


SCIENTIFIC ARTICLE

Biomechanical Comparison of INTERTAN Nail and Gamma3 Nail for Intertrochanteric Fractures

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Objective: To compare the biomechanical stabilities of Gamma3 nail and INTERTAN nail (ITN) for stable (AO/OTA 31A1.1) and unstable (AO/OTA 31A2.2) femoral intertrochanteric fracture.

Methods: Twenty-four synthetic femora were randomly divided into four groups. After internal fixation (Gamma3 nail or ITN) had been implanted, stable and unstable intertrochanteric fracture models were produced. A cyclic testing protocol with increasing loads was performed for both stable and unstable intertrochanteric fracture models, and then torsional test and axial compression failure test were conducted. Stiffness, failure load, torque, and fragment displacement were recorded.

Results: For stable fracture model: fragment displacement in ITN group were smaller than Gamma3 nail group (Gamma3 nail: 1.66 ± 0.13 mm; ITN: 1.55 ± 0.1 mm); stiffness (Gamma3 nail: 1142.6 ± 161.1 N/mm, ITN: 1159.3 ± 203.5 N/mm, $P = 0.872$) and failure load (Gamma3 nail: 5715.42 ± 616.34 N, ITN: 5690.27 ± 625.59 N, $P = 0.951$) of the two nails were similar after cyclic test; torque of the ITN group was larger than the Gamma3 nail group. For unstable fracture model: fragment displacement in ITN group was significantly smaller than in the Gamma3 nail group when the axial load was larger than 800 N (Gamma3 nail: 3.59 ± 0.19 mm; ITN: 2.93 ± 0.28 mm); ITN group showed a significantly higher failure load than Gamma3 nail group (Gamma3 nail: 2942.77 ± 573.4 N, ITN: 3672.3 ± 790.5 N, $P = 0.011$); torque was significantly higher for the ITN group compared to the Gamma3 nail group for three different angles.

Conclusions: Both ITN and Gamma3 nail can maintain sufficient biomechanical stability for stable intertrochanteric fractures, but ITN was a better choice for unstable intertrochanteric fractures.

Key words: Biomechanical testing; Gamma3 nail; InterTAN nail; Intertrochanteric fractures

Introduction

With the aging population, the incidence of intertrochanteric fractures has also increased gradually¹. Some epidemiological studies reported that more and more people in Asia have suffered from hip fractures in recent years, especially among older people with osteoporosis^{2,3}. Implants for the internal fixation of intertrochanteric fractures including extramedullary plates and intramedullary nails have evolved tremendously in the past decades. Both

intramedullary nails and extramedullary plates can be used for the fixation of stable intertrochanteric fractures. Several clinical studies have reported that proximal femoral nails may be superior to plates for unstable fracture patterns^{4,5}. Moreover, there has also been a sharp increase in the use of intramedullary nails for stable intertrochanteric fractures, especially among young surgeons⁶.

The INTERTAN Nail (ITN) uses an integrated two-screw system, providing increased stability and resistance to

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femoral head rotation compared with the conventional Gamma nails. Currently, the intramedullary nails showed better clinical outcomes and a higher biomechanical stability compared with dynamic hip screw (DHS), proximal femoral nail antirotation (PFNA) devices. A prospective cohort study that compared the ITN and Gamma3 nail showed that there were no significant differences between the two nails in terms of functional outcome concerning the postoperative mobility and Harris Hip Score (HHS) with 1 year of follow-up⁷. A randomized controlled trial (RCT) with 5 years of follow-up demonstrated that the ITN performed better in functional outcome and length of hospital stay within 6-month follow-up; however, no significant differences were recorded after 5 years of follow-up⁸. Wu *et al.*⁹ reported that ITN may have a tendency for better outcomes for patients with unstable intertrochanteric fractures. Therefore, no consensus has been reached on the functional recovery for patients with intertrochanteric fractures fixed by ITN.

At present, few studies reported the biomechanical properties of ITN in stable and unstable femoral intertrochanteric fracture models when compared with Gamma3 nails. In this biomechanical study, we constructed stable and unstable femoral intertrochanteric fractures with ITN and Gamma3 to: (i) to evaluate the biomechanical properties in relation to axial stiffness, torsional stiffness, and failure load of these two types of implant; (ii) compare the stability of the two internal fixation techniques in treating femoral intertrochanteric fractures to further assess the timing and mode of postoperative functional exercise; and (iii) based on the results, to recommend the appropriate implants for stable and unstable femoral intertrochanteric fractures and to provide some references concerning clinical treatment of femoral intertrochanteric fractures.

