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A Biomechanical Comparison of Locked and Unlocked Long Cephalomedullary Nails in a Stable Intertrochanteric Fracture Model

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Abstract

Objectives—This study compared the torsional properties of stable intertrochanteric femur fractures in a cadaveric bone model utilizing two different distal fixation strategies: unlocked long cephalomedullary nailing versus dynamically locked nailing.

Methods—14 matched pairs of cadaveric femora were randomly assigned to one of two distal fixation treatment groups; a single distal interlock screw placed in the dynamic orientation or no distal screw fixation. A stable two part intertrochanteric fracture was produced. Specimens were potted and mounted in a double gimbal fixture facilitating unconstrained motion in the sagittal and coronal planes. Specimens were cyclically loaded dynamically in both internal and external rotation. Range of motion, internal and external rotation stiffness, torsion stiffness, torsion yield and ultimate torsion magnitude were calculated.

Results—The samples instrumented with a distal locking screw reported statistically significantly greater internal ($1.54 \pm 0.81 \text{ Nm/}^\circ$ versus $1.08 \pm 0.35 \text{ Nm/}^\circ$, $p = 0.026$) and external rotational stiffness ($1.42 \pm 0.72 \text{ Nm/}^\circ$ versus $0.86 \pm 0.36 \text{ Nm/}^\circ$, $p = 0.009$). Samples with locked distal fixation were statistically stiffer and displayed statistically less displacement at the yield and peak torque. The yield torque was statistically significantly higher in the samples without distal fixation ($14.2 \pm 3.3 \text{ Nm}$ versus $10.6 \pm 3.8 \text{ Nm}$, $p = 0.037$). The peak torque was comparable between locked and unlocked samples ($15.0 \pm 4.6 \text{ Nm}$ versus $16.2 \pm 4.2 \text{ Nm}$, $p = 0.492$).

Conclusion—Distal locking of femoral intramedullary nails increases the stiffness of the nail-femur construct. Unlocked samples displayed statistically significant higher yield torque while maintaining comparable peak torque as the locked samples. This study indicates that treating stable intertrochanteric fractures with unlocked, long intramedullary nails may be an acceptable option, although further clinical study will be needed to test this assertion.

Keywords

Intertrochanteric fracture; Cephalomedullary nail; Distal interlocking screw

Introduction

Intertrochanteric fractures continue to pose a major challenge for orthopaedic surgeons. Presently, it is estimated that 250,000 hip fractures occur annually in the United States. Investigators predict this incidence to approach 500,000 by 2040, half of which will be intertrochanteric fractures.¹⁻⁴ Given the magnitude of this problem, considerable resources have been expended in an attempt to determine optimal treatment fixation. Anglen et al found that from 1999 to 2006, there was a dramatic increase in the preference for utilization of intramedullary nails (IMN) versus sliding compression screws. IMN fixation rate rose from 3% in 1999 up to 67% in 2006.⁵ Both long and short intramedullary nails are utilized for the treatment of intertrochanteric fractures.

The load bearing of an IMN is dependent upon fracture pattern and reduction. If significant cortical contact can be attained a large portion of the compressive loads will be supported by the cortices; however, without cortical contact, compressive loads are transmitted distally through the nail to the distal interlocking screws.^{6,7} With stable intertrochanteric fractures, defined as fracture patterns without posteromedial comminution, anatomic fracture reduction restores the ability of the bone to transmit compressive loads across the medial cortex.

In an intertrochanteric fracture patient treated with a long IMN, the nail bone construct is subjected to three types of loading: compression, torsion and bending. Physiologic loading is a combination of all three. Multiple studies have examined the impact of distally locking the long cephalomedullary nail under axial (compression) loading; however, the impact of locking the nail under torsional loading is not fully understood. Additionally, the femur sustains substantial torsional forces of 10–30Nm during daily activities such as squatting, rising from a seated position and falling^{8,9}, which can lead to periprosthetic fracture and implant failure^{10,11}.

It is generally accepted that locking a cephalomedullary nail distally should improve rotational stability of the fracture-nail construct. However, given the knowledge of the biomechanics of nail load sharing with a stable fracture pattern the question of how much rotational stability is required by the nail fracture construct arises. We hypothesized that an unlocked long cephalomedullary nail would provide adequate fracture fixation stability compared to a distally locked long cephalomedullary nail for the treatment of a stable (A1.1, A1.2, A1.3) intertrochanteric fracture when stressed biomechanically under a torsional load.

