relation to treatment. The exclusion criteria were as follows: (i) patients aged over 17 years or less than 3 years; (ii) patients with intra-articular fractures; (iii) those with comminuted fractures; (iv) patients with open fractures causing infection; (v) those with acute or chronic infection in local soft tissues; (vi) patients with hematopoietic dysfunction; (vii) patients that had bone fractures complicated with (viii) epiphyseal injury or with (viii) patients that had bone fractures complicated with vascular-nerve injury; and (ix) those with less than 6 months' follow-up or incomplete medical history.

Fixation Treatments

The patients in the MPIF group underwent metal plate internal fixation. The patients in the ESIN group were treated with elastic stable intramedullary nailing for internal fixation. After admission, routine examination and treatment were performed to reduce inflammation and pain and to activate blood and resolve stasis. All patients were placed in the supine position before surgery. General anesthesia was used before surgery. Brachial plexus block was performed as an alternative or as an adjunct to general anesthesia for surgeries of upper extremities.

Metal Plate Internal Fixation

According to fracture type and site, an appropriate metal plate (Suzhou Gemmed Medical Instrument, China) and L-incision compatible with the plate size were chosen. A balloon tourniquet was placed at the upper third of the upper arm of the affected limb, and a longitudinal incision was made on the dorsal ulnar side of the forearm of the affected limb. We then exposed the fracture site and carefully cleaned the site, including removing granulation tissues and hematoma. After the reduction, a metal plate was fixed across the fracture line with no fewer than two screws, followed by conventional suturing. Plaster of Paris casting for external fixation was performed after the surgery, along with routine observation and treatment.

Elastic Stable Intramedullary Nailing

The surgery was conducted with the help of a C-Arm X-ray machine (Nanjing Huadong Electronics Group Medical Equipment, China). The narrowest diameter of the medullary canal was measured to determine the size of the nail (Tianjin Walkman Biomaterial, China) to be inserted. The internal diameter had to be at least one-third of that of medullary canal. A balloon tourniquet was placed at the upper third of the upper arm of the affected limb before nailing. The entry point should be away from the joint capsule so as

not to damage the nerves, vessels, and epiphyseal plates. With this in mind, we evaluated pain and motion at the fracture site, then chose the most appropriate entry point and inserted the pre-curved intramedullary nail into its proper position and cut off the remaining part. A hand-drawn schematic diagram of the operation is shown in Fig. 1 After the surgery, external fixation by plaster of Paris casting was conducted, and routine observation and treatment followed, including nutritional support and anti-infection treatment.

Observation Indicators**Clinical Indicators**

Hospitalization time, operation time, intraoperative blood loss, and fracture healing time were the main clinical indicators.

Duration of Fracture Healing

The duration of fracture healing was confirmed when: (i) there was successive formation of bone callus across the fracture line based on imaging examination; (ii) at least 3 min of continuously independent walking was possible on flat ground, (iii) there was no deformation on the fracture site within 2 weeks; and (iv) there was no local abnormal movement, tenderness, and longitudinal percussion pain.

Complications

Patients were monitored for complications, including osteomyelitis, nonunion, skin irritation response, and inflammatory granuloma. Incidence of postoperative complications refers to the ratio of the number of cases of complications to the total number of people in the group.

Clinical Efficacy**Evaluation of Bone Healing**

In addition, clinical efficacy was observed during 6-month follow-up. The patients received checkups every 2 weeks in the first month, and then every 2 months. During this period, bone healing was evaluated by comparing the early imaging results after admission with the initial postoperative X-ray film and the standard frontal and lateral X-ray films during follow-up.

Johner–Wuhs Evaluation Method

According to the Johner–Wuhs evaluation method, the recovery condition was considered: excellent when patients presented with normal joint range of motion and gait without pain and infection; good when patients presented with healing bone, 75% range of motion, and light vascular and nerve injury without infection; fair when patients presented with limping gait, more than 50% range of motion, infection, and serious vascular or nerve injury; and poor when patients had delayed bone healing, less than 50% range of motion, infection, obvious pain and weakness, and serious vascular or nerve injury. Based on the evaluation, the acceptance rate

(%) = number of excellent and good cases/number of total cases \times 100%.

