Effect of Distal Interlock Fixation in Stable Intertrochanteric Fractures

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abstract

The objective of this study was to evaluate the torsion stiffness of locked and unlocked distal fixation of long cephalomedullary nail constructs, in both a fresh fracture and healed, stable intertrochanteric fracture model. Samples were tested in both internal and external rotation (0±3 Nm) for a duration of 10 cycles. Each femur was tested without instrumentation (intact femur), with instrumentation and no fracture (healed intertrochanteric fracture), and with instrumentation with an osteotomy creating a stable intertrochanteric fracture (fresh fracture). All specimens were instrumented with a long cephalomedullary nail. A distal interlock was placed in the dynamic position in 1 femur, and the other femur of the matched pair was left unlocked.

Mean external (ER) and internal (IR) rotation stiffness for intact femurs without instrumentation (ER, 2.1±0.5 Nm/degree; IR, 2.2±0.5 Nm/degree) was statistically stiffer (P<.05 for all) compared with fresh fractured locked (ER, 1.1±0.2 Nm/degree; IR, 1.1±0.3 Nm/degree) and fresh fractured unlocked (ER, 0.9±0.3 Nm/degree; IR, 1.0±0.2 Nm/degree) samples. Similarly, healed locked (ER, 2.5±0.2 Nm/degree; IR, 2.8±0.1 Nm/degree) and healed unlocked (ER, 2.5±0.5 Nm/degree; IR, 2.4±0.3 Nm/degree) samples had statistically higher stiffness compared with fresh fractured treatments.

These results suggest that the unlocked distal constructs provide similar torsional strength compared with fixed fixation in these models.
Hip fractures present an increasingly common surgical problem for the orthopedic and medical community. An estimated 1.66 million hip fractures occurred worldwide in 1990. According to epidemiologic projections, this worldwide annual number will increase to 6.26 million by the year 2050.1–3 Intertrochanteric hip fractures account for approximately one-half of all hip fractures.4 It has been shown that intertrochanteric fractures are increasing in incidence compared with cervical neck fractures, with the relative number of observed fractures increasing in both sexes and all age groups during the recent decades.1

Many different types of hardware are available to fix these fractures. The use of cephalomedullary nails has increased over the past several years, from 3% in 1999 to 67% in 2006.5 Short and long intramedullary nails are accepted treatment options for various intertrochanteric fractures. At the authors’ institution, a long cephalomedullary nail is currently the implant of choice. Some studies suggest that long nails may be less likely to refracture than short nails and thus provide a more stable construct.5 These nails may protect against future femur fractures by instrumenting the entire femur compared with a short nail. Both of these intramedullary nails function as internal splints that allow for secondary fracture healing.

Intramedullary nails are assumed to bear most of the load initially, and then gradually transfer it to the bone as the fracture heals.7 In current practice, with reaming of the canal and the use of locking screws, physiologic loads are transmitted to the proximal and distal ends of the nail through the screws. When interlocking screws are absent, the implant acts to guide the axial compaction motion of the bone along the longitudinal axis of the nail. Intramedullary reaming promotes increased contact area between the nail-bone construct and thus improves construct stability. The friction of the nail within the medullary cavity determines the resistance to motion.7 Biomechanically, reamed nails provide superior fixation stability compared with undreamed nails.8

The physiologic loading of the nails is a combination of 3 forces; torsion, compression of the medial aspect of the nail, and tension on the lateral aspect.7 When cortical contact across the fracture site is achieved postoperatively, most of the compressive loads are borne by the bony cortex; however, in the absence of cortical contact, compressive loads are transferred to the interlocking screws.7 In stable intertrochanteric fractures with adequate reduction, good cortical contact exists. Thus, the cortical bone absorbs the compressive loads and less theoretical benefit exists for use of a distal interlock. However, the influence of torsional forces on the nail fracture construct is not fully understood, and what contribution a distal interlock may provide to the nail-fracture construct should be further analyzed.

After intertrochanteric fracture fixation with an intramedullary nail, many surgeons allow patients to weight bear as tolerated.9 If a patient walks without aid, he or she would theoretically place at least 1.2 times his body weight across the nail-fracture construct.10 Exactly how much weight to allow patients to bear has been a challenging question for orthopedic surgeons.9,11 In an effort to better understand all phases during the fracture-healing process, the authors simulated and evaluated both healed and freshly fractured intertrochanteric injuries in a cadaveric model. A healed fracture model may add to the existing literature regarding patient rehabilitation. This is an important issue to look at from an economic standpoint. As previously reported by Haentjens et al,12 the cost of treatment for a hip fracture in Belgium the year after the fracture was $13,470, compared with $9534 during the initial hospitalization.