Materials and Methods

Testing Specimens

Twenty-four standard fourth generation synthetic femora (model 3403; Sawbones Worldwide, WA, USA) were used to evaluate the biomechanical characteristics of ITN and Gamma3 nail for the fixation of stable and unstable intertrochanteric fractures. Femora were assigned to four groups randomly (N = 6 per group). For the stable intertrochanteric fracture model and the unstable intertrochanteric fracture model, femora were randomly assigned to receive either an ITN or a Gamma3 nail. Before creating the intertrochanteric fracture model, all femora were resected from the distal femur, retaining 30 cm proximal femur. To simulate the biomechanical experiment of human standing with one leg in physiological state, the proximal femur was fixed by fixtures with 10° adduction/10° extension out-of-plane configuration¹⁰. And then 5 cm length of distal femur was embedded with the dental acrylic resin powder. Next, a series of proximal femoral osteotomies were performed simulating a stable (AO/OTA 31A 1.1) and unstable (AO/OTA 31A 2.2) intertrochanteric fracture, as previously reported^{11,12}.

Modeling Procedure

To ensure reproducible fracture model geometry and consistency, a surgical navigation device was designed and produced by a 3D printer (Fig. 1). We used a computer-aided system and Mimics software (Mimics v17.0, Materialize's interactive medical image control system, Leven, Belgium) to design the surgical osteotomy stent, and the accuracy of osteotomy angle and osteotomy position can be well guaranteed. A brief description of the surgical guide plate production process is as follows: Firstly, we use computed tomography (CT) scan to obtain the relevant data of the femora, and then import it into Mimics software for 3D reconstruction. When the osteotomy protocol is determined, we insert the osteotomy plate to determine the osteotomy plane, and place the Kirschner wire from the fixed guide plate. Minimize the original femur model by approximately 1.2 times in the Mimics software. The enlarged model subtracts the original femur from the Boolean operation to obtain a uniform thickness of the guide plate model. The inner surface of the guide plate model is exactly the same as the femur surface, which makes the osteotomy more accurate. Cut the plate and the Kirschner wire on the guide plate model to access the initial guide plate. Finally, cut the initial guide to obtain a suitable size model. An oblique osteotomy was created from the central lateral aspect 1 cm beneath the apex of the greater trochanter to the pinnacle of the lesser trochanter. This fracture type is referred to as the stable fracture model in our study. From the top of lesser trochanter, osteotomy was performed about 30° upward along the fracture line of the stable fracture model. The lesser trochanter and all calcar support were completely removed. This fracture type is referred to as the unstable fracture model in our study. All implants (INT and Gamma3) were inserted by the same orthopaedic surgeon according to standard surgical technique recommended by the manufacturer. And we performed X-ray to make sure that the inserted implants were appropriately (Fig. 2).

Biomechanical Testing

Before the biomechanical test, all specimens were subjected to an axial pressure of 50–400 N for 10 cycles with a loading rate of 1 Hz to eliminate creep effect. The biomechanical test consists of two parts: axial compression test and torsional test. All specimens were subjected to axial cyclic loading test and torsional test, and finally axial compression failure test was performed.

Axial Compression Test

Axial cycling load compression was applied to simulate the stress experienced by patients with 70 kg body weight at 4–6 weeks postoperatively¹³. Once the implants were settled well and distal ends were embedded, the four groups of model bones were fixed on the biomechanical test machine (Bose ElectroForce® 3510) to perform the biomechanical test. Firstly, the axial compression test is carried out under cyclic loading.

