Original Article

Clinical study on the effect of intramedullary fixation and extramedullary fixation on unstable intertrochanteric fractures

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Background: Intertrochanteric fracture of femur is a common fracture in the elderly, and the number of intramedullary nails used to manage intertrochanteric fractures has steadily increased, but the evidence for the clinical efficacy of this practice is lacking. The present study retrospectively compared the clinical outcomes and imaging features of patients with unstable intertrochanteric hip fractures treated with traditional extramedullary hip screws (AO/OTA 31-A2) and patients with the same injury treated with newer intramedullary screws.

Methods: Lower limb measurement (LLM) for the main results of the hip-specific tools, functional independence measure (FIM), and "timed up and go" (TUG) to test the scale and timing of the 2-minute walk test were used as secondary tools for clinical outcomes. Other detailed radiological parameters to evaluate the fracture movement, such as heterotopic ossification, and implant failure, were also recorded.

Results: There were no significant differences between the intramedullary and extramedullary treatment groups in terms of the measures acquired by the primary or secondary clinical outcome tools (P>0.05), but the radiographic parameters favored the intramedullary treatment group as it showed reduced femoral neck shortening.

Conclusions: Although treatment with intramedullary nailing resulted in better radiographic assessment results, this did not translate into better functional recovery outcomes.

Keywords: Intramedullary nail; outside the medullary nail; intertrochanteric fracture; surgical treatment

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Introduction

Intertrochanteric fractures of the hip are common in older adults (1). Although the incidence of these fractures has declined slightly in Europe and the United States, the number of these fractures has doubled in the past 30 years due to the increase in the number of older adults, and this trend is expected to continue (2-5). The medical costs of hip fractures in the older adults will continue to place an increasing financial burden on the health care system, with the total annual cost of hip fracture care in the United States expected to double to $16 billion by 2020, yet a significant portion of this cost is directly related to the cost of implants (6). Therefore, the clinical efficacy of more expensive implants should be objectively evaluated before they are widely used. Thus, the aim of this study was to compare the efficacy of a newer intramedullary nail for unstable intertrochanteric fractures (AO/OTA31-A2) with that of a more traditional plate-screw device. The introduction of the original extramedullary sliding screw device in the 1950s revolutionized the treatment of intertrochanteric fractures, and it quickly became the standard for the acute treatment of intertrochanteric fractures (7). However, in the 1990s, the head bone marrow nail became popular despite a lack of solid evidence of its superior performance (8).

Some biomechanical studies have pointed to the advantage of intramedullary devices in the management of proximal femoral fractures; however, despite the increasing use of intramedullary devices for the treatment of all intertrochanteric fractures, there have been no improvement in outcomes (9). In fact, the current clinical evidence seems to favor the use of more economical extramedullary devices, and while the mechanical advantages of intramedullary devices may not lead to improved outcomes in patients with simple intertrochanteric fractures, the more complex models of instability involved (10). The objective of this retrospective study was to clarify the clinical and radiographic outcomes of patients with unstable interhip fractures treated with an extramedullary device (AO/OTA 31-A2) and to compare them with those of patients treated with an intramedullary device for the same injury. We present the following article in accordance with the STROBE reporting checklist (available at https://dx.doi.org/10.21037/apm-21-3635).

Methods

Patient inclusion study

This study collected medical records of patients with intertrochanteric hip fractures that were identified as unstable upon admission to the emergency department or other settings. All procedures performed in this study involving human participants were in accordance with the Declaration of Helsinki (as revised in 2013). This study was approved by the ethics committee of Xiangyang Central Hospital (No. 2021-063). As a retrospective clinical study, the informed consent of patients was not required.

Grouping analysis

Patients were grouped according to treatment, clinical follow-up evaluations were performed by qualified research assistants with access to all patient files and documentation at each participating site, and imaging evaluations were performed by an independent orthopedic surgeon.

Inclusion criteria and exclusion criteria

The inclusion criteria for patients were the following: (I) aged 55 years or older; (II) with type A2 intertrochanteric fracture (AO/OTA 31-A2); (III) with isolated fractures; (IV) qualified for surgery; and (V) with fractures occurring within 2 weeks of admission.