The specimens were maintained in a freezer at −20°C until approximately 12 hours prior to mechanical testing. The specimens were thawed to room temperature, and all residual soft tissue and musculature surrounding the femur was removed via careful dissection. All 10 femurs were then tested without instrumentation for baseline intact analysis. The matched pairs were divided into the locked and unlocked groups. Each femur was to be tested without instrumentation (intact femur), with instrumentation and no fracture (healed intertrochanteric fracture), and with instrumentation with an osteotomy creating a stable intertrocalmedullary nail constructs using a novel unconstrained loading device in a fresh fracture stable intertrochanteric fracture model and a healed intertrochanteric fracture model. The authors’ previous work showed that locked nails provided a statistically significantly stiffer construct compared with an unlocked model in a stable intertrochanteric fracture.13 Increased stiffness in the locked samples also resulted in a statistically lower yield torque compared with unlocked samples. The authors hypothesized that a femur with a long locked cephalomedullary nail may be stiffer than an intact femur. In this study, they compared the stiffness of an intact femur to an intact femur with a nail healed fracture to a femur with a trochanteric fracture fixed with a nail fresh fracture both with (locked) and without (unlocked) distal interlock fixation.

**Materials and Methods**

A total of 10 osteoporotic human female femur samples (5 matched pairs; mean age, 85.0±5.8 years) were used for this study. The specimens were screened for gross anatomical defects and excluded from the study if abnormalities were found. Bone mineral density measurements were performed on the proximal femur using dual energy x-ray absorptiometry to ensure no difference between each femur in the matched pair.

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Distal interlock fixation in stable intertrochanteric fractures

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The distal condyles were potted in urethane with the assistance of a custom alignment fixture. The potted condyles were then mounted in a previously validated, double gimbal fixture facilitating unconstrained motion in the sagittal and coronal planes. Proximally, the head of the femur was coupled with the actuator of an Instron Biaxial Servohydraulic Load Frame (Instron Corp, Canton, Massachusetts) with the use of an additional double gimbal fixture (Figure 1). Prior to testing, samples were oriented as such that the axial loading vector coincides with the center of the femoral head passing through the intercondylar notch in the coronal plane and the femoral epicondyles in the sagittal plane in the unloaded state.

Specimens were cyclically loaded for 10 cycles in internal and external rotation to 3 Nm in load control at a frequency of 0.05 Hz for 10 cycles with a static axial compressive load of 20 N. Torque and displacement data were recorded digitally at a frequency of 25 Hz. External and internal rotation stiffness and total range of motion were quantified. The specimens were not tested until failure to evaluate intact, with instrumentation, and with instrumentation with a stable intertrochanteric fracture in a repeated manner with the same specimen.

A total of 10 samples (5 matched pairs) were randomly assigned to 1 of 2 distal fixation treatment groups: a single distal interlock screw placed in the dynamic orientation and no distal interlock. A surgeon (P.M.K., B.V.) trained in the implantation of these treatment techniques performed all surgical procedures in general accordance with the Instructions for Use Guidelines. Proximally, lag screws were placed in the center-center position, previously described by Baumgartner et al., for all treatments. Intramedullary nail and lag screw angles were measured for each femur. The proximal set-screw was placed to allow sliding of the lag screw, and a single distal interlocking screw in the dynamic position was used in the distal fixation group. Anteroposterior and lateral radiographs were obtained prior to mechanical testing to ensure proper implant placement and to measure tip apex distance. All were less than 25 mm. Mechanically testing was performed again as stated previously. This testing represented the healed instrumented femurs.

The specimens had a stable intertrochanteric fracture made after they were tested. A standard stable 2-part intertrochanteric fracture was produced by a straight sagittal saw as previously described by Rosenblum et al. 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. The specimens were tested as stated previously. This group represented the fractures immediately after instrumentation (fresh fractures).

A paired t test was performed to determine that significant differences exist between the 2 treatment groups with regard to bone density and T-score. A 2-factor (treatment [interlock or no interlock] and test condition [intact, fresh fracture, healed fracture]) repeated measures analysis of variance evaluated outcome variable differences for the dynamic torque between treatment groups using SigmaPlot version 12.0 statistical software (Systat, San Jose, California). Statistical differences were identified with a Holm-Sidak post hoc test. In all cases, statistical significance was set at a P value less than .05 a priori.

