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Helical blade versus sliding hip screw for treatment of unstable intertrochanteric hip fractures: A biomechanical evaluation☆

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Summary

Objective: To compare the fixation stability in the femoral head with sliding hip screw versus helical blade designs for unstable, intertrochanteric hip fractures.
Methods: A simulated, unstable intertrochanteric hip fracture was created in six pairs of cadaveric femurs. One of each pair was treated using an intramedullary nail with a sliding hip screw (ITST) for femoral head fixation and the other was treated with a nail with a helical blade (TFN). Each specimen was cyclically loaded with 750 N vertical loads applied for 10, 100, 1000 and 10,000 cycles. Measurements for femoral head displacement, fracture fragment opening and sliding were made. Specimens were then loaded to failure.
Results: There was significantly more permanent inferior femoral head displacement in the ITST samples compared to the TFN samples after each cyclic loading (all p values < 0.05). There was significantly more permanent fracture site opening and inferior displacement in the ITST group compared with the TFN group at 1000 and 10,000 cycles ($p < 0.05$). Final loads to failure were not significantly different ($p = 0.51$) between the two treatment groups.

Nine specimens demonstrated fracture extension into the anteromedial cortex and subtrochanteric region and three specimens, which had an ITST implant, demonstrated a splitting fracture of the femoral head.

☆ The devices used in the current investigation (Intertrochanteric-Subtrochanteric Fixation System (ITST, Zimmer Inc., Warsaw, IN) and the Trochanteric Fixation Nail (TFN, Synthes Ltd., Paoli, PA)) are approved for the treatment of hip fractures Support for the current investigation was provided by Zimmer Inc., Warsaw, IN.

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Conclusion: This study demonstrated that fixation of the femoral head with a helical blade was biomechanically superior to fixation with a standard sliding hip screw in a cadaveric, unstable intertrochanteric hip fracture model.

Introduction

The primary objective for the management of patients with unstable intertrochanteric hip fractures is the successful return to safe mobility.[9,12] The accomplishment of this goal relies on the fixation stability and strength of the chosen treatment construct. Although biomechanical differences between extramedullary and intramedullary implants have been examined,[1–4,6,10] few comparisons have been made with regard to intramedullary implant designs, particularly with respect to fixation of the femoral head. Two of the many intramedullary implants used in the management of unstable intertrochanteric hip fractures are the intertrochanteric–subtrochanteric fixation system (ITST, Zimmer Inc., Warsaw, IN) and the trochanteric fixation nail (TFN, Synthes Ltd., Paoli, PA). The basic designs of these two implants are similar in that the intramedullary nail has an anatomic lateral bend which allows for a trochanteric insertion site, have an anatomic head–neck angle of 130°, and are available with distal diameters from 10–15 mm, and as both short and long nails. The major difference between these two implant designs is the manner in which the femoral head is stabilised. The ITST implant uses a sliding hip screw inserted with the conventional drill and tap method, while the TFN uses a helical blade inserted by impaction without pre-drilling and tapping (Fig. 1).

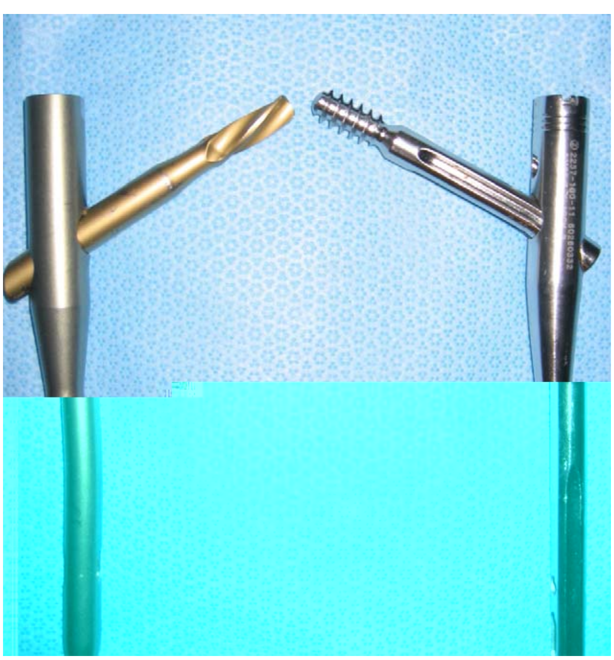

Figure 1 The helical blade design of the trochanteric fixation nail (left) and the lag screw design of the intertrochanteric/subtrochanteric fixation system (right).

