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Original Article

Exchange intramedullary nails with or without an augmentation locking plate in the treatment of aseptic femoral shaft non-unions after nailing

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Abstract: Objective: The aim of this study was to discuss the clinic effects of exchange intramedullary nails with or without an augmentation locking plate in the treatment of aseptic femoral shaft non-unions after nailing. Methods: From January 2008 to May 2016, 37 patients with aseptic femoral shaft non-unions after nailing were treated with exchange nailing (EN, 14 patients) and augmentation plating (ENAP, 23 patients), respectively. Patients were evaluated by imaging and clinical function at l, 2, 3, 6, and 12 months after surgery and every year, postoperatively, to observe the callus and recovery conditions of the affected limb. Results: There were no significant differences in follow-up times, blood loss, leg length discrepancy (LLD), time to union, or AAOS scores between EN and ENAP groups. Three cases in the EN group failed to achieve union and were subsequently treated with augmentation locking plates and simultaneous autogenous bone grafting. All 23 cases in the ENAP group obtained osseous union. Operating times of the EN group were shorter than the ENAP group (t=4.035, P<0.001). Fisher's exact test showed a lower union rate of EN compared with ENAP (78.6% vs. 100%; X^2=5.363, P=0.021). No screw loosening, plate breakage, or loss of reduction was found during follow-up. No wound infections, neurovascular injuries, or malunions were observed. Conclusion: EN is a suitable procedure for isthmal and non-comminuted femoral shaft non-unions. ENAP is an effective solution for various types and sites of femoral shaft non-unions and the best choice for repeated failure cases.

Keywords: Femoral fracture, aseptic, non-union, intramedullary, fracture fixation, bone plate, autologous bone graft

Introduction

Patients treated with intramedullary nailing of femoral shaft fractures may develop non-unions that are difficult to cure. Common treatments for femoral shaft non-unions include exchange nailing (EN), reservation nailing and augmentation plating (RNAP), and exchange nailing and augmentation plating (ENAP). Surgical effects and indications have remained hotly disputed, however [1-4]. This present study conducted a retrospective analysis on 37 cases of non-infectious non-unions after intramedullary nailing of femoral shaft fractures, aiming to evaluate the treatment effects of exchange nailing with or without locking plates.

Patients and methods

Patients

This study included a total of 37 cases of patients with aseptic non-union of femoral shaft fractures after intramedullary nailing, admitted to Puai Hospital from January 2008 to May 2016. Of these patients, 14 were treated with exchange nailing (EN), including 9 males and 5 females, with an average age of 46.4 years (range: 23 to 61). Twenty-three cases were treated by exchange nailing and augmentation plating (ENAP), including 16 males and 7 females, aged 19-65 (mean 43.8) years. This study was approved by the Research Ethics Committee at Puai Hospital. All patients pro-

Table 1. Comparison of general characteristics between EN and ENAP groups

Indicators	EN group	ENAP group	Statistics
Case number	14	23	-
Gender (male/female)	9/5	16/7	X^2=0.111, *P*=0.739
Age (years)	46.4±10.3	43.8±10.5	*t*=0.715, *P*=0.479
Nonunion position (case)			
1/3 upper femoral shaft	3	5	X^2=0.330, *P*=0.848
1/3 middle femoral shaft	10	15	
1/3 lower femoral shaft	1	3	
AO/ASIF classification (case)			
32-A	2	6	X^2=0.720, *P*=0.698
32-B	10	14	
32-C	2	3	
Weber-Cech classification (case)			
Hypertrophic type	3	7	X^2=0.358, *P*=0.550
Trophic type	11	16	
Nonunion duration (month)	13.4±2.3	15.8±5.4	*t*=1.540, *P*=0.132

vided informed consent approving the use of their clinical data.

Treatment methods

For the EN group, patients lied on a traction table in the supine position to show the nonunion position from the original surgical incision or anterior lateral incision with a minimally invasive method. They underwent subperiosteal dissection to protect local blood supply. The original intramedullary nail was taken out. Granulation on the fracture end and fibrous scars were removed. Slotting, drilling, and decortication were conducted to sclerotic bone while callus and sclerotic bone remained as much as possible, reducing bone defects and avoiding limb length deformity. After restoration of fracture end, temporary fixation was carried out. The guide pin was inserted for full intracavity reaming and then intracavity granulation and fibrous scars were cleared. Reaming was continued until resistance to the reaming drill obviously increased or the diameter was 1-1.5 mm greater than the largest intramedullary nail. Larger and longer intramedullary nails were installed and fixed with locking nails. In this group, larger intramedullary nails (Smith Nephew/Synthes) were exchanged in all patients, as the diameter was 1-2 mm greater. Intramedullary nails at the original length were used in 12 cases, while nails at 40 mm greater length were used in 2 cases.