**RESULTS**

Bone density was not statistically different between locked and unlocked treatment groups (P=.898) (Table). Mean external (ER) and internal (IR) rotation stiffness for

Figure 1: Testing setup with the femur in a double gimbal fixture facilitating unconstrained motion in the sagittal and coronal planes.
intact femurs without instrumentation (ER, 2.1±0.5 Nm/degree; IR, 2.2±0.5 Nm/degree) was statistically stiffer (P<.05 for all) compared with fresh fractured locked (ER, 1.1±0.2 Nm/degree; IR, 1.1±0.3 Nm/degree) and fresh fractured unlocked (ER, 0.9±0.3 Nm/degree; IR, 1.0±0.2 Nm/degree) samples (Figure 2). Similarly, both healed locked (ER, 2.5±0.2 Nm/degree; IR, 2.8±0.1 Nm/degree) and healed unlocked (ER, 2.5±0.5 Nm/degree; IR, 2.4±0.3 Nm/degree) samples had statistically higher stiffness compared with fresh fractured treatments (Figure 2). No statistically significant differences existed among intact, healed locked, or healed unlocked treatment groups (Figure 2).

In this biomechanical testing model, range of motion (ROM) data correlated with the above stiffness results. As the specimens were loaded in IR and ER to 3 Nm, gross ROM data were recorded. Pairwise multiple comparison procedure testing (Tukey test) showed no statistically significant difference between intact vs healed locked (P=.0991) and intact vs healed unlocked (P=.100) models. No difference was observed in the unlocked vs locked healed treatment groups (P=.100). Significantly, in all comparisons of the fresh fracture model, both locked and unlocked, statistically significant more ROM existed compared with the intact or healed groups: fresh fractured locked vs intact (P=.012), fresh fractured locked vs healed locked (P=.021), fresh fractured locked vs healed unlocked (P=.033), fresh fracture unlocked vs intact (P=.004), fresh fracture unlocked vs healed unlocked (P=.015), and fresh fracture unlocked vs healed locked (P=.10). However, when comparing ROM between the 2 fresh fracture treatment groups, no statistically significant difference was observed in ROM between fresh fracture unlocked vs fresh fracture locked (P=.998).

**DISCUSSION**

The benefits to not placing distal interlocks are numerous, including decreasing the amount of operative time needed for fixation, which lowers cost and decreases the amount of time the patient is under anesthesia. This is especially important in an older patient population, which is more prone to having multiple comorbidities. In addition, no placing distal interlocks decreases the amount of radiation exposure to everyone in the operating room.

The current study is limited. Fresh frozen cadaver tissue was used, and consequently the authors cannot truly foretell in vivo biomechanical properties. However, fresh frozen cadaver tissue is the best medium for evaluating biomechanical properties because it most closely approximates in vivo biomechanical characteristics. In addition, the authors believe that the unconstrained loading model is beneficial because it more closely represents an in vivo loading method. This technique has been previously used for femoral fixation in a compression model.15,17

To the current authors’ knowledge, this is the first article to describe the use of this technology in a torsion model. Physiologic loading is a combination of axial compression and torsion forces. The authors limited their investigation to various torsional loads; however, a constant compressive force was applied throughout testing. They recognize the small sample size as an additional limitation and attempted to reduce this effect via the repeated measures aspect of this investigation. The cost of implants and availability of osteoporotic paired femora samples with equivalent bone density remains a large limitation for these research pursuits. In addition, the authors recognize that testing all specimens to failure may have provided further information regarding ultimate failure strength. Although they feel this information would have

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**Table**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Locked Distal Fixation</th>
<th>No Distal Fixation</th>
<th>P, 1-β</th>
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<tr>
<td>Density, g/cm²</td>
<td>0.67±0.21</td>
<td>0.68±0.25</td>
<td>.898, 0.05</td>
</tr>
<tr>
<td>T-score</td>
<td>−2.64±1.66</td>
<td>−2.60±1.98</td>
<td>.946, 0.05</td>
</tr>
</tbody>
</table>

*No significant difference with regard to bone mineral density was found between the 2 groups.*

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**Figure 2:** Graph showing the difference in stiffness during cyclic torsion for intact, fresh fracture locked, fresh fracture unlocked, healed locked, and healed unlocked femurs. Abbreviations: Ext Rot, external rotation; Int Rot, internal rotation.

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been important and useful, it was not the goal of the study. The biomechanical testing was an attempt to further the understating of torsional stiffness in stable intertrochanteric fractures treated with long cephalomedullary nails in both locked and unlocked configurations in an acute as well as a healed fracture model, and to this end the authors feel that they succeeded.

In this study, no difference was found in IR and ER stiffness between healed locked, healed unlocked, and intact specimens. In addition, no statistically significant difference was found in ROM between healed locked, healed unlocked, and intact specimens. This proves the authors’ hypothesis to be incorrect. However, this also suggests that minimal benefit exists for placing a distal interlock screw for intertrochanteric fractures that are stable once the fracture is healed. The study’s ROM data support the idea of distal interlock screws providing negligible fixation benefit in an acute fracture model. No statistically significant difference was found in ROM between locked and unlocked fresh fracture samples. However, when both locked and unlocked fresh fracture models were compared with both healed and intact femurs, statistically significantly more ROM existed.