Materials and Methods

28 osteopenic human femur samples (14 matched pairs, 84.9 ± 6.0 years) were utilized for this investigation. All specimens were inspected for gross anatomical defects and excluded if abnormalities were found. Dual energy x-ray absorptiometry was performed and bone mineral density measurements were calculated for all specimens. All specimens were kept in a freezer at -20°C , approximately 12 hours prior to the mechanical testing the specimens were thawed and all soft tissue was removed.

Creation of Fracture

A standard stable two part intertrochanteric fracture was produced by a straight sagittal saw as previously described by Rosenblum et al.¹² A cut was made through the anterior femoral attachment of the joint capsule distally spanning the medial femoral cortex and proximally spanning the tip of the greater trochanter.

Sample Instrumentation

Standard Gamma 3 2.0 intramedullary nails (Stryker, Mahwah NJ) were inserted in each cadaveric femur. A total of 28 samples were used, 14 matched pairs were randomly assigned to one of two distal fixation treatment groups; a single distal interlock screw placed in the dynamic orientation and no distal fixation. To optimize tip-apex distance, as previously described by Baumgaertner et al,¹³ lag screws were placed in the center-center position for all treatments. A surgeon trained in the implantation of these treatment techniques performed all surgical procedures in general accordance with the Instructions for Use Guidelines.¹⁴ Intramedullary nail and lag screw angles were measured for each femur. The proximal set-screw was placed to allow sliding of the lag screw. In the distal fixation group, a single 5mm distal interlocking screw was placed in the dynamic position. Anterior to posterior (A-P) and lateral radiographs were obtained prior to mechanical testing to insure proper implant placement and to measure tip apex distances.

Mechanical Testing

The distal condyles were potted in urethane (Smooth On, Easton, PA). The condyles were then mounted in a previously validated, double gimbal fixture enabling unconstrained motion in the coronal and sagittal planes.^{15–18} Proximally, an additional double gimbal fixture was used to couple the head of the femur with the actuator of the Instron biaxial servohydraulic load frame (Instron Corp, Canton, MA) (Figure 1). Prior to loading, samples were positioned in such fashion that the axial loading vector coincided with the center of the femoral head proximally and continued through the intercondylar notch (coronal plane) and the femoral epicondyles (sagittal plane).

Specimens were loaded for 10 cycles in both internal and external rotation at 3 Nm with a static axial compressive load of 20 N under torsion control at a frequency of 0.1Hz. Initial dynamic pilot tests included both a $\pm 3\text{Nm}$ and $\pm 6\text{Nm}$ test. However, these trial samples reported fracture during the dynamic test at this higher $\pm 6\text{Nm}$ torque level. These pilot specimens were excluded in our analysis of the results. Thus, for our test methodology we elected to have nondestructive testing at $\pm 3\text{Nm}$, with subsequent testing to failure. Fracture displacement and torque data was recorded digitally at a frequency of 25 Hz. Following dynamic testing, samples were loaded in external rotation at a displacement rate of 10° per minute until catastrophic failure or 70° of displacement.

For the dynamic nondestructive test, range of motion and internal and external rotation were calculated. Torsion stiffness, torsion yield and ultimate torsion magnitude were calculated during the quasi static torque to failure test. Stiffness and torsion yield were calculated by a single blinded investigator using a custom program (National Instruments, Austin, TX). In all instances, the initial linear portion of the torque versus displacement curve where the r

squared value maximized was used for the calculation of stiffness. A two percent offset yield calculation was made by the same metric using a gauge length of 82.5mm, representing a standardized distance of the distal end of the lag screw within the femoral head and its intersection with the intramedullary nail (100mm lag screw length minus half of the mean mid-shaft bone diameter of 35mm). Yield was defined as the intersection point of the actual torque versus displacement curve and the 2% offset line. In all instances, the mechanism of failure was also recorded, for all specimens the mechanism of failure was failure of the nail through the greater trochanter producing a spiral or oblique fracture pattern.

Statistical Analysis

Paired t-tests assessed outcome variable differences for both the dynamic and torque to failure tests between treatment groups using SigmaPlot (version 12.0, Systat, San Jose, CA). A paired t test was used to determine if significant differences exist between the two treatment groups with regard to bone density and T-Score. In all comparisons, statistical significance is set to $p < 0.05$.

Results

For the nondestructive dynamic test, the group with a distal locking screw reported statistically significantly greater internal ($1.54 \pm 0.81 \text{ Nm}^\circ$ versus $1.08 \pm 0.35 \text{ Nm}^\circ$, $p = 0.026$) and external rotational stiffness ($1.42 \pm 0.72 \text{ Nm}^\circ$ versus $0.86 \pm 0.36 \text{ Nm}^\circ$, $p = 0.009$) compared to the unlocked samples. Samples instrumented without distal locking fixation reported more displacement throughout the test. However, these differences were not statistically significant ($p = 0.14$, Table 1).