This investigation performed a biomechanical evaluation and comparison of these two designs for fixation stability of cadaveric, unstable intertrochanteric hip fractures. Our hypothesis was that there would be no significant difference between the two implant designs with respect to fracture fragment displacement after cyclic loading and ultimate load to failure as both devices occlude a similar area within the femoral head.

Materials and methods

Six matched pairs of embalmed cadaver femurs were selected on the basis of plain X-rays and were DEXA scanned using a Hologic Scanner (Boston, MA) with a water bath tissue phantom in order to determine bone density and exclude specimens with pathological lesions from the study. The femoral condyles were removed and equal lengths of the femoral shafts of each specimen were potted with a low-melting temperature alloy in 6 cm square steel tubes that were 20 cm long. Throughout the experiment, each specimen was kept tightly wrapped in airtight double bags to avoid desiccation and by the use of saline soaked gauze during testing.

An experimental unstable intertrochanteric hip fracture was simulated in each potted cadaveric femur. First, a saw was used to create an oblique osteotomy at the intertrochanteric line, using a saw guide. Next, the posteromedial buttress and lesser trochanter were removed as a third fragment. After the unstable fracture pattern was created, one specimen from each matched pair was randomly selected to undergo fracture fixation using the ITST implant while the other was fixed with the TFN, according to the surgical protocol for each device. After implantation, each specimen was radiographed to ensure appropriate component positioning, with tip-apex distances being assessed. In order to measure stability of the head fragment during loading, a displacement gauge (IDC-25E, Mitutoyo Co., Miyazaki, Japan) was mounted parallel to the femoral shaft, with its

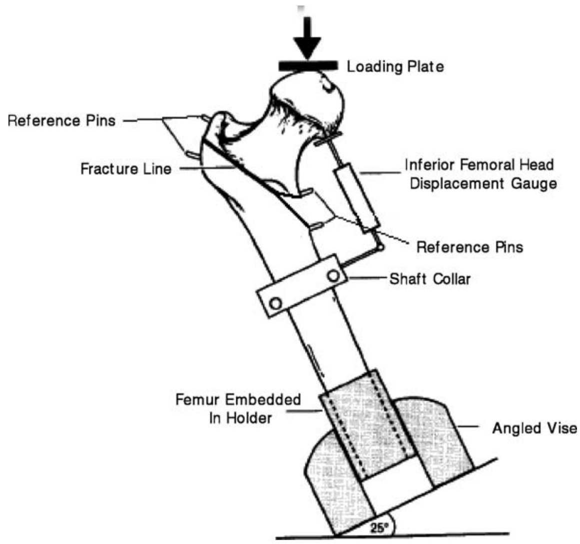

Figure 2 Biomechanical testing set-up for evaluation of fracture fixation stability with cyclic loading and load to failure.

plunger contacting the inferior aspect of the femoral head with an attached flat plate. Four short (1.0 cm) 0.062 inch Kirschner wire segments were inserted into the cadaveric femurs on each side of the fracture line at two locations on the head fragment, projecting 5 mm from the bone to act as reference pins for measurement of displacement. Two pins were placed superolaterally at the edge of the simulated fracture to measure opening of the osteotomy, and two were placed inferomedially to measure shearing displacement of the osteotomy (Fig. 2).

Biomechanical evaluation of each specimen was then performed by securing the potted bone/implant constructs in a vice at 25° adduction in the coronal plane and neutral in the sagittal plane to simulate one-legged stance (Fig. 2).[8] An Instron 2000 Universal Material Testing Machine (Instron, Canton, MA) was used for loading, using a polished flat applicator that permitted free movement of the femoral head when loaded. Each specimen was initially loaded with 750 N and allowed to come to equilibrium (120 s) before displacement measurements. Measurement of the opening distance between the superolateral reference pins and the distance between the heads of the inferomedial reference pins was made using a digital caliper with a resolution of 0.1 mm and an accuracy of 0.05 mm (Avenger 6" Digital Caliper, Boulder City, NV). The specimen was then unloaded and allowed to reach equilibrium before the measurements were repeated to determine if permanent displacement of the fracture fragments had occurred. Next, each specimen was cyclically loaded, with 750 N vertical loads applied at a rate of 3 Hz for 10, 100, 1000, and 10,000 cycles. Each specimen was allowed to reach equilibrium (120 s) after each cyclic interval, and displacement measurements both loaded and unloaded were taken.

Finally, each specimen was axially loaded to failure recording load-displacement data. Failure was defined as an acute 10% or more reduction in the amount of load borne by the bone/implant construct. The specimens were visually and radiographically examined in order to determine the mode of failure.