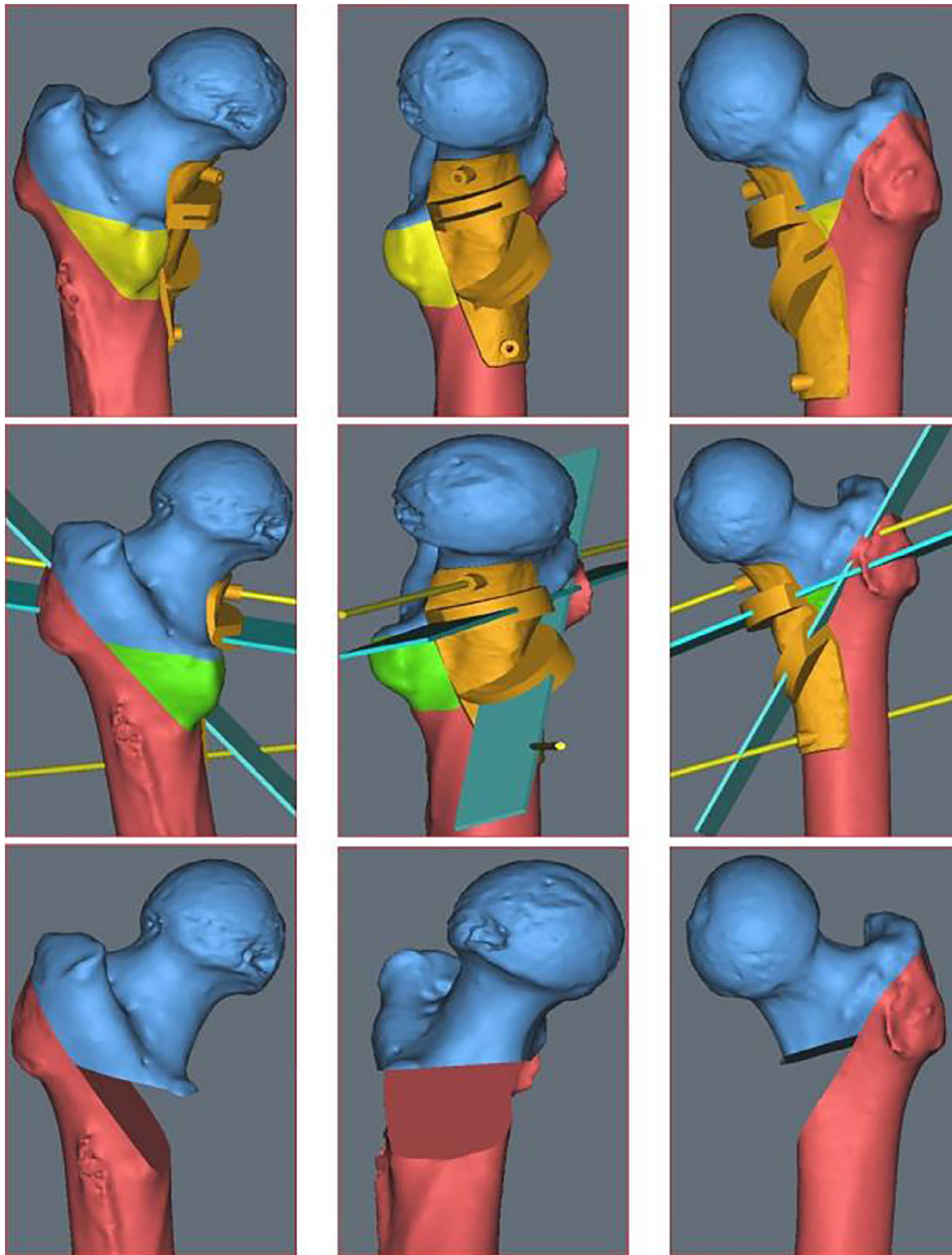


Fig. 1 Illustration for stable and unstable intertrochanteric fracture models by surgical navigation system.

The parameters of axial compression test under cyclic loading are as follows: The initial load is 400 N, the incremental load is 100 N, and the maximum load set to 1400 N, which is divided into 10 subgroups: 400–500 N, 400–600 N, 400–700 N, 400–800 N, 400–900 N, 400–1000 N, 400–1100 N, 400–1200 N, 400–1300 N, and 400–1400 N. Each subgroup was conducted in a cycle of 10000 times, respectively, with a loading rate of 1 Hz. After the cyclic test, the average fracture gap movements were recorded. Through the axial fatigue test, the rigidity of the model bone was calculated with data of the 400–1400 N group.