The exclusion criteria were the following: (I) with a fracture caused by a malignant tumor; (II) an inability to walk before fracture; (III) severe dementia; (IV) limited life expectancy due to the high number of medical complications; (V) medical contraindications; and (VI) an inability complies with rehabilitation treatment or fill in forms.

Patient records were collected for 12 months of follow-up, and continuous clinical and radiographic assessments were performed. Radiographs were evaluated immediately post operation and at predetermined follow-up intervals. Clinical evaluations were performed at 6 weeks, 3 months, 6 months, and 12 months.

Surgical procedure record

In this study, the surgical data collected from patients were analyzed. The surgical procedures for extramedullary and intramedullary devices generally include the use of a fracture table and closed reduction under fluoroscopic guidance. Apart from this, however, the procedures for various implants vary widely. To insert the extramedullary device, a lateral incision is made in the proximal femur, and the fascia is split to expose the underlying lateral muscle. The fascia of this muscle is then opened and retracted forward to expose the femur. Under fluoroscopic guidance, the femoral head screw is placed centrally within the femoral head, and a side plate is attached to the hip screw. The board varies in length from 2 to 6 holes. A dynamic hip screw (DHS) is used in all patients treated with extramedullary fixation, but the exact technique used for the different intramedullary screws used in this study varied slightly. Generally, however, the incision is made in the hip, in line with the proximal femur, and a guide wire is placed into the greater trochanter and down the medullary duct. The great rotor is then drilled. The nail is finally inserted and attached to the femoral head with a single screw, double screw, or spiral blade, depending

Table 1 Clinical features included in the study

Features	DHS	Nails
Men (N)	61	55
Female (N)	31	57
Mean age (SD), year	80 (9.9)	82 (8.6)

DHS, dynamic hip screw.

on the implant used. In order to maintain the dynamic characteristics of all implants and to allow pressure across the intertrochanteric fracture, these devices are not locked proximally. In this study, all patients were treated with short screws designed specifically for intertrochanteric fractures.

Clinical parameters

In the retrospective case data, the main functional outcome tool we used was lower extremity measure (LEM). Functional independence measure (FIM) and timed up and go (TUG) tests, which measure the time it takes to get up from a sitting position and walk 20 meters, were also carried out. The position of the implant was assessed anteroposterally and laterally using the tip-to-tip distance described by Hoffmann *et al.* (11). All radiographs were calibrated, and the shortening of the femoral neck was measured. In addition, radiographs were evaluated for heterotopic ossification, and Brooker staging was performed in each case.

Statistical analysis

The clinically relevant differences in the LLM scores (the primary causal outcome variable) were assumed to be 5%. At 6 weeks, the mean LLM score of community-living hip fracture patients was about 70 [standard deviation (SD), 12 points]. Using Query software (Statistical Solutions Ltd., Boston, MA, USA) and a *t*-test, a 5-point difference in LLM scores was detected between the 2 treatment groups at a level of significance of 5% (bilateral).

Bias analysis and heterogeneity analysis

Heterogeneity between studies was assessed using I^2 statistics, 25%, 50% and 75% representing low, medium and high heterogeneity, respectively, if $I^2<50\%$ and $P>0.1$ between studies using fixed effect models and if $I^2>50\%$ and $P<0.1$ from chi-square analysis showed study heterogeneity

Data induction and arrangement

The clinical data collected in this study are presented in descriptive statistics as mean and SD, with appropriate proportions, to summarize data at baseline, 6 weeks, 3 months, 6 months, and 12 months. The intentional treatment method was used in the main analysis. Any missing data were attributed by using the multiple attribution technique based on the Markov chain Monte Carlo method. We also performed a plan-by-plan analysis, which included only patients who completed the assessment. A 2-sided *t*-test was used to compare the primary (LLM score) and the secondary outcomes between the 2 groups at each time point. We performed *t*-tests in this study because they are considered valid for large samples (usually more than 30). If the deviation from the normality hypothesis was very large, a nonparametric test (Wilcoxon signed-rank test) was also used. A mixed-effects model suitable for longitudinal data was used to compare LLM scores between the 2 groups throughout the study period, with the correlations between measurements at different times being taken into account. Nonparametric methods were also used in these models to model fractional or logarithmic levels when the data were very skewed.