For the torque to failure test, samples with locked distal fixation were statistically stiffer, however had statistically less displacement at the yield torque (Table 2). The yield torque, or region where plastic deformation occurs, was statically significantly higher in the samples without distal fixation ($14.2 \pm 3.3 \text{ Nm}$ versus $10.6 \pm 3.8 \text{ Nm}$, $p = 0.037$). Peak torque between treatment groups was not statistically different. Figure 2 illustrates the relationship between mean peak and mean yield torsion values between constructs. There were no differences with regard to bone mineral density (Table 3) or tip apex distance (Table 4) between treatment groups.

Discussion

Together with femoral neck fractures, intertrochanteric hip fractures represent perhaps the most significant public health problem facing orthopaedic surgeons today.⁴ The success of the surgical treatment for these injuries depends to a large extent on the stability of the fixed fracture. Kaufer et al illustrated how the stability of the fracture-implant assembly depended on five factors: the quality of the bone, the fracture pattern, the reduction achieved, the design of the implant selected, and the position of the implant within the bone.¹⁹ Our present biomechanical study further investigates torsion as a mode of failure, and provided data regarding the effects of distal dynamic locking screw fixation.

Multiple authors have evaluated the biomechanical stability of intertrochanteric fractures. However, the exact indications for locking a long IMN are not fully understood. In this study, we confirmed that locking an IMN distally increases the stiffness of the nail-femur construct in both internal and external rotation. The most provoking finding was that unlocked samples displayed statistically significant higher yield torque, while maintaining comparable peak torque as the locked samples. One may postulate that the unlocked nail was able to withstand more external rotation stress before failure than a dynamically locked nail and is an acceptable clinical fixation option, although further study is required to test this hypothesis.

In a previous investigation, our group examined the effect of torsional loading to failure on a “healed” intertrochanteric (IT) fracture model treated with a long cephalomedullary nail in statically locked and unlocked configurations compared to the uninstrumented femur utilizing a similar study protocol utilizing in this investigation.¹⁵ This study revealed that distally unlocked nails provided similar torsional strength compared to distally locked nails. The results of the current investigation with our “unhealed” fracture model provide further support to the assertion that treating intertrochanteric femur fractures with unlocked long intramedullary nails may be an acceptable treatment option.

The potential clinical implications of this study are numerous. Our biomechanical testing results suggest that an unlocked construct remains equivalent to a locked construct with regard to catastrophic failure torque magnitude and may be superior to locked constructs with regard to plastic deformation. A construct which provides adequate fixation stability for fracture healing, while at the same time is tolerable of more torque is preferred. Consequently, it is our belief that in choosing between a distally locked versus unlocked nail in the treatment of a stable intertrochanteric fracture, an unlocked IMN is an acceptable choice

This study is similar to the investigation by Gallagher et al²⁰, which revealed maximal torsional loads of 29Nm and 58Nm for unlocked and locked nails, respectively. Our study revealed lower maximal torsional loads of 16Nm and 15Nm for locked and unlocked nails. There are several possible explanations for the contrasting results. Gallagher’s study did not assess BMD, and may have had samples with higher BMD as compared to the osteopenic samples studied in this investigation. They also utilized 11mm nails with a neck-shaft angle of 130 degrees in all cases, while we utilized implants based on the optimal fixation based on the femoral anatomy of each specimen. These methodological differences may account for the contrasting results for load to failure of intertrochanteric cephalomedullary nail fixation.

Our present study has several important limitations. We used fresh frozen cadaver tissue and therefore, cannot unequivocally predict *in vivo* biomechanical properties. Additionally, we feel the unconstrained loading model is valuable as it should closely represent an *in vivo* loading method. Furthermore, our study only investigated locking in dynamic mode. Our decision for choosing a dynamic locking position was based on clinical observations. Our senior author has observed dynamic locking mode to be a beneficial construct allowing compression across the fracture site. We also recognize that the determination for gauge

length and thus the yield torque calculation is based on a theoretical assumption that the fulcrum length of 82.5mm represented the end of the lag screw to its intersection with the nail. Using a normal distribution function with the current yield calculations and standard deviation values, we would predict that 1% of unlocked compared to 11% of locked samples would fail when tested to 6Nm. Our limited pilot dataset reported fracture incidence rates larger than these predictions (22% unlocked and 33% locked). Using a small gauge length (nail diameter of 11mm), would warrant the same statistically significant difference with regard to yield load (unlocked: 7.99 ± 5.29 and locked: 4.73 ± 2.29 Nm, $p = 0.033$). Using the same prediction model for a 6 Nm test would estimate fractures in 35% of unlocked and 72% of locked samples. Thus, our estimation for yield may be conservative, but the true yield likely is encompassed within this range where unlocked fixation is at least comparable. Finally, we recognize that there are limitations to our loading protocol. We chose 10 cycles of loading as we found that plots of the torque versus displacement data for each cycle indicated that hysteresis was not evident in our system. Biomechanical testing is an imperfect model of *in vivo* loads and our model may appear simplistic in that we only chose to investigate torsional loading, however, that was one important our goal for this study.