No difference was found in stiffness in either the healed locked and unlocked groups or the fresh fracture locked and unlocked groups. These results support the authors’ prior work. The locked nail was statistically stiffer (ER, 1.4±0.7 Nm/degree; IR, 1.5±0.8 Nm/degree) compared with the unlocked nail (ER, 0.9±0.4 Nm/degree; IR, 1.1±0.4 Nm/degree) (P=.026 and P=.009, respectively) in a stable intertrochanteric fresh fracture model. The authors’ previous work indicated that in a quasistatic torsion to failure test, locked nails had a statistically significantly lower torsion yield value (10.6±3.8 Nm/degree) vs unlocked nails (14.2±3.3 Nm/degree). The nature of this test methodology suggests that the locked nails may have plastically deformed during the simulated healed instrumented tests. In the current study, no difference was found in torsional stiffness between the locked fresh fracture (ER, 1.1±0.2 Nm/degree; IR, 1.1±0.3 Nm/degree; P=.599) and unlocked (ER, 0.9±0.3 Nm/degree; IR, 1.0±0.2 Nm/degree; P=.935) specimens. The authors’ previous study illustrated that in a stable intertrochanteric fracture, a locked cephalomedullary nail fails at a lower torsional moment than an unlocked nail at the proximal fracture site. Combining their biomechanical testing data with regard to torsional stability and the potential for plastic bone deformation in a freshly fractured scenario with the previously mentioned potential staff, patient, and cost benefits suggests that an unlocked intramedullary nail is a viable treatment option.

Duda et al. mathematically calculated the forces and moments of the femur during walking. Using their analysis, a 70-kg person would produce 2.8 Nm of force on the proximal femur. The current authors’ previous work resulted in failures occurring in a loading scenario greater than 3 Nm at the fracture site. These factors guided their decision to use 0±3 Nm as a testing parameter due to the repeated measures testing sequence facilitated in this study. They estimate the gimbal tolerances as negligible because a solid steel rod was torqued dynamically prior to the testing of the samples and reported less than 1° of deflection at torsion values of 10 Nm. Future research will be conducted using the healed fracture model with the goal of evaluating secondary fractures that are often reported clinically in this model.

Regardless of the distal fixation strategy used, the construct is significantly less stiff. Thus, the risk of nonunion, malunion, or fracture nail construct failure is highest in the acute fracture period. Therefore, a more conservative rehabilitation protocol may be needed in select patients in the early part of the rehabilitation process. Delirium and dementia are risk factors for adhering to rehabilitation protocols. Yiannopoulou et al. reported that 85% of patients with hip fractures had increased symptoms of dementia compared with 61.5% of a control group. It has been documented that patients with dementia have more difficulty adhering to a rehabilitation protocol and are at an increased risk of not returning to their prefracture level of function. Consequently, a conservative rehabilitation protocol with a walking aide should be considered in older patients, and partial weight bearing may be considered in patients who could adhere to it. The patient’s mental status and physiological conditioning must be considered when making recommendations.

The incidence of postoperative secondary femoral shaft fractures for different types of nails ranges from 0% to 2.3%. Norris et al. reported that long nails had a slight tendency toward a lower risk of fracture, although the difference was not statistically significant (1.1% vs 1.7%; P=.28). Even with this lower risk, secondary fractures still present a challenging problem to the orthopedic community. To the authors’ knowledge, this is the first biomechanical study to look at a healed model for locked and unlocked long cephalomedullary nails. These data support their current clinical practice of treating stable intertrochanteric fractures with unlocked long cephalomedullary nails. Given the current results, the authors have begun a clinical study examining the implications of unlocked vs locked long cephalomedullary nails. To date, no nonunions or implant failures have occurred in the unlocked cohort.

Conclusion

The results of this study suggest that unlocked distal constructs provide similar torsional stiffness compared with locked fixation in intertrochanteric fractures that are either stable or stable after reduction. Due to the increased operative time, increased complexity of inserting locking distal fixation, and apparent equivalent stiffness, an unlocked long cephalomedul-
Intramedullary nailing of the lower extremity may provide a viable treatment option for stable intertrochanteric fractures. Immediately following nail fixation of a stable intertrochanteric fracture (fresh fracture), both treatments (locked and unlocked) resulted in inferior torsional stiffness compared with the intact and healed constructs.

REFERENCES