Results

Basic clinical characteristics of patients

A total of 204 patients were retrospectively analyzed in this study, the basic clinical characteristics of whom are shown in *Table 1*. The 2 groups were similar in age; the nail group had roughly equal numbers of men and women, while the majority of patients in the DHS group were women. In all, 92 patients underwent DHS (*Figure 1*), 42 received the trochanteric fixation nail (TFN); 48 received InterTan nails, and 22 received Gamma nails (*Figures 2,3*). Two DHS implants and one TFN failed and were modified for hip replacement (*Figure 4*). No other patients in the study cohort had implants removed during the study period, but 19 patients died within 12 months of hip fracture and 8 patients were unable or unwilling to return for follow-up (*Table 2*).

Imaging results

The mean top-to-top distance was 17 mm for the nail group and 18 mm for the DHS group. At 12-month follow-up, the nail group had a significantly higher incidence of Brooker-1

Figure 1 Preoperative imaging features of the 3 intramedullary devices used in this study.

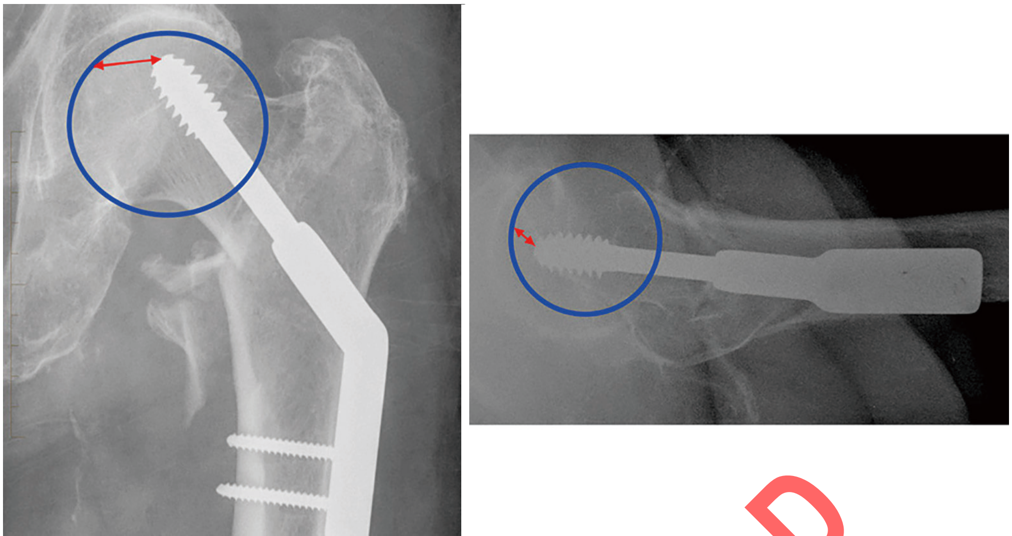

Figure 2 Measurement of tip-tip distance.

