

ORIGINAL RESEARCH ARTICLE

Clinical efficacy of titanium elastic nail fixation for the treatment of pediatric limb fractures and its impact on postoperative bone mineral density and bone metabolism levels

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ABSTRACT

Objective: This study was designed to examine the clinical efficacy of titanium elastic nail (TEN) fixation in treating pediatric long bone fractures of the limbs and its impact on bone mineral density (BMD) and bone metabolism.

Methods: Sixty children with long bone fractures of the limbs were divided into the control group (underwent open reduction and internal fixation with a plate) and the observation group (received TEN fixation) ($n = 30$ each group). Surgical indicators (operative time, intraoperative blood loss, fracture healing time, and hospital stay), fracture healing excellence rate, complication incidence, and overall clinical effectiveness were compared. BMD, serum basic fibroblast growth factor (bFGF), total type I collagen N-terminal propeptide (TPINP) levels, the Hospital for Special Surgery (HSS) knee function score, Harris hip function score, and Mayo Elbow Performance Score (MEPS) were assessed.

Results: The observation group exhibited superior surgical indicators, higher fracture healing excellence rate, overall clinical effectiveness, and lower complication incidence than controls (all $p < 0.05$). At 3 months postoperatively, BMD and bFGF had increased, and TPINP had decreased compared to preoperative values in both cohorts, with the observation group showing higher/lower measures (all $p < 0.05$). At 6 months postoperatively, the observation group achieved higher HSS, Harris, and MEPS scores compared with the control group (all $p < 0.05$).

Conclusion: TEN fixation accelerates fracture healing, reduces complications, improves BMD and bone metabolism, and restores joint function in children with long bone fractures of the limbs.

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Introduction

The long bone fractures of the limbs in children are one of the most common injuries in pediatric orthopedics. These fractures can account for over 90% of pediatric fracture cases [1–3]. They are mostly caused by high-energy trauma such as falls, sports injuries, or traffic accidents, with falls being the primary cause of injury [4]. Improper treatment can lead to serious complications such as malunion of fractures, limb length discrepancy, and joint dysfunction, which can have long-term impacts on the quality of life of affected children [5, 6]. Due to the unique growth and developmental characteristics of children's bones, including open epiphyses, thick periosteum with abundant blood supply, and strong remodeling capacity, the treatment principles for children differ from those for adults [3, 5]. How to provide stable fixation while maximizing the protection of the epiphyses and periosteal blood supply has always been a core concern for clinicians.

Traditionally, open reduction and internal fixation with plates have been widely used for displaced or unstable long bone fractures of the limbs [7]. Although this surgical approach can provide good anatomical reduction and rigid fixation, it involves significant trauma, requires extensive soft tissue dissection, and may damage the periosteal blood supply, and the placement of plates may have potential effects on the epiphyses [7, 8]. Recently, with the

advancement of minimally invasive concepts and innovations in implant materials, the fixation technique using titanium elastic nails (TENs), also known as Elastic Stable Intramedullary Nailing technique, has been widely recognized as the 'gold standard' for treating long-bone shaft fractures in children due to its advantages of minimal trauma, simple operation, and compliance with the biological characteristics of children's bones [8–10]. This technique employs the mechanical principle of two-point fixation, where pre-bent elastic nails are symmetrically inserted into the medullary cavity to convert the stress at the fracture site into physiological compressive stress, maintaining fracture stability while preserving micromotion at the fracture site, which is conducive to callus formation and remodeling [8, 11].

However, existing research has paid relatively little attention to changes in bone mineral density (BMD) and bone metabolism levels after surgery. The healing of fractures represents an intricate biological cascade governed by the coordinated interplay of bone formation and resorption [12]. BMD and bone metabolism markers such as basic fibroblast growth factor (bFGF) and total procollagen type I N-terminal propeptide (TPINP) can objectively reflect the repair status of bone tissue [12]. Nevertheless, systematic research on bone metabolism changes after elastic intramedullary nail fixation remains limited.