For the ENAP group, patients lied on a traction table in the supine position. As with the method of exchange nailing, fracture ends were shown and treated. When reaming was conducted, larger and longer intramedullary nails were installed. After the locking nails were fixed, the injured limbs were flexed and rotated. There was still unstable rotation and pendulum phenomena to varied degrees in fractured ends. Therefore, 6-8 hole-locking plates (Synthes) were placed in the lateral fractured end or on butterfly sclerite. With the fractured end as center, both ends were respectively single cortical fixed with 2-3 locking screws. Injured limbs were flexed and rotated again and no unstable rotation or pendulum phenomena were observed. Larger intermedullary nails (Synthes) were exchanged in all patients of the group and the diameter was 1-2 mm greater. Intermedullary nails at the original length were used in 16 cases, while longer ones were used in 7 cases, as the length was 20-40 mm greater.

Both groups underwent autologous iliac grafting. After fracture reduction and correction of shortening deformities, autologous iliac bones were taken according to the shape and size of bone defects and modified to the appropriate form to be inlaid into bone slots or defects. Fracture interspace was filled with cancellous bone, while redundant iliac bones were cut into strips to place around fracture ends. If necessary, allogeneic bone materials were added (3 cases in ENAP groups, Hubei Osteolink/Datsing BIO-GENE).

During postoperative treatment and recovery, both groups used postoperative wound drainage tubes. These were removed after 48 hours. When anesthetic effects subsided, lower limbs were trained for isometric muscle force. When the drainage tubes were removed, guided exer-

Figure 1. A representative case of the EN group. A man at the age of 50 was injured due to high falling. The original fracture was AO/ASIF classified to be type A. Images (A) and (B) were taken 15 months after original intramedullary nailing. The patient was diagnosed to be hypertrophic non-union and underwent motorization surgery 7 months after nailing. Images (C) and (D) were immediately taken when EN surgery was finished. Images (E) and (F) were taken 3 months after surgery. Images (G) and (H) were taken 6 months after surgery. Images (I) and (J) were taken 12 months after surgery, showing osseous unions. Images (K) and (L) show function 12 months after surgery.

cises of active flexion and extension of knees were taken.

Outcome indicators

At 1, 3, 6, and 12 months and every year after surgery, conditions were checked. Fracture healing states were checked via imaging, guiding functional training and load bearing of injured limbs. Lower limb function was scored with the criteria of American Academy of Orthopedic Surgeons (AAOS) [5]. Outcomes of the two groups were compared, including surgical time, bleeding amount, healing time of non-union, flexion and extension angle of knees of injured limbs 12 months after surgery, limb length deformities, and AAOS scores. Complications were recorded, including incision infections, neurovascular damage, implant looseness, and rupture and loss of fracture reduction.

Statistical analysis

SPSS19.0 was used for statistical analysis. Quantitative data are expressed as mean and standard deviation. Intergroup comparisons were conducted with independent sample t-tests. Qualitative data are expressed as rates and intergroup comparisons were checked with X^2. $P<0.05$ indicates that differences are statistically significant.

Results

General characteristics of patients

As shown in **Table 1**, there were no differences in gender, age, fracture position, fracture type, non-union classification, and duration of non-union between EN and ENAP groups. Of the 14 patients in the EN group, 8 cases were injured by traffic accidents, 4 cases by high falling, and 2 cases by falling. AO/ASIF classification of primitive fractures indicated that 2 cases were type A, 10 were type B, and 2 were type C. All cases were closed fractures. Weber-Cech classification of non-unions showed that 3 cases were hypertrophic and 11 cases were atrophic. The diameter of intramedullary nails was 9-12 mm (mean 10.3 mm). Non-union lasted 9-17 (mean 13.4) months. Of the 23 patients in the ENAP group, 16 cases were injured by traffic accidents, 5 cases by high falling, and 2 cases by falling. AO/ASIF classification of primitive fractures indicated that 6 cases were type A, 14 cases type B, and 3 cases type C. A total of 21 cases were closed fractures and 2 cases were Gustilo-Anderson II open fractures. Weber-Cech classification of non-unions showed that 7 cases were hypertrophic and 16 cases were atrophic. The diameter of intramedullary nails was 9-11 mm (mean