Quality of Life Score

Postoperative quality of life scores between the two groups were compared according to the MOS 36-Item Short Form Health Survey (SF-36) with a maximum score of 100 points¹⁴. The higher the score, the better the quality of life.

Secondary Indicators

In addition, indicators like body mass index, preoperative hemoglobin, and platelet count were taken into consideration. The postoperative satisfaction rate refers to the percentage of satisfied or partly satisfied cases among a group. Adjacent joints with normal range of motion with full extension were evaluated as excellent; adjacent joints with partially limited range of motion with some loss of

extension were evaluated as good; those with largely limited range of motion and large loss of extension (stiffness) were evaluated as bad. The acceptance rate for adjacent joint function refers to the ratio of the number of excellent and good cases to the total number of patients in a group.

Statistical Analysis

Data analyses were performed with the SPSS 20.0 software package (SPSS, Chicago, IL, USA). A two-sample independent *t*-test was adopted for the measurement data (hospitalization time, fracture healing time, operation time, intraoperative blood loss, and quality of life score), expressed as mean \pm standard deviation, while the χ^2 -test was adopted for the enumeration data (incidence of postoperative complications, acceptance rate for recovery condition, postoperative satisfaction rate, postoperative satisfaction rate, and effective rate for adjacent joint function), expressed as the percentage or case (*n*). *P*-values $<$ 0.05 were considered statistically different.

Results

Baseline Characteristics

There were no statistical differences between the two groups for sex, age, fracture site, cause of injury, preoperative hemoglobin, and platelet count, as shown in Table 1 (all *P* $>$ 0.05), suggesting that the two groups in this study were comparable.

Operation-Related Outcomes

We compared the operation-related indicators of the two groups, and the results showed that the hospitalization time, fracture healing time, operation time, and intraoperative blood loss in the ESIN group (5.97 ± 1.88 days, 55.89 ± 5.61 days, 43.74 ± 4.96 min, and 8.14 ± 1.34 mL, respectively) were significantly less than those in the MPIF group (14.49 ± 1.92 days, 90.14 ± 6.73 days, 76.10 ± 4.65 min, and 49.71 ± 4.94 mL, respectively) (all *P* $<$ 0.001). The above indicators were compared for different fracture sites between the two groups. The results showed that the ESIN group was significantly superior to the MPIF group in terms of those indicators (*P* $<$ 0.001). See Tables 2 and 3.

Outcome of Clinical Efficacy

In the MPIF group, there were 79 cases with excellent outcomes and 60 with good outcomes, along with 21 cases with a bad recovery; while the numbers in the ESIN group were 110, 54, and 11, respectively. The effective rate of the ESIN group (93.71%) was significantly higher than that of the MPIF group (79.43%), as shown in Table 4 (*P* $<$ 0.001).

Outcome of Quality of Life Score

Before the surgery, there was no statistical difference in the quality of life score between the MPIF group and the ESIN group (63.12 ± 3.83 , 62.43 ± 3.24 , respectively; *P* $>$