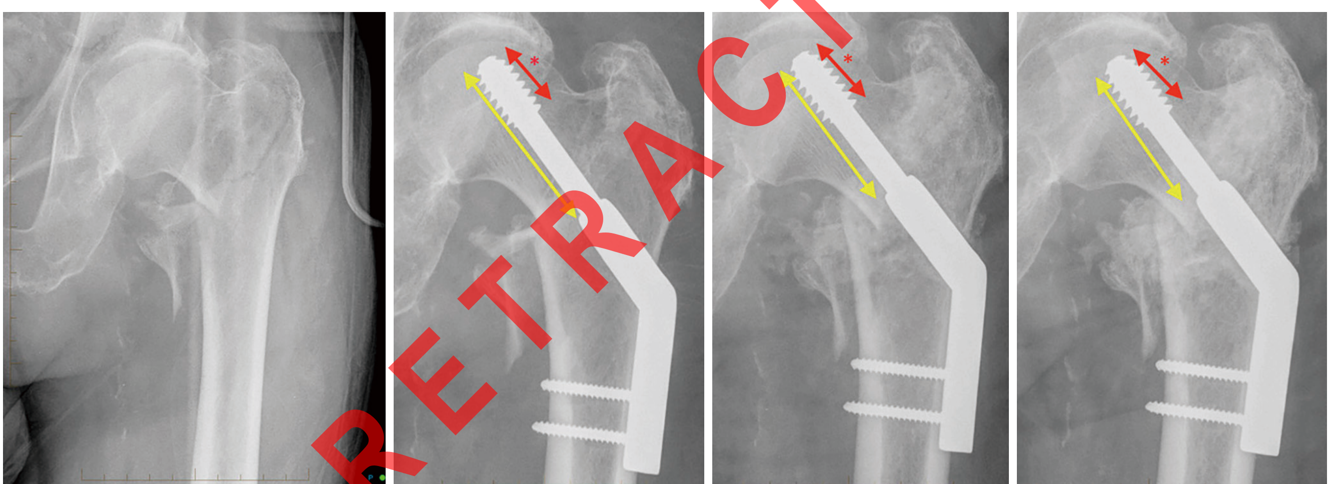

Figure 3 The images were electronically calibrated with use of the known length of the threaded portion of the lag screw (asterisk).

heterotopic ossification, but there was no difference between the 2 groups for stage 2 or 3 (*Table 3*). The mean neck length loss was 1.0 cm for DHS implants and 0.2 cm for nails (*Table 4*). All of the collapses or fractures occurred within the first 6 weeks after exponential surgery.

Clinical outcome

The baseline LLM score before injury was 74.5 in the DHS group and 71.0 in the nail group, but this difference was not significant. Although there was a steady improvement in LLM scores over a 12-month period, neither the nail group nor the DHS group returned to preinjury levels ($P<0.05$). There was no difference in LLM scores between the 2 groups at either study time point. Similarly, there was no difference in FIM scores between the 2 groups ($P>0.05$). Results from the 2-minute timed walking test also improved significantly over time after surgery, but there was no difference in walking distance between the 2 groups at any follow-up time point ($P>0.05$), nor did results from the

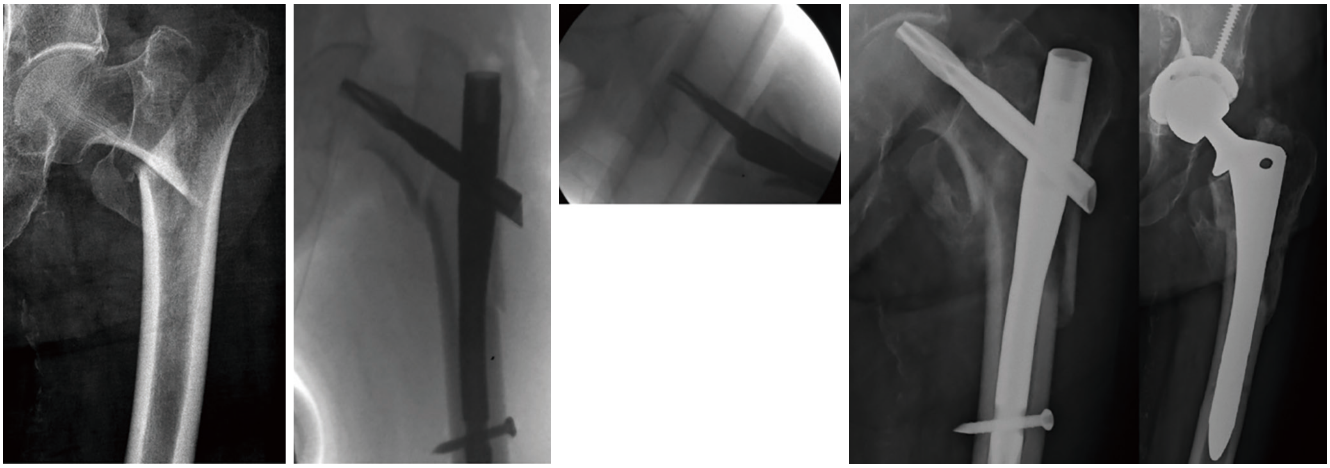

Figure 4 From left to right: displaced intertrochanteric fracture stabilized with a TFN. TFN, trochanteric fixation nail.