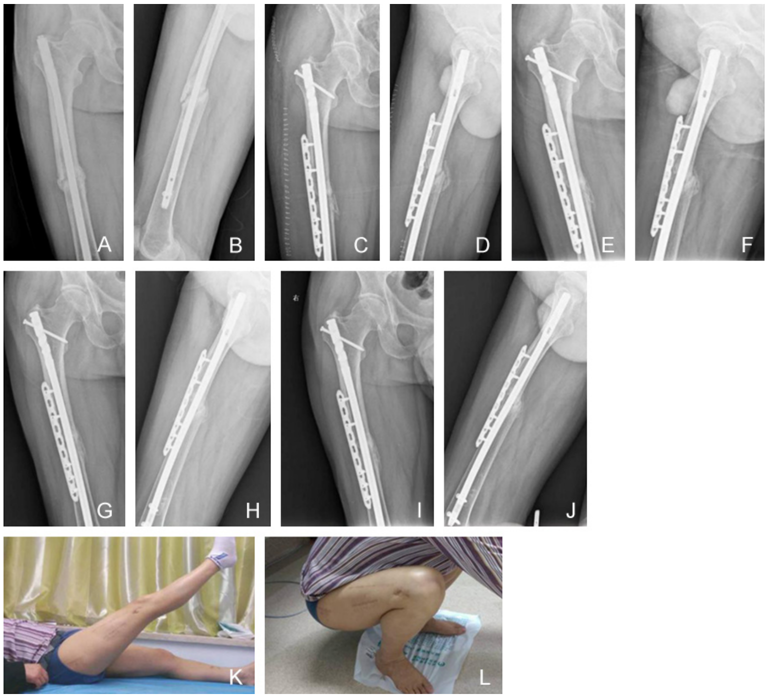

Figure 2. A representative case of the ENAP group. A man at the age of 56 was injured by high falling. The original fracture was AO/ASIF classified to be type A. Images (A) and (B) were taken 15 months after original intramedullary nailing. The patient was diagnosed to be atrophic non-union and underwent motorization surgery 7 months after nailing. Images (C) and (D) were immediately taken when the ENAP surgery was finished. Images (E) and (F) were taken 3 months after surgery. Images (G) and (H) were taken 6 months after surgery. Images (I) and (J) were taken 12 months after surgery, showing osseous unions. Images (K) and (L) showed the function 12 months after surgery.

10.6 mm). Bone non-unions lasted 9-32 (mean 15.8) months.

Treatment outcomes

The EN group had a surgical time of 60-150 (mean 108) minutes and bleeding amount of 250-550 (mean 391) mL. Follow-up was 12-26 (mean 14.5) months. A total of 11 cases developed osseous unions, while healing lasted 4-9 (mean 5.9) months. At 12 months after surgery, the limbs were shortened by 1-2 (mean 0.6) cm. Three cases were not healed and underwent a second surgery. Intramedullary nails were reserved and locking plates were used. Moreover, bone grafting was conducted. Finally, the non-unions were treated. Healing time lasted 6-18 (mean 10.1) months. A typical case from the EN group is shown in **Figure 1**.

The ENAP group had a surgical time of 80-165 (mean 136) minutes and bleeding amount of 200-650 mL (mean 430 mL). Follow-up was 12-30 (mean 15.6) months. All cases obtained osseous unions. Healing lasted 4-10 (mean 6.5) months. At 12 months after surgery, the injured limbs were shortened by -0.5-2 (mean 0.8) cm. A typical case is shown in **Figure 2**.

There were no significant differences in follow-up time, bleeding amount, healing time, limb length deformity, flexion angle, and AAOS scores between the two groups. Surgical time of the EP group was significantly less than that of the ENAP group (t=4.035, P<0.001). Healing rates of the EN group were significantly lower than the ENAP group (78.6% vs. 100%, X^2=5.363, P=0.021, **Table 2**). No incision infections, damage of vascular nerves, or malunions (limb length deformity LLD>2 cm, angulation deformity >10° or rotation deformity >10°) occurred in either group.

Discussion

The key to treating non-unions after intramedullary nailing of femoral shaft fractures is to recover and maintain the stability of the fractured end [6, 7]. Common methods include exchange nailing, reservation nailing and augmentation plating, and exchange nailing and augmentation plating.

Indications of EN

Many studies have reported that EN has excellent effects [8-11], as healing rates have reached 72%-100%. Crowley DJ et al. [12] suggested the treatment of EN as the standard method of treating non-unions after intramedullary nailing, with plating and external fixation as remedial measures when EN fails. However, some studies have proven that intramedullary nailing couldn't achieve stable rotating fixation of fractured ends, with success rates of only 53%-58% [13, 14]. Park J et al. [15] reported that the failure rate was up to 72% when EN was conducted for non-unions of non-isthmus