Torsional Test

When cycling test was completed, the torsional test started with the following parameters: Starting from 0°, the maximum torsion angle set to 3° with a loading rate of 0.1°/s. Torque at the angle of 1°, 2°, 3° were recorded, respectively.

Axial Failure Tests

When all tests were completed, axial compression failure test performed with a loading rate of 4.6 mm/s continuously, until fatigue failure was found. Fatigue failure was defined as follows: fracture gap movements greater than 15 mm, nail



Fig. 2 Radiographs of stable and unstable intertrochanteric fracture with internal fixation and biomechanical loading experiment on Instron testing machine. A-Stable intertrochanteric fracture; B-Unstable intertrochanteric fracture.

cutting-out, or fracture line found around the distal locking nail.

Statistical Analysis

SPSS19.0 statistical software package was used to analyze the biomechanical results. Normal distribution was investigated using the Shapiro–Wilk test. The paired *t*-test was used to compare normally distributed results. Wilcoxon signed-rank test was chosen to assess differences between groups concerning the investigated abnormally distributed variables. The type I error probability was set to $\alpha = 0.05$ for all tests.

Results

Axial Cyclic Loading Test

Stable Intertrochanteric Fracture Model

Fragment displacement increased gradually with the axial pressure increased in both the Gamma3 and ITN groups (Fig. 3). There was no significant difference was found between the two groups in different load subgroup. When the axial pressure reached 1400 N, the fracture gap movements in the Gamma3 and ITN groups were 1.66 ± 0.13 mm and 1.55 ± 0.1 mm, respectively, and the stiffness in the two groups was 1142.6 ± 161.1 N/mm and 1159.3 ± 203.5 N/mm ($P = 0.872$), respectively.

Unstable Intertrochanteric Fracture Model

With axial pressure increased, the fragment displacement increased gradually in both the ITN and Gamma3 groups. No statistically significant differences existed between the two groups ($P = 0.977$, $P = 0.653$) when the axial load is 400–500 N and 400–600 N. However, when the maximal axial load was more than 700 N, the fracture gap movement between the two groups showed significant difference (Fig. 3). When the axial pressure reached 1400 N, the fracture gap movements in ITN and Gamma3 groups were 2.93 ± 0.28 mm and 3.59 ± 0.19 mm, respectively, and the stiffness was 776.1 ± 53.1 N/mm and 667.9 ± 78.2 N/mm ($P = 0.023$). The average axial stiffness of ITN was 16.2% larger than that of Gamma3. During the axial cyclic loading test, no fixation failure was found in any of the specimens.

Torsional Test

Stable Intertrochanteric Fracture

Torque were gradually increased with a twist angle of 1° , 2° , and 3° in the Gamma3 and ITN groups. When compared with the Gamma3 group, the torque was significantly larger in the ITN group (Fig. 4). When the twist angle reached 3° , the average torque in the ITN group (7.67 ± 0.83) was 38% larger than that in the Gamma3 group (4.75 ± 0.51). There were significant differences in torque between two groups with a twist angle of 1° ($P = 0.007$), 2° ($P = 0.001$) and 3° ($P = 0.0001$).

