Abstract

Recently, a new, shorter IM nail using two 6 mm reconstruction screws for proximal fixation was introduced in two versions for femoral insertion: piriformis fossa (FAN) and greater trochanter (TAN). These nails were compared experimentally for their fixation stability, proximal load transmission, and failure strength in an unstable intertrochanteric fracture model in cadaveric femurs. Vertical and axial loads were first applied to the intact femurs. Fractures were created, subsequent fixation applied, and the femurs underwent a series of both vertical and axial loading tests. There was no significant difference in strain readings between the nails for either axial loading or cyclical loading. There was no statistically significant difference between the loads to failure for the trochanteric nails and the standard antegrade nails. The average ultimate load for the FAN and TAN nails were 3010 N and 2830 N respectively. These two nails performed very similarly throughout our testing.

Effect of Piriformis Versus Trochanteric Starting Point on Fixation Stability of Short Intramedullary Reconstruction Nails

Edward T. Su, M.D., Hargovind DeWal, M.D., Roy Sanders, M.D., Frederick J. Kummer, Ph.D., Mohammed Mujtaba, M.D., and Kenneth J. Koval, M.D.

Standard intramedullary (IM) nails are usually used for subtrochanteric and more distal femoral fractures; shorter IM nails such as the Gamma (Stryker, Howmedica-Osteonics, Rutherford, NJ), and IMHS (Smith & Nephew, Memphis, TN) are used for more proximal fractures. The former usually rely on two 6 mm to 7 mm proximal fixation screws in the femoral head and neck; the latter, on a large single screw similar to the sliding hip screw.

One of the problems with some of the longer IM nails is the insertion point in the proximal femur. The piriformis fossa is difficult to get to, and often the fracture may involve this area, so that insertion of the nail at this point results in further comminution of the fracture. Previous studies have also shown an increased risk of femoral fracture during the insertion of the nails, due to the fact that the femur is bowed while the nails are straight. To avoid these problems, however, long Gamma (Stryker, Howmedica-Osteonics, Rutherford, NJ) and IMHS (Smith & Nephew, Memphis, TN) nails are available.

For the shorter nails, there are two types of proximal screw configuration available. For nails inserted into the piriformis fossa, two proximal locking screws are used for fixation of the head and neck. For nails inserted into the greater trochanter, one large lag screw is used for fixation in the head and neck. When comparing these two types of nails, it is unclear whether the insertion point or the type of proximal fixation is primarily responsible for any differences.

Recently, a new, shorter IM nail using two 6 mm reconstruction screws for proximal fixation was introduced in two versions for femoral insertion: piriformis fossa (FAN) and greater trochanter (TAN) (Fig. 1). Because these two IM nails differ in design (the TAN has a proximal bend), they have differences in their accommodation in the medullary canal and slight differences in fixation screw lengths (Fig. 2). Both nails use two proximal reconstruction screws at 135° for proximal fixation, so the only significant design difference is the bend allowing for trochanteric insertion. Thus, unlike the previously mentioned nails, theses nails differ by only one variable, rather than two. The following experiment compared them with respect to fixation stability, proximal load...
transmission, and failure strength in an unstable intertrochanteric fracture model.

Methods and Materials

Ten matched pairs of osteopenic embalmed cadaver femurs were selected on the basis of a bone density of 0.3 to 0.5 g/cm² (QDR-2000 Supine Lateral X-Ray Bone Densitometer, Hologic, Waltham, MA). Radiographs in two planes were taken to exclude samples with morphologic abnormalities. The femurs were stripped of all soft tissues and the distal femoral condyles were removed at a level 15 cm distal to the inferior edge of the lesser trochanter. The femoral shafts were then potted with a low melting lead-tin alloy in 6 cm x 20 cm steel tubes. The specimens were wrapped with saline soaked gauze and sealed in airtight double bags when not in use to avoid desiccation throughout the experiment.