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Based on this, the objective of this study is to assess the clinical outcomes of TEN fixation and traditional open reduction and internal fixation with plates for treating long bone fractures of the limbs in children, with a particular focus on observing the effects of the two surgical approaches on postoperative BMD, bone metabolism levels, and joint function recovery in affected children, in order to provide more comprehensive evidence-based medical guidance for the selection of surgical approaches for pediatric limb fractures.

Materials and methods

Ethics statement

This study was approved by the Ethics Committee of Xixia Branch of Ningxia Hui Autonomous Region People's Hospital. A written-informed consent was obtained from both the participating children and their parents or legal guardians.

Study subjects

Sixty pediatric patients with long bone fractures of the limbs admitted to Xixia Branch of Ningxia Hui Autonomous Region People's Hospital from October 2022 to January 2024 were chosen and subsequently divided by random number table into a control group and an observation group, each comprising 30 cases.

Inclusion criteria include the following: The patient who (1) diagnosed with long bone fractures of the limbs via X-ray examination; (2) presented with symptoms such as local swelling, dysfunction, and pain; (3) had fresh fractures with no prior history of long bone fractures of the limbs; (4) had complete clinical data. (5) The guardians of the pediatric patients signed informed consent forms.

Exclusion criteria include the following: The patient who (1) Comminuted or pathological fractures; (2) Combined with fractures at other sites; (3) Accompanied by nerve or major vascular injuries; (4) Had coagulation disorders or other hematological diseases; (5) Had surgical contraindications.

Randomization process and blinding

Using a random number table, 60 pediatric patients were equally divided into two groups. First, the patients were numbered from 1 to 60. Random numbers were then selected from any row of the random number table until 60 random numbers were obtained. Each two-digit number read was used as a random number corresponding to the patient numbers 1–60. All random numbers were sorted in the ascending order, with random numbers 1–30 assigned to the control group and 31–60 to the observation group. Information including patient numbers, corresponding random numbers, and group assignments was recorded on cards, which were then placed in opaque, sealed envelopes for allocation concealment. The envelope numbers corresponded one-to-one with the card numbers. Patients were grouped by opening the envelopes in the order of their hospital admission. The generation of random numbers and the preparation and storage of envelopes were performed by researchers not involved in patient recruitment, treatment, or grouping.

Due to the different surgical methods, blinding the researchers in this study was challenging; therefore, blinding was implemented for the pediatric patients and their guardians. Blinding was also maintained for outcome assessors and statistical analysts regarding patient grouping.

Surgical methods

1. Control group: Open reduction and internal fixation with a plate were performed. The pediatric patients were placed in a supine position, and an appropriate anesthesia method was selected based on the specific condition. After anesthesia, the surgical area was disinfected. Depending on the fracture site, the fracture joint tissues were adequately freed, and the fracture ends were fully exposed. Reduction of the fracture site was performed under direct vision. A compression plate of appropriate length was fixed on the bone surface, secured with screws to enhance plate stability, and a drainage tube was left in place. The incision was sutured layer by layer. To prevent incision infection, antibiotics were continuously administered postoperatively to reduce inflammatory responses. If the fracture site was unstable, a plaster cast was used for fixation to ensure stability. The fixation devices were gradually removed based on the patients' bone healing progress.
2. Observation group: TEN fixation was performed. The pediatric patients were placed in a supine position, and an anesthesia method was selected after evaluating the condition. The surgical area was thoroughly disinfected. During surgery, effective protective measures (lead plates and lead caps) were taken for the patients' heads, and the fracture site was identified using fluoroscopic instruments for precise localization. The insertion site was at the end of the long-bone away from the fracture site, where a hole was made. A titanium elastic intramedullary nail (one-third the diameter of the long-bone marrow cavity) was used for internal fixation of the fracture site. Reduction of the fracture site was performed using a C-arm fluoroscopic instrument, and the intramedullary nail was inserted. A drainage tube was left in place, and the incision was sutured layer by layer. Antibiotics were administered postoperatively to prevent inflammatory reactions at the surgical site. A brace was used to protect the fracture site for 3 weeks. After callus formation, the external fixation device was removed. The internal fixation device was removed 6 months postoperatively based on the recovery of the fracture site.