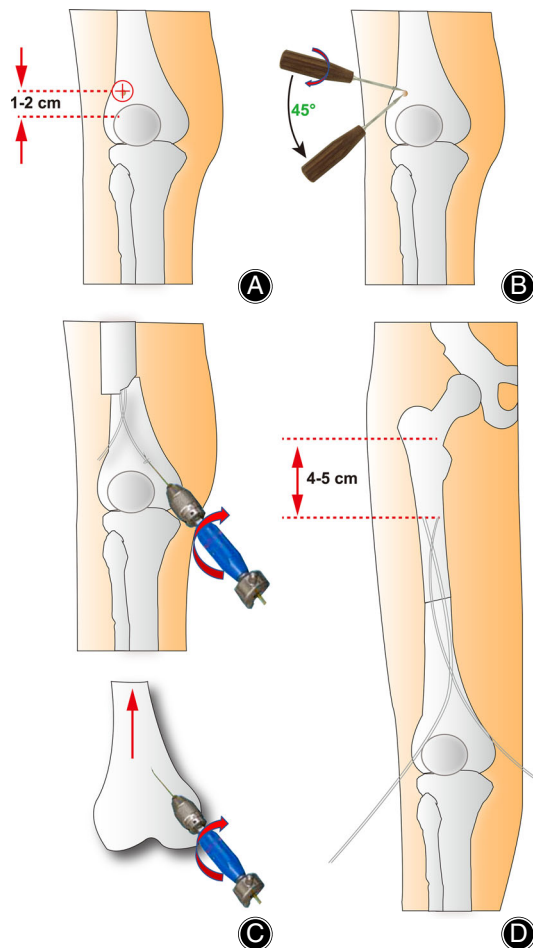


Fig 1 Schematic diagram of the operation. (A) Selection of the insertion point; (B) Bone drilling into the open bone hammer in a perpendicular direction; (C) Insertion of prebent intramedullary nail; (D) Cutting-out of the intramedullary nail with approximately 1 cm of nail left to facilitate nail removal.

TABLE 2 Comparisons of operation related indicators ($\bar{x} \pm s$)

	Hospitalization time (day)	Fracture healing time (day)	Operation time (min)	Blood loss (mL)
MPIF group (n = 175)	14.49 ± 1.92	90.14 ± 6.73	76.10 ± 4.65	49.71 ± 4.94
ESIN group (n = 175)	5.97 ± 1.88	55.89 ± 5.61	43.74 ± 4.96	8.14 ± 1.34
t	42.01	51.73	62.99	107.49
P	<0.001	<0.001	<0.001	<0.001

ESIN, elastic stable intramedullary nailing; MPIF, metal plate internal fixation.

TABLE 3 Comparisons of operation related indicators in different fracture sites ($\bar{x} \pm s$)

Fracture site	Indicator	MPIF group	ESIN group	t	P
Upper limb	Hospitalization time (day)	14.70 ± 1.85	5.91 ± 1.95	30.19	<0.001
	Fracture healing time (day)	90.44 ± 6.50	55.26 ± 5.69	37.94	<0.001
	Operation time (min)	76.52 ± 4.45	44.12 ± 4.64	46.55	<0.001
	Intraoperative blood loss (mL)	49.47 ± 5.20	8.15 ± 1.26	74.86	<0.001
Lower limb	Hospitalization time (day)	14.33 ± 1.97	6.03 ± 1.80	29.00	<0.001
	Fracture healing time (day)	89.90 ± 6.93	56.63 ± 5.46	34.92	<0.001
	Operation time (min)	75.77 ± 4.79	43.29 ± 5.31	42.74	<0.001
	Intraoperative blood loss (mL)	49.90 ± 4.74	8.12 ± 1.44	75.97	<0.001
Proximal	Hospitalization time (day)	14.58 ± 2.00	6.19 ± 1.73	23.91	<0.001
	Fracture healing time (day)	91.19 ± 6.28	56.80 ± 5.24	31.72	<0.001
	Operation time (min)	76.10 ± 4.44	43.50 ± 5.17	35.72	<0.001
	Intraoperative blood loss (mL)	49.76 ± 5.16	7.93 ± 1.36	60.49	<0.001
Middle	Hospitalization time (day)	14.69 ± 2.00	5.86 ± 1.97	27.05	<0.001
	Fracture healing time (day)	90.34 ± 6.75	55.77 ± 5.60	33.98	<0.001
	Operation time (min)	76.43 ± 4.05	43.65 ± 5.04	43.47	<0.001
	Intraoperative blood loss (mL)	49.79 ± 4.88	8.30 ± 1.39	71.15	<0.001
Distal	Hospitalization time (day)	14.13 ± 1.68	5.84 ± 1.92	21.69	<0.001
	Fracture healing time (day)	88.75 ± 7.04	54.70 ± 6.06	24.04	<0.001
	Operation time (min)	75.63 ± 5.61	44.27 ± 4.54	28.39	<0.001
	Intraoperative blood loss (mL)	49.54 ± 4.88	8.13 ± 1.20	51.73	<0.001

ESIN, elastic stable intramedullary nailing; MPIF, metal plate internal fixation.