Our study confirmed that locking an IMN distally increases the stiffness of the nail-femur construct in both internal and external rotation. Most significantly our findings demonstrated that unlocked samples displayed statistically significant higher yield torque while maintaining comparable peak torque as the locked samples. We recognize that the gauge length determination in this model is subject to debate. However, based on our findings, our data suggests that unlocked constructs may benefit from more displacement and thus tolerate higher torsional loads prior to plastic deformation. This suggests that a femur with a locked distal construct may fracture earlier when subjected to torsional loading than one with an unlocked nail. Consequently, it is our belief that in choosing between a distally locked long IMN versus unlocked long IMN in the treatment of a stable intertrochanteric fracture, an unlocked nail may be an acceptable treatment option, although clinical studies will be needed to test this assertion.

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Figure 1.

Picture of a femur in the custom alignment fixture to test the femur in torsion.

Testing set up with the femur in a double gimbal fixture facilitating unconstrained motion in the sagittal and coronal planes.

Figure 2.

Yield and Peak Torque Relationship

This graph represents the mean torque versus displacement data for the aggregate locked and unlocked samples tested. The mean yield and mean peak torsional values are identified with in the graph.

Table 1

Summary of results from nondestructive torsion testing (Mean $\pm$ S.D.). This table shows external rotation (ER) and internal rotation (IR) stiffness along with displacement for intramedullary nails with locked distal fixation and no distal fixation for all 14 matched pairs (28 specimens).

Treatment	ER Stiffness (Nm/°)	IR Stiffness (Nm/°)	Total Displacement (°)
Locked Distal Fixation	1.42 $\pm$ 0.72	1.54 $\pm$ 0.81	7.19 $\pm$ 4.99
No Distal Fixation	0.86 $\pm$ 0.36	1.08 $\pm$ 0.35	10.46 $\pm$ 7.27
<i>p</i> value, 1 - β	0.009, 0.995	0.026, 0.569	0.144, 0.187

Table 2

Summary of results from external rotation torque to failure testing (Mean $\pm$ S.D.). This table shows the yield torque for the intramedullary nails with no distal fixation is greater than the yield torque for locked distal fixation. Displacement is at yield and peak is greater for the the IMN with no distal fixation compared to the nails that are locked. The data includes 14 matched pairs (28 specimens).

Treatment	Yield Torque (N•M)	Peak Torque (N•M)	Stiffness (N•M/°)	Displacement at Yield (°)	Displacement at Peak (°)
Locked Distal Fixation	10.6 $\pm$ 3.8	15.0 $\pm$ 4.6	1.9 $\pm$ 0.8	8.7 $\pm$ 4.9	19.4 $\pm$ 10.8
No Distal Fixation	14.2 $\pm$ 3.3	16.2 $\pm$ 4.2	1.0 $\pm$ 0.5	21.4 $\pm$ 6.6	26.9 $\pm$ 8.2
<i>p</i> value, 1- β	0.037, 0.503	0.492, 0.050	0.001, 0.979	<0.001, 0.999	0.118, 0.230

Table 3

Summary of the proximal femur bone mineral density and t Score (Mean $\pm$ SD). This table shows there is no difference in bone mineral density between the two groups, 14 matched pairs (28 specimens).

Treatment	Density (g/cm ²)	T Score
Locked Distal Fixation	0.70 $\pm$ 0.19	-2.24 $\pm$ 1.49
No Distal Fixation	0.67 $\pm$ 0.19	-2.47 $\pm$ 1.49
<i>p</i> value, 1 - β	0.114, 0.234	0.136, 0.197

Table 4

Shows there is no difference between the two groups with regards to tip apex (Mean $\pm$ SD) for 14 matched pairs (28 specimens).

Treatment	AP Distance (mm)	Lateral Distance (mm)	Tip Apex Distance (mm)
Locked Distal Fixation	8.0 $\pm$ 2.0	7.6 $\pm$ 1.7	15.6 $\pm$ 3.0
No Distal Fixation	7.9 $\pm$ 1.7	7.7 $\pm$ 1.4	15.6 $\pm$ 2.8
<i>p</i> value, 1 - β	0.497, 0.060	0.888, 0.50	0.954, 0.50