Observation indicators

1. Surgical indicators: The operative time, hospital stay, fracture healing time, and intraoperative blood loss were recorded for both groups.
2. Excellent and good rate of fracture healing: A 6-month postoperative follow-up was conducted, and the fracture healing status of patients in both groups was evaluated using the Flynn scoring criteria, as follows: Excellent: No pain, shortening, angulation, deformity, or defect at the fracture site; joint function returned to normal. Good: Mild pain at the fracture site; shortening deformity and rotation < 1 cm and < 5°, respectively; normal joint function. Fair: Significant pain at the fracture site; shortening deformity < 2 cm; slightly restricted joint mobility. Poor: Severe pain at the fracture site; severely restricted joint function. The excellent and good rate of fracture healing = (number of excellent + good cases)/total number of cases × 100%.
3. Joint function: A 6-month postoperative follow-up was performed to assess and compare the joint function of patients

Table 1. Comparison of general information between the two groups [$(\bar{X} \pm s)$, n (%)].

General information	Control group ($n = 30$)	Observation group ($n = 30$)	t/χ^2	P
Age (years)	8.63 ± 1.50	8.43 ± 1.45	0.525	0.602
Gender [n (%)]				
Male	18 (60.00)	17 (56.67)	0.069	0.793
Female	12 (40.00)	13 (43.33)		
Fracture type [n (%)]			1.669	0.434
Tibial shaft fracture	7 (23.33)	5 (16.67)		
Femoral shaft fracture	13 (43.33)	18 (60.00)		
Radius and ulna fracture	10 (33.33)	7 (23.33)		
Cause of fracture [n (%)]			1.508	0.471
Traffic accident	15 (50.00)	13 (43.33)		
Fall from height	10 (33.33)	8 (26.67)		
Other causes	5 (16.67)	9 (30.00)		

with different fracture types in both groups. For ulnar and radial fractures, the Mayo Elbow Performance Score (MEPS) was employed to measure elbow function; for femoral shaft fractures, the Harris hip score was used to assess hip function; and for tibial shaft fractures, the Hospital for Special Surgery (HSS) knee score was applied to examine knee function. All scores were out of 100 points, with higher scores indicating better joint function.

4. BMD and bone metabolism-related indicators: BMD was assessed via dual-energy X-ray absorptiometry preoperatively and at 3 months after surgery. At the same time points, 3 mL of fasting venous blood was drawn from each patient, centrifuged at 3000 r/min for 10 minutes, and the supernatant was collected. Serum bFGF levels were determined using enzyme-linked immunosorbent assay, and the Roche e602 electrochemiluminescence analyzer was used to detect serum TPINP.
5. Complication incidence: The occurrence of postoperative complications such as infection, malunion, and delayed fracture healing was recorded for both groups of pediatric patients, and the complication incidence was calculated as follows: Complication incidence = (number of pediatric patients with complications/total number of cases) $\times$ 100%.
6. Clinical efficacy: Markedly effective: Mild tenderness at the fracture site 30 days postoperatively; X-ray examination shows fracture union with callus formation. Effective: A small amount of callus formation at the fracture site 30 days postoperatively as shown by X-ray examination. Ineffective: Severe tenderness at the fracture site 30 days postoperatively; X-ray examination shows nonunion of the fracture. The total effective rate = (number of markedly effective + effective cases) / total number of cases $\times$ 100%.