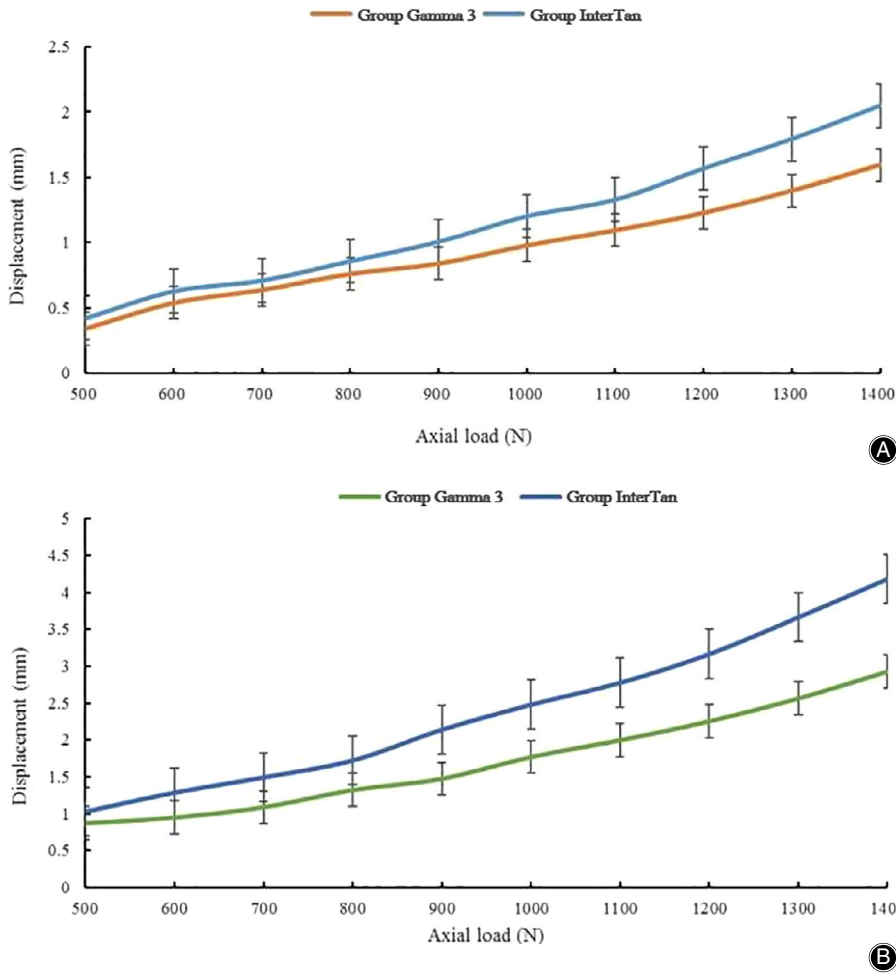


Fig. 3 Load–displacement curve of INTERTAN nail group and Gamma3 nail group. (A) Load–displacement curve of stable intertrochanteric fracture model; (B) Load–displacement curve of unstable intertrochanteric fracture model. Through the slope of the curve, the INTERTAN group showed greater axial stiffness in unstable intertrochanteric fracture.

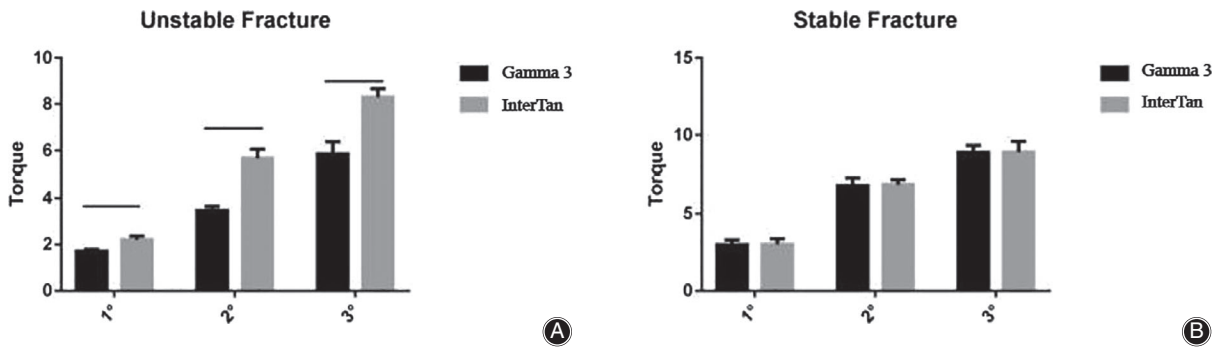


Fig. 4 Comparison of torque at different twist angles between INTERTAN nail group and Gamma3 nail group. (A) Torque at different twist angles in stable intertrochanteric fracture models; (B) Torque at different twist angles in unstable intertrochanteric fracture models. INTERTAN group shows greater torque in unstable intertrochanteric fracture.

Unstable Intertrochanteric Fracture

With twist angle enlarged, the torque increased gradually in both the Gamma3 and ITN groups. When compared with the Gamma3 group, the torque was significantly larger in the ITN group (Fig. 4). There were significant differences in torque between the two groups with a twist angle of

1° ($P = 0.004$) and 2° ($P = 0.015$). However, we failed to find any significant difference in a twist angle of 3° ($P = 0.357$).