Repeated measures ANOVA was used to evaluate the relationship between fragment displacement and load to failure data for the two treatment groups, and fragment displacement and the number of loading cycles. Additionally, Pearson correlations were performed between specimen bone mineral density and fragment displacement and between specimen bone mineral density and load to failure. A p-value of <0.05 was considered to be statistically significant for all analyses.

Results

DEXA scanning of the intact specimens demonstrated that the femurs were generally osteopenic with a mean Ward's triangle bone density of 0.346 g/cm^2 (range 0.096–0.653 g/cm^2). There was no significant difference in bone mineral density between the TFN and ITST treatment groups ($p = 0.91$).

There was significantly more inferior femoral head displacement seen in the ITST treatment group compared to that seen in the TFN treatment group after initial loading with 750 N ($p < 0.03$) and after each cyclic loading ($p < 0.018$, $p < 0.02$, $p < 0.036$ and $p < 0.049$, respectively). There was significantly more permanent inferior femoral head displacement in the ITST treated samples compared to that seen in the samples treated with the TFN implant after each cyclic loading ($p < 0.048$, $p < 0.026$, $p < 0.039$ and $p < 0.038$, respectively) (Table 1).

There was significantly more fracture site opening in both the loaded and unloaded states in the ITST group compared with the TFN group at 1000 and 10,000 cycles ($p < 0.045$ and 0.035 in the loaded state and $p < 0.02$ and 0.049 in the unloaded state). Similarly, there was more inferior displacement both loaded and unloaded for the ITST than the TFN treated groups after 1000 and 10,000 cycles ($p < 0.045$ and 0.043 for the loaded state and $p < 0.026$ and 0.034 in the unloaded state) (Table 1).

Final loads to failure were not significantly different ($p = 0.51$) between the two treatment

Table 1 Mean fracture fragment displacements in millimeters (standard deviation) for loaded and unloaded states

Treatment	Number of cycles	Inferior head displacement (mm)	Superior pin displacement (mm)	Inferior pin displacement (mm)
TFN				
Loaded (750 N)	0	2.78 (0.69)*	1.09 (0.92)	1.54 (0.68)
	10000	3.32 (0.92)*	3.17 (0.40)*	3.22 (0.50)*
Unloaded	0	0.93 (0.53)	0.31 (0.19)	0.58 (0.51)
	10000	1.56 (0.63)*	2.14 (0.40)*	2.21 (0.38)*
ITST				
Loaded (750 N)	0	3.98 (0.92)*	2.59 (1.06)	2.28 (1.03)
	10000	4.65 (1.13)*	5.21 (1.04)*	5.46 (1.02)*
Unloaded	0	1.70 (0.72)	0.77 (0.69)	1.1 (0.68)
	10000	2.64 (0.91)*	3.52 (1.05)*	4.48 (1.2)*

* Statistical significance between the two treatments.

groups. The mean load to failure for the specimens treated with the TFN implant was 3860 N (range 2670—4550 N) compared to a mean of 3610 (range 2660—4230 N) in those treated with the ITST implant. Nine specimens demonstrated fracture extension into the anteromedial cortex and subtrochanteric region and three specimens treated with an ITST implant demonstrated a splitting fracture of the femoral head. (Fig. 3) These three cases had measured tip-apex distances of 16, 18 and 19 mm, respectively.

Regression analysis of the displacement data demonstrated a non-linear relationship between femoral head displacement and the number of axial loading cycles. The majority of the fracture fragment displacement occurred after the initial load, with continuation of displacement as the number of loading cycles increased, but at a decreasing rate of displacement. Correlations between bone mineral density and femoral head displacement showed a significant inverse relationship (correlation coefficient: −0.53, $p < 0.0001$) with the most osteopenic specimens having the largest displacements and the lowest loads to failure (correlation coefficient: 0.93, $p < 0.0001$).

Figure 3 Head splitting fracture observed in ITST specimen during axial loading to failure.

Discussion

In this investigation, we found that the intramedullary fixation provided by the trochanteric fixation nail demonstrated significantly increased fracture fixation stability compared to the intertrochanteric—subtrochanteric nail, in regard to inferior femoral head displacement, superior fracture site opening and fragment sliding with cyclic axial loading. Additionally, there was more permanent fracture fragment displacement in the specimens treated with the ITST implant than in those treated with the TFN. We believe the increased stability seen in the TFN treated specimens can be attributed to the helical blade design used for femoral head fixation.