Statistical methods

All data in this study were analyzed using the SPSS 22.0 software. Categorical data are expressed as n (%), and the chi-square (χ^2) test was used for comparisons. Measurement data underwent normality testing, and normally distributed data are presented as mean $\pm$

Table 3. Comparison of fracture healing rates between the two groups [n (%)].

Group	n	Excellent	Good	Fair	Poor	Excellent and good rate
Control group	30	15 (50.00)	7 (23.33)	5 (16.67)	3 (10.00)	22 (73.33)
Observation group	30	19 (63.33)	10 (33.33)	1 (3.33)	0 (0.00)	29 (96.67)
χ^2						6.405
P						0.011

standard deviation ($\bar{X} \pm s$). Comparisons between two groups were made utilizing the two independent samples t -test, and the paired samples t -test was conducted for comparisons within groups. A p -value < 0.05 was considered statistically significant.

Results

General information

No significant differences in general information (age, gender, fracture type, and cause of fracture) were observed between both groups ($p > 0.05$), indicating comparability (Table 1).

Surgical indicators

The observation group demonstrates shorter operative time, fracture healing time, and hospital stay as well as less intraoperative blood loss compared with the control group ($p < 0.05$) (Table 2).

Excellent and good rate of fracture healing

The observation group outperformed the control group in terms of the excellent and good rate of fracture healing ($p < 0.05$) (Table 3).

BMD and bone metabolism-related indicators

Preoperative BMD, bFGF, and TPINP levels were comparable between groups ($p > 0.05$). Postoperatively, BMD and bFGF levels increased, while TPINP levels decreased in both groups. The observation group showed higher/lower levels compared to the control group ($p < 0.05$) (Table 4).

Bone and joint function scores

Postoperative MEPS score, Harris score, and HSS score in the observation group were all higher than those in the control group ($p < 0.05$) (Table 5).

Complication incidence

The overall complication incidence was lower in the observation group compared to the control group ($p < 0.05$) (Table 6).

Table 2. Comparison of surgical indicators between the two groups [$\bar{X} \pm s$].

Group	N	Operative time (min)	Intraoperative blood loss (mL)	Fracture healing time (d)	Hospital stay (d)
Control group	30	95.61 ± 3.60	130.84 ± 11.54	77.93 ± 3.81	12.43 ± 2.58
Observation group	30	69.72 ± 2.57	65.37 ± 3.56	56.70 ± 3.02	6.67 ± 1.18
t		32.050	29.690	23.910	11.120
P		< 0.001	< 0.001	< 0.001	< 0.001

Table 4. Comparison of BMD and bone metabolism-related indicators between the two groups ($\bar{X} \pm s$).

Group	n	BMD (g/cm ²)		bFGF (ng/mL)		TPINP (ng/mL)	
		Preoperative	Postoperative	Preoperative	Postoperative	Preoperative	Postoperative
Control group	30	0.48 ± 0.04	0.63 ± 0.08*	315.53 ± 11.02	430.18 ± 28.64*	50.48 ± 1.60	43.09 ± 2.49*
Observation group	30	0.50 ± 0.06	0.80 ± 0.11*	316.17 ± 10.85	458.63 ± 29.35*	49.63 ± 1.75	32.61 ± 2.68*
t		1.526	6.899	0.227	3.800	1.967	15.690
P		0.133	<0.001	0.822	<0.001	0.054	<0.001

Note: *P < 0.05 compared with the same group preoperatively. BMD: bone mineral density.

Clinical efficacy

The observation group achieved a higher overall clinical effectiveness rate ($p < 0.05$) (Table 7).

Discussion

This study analyzed the clinical effects of TEN fixation and open reduction and internal fixation with a plate in pediatric limb fractures. The results showed that TEN fixation outperformed open reduction and internal fixation with a plate in multiple indicators.