Axial Compression Failure Test

For the stable fracture model, the average failure loads of the Gamma3 and ITN groups were 5715.42 ± 616.34 N and

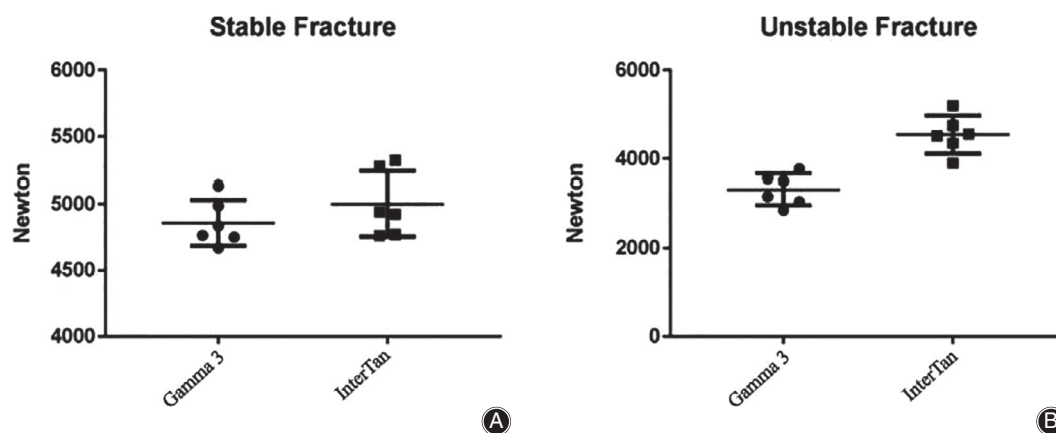


Fig. 5 Comparison of failure load between INTERTAN nail group and Gamma3 nail group. (A) The results of failure test for stable intertrochanteric fracture models; (B) The results of failure test for unstable intertrochanteric fracture models. INTERTAN group show higher failure load in unstable intertrochanteric fracture.

5690.27 ± 625.59 N, respectively (Fig. 5), and no significant difference was found between the two groups ($P = 0.951$). For the unstable fracture model, the average failure loads of Gamma3 and ITN groups were 2942.77 ± 573.4 N and 3672.3 ± 790.5 N, respectively, and there was significant difference between the two groups ($P = 0.011$). The failure loads of ITN was 24.8% larger than that of Gamma3.

Discussion

In recent years, a variety of intramedullary and extramedullary fixations have been used in the treatment of intertrochanteric fractures. However, there are still controversies about the optimal treatment for intertrochanteric fractures, especially for unstable intertrochanteric fractures. It was not clear which of these techniques provides better clinical outcomes. Therefore, there is a need for an evidence base or recommendations to help surgeons make clinical decisions and develop optimal fixation techniques. The primary purpose of our study was to characterize and quantify micromovement in stable and unstable intertrochanteric fractures fixed with Gamma3 nail and ITN during fatigue testing. According to our study, the basic biomechanical properties of the Gamma3 nail construct and the ITN construct were similar for stable fracture model. However, for unstable fracture model, the ITN construct showed better anti-torsion ability. In addition, the ITN prevented fatigue failure of the femoral head more effectively than the Gamma3 nail.

At present, treatments of intertrochanteric fractures are still giving priority to intramedullary nail fixation, such as Gamma nail, ITN, and proximal femoral nail (PFN)¹⁴⁻¹⁶. There are several advantages for intertrochanteric fracture fixation using intramedullary nail such as minimal invasion, shorter operation time, better periosteal protection, and less complications. Gamma3 nail improved the proximal valgus angle to make it well in line with the biomechanical

properties of the femur. “Three-point fixation” is achieved through the combination of intramedullary nail and tension screw to integrate the upper femur and femoral neck firmly. Moreover, the distal self-locking screw fixed with intramedullary nail can effectively prevent the rotation and shortening of the femur. Calderazzi¹⁷ reported the Gamma3 nail was a safe treatment for intertrochanteric fractures with less postoperative complications through analyzing 121 cases of intertrochanteric fractures treated with the Gamma3 nail retrospectively. Kempf¹⁸ reported that 83.4% patients could sustain off-bed weight-bearing activities in the first week after operation with a 100% fracture healing rate using Gamma3 nail fixation and deep venous thrombosis was found in only one patient after surgery. Pascarella¹⁹ retrospectively analyzed the effect of three different Gamma nails in the treatment of 2144 patients with intertrochanteric fractures and found that Gamma3 nail was significantly superior to the standard Gamma nail and the intertrochanteric Gamma nail in reducing postoperative complications. Previous studies have shown that the Gamma3 nail has significant clinical advantages in the treatment of intertrochanteric fractures.