Table 2 Follow-up outcome indicators

Point in time	DHS	Nails	Total
Baseline	92	112	204
6 weeks	89	105	194
3 months	85	96	181
6 months	85	93	178
12 months	80	87	167

DHS, dynamic hip screw.

Table 3 Different stages of heterotopic ossification after 12 months

Heterotopic ossification	DHS	Nails
None	57	38
Stage 1	12	35
Stage 2	7	9
Stage 3	4	5

DHS, dynamic hip screw.

TUG test differ significantly between the 2 groups (P>0.05).

Discussion

Currently, treatment failure rates for intertrochanteric hip fractures range from 9% to 16%, with successful surgical integration often being achieved at the expense of a significantly shorter femoral neck (12). In the past, implants that restore and maintain the anatomy of the hip have resulted in high failure rates. However, from a biomechanical point of view, the intramedullary device may have a distinct advantage as it is a load-sharing device that can be closer to the load-bearing axis than can the plate-hip screw device. In addition, because the distal cortex of the proximal piece is adjacent to the medial nail, the number of femoral neck collapses is reduced (13). Advances in intramedullary design are promising, but clinical outcomes have been mixed (14). Due to studies of femur fractures at the distal locking bolt, intramedullary devices have affected weight-bearing changes in the patient's body, but the new implant design appears to have successfully addressed this probLLM, eliminating the need for surgical modifications by abandoning distal locking or using long implants (15). Due to the large proximal diameter of the implant, extensive articulation of the greater trochanter and partial separation of the gluteus medius muscle are required. This can lead to adductor weakness and a crestfallen gait. Some studies have shown an increased rate of resurgery following the use of these early hip screw devices compared to the use of tabular hip screw implants (16). Other studies have shown that the use of nails can reduce blood loss and surgical time (17). Recent randomized prospective studies of all intertrochanteric fracture types seem to show the same outcome regardless of the implant used. Despite the lack of supporting clinical evidence, the use of intramedullary implants has been steadily increasing in North America (18); for example, between 1999 and 2006, the use of intramedullary implants increased from 3% to 67% (19). The wide variation in the use of these implants suggests that other factors besides their clinical efficacy determine their use.

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Table 4 Comparison of primary and secondary outcomes of femoral neck shortening between treatment groups

Variable/point in time	DHS, mean (SD)	Nails, mean (SD)	SD	95% CI	P
Femoral neck shortening (cm)					
6 weeks	1.0 (0.95)	0.2 (0.44)	0.86	0.62, 1.11	<0.001
3 months	1.2 (0.97)	0.2 (0.50)	0.94	0.67, 1.22	<0.001
6 months	1.1 (0.98)	0.3 (0.52)	0.88	0.61, 1.16	<0.001
12 months	1.0 (0.85)	0.2 (0.48)	0.82	0.54, 1.09	<0.001
LLM (points)					
Baseline	74.5 (20.02)	71 (20.46)	3.43	–3.05, 9.91	0.3
6 weeks	42.1 (20.45)	44 (20.13)	–2.30	–9.00, 4.41	0.50
3 months	55.4 (24.02)	56 (22.41)	–0.60	–8.22, 7.03	0.88
6 months	63.9 (22.28)	61 (23.20)	2.88	–4.58, 10.35	0.45
12 months	64.4 (25.00)	66 (21.10)	–1.57	–9.46, 6.32	0.69
2-minute walk test (m)					
6 weeks	47 (22.89)	46 (24.76)	0.74	–8.63, 10.10	0.88
3 months	71 (30.81)	62 (28.70)	9.06	–2.22, 20.34	0.11
6 months	75 (32.86)	70 (30.82)	5.49	–6.21, 17.19	0.35
12 months	81 (36.00)	80 (35.55)	1.29	–13.06, 15.64	0.86
TUG(s)					
6 weeks	34 (23.19)	48 (64.20)	–14.76	–32.37, 2.85	0.10
3 months	26 (20.07)	26 (18.95)	0.32	–6.67, 7.32	0.93
6 months	21 (12.76)	24 (22.76)	–2.71	–8.96, 3.55	0.39
12 months	20 (15.87)	19 (22.74)	0.91	–6.84, 8.67	0.82
FIM total					
Baseline	113 (13.69)	109 (18.46)	3.80	–1.03, 8.63	0.12
6 weeks	98 (21.46)	93 (23.39)	4.33	–2.85, 11.50	0.24
3 months	103 (22.64)	99 (23.79)	3.16	–4.36, 10.69	0.41
6 months	106 (24.68)	104 (22.75)	2.18	–5.66, 10.01	0.58
12 months	111 (17.83)	106 (23.00)	4.77	–2.20, 11.74	0.18