0.05). After the surgery, the scores of both groups were improved, while the score of the ESIN group was significantly higher than that of the MPIF group (85.96 ± 6.45 , 79.13 ± 6.25 , respectively; $P < 0.001$). See Table 5, Fig. 2.

Outcome of Postoperative Satisfaction

Rating of postoperative satisfaction was performed by the patients or their families before discharge. In the MPIF group, there were 103 full satisfactory cases and 48 partial satisfactory cases, along with 24 dissatisfactory cases; while the numbers in the ESIN group were 151, 14, and 10, respectively. The satisfaction rate of the ESIN group (94.29%) was significantly higher than that of the MPIF group (86.29%) ($P < 0.05$) (Table 6).

Outcome of Adjacent Joint Function

In the MPIF group, 89 cases had excellent adjacent joint function, 72 had good adjacent joint function, and 14 had a bad outcome; while in the ESIN group, 132 cases had excellent adjacent joint function, 43 cases had good adjacent joint function, and no cases had a bad outcome. The acceptance

for adjacent joint function in the ESIN group (100%) was significantly higher than that in the MPIF group (92%) ($P < 0.05$) (Table 7).

Postoperative Complications

Postoperative complications, such as osteomyelitis, nonunion, skin irritation response, and inflammatory granuloma,

TABLE 4 Comparisons of postoperative complications (n/%)

	MPIF group (n = 175)	ESIN group (n = 175)	χ^2	P
Osteomyelitis	6 (3.43)	0 (0)		
Nonunion	0 (0)	0 (0)		
Skin irritation response	5 (2.86)	2 (1.14)		
Inflammatory granuloma	7 (4.00)	5 (2.86)		
Complication rate	10.29	4.00	5.212	0.022

ESIN, elastic stable intramedullary nailing; MPIF, metal plate internal fixation.

TABLE 5 Comparison of clinical efficacy (n/%)

	Excellent	Good	Fair	Poor	Acceptance
MPIF group (n = 175)	79 (45.14)	60 (34.29)	21 (12.00)	15 (8.57)	139 (79.43)
ESIN group (n = 175)	110 (62.86)	54 (30.86)	11 (6.29)	0 (0)	164 (93.71)
χ^2	23.525				15.361
P	<0.001				<0.001

ESIN, elastic stable intramedullary nailing; MPIF, metal plate internal fixation

of the two groups were compared. There were 6 cases of osteomyelitis, 5 cases of skin irritation response, and 7 cases of inflammatory granuloma in the MPIF group. There were 2 cases of skin irritation response and 5 cases of inflammatory granuloma in the ESIN group. The incidence of these complications in the ESIN group (4.00%) was much lower than that in the MPIF group (10.29%) ($P < 0.05$) (Table 8).

Discussion

Limb long bone fractures in children can be treated using a variety of interventions, such as bone traction, manual reduction, external fixation, and plate internal fixation^{6,7}. Appropriate surgical procedures and fixation materials are key to recovery and prognosis. ESIN works by introducing two elastic nails through the metaphysis into the medullary canal and then the fracture site, which impacts the opposite metaphysis to resist deformation. Through this three-site rigid internal fixation, ESIN permits jiggling movements at the fracture site with rigid fixation to facilitate bone union¹⁵. Therefore, we retrospectively analyzed the clinical data of patients with limb long bone fractures to explore the clinical efficacy of ESIN.

In surgery, reserved blood supply and good nutrition for the fracture ends provide a good biological environment for bone union¹⁶. The periosteum was protected and kept as

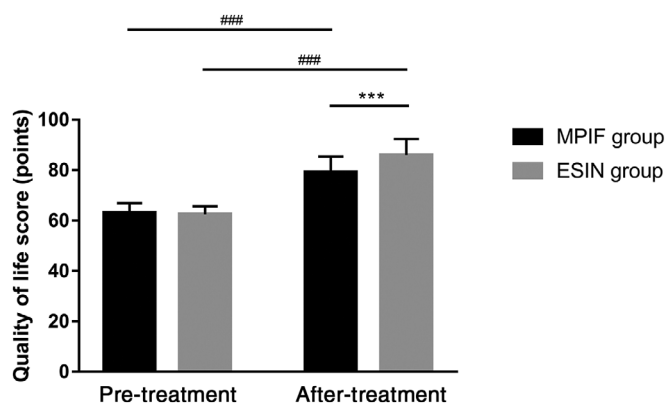


Fig 2 Comparison of quality-of-life score. Compared with the MPIF group, $*P < 0.001$; compared with pretreatment, $*P < 0.001$. ESIN, elastic stable intramedullary nailing; MPIF, metal plate internal fixation.