Table 2. Comparison of treatment outcomes between EN and ENAP groups

Indicators	EN group	ENAP group	Statistics
Follow-up time (month)	14.5±4.0	15.6±4.3	t=0.748, P=0.459
Surgical time (min)	108±23	136±18	t=4.035, P<0.001
Bleeding amount (ml)	391±78	430±89	t=1.366, P=0.181
Flexion angle (°)	113.2±14.0	107.2±11.9	t=1.400, P=0.170
Extension angle (°)	-2.9±4.3	-2.0±4.2	t=0.630, P=0.533
LLD (cm)	0.6±0.9	0.8±0.7	t=0.718, P=0.477
Union time (month)	5.9±1.6	6.5±1.4	t=1.096, P=0.281
Reoperation (case)	3	0	X^2=5.363, P=0.021
AAOS score (score)	89.0±5.0	89.7±4.6	t=0.459, P=0.649

femur. As for non-isthmus femoral non-unions, larger intramedullary nails still could not make cortical bone tightly attach to intramedullary nails, prevent pendulum phenomenon, or rotation of fractured ends. Reaming had little effect on grinding non-union position. Ru JY et al. [16] reported that the healing rate of EN was 86.2% (75/87 cases). Of the 12 cases of non-unions, 2 cases were isthmus non-unions with >3 cm bone defects, while 10 cases were non-isthmus non-unions. Yang KH et al. [17] also considered that non-isthmus femoral non-unions were a risk factor in EN. The healing rate of EN in isthmus and non-isthmus was 50% and 87%, respectively. In this study, 3 cases in the EN group were non-unions. One case was 1/3 upper femoral type A fracture (isthmus), with bone absorption defects and short arm of force of proximal intramedullary nail. One case was 1/3 middle femoral type B fracture (isthmus), with a third fracture block at the size of about 3 cm. One case was 1/3 lower femoral type A fracture (non-isthmus) with bigger medullary cavity. Jianzheng Zhang et al. [18] suggested that the absolute indication of EN was femoral isthmus and non-comminuted bone non-union. It was considered that if there is a bone defect or a third fracture block [19] in isthmus non-unions, EN fails easily.

Indications of reservation nailing and augmentation plating (RNAP)

RNAP has been reported to possess good healing effects [20-24], with a healing rate of 97%-100%. Ru JY et al. [16] held that augmentation plating had a higher healing rate than EN, as well as a shorter healing time, especially for patients with non-isthmus non-unions and isthmus non-unions with bone defects. Vaishya R et al. [24] considered that original intramedullary nails are utilized to maintain axial stability while an augmentation of lateral plates compresses bone blocks for restoration. It also increased effective contact, decreased non-union interval, corrected rotation instability, and reduced tender moving of fractured ends, as well as fully and effectively grafting for osteogenesis. However, the present study regards the method to be used on the basis that original intramedullary nails are stable and effective. Due to the long-term instability of fractured ends, main intramedullary nails and locking nails of both ends must bear great axial, rotating, and lateral stress, risking metal fatigue or recessive rupture, osteolysis around main nails, and locking nails [25]. Reservation of intramedullary nails increases the risk of reoperation. Therefore, in this study, only 3 cases in the EN group underwent RNAP and grafting. They were finally healed. In addition, RNAP cannot solve problems, such as if the fractured end is angulated and rotated malformation, with more than 2 cm LLD caused by motorization or locking pin rupture [26].

Indications of ENAP

Considering that treatment with only EN or RNAP causes many problems, Wang Z et al. [27] adopted the method of ENAP, which has worked well. He considered that the method was effective from four aspects: (1) Use of larger and longer intramedullary nails in reaming increases stability, while locking plates help rotation stability. Combined utilization disperses stress and allows early loading; (2) Reaming activates osteogenesis; (3) It facilitates bone grafting and maximizes osteogenic effects; and (4) Plate-bone-intramedullary nails integrates into each other, providing a stable biomechanical environment. In this study, 23 cases of non-unions in the ENAP group had a healing rate of 100%. The exchange of original intramedullary nails corrected deformities, especially atrophic non-unions with bone defects and shortening deformities caused by motorization [26]. As intramedullary nails determine the degree of shortening and angulations, exchange of larger nails prevents rotation to some degree. The angle stability of locking plates effectively eliminates rotation instability and pendulum phenomenon of fractured ends. In patients suffering long-term non-union and osteoporosis, the locking plate avoids bolt looseness and prevents restoration loss [28]. Reaming of intramedullary nails gives a rise of blood supply to the fractured end [29] and squeezes cancellous bone fragments caused by reaming into non-union intervals, exerting the effects of bone grafting. Autogeneic iliac grafting [30] activates the response of local growth factors and inflammatory factors, as well as biological osteogenesis [6, 11]. As an inner stent, the locking plate scarcely interferes periosteum and benefits revascularization of sclerosis.

This study was limited, however, by the small number of treatment cases without distinguishing non-union positions. This may have resulted in deviation of evaluation. In conclusion, present results suggest that EN treatment requires a short surgical time, but it is only applicable to non-comminuted non-unions in the femoral isthmus. ENAP treatment can be applied to many indications, including different types of femoral shaft non-unions in varied positions. It can correct angulation, rotation, and LLD while facilitating grafting and promoting healing. It is an effective option when treatment of femoral shaft non-union fails.

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Disclosure of conflict of interest

None.

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