The design of the helical blade allows for improved purchase in the femoral head, accomplished through radial compaction of the cancellous bone around the flanges of the blade during insertion.[5] The retention and compaction of the cancellous bone of the femoral head with the helical blade is advantageous compared to the bone loss that occurs with the drilling and insertion of the standard sliding hip screw.[5] Because the area of bone occluded within the head by both devices is similar, bone compaction is the most likely factor explaining the differences in behaviour seen during loading.

In a cadaveric, supracondylar femur fracture model, Ito et al, evaluated the impact insertion of a blade-like device had on fracture stability compared to the conventional distal locking bolt used with a retrograde distal femoral nail.[7] The authors found that interlocking with the spiral blade was 13—21% stronger and 41% stiffer than that seen with conventional distal locking bolts. The authors concluded that increasing the bone—implant interface surface with the spiral blade device improved stability of fracture fixation in osteoporotic specimens, providing a significant advantage over the smaller contact interface provided by the threads of a conventional locking bolt.[7]

A similar biomechanical advantage of the blade design over the conventional lag screw was demonstrated by Sommers et al.[11], in a comparison of cut-out resistance provided by implants utilised for trochanteric fracture fixation.[11] In a cellular polyurethane foam surrogate model of the femoral head, the authors demonstrated that the helical blade of the trochanteric fixation nail provided the greatest resistance to cut-out compared to the lag screw design of the extramedullary dynamic hip screw and the intramedullary gamma nail. Additionally, the blade-type design of the TFN significantly delayed the occurrence of femoral head rotation and varus migration around the implant compared to that which occurred about the lag screw of the DHS and gamma nail.[11]

The findings of our current study support those of Sommers et al., with respect to implant cut-out resistance. Application of increasing load to fixation failure resulted in three head splitting fractures with the lag screw design of the ITST, an occurrence which was not seen in the specimens treated with the TFN implant. We believe that the retention and compaction of the cancellous bone around the helical blade of the TFN provided increased resistance to implant migration and cut-out compared to that seen with the ITST design. This mechanical advantage could potentially translate into fewer clinical failures in the clinical setting.

Evaluation of the data from the biomechanical testing in our study indicated that fracture fragment displacement in unstable intertrochanteric hip fractures is directly related to bone quality, with larger displacements occurring in more osteopenic bone. Additionally, we found that load to implant failure was directly related to bone mineral density. The biomechanical advantages seen with helical blade fixation of the femoral head compared to sliding hip screw designs may be useful in managing fractures in patients with poor bone quality.

There are several limitations of our investigation. They include the use of cadaveric specimens with their inherent variability. We attempted to standardise our treatment groups through pre-testing DEXA scanning and X-ray evaluation to rule out any occult pathology that would alter the results. Although there was no significant difference in the bone mineral density between treatment groups in the study, there was a relatively large range of density in our specimen pairs. Another limitation to the study is the creation of an artificial fracture to simulate an unstable intertrochanteric hip fracture pattern. Where this artificial fracture does not truly represent the manner in which an unstable intertrochanteric fracture occurs, the ability to examine a construct with no interdigitating fracture fragments allowed us to assess the fracture fixation by the implant in its purest form. In our evaluation of the implants we used the ITST without the available auxiliary screw. We do not believe that this significantly affected the results of the biomechanical testing as it is only the larger superior screw which resists macromotion. Only if the two screws were offset or splayed would there be an effect. Finally, the biomechanical evaluation performed in this study used axial loading to simulate the forces of a one-legged stance. While our testing apparatus attempted to recreate loading the mechanical axis, we acknowledge that physiologic loading during activity is more complex and that greater loads can occur.

Conclusion

This study performed a biomechanical evaluation and comparison of the Trochanteric Fixation Nail (TFN) and the Intertrochanteric/Subtrochanteric Fixation System (ITST). This comparison allowed for the evaluation of the biomechanical differences in femoral head fixation provided by the helical blade design of the TFN and the sliding hip screw design of the ITST. We found that specimens implanted with the helical blade of the TFN were significantly less prone to inferior displacement of the femoral head, opening at the superior aspect of the fracture site and inferior shear fracture fragment displacement than those treated with the lag screw of the ITST implant. The improved biomechanical properties of the TFN implant could be attributable to the impaction of the cancellous bone around the flanges of the helical blade and the resulting increased quality of the implant—bone interface to sustain loading afforded by the blade design. Our findings support the helical blade as a biomechanically superior implant design compared to the standard sliding hip screw for fracture fixation in the unstable intertrochanteric hip fracture pattern commonly seen in the elderly, osteoporotic patient population.

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