DHS, dynamic hip screw; LLM, lower limb measurement; FIM, functional independence measure; TUG, timed up and go.

Most studies have focused on radiographic evidence of failure and resurgery outcomes without considering the patient's recovery of joint function (20-24), and most have involved the first generation of intramedullary devices in which design modifications of the latest generation of nails have partially corrected earlier design flaws, with peri-implant and prosthesis fractures now being relatively rare complications (25-28). From an economic point of view, the implantation cost of intramedullary nailing should be considered, as treating patients with intertrochanteric fractures can increase costs by three- to five-fold (29,30).

Our retrospective study showed no significant difference in clinical function assessed by hip-specific LLM score at different time points, regardless of implant type (P>0.05) (31-33). At the 12-month follow-up, the LLM score was significantly lower than the initial value before the fracture, suggesting that overall function after the fracture was reduced regardless of the treatment (34). We also found a significant reduction in nail-induced femoral neck shortening—almost 1 cm more in the DHS group—suggesting a clear correlation between femoral neck shortening and clinical deterioration, possibly because adductor invasion negates the biomechanical advantage in this patient population (35). At present, the clinical surgical treatment of elderly femoral rotor fracture is mainly internal fixation and artificial hip device, for stability between rotor fracture can choose internal fixation treatment, to enhance the purpose and pertinence of treatment, for severe osteoporosis between crushing rotor fracture, internal fixation surgical treatment has the risk of fracture fixation failure, leading to fracture does not heal. The advantages of artificial joint replacement therapy for elderly patients with severe osteoporosis intertrochanteric fracture include short operation time, early postoperative ground loading and recovery of hip function. Compared with internal fixation, the use of artificial joint replacement for the treatment of elderly comminuted intertrochanteric fracture has the advantages of early postoperative functional exercise of the hip joint, reducing postoperative complications, and alleviating the psychological and economic burden of patients.

The main limitation of this study is the incomplete case data of the included participants. Advanced age and medical comorbidities led to an almost 10% mortality in the first year after fracture. In addition, 8 patients were unwilling or unable to continue to participate in the study, and these patients might have experienced adverse reactions and additional surgeries without our knowledge (36). The failure rate of internal fixation for comminuted intertrochanteric fractures is 27%, and the incidence of ischemic necrosis of femoral head after intertrochanteric fractures is 2%, which may be related to poor fracture reduction, operation time, and intraoperative destruction of femoral head blood supply.

In short, in order to determine whether intramedullary implants have distinct advantages depending on fracture type, the results showed AO/OTA 31-A2 type fractures. The results showed that use of the intramedullary device significantly reduced the shortening of the fracture position but did not translate into significant differences in LLM and FIM measures or general body function.

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Footnote

Reporting Checklist: The authors have completed the STROBE reporting checklist. Available at https://dx.doi.org/10.21037/apm-21-3635

Data Sharing Statement: Available at https://dx.doi.org/10.21037/apm-21-3635

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://dx.doi.org/10.21037/apm-21-3635). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. All procedures performed in this study involving human participants were in accordance with the Declaration of Helsinki (as revised in 2013). This study was approved by the ethics committee of Xiangyang Central Hospital (No. 2021-063). As a retrospective clinical study, the informed consent of patients was not required.

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