The results of this study revealed that surgical indicators in the observation group were superior to those in the control group. This result fully demonstrates the clinical advantages of TEN fixation as a minimally invasive internal fixation technique. TEN fixation employs a technical approach involving closed reduction and small-incision insertion, eliminating the need for extensive periosteal and soft tissue dissection. This technique largely maintains blood supply at the fracture site, establishing an optimal biological setting for healing [7, 13]. In contrast, open reduction and internal fixation with a plate require a larger surgical incision and extensive exposure of the fracture site during surgery, causing significant disruption to the local soft tissue blood supply. Consequently, it is associated with longer operative times and greater blood loss [7, 13]. Liu et al. also confirmed that TEN fixation results in less intraoperative blood loss and shorter operative times compared to plate fixation [7].

Furthermore, the excellent and good rate of fracture healing was higher in the observation group, suggesting that TEN fixation offers advantages in promoting fracture healing. bFGF is an important angiogenic and osteogenic factor that promotes the proliferation and differentiation of osteoblasts, playing a crucial role in the fracture healing process [14]. PINP is a bone formation marker whose level reflects the synthesis rate of type I collagen [15]. In this study, the increase in bFGF levels was more pronounced in the observation group, suggesting that the minimally invasive technique of TEN

Table 7. Comparison of clinical efficacy between the two groups [n (%)].

Group	n	Markedly effective	Effective	Ineffective	Total effective rate
Control group	30	14 (46.67)	6 (20.00)	10 (33.33)	20 (66.67)
Observation group	30	20 (66.67)	7 (23.33)	3 (10.00)	27 (90.00)
χ^2					4.812
P					0.028

fixation may help protect the local microenvironment at the fracture site and promote the release of osteogenic factors. Meanwhile, the more significant decrease in PINP levels may be related to the normalization of bone remodeling after stable fixation of the fracture. The improvement in BMD further confirms the positive impact of TEN fixation on the quality of fracture healing.

Additionally, the postoperative MEPS, Harris score, and HSS score were all superior in the observation group, indicating that TEN fixation is more conducive to early recovery of joint function. This advantage primarily stems from the minimally invasive nature of the technique: smaller surgical trauma means less postoperative pain and less soft tissue swelling, enabling children to engage in functional exercises earlier [16, 17]. Moreover, the intramedullary fixation method of TEN fixation does not interfere with the muscle attachment points around the joint, avoiding soft tissue irritation and joint stiffness that may be caused by plate fixation [13]. Gönder et al.'s comparative study on distal tibial fractures in children showed that the long-term functional outcomes of three fixation methods (TEN fixation, plate, and Kirschner wire) were all satisfactory. However, the plate group had faster early recovery, while TEN fixation achieved a good balance between minimally invasiveness and stability [18].

Notably, this study displayed that the overall complication rate was lower in the observation group. Existing studies indicate no significant difference in complications such as infection and angular deformity between TEN fixation and plate fixation [7]; additionally, Dong et al.'s study showed that the postoperative complication rate was lower in the TEN group than in the plate fixation group [19]. These differences may be related to the operator's proficiency, case selection, and follow-up time. The follow-up period in this study was relatively short, and some long-term complications may not have fully manifested. Furthermore, complications related to elastic intramedullary nails, such as internal fixation irritation, are mostly minor issues that often resolve spontaneously after the removal of the internal fixation. Nevertheless, in clinical practice, it is still essential to strictly adhere to surgical indications, standardize operative techniques, and strengthen postoperative follow-up.

In the surgical treatment of pediatric long bone fractures, TEN fixation, plate fixation, and screw fixation each possess distinct biomechanical properties and specific indications. Surgeons must make comprehensive decisions based on fracture characteristics, patient age, skeletal maturity, and soft tissue conditions [20, 21]. TEN fixation is based on the principle of elastic stability, allowing physiological micromotion at the fracture site to stimulate callus formation, while its minimally invasive insertion maximally preserves periosteal blood supply [21, 22]. Its classic indications

Table 5. Comparison of bone and joint function scores between the two groups ($\bar{X} \pm s$, points).