TABLE 6 Comparison of quality of life score ($\bar{x} \pm s$)

	Before operation	After operation
MPIF group (n = 175)	63.12 \pm 3.83	79.13 \pm 6.25###
ESIN group (n = 175)	62.43 \pm 3.24	85.96 \pm 6.45###
t	1.81	10.06
P	0.071	<0.001

Compared with preoperation, ### $P < 0.001$; ESIN, elastic stable intramedullary nailing; MPIF, metal plate internal fixation.

intact as possible to promote fracture healing through ESIN¹⁷. Qu *et al.* selected 100 cases with limb long bone fractures as research objects and their results showed that the hospitalization time, fracture healing time, and intraoperative blood loss in the patients treated with ESIN were much less than those in the patients with MPIF⁵. This indicated that the flexible intramedullary nail was conducive to pain relief and fracture healing. Jiang *et al.* analyzed the clinical data of 64 children with limb long bone fractures and found that the excellent and good rate of ESIN were much higher than those for MPIF¹⁸. The present study showed that the hospitalization time, fracture healing time, and intraoperative blood loss of the ESIN group were much less than those of the MPIF group, which was consistent with the above results. In addition, it suggested that the quality-of-life score of the ESIN group was higher than that of the MPIF group after comparing postoperative outcomes. The

TABLE 7 Comparison of postoperative satisfaction (n/%)

	Dissatisfaction	Partial satisfaction	Full satisfaction	Satisfaction
MPIF group (n = 175)	24 (13.71)	48 (27.43)	103 (58.86)	151 (86.29)
ESIN group (n = 175)	10 (5.71)	14 (8.00)	151 (86.29)	165 (94.29)
χ^2	-	-	-	6.385
P	-	-	-	0.012

ESIN, elastic stable intramedullary nailing; MPIF, metal plate internal fixation.

TABLE 8 Comparison of adjacent joint function (n/%)

	Excellent	Good	Bad	Acceptance
MPIF group (n = 175)	89 (50.86)	72 (41.14)	14 (0.80)	161 (92.00)
ESIN group (n = 175)	132 (75.43)	43 (24.57)	0 (0)	175 (100)
χ^2	-	-	-	14.583
P	-	-	-	<0.001

ESIN, elastic stable intramedullary nailing; MPIF, metal plate internal fixation.

findings strongly suggest that ESIN is highly effective and contributes to fracture healing.

In bone fracture repair surgery, complications such as delayed healing time, bone deformities, and nonunion often occur due to ignorance of principles of biomechanics and operation errors¹⁹. However, the elastic nail can reduce complications because of its special structure and working principle^{20,21}. Some studies have shown less complications for ESIN as compared with conventional treatments^{22,23}. In this study, no nonunion occurred in either group. In the ESIN

group, there were 2 cases of skin irritation response and 5 cases of inflammatory granuloma. There were 6 cases of osteomyelitis, 5 cases of skin irritation response, and 7 cases of inflammatory granuloma in the MPIF group. The results showed that the incidence of complications was much lower in the ESIN group than in the MPIF group, indicating that ESIN can reduce postoperative complications in children with long bone fractures.

Although we have achieved certain positive results, several limitations exist in this study. Research with large sample sizes is needed in future because of potential biased results with a small sample. This was a single-center study of ESIN, but in future studies, multi-center results should be included for comparison. Long-term prognoses may differ from those determined with the short 6-month follow-up fracture healing results, and 10 months or longer follow-up should be taken into consideration in later research to obtain a more precise conclusion.

In summary, ESIN is an effective procedure for limb long bone fractures in children. It can improve fracture healing and enhance quality of life due to its good clinical efficacy, associated favorable prognosis, and low complication rate.

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