As a new generation intramedullary implant, ITN is specifically designed for proximal femoral fractures. Currently, there are few high-quality clinical trials that compare ITN and Gamma3 nail. ITN has been shown to be as effective as Gamma3 nail in treating intertrochanteric fractures. Berger-Groch showed that the functional recovery of ITN was better than that of Gamma3 nail at 6 months postoperatively, however, no significant difference was found at 5-years follow-up²⁰. Another cohort study showed that ITN was well suited for treating intertrochanteric fractures in the Asian population. Among 100 patients, the average healing time was 18 weeks and only two cases found femoral head cut-out¹.

As we all know, favorable therapeutic effects are closely related to their biomechanical stability. A biomechanical test conducted by Nüchtern *et al.*²¹ that compared the effect of

ITN in treating intertrochanteric fractures with Gamma3 nail showed that the biomechanical stability of ITN was superior than Gamma3 nail in axial loading failure test and cyclic loading test for unstable intertrochanteric fracture. It is noteworthy that no torsional test was reported in their biomechanical study, and the anti-torsion properties of ITN and Gamma3 nail could not be determined. According to our biomechanical results of axial compression failure test, no significant difference was found in failure loads between the two groups in the stable intertrochanteric fracture models. There were significant differences between the two groups in failure loads for unstable intertrochanteric fracture models; however, only having results for axial failure load was not enough to draw the conclusions that ITN was superior to Gamma3 nail in biomechanical properties. For axial cyclic loading test, our results showed statistical significance between the two groups, but only a small difference of the fragment displacement was found between the two groups. Although the fragment displacement in ITN group was smaller than that of Gamma3 nail group, the actual gap between them was less than 0.1 mm. Regarding the unstable intertrochanteric fracture models, the biomechanical stability of ITN was significantly better than Gamma3 nail when the axial pressure was larger than 800 N, and the difference of fragment displacement between the two groups was 0.4–0.7 mm. Hoffmann *et al.*¹⁰ reported that ITN was superior to Gamma3 nail in anti-fatigue performance and axial stiffness, moreover, ITN can reduce the movement of the femoral head and relative displacement of fracture fragments. This was consistent with our results.

The proximal cross-sections of ITN long nail are trapezoidal. It is a remarkable fact that this design not only enhanced the anti-rotation stability, but also effectively resisted the lateral stress and enhanced the support to the lateral wall. All of these designs increased the biomechanical

stability of ITN. This may be a reason that ITN had a better axial compressive capacity when compared with the Gamma3 nail. ITN also showed good anti-torsion properties in our study. With the twist angle of 1°, 2°, and 3°, the average torques of ITN group were 23%, 41.5%, 48% higher than that of Gamma3 nail group in stable fracture models, while 54.6%, 71.9%, and 29.4% higher in unstable fracture models. This result demonstrated that ITN had a better anti-torsion capability than Gamma3 nail. This may be due to the combined interlocking nail in ITN, which enhanced the rotation stability and angular stability. Thus, it significantly promoted the anti-cut and anti-torsion properties of the tensile nail.

However, there were some limitations in this study: (i) a relatively small number of sawbones were included in our study; if more sawbones had been included, the statistical efficacy of our analysis would increase; (ii) the difference of biomechanical properties between the sawbones and fresh corpse femurs may have an impact on the results; (iii) we did not take soft tissue and muscles into account in our study; however, soft tissue and muscles tend to stabilize the fracture; and (iv) biological factors that may affect the results such as differences in size, weight, bone density, or individual fracture configuration are not addressed in this study.

Conclusions

In summary, ITN and Gamma3 nail had similar biomechanical properties in stable intertrochanteric fracture models and both of them met the requirements of early load-bearing activities. For unstable intertrochanteric fractures models, the axial anti-pressure and anti-torsion capacities in ITN group were significantly superior to Gamma3 nail group.

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