Group	MEPS score		Harris score		HSS score	
	n	Postoperative	n	Postoperative	n	Postoperative
Control group	10	82.30 ± 6.11	13	78.23 ± 4.83	7	79.86 ± 8.49
Observation group	7	91.14 ± 4.49	18	81.89 ± 3.69	5	90.40 ± 4.83
t		3.251		2.392		2.482
P		0.005		0.024		0.032

Table 6. Comparison of complication incidence between the two groups [n (%)].

Group	n	Infection	Malunion	Delayed healing	Total complication rate
Control group	30	5 (16.67)	2 (6.67)	1 (3.33)	8 (26.67)
Observation group	30	1 (3.33)	1 (3.33)	0 (0.00)	2 (6.67)
χ^2					4.320
P					0.038

include transverse or short oblique diaphyseal fractures of the femur, tibia, and forearm in children aged 5–11 years with body weight < 50 kg [22–24]. However, TEN offers relatively insufficient rotational stability, with limited torsional resistance for long oblique, comminuted, or subtrochanteric fractures, and requires a secondary surgery for implant removal [22, 23]. Plate fixation provides absolute rigid stability, with the strongest bending and torsional resistance among all internal fixation methods, making it suitable for fracture types demanding high stability [25, 26]. Its primary indications include the following [22, 23, 27, 28]: (1) long bone fractures in adolescents (> 11 years) with near-skeletal maturity, where rigid fixation can support early weight-bearing; (2) unstable fracture patterns such as subtrochanteric, long oblique, or comminuted fractures; (3) intra-articular or metaphyseal fractures, where plates enable anatomic reduction and maintain articular surface congruity. Its limitations, however, include extensive soft tissue dissection that may compromise blood supply and increase the risk of delayed union [16, 21]. Screw fixation is generally not used as a standalone fixation method for diaphyseal fractures in pediatric orthopedics but is primarily indicated for [26, 27]: (1) metaphyseal fractures (e.g. lateral humeral condyle fractures and femoral neck fractures) as the primary compression device; (2) adjunctive augmentation for plate fixation; (3) transphyseal fixation in Salter-Harris types III and IV epiphyseal fractures, with the screw placed perpendicular to the physis to allow continued bone growth. Standalone screw fixation has very limited application in pediatric long bone diaphyses due to its lack of axial and rotational stability and is typically used only as temporary fixation or in combination with external fixators [27].

Based on the characteristics of the aforementioned three techniques, clinical decision-making should follow a tiered approach: first, assess the fracture site – intra-articular or metaphyseal fractures should prioritize screw or plate fixation; for diaphyseal fractures, we further evaluate patient age and weight – patients aged 5–11 years with weight < 50 kg should receive TEN as the priority, while those > 11 years or > 50 kg require further evaluation based on fracture stability; stable patterns may be managed with TEN but with caution regarding insufficient rotational control, while unstable patterns warrant plate fixation. Additionally, soft tissue conditions, surgeon proficiency, and family preferences are important factors influencing the final decision [20, 29]. This tiered decision-making model helps maximize fracture healing quality while minimizing complications and promoting functional recovery.

In conclusion, when indications are strictly observed, compared to open reduction and internal fixation with a plate, TEN fixation can accelerate fracture healing, reduce complications, improve BMD and bone metabolism, and restore joint function in pediatric limb fractures. This provides evidence-based support for the selection of surgical methods for pediatric fractures of the long-bones of the extremities.

Several limitations should be acknowledged. First, the small sample size may restrict the broader applicability of the conclusions. Second, the short follow-up period was insufficient for observing long-term complications and the long-term dynamic changes in bone metabolism markers. The long-term outcomes and safety of TENs require further validation through multi-center, large-sample, and extended follow-up investigations.

Declarations

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Conflicts of interest

The authors declared that they have no conflicts of interest regarding this work.

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