One linear strain gauge was mounted on the medial aspect of each femur using cyanoacrylate cement, one centimeter inferior to the planned location of the fracture site. An electronic displacement gauge was attached to the femur, just distal to the proposed fracture site, parallel to the axis of the femoral shaft, with the spring gauge element contacting the inferior femoral head to measure inferior displacement of the head with axial loading. The specimens were secured on the testing platform with a vise at 25° adduction in the coronal plane, and neutral in the sagittal plane to simulate one-legged stance. Mechanical testing of the intact femurs was performed to provide control values for femoral strain and inferior head deflection in axial loading. A MTS Material Testing Machine (MTS, Minneapolis, MN) was used to apply vertical loads directly onto the femoral head with a flat applicator to allow free horizontal movement of the femoral head. The axial load was applied in increments of 250 N to 1000 N; the medial strain and the inferior head displacement was recorded after ten seconds of loading.

The nails used for this study were the Smith & Nephew TAN and FAN nails (Smith & Nephew, Memphis, TN). The holes for the proximal locking screws
are angled at 135° in both nails. The only difference between the nails is a 5° bend 8 cm from the top of the TAN nail to allow for trochanteric insertion. They both have a hole and slot distally for distal interlocking screws.

One femur from each matched pair was randomly assigned to the TAN group. The other femur was assigned to the FAN group. Using a thin-blade oscillating saw, a four-part unstable intertrochanteric hip fracture was created. The first fracture line was created through the intertrochanteric ridge. A second fracture line was created around the lesser trochanter. This fracture line was extended obliquely and superiorly to the anterior portion of the intertrochanteric fracture line. Finally, a transverse fracture line was created at the base of the greater trochanter. The fractures were reduced and the instrumentation was performed under direct vision and fluoroscopic guidance. Starting holes were first drilled in either the greater trochanter or piriformis fossa, as appropriate for each nail (Fig. 3). The nails were then inserted with the alignment jig. The 6.0 mm reconstruction screws were placed, using the alignment jig, so that the inferior screw was resting on the medial calcar of the femoral neck. The superior screw was located in the center of the femoral head. Screw lengths were measured both radiographically and directly with a depth gauge. The screws ended in the subchondral bone less than 1 cm from the articular surface. Distal interlocking screws were not used in any of the femurs, as the alignment jig for distal locking screws for the TAN was not available for the experiment. Also, distal interlocking screws are not essential for stable fixation of this proximal fracture pattern.

After fracture fixation, the femurs were again loaded axially, with 250 N increments to 1000 N, while recording the medial femoral strain and the inferior head displacement at each load interval. The femurs were then cyclically loaded to 750 N for 100, 1000, and 10,000 cycles in a sinusoidal manner at 3 Hz. After each cycle...
interval, the inferior head displacement and strain were recorded both with and without loading to 750 N.

Finally, the femurs were then loaded to failure. Axial loads were applied to the femoral head at a rate of 1.0 cm/min, continuously recording load until failure, which was defined as fracture of the femoral head, neck, or shaft, extension of the prior fracture, screw cutout through the head, or deformation of the implants.

Analysis of Data
The data for the FAN- and TAN-fixed matched pairs were analyzed using paired t-tests and repeated measures analysis of variance to assess differences between treatment techniques. A significance level of $\alpha = 0.05$ was used.

Results
There was no significant difference in strain readings between the nails for either axial loading or cyclical loading. Due to variations in insertion technique, 4 femurs from each group were found to have a 1 to 2 mm gap in the medial cortex fracture after fixation. This gap prevented load transfer across the fracture, and hence there were no significant changes in strain along the medial cortex. There was a significant difference in strain curves and displacement curves when compared to the curves of the intact femurs. The slope for the strain curve changed from -0.560 to -0.166 after fixation with the FAN device ($p < 0.05$). The slope for the strain curve changed from -0.605 to -0.325 after fixation with the TAN device ($p < 0.05$). The slope for the displacement curve changed from 0.160 to 1.48 after fixation with the FAN device ($p < 0.05$). The slope for the displacement curve changed from 0.168 to 1.75 after fixation with the TAN device ($p < 0.05$).

Axial Loading
At a load of 1000 N, the average inferior displacement of the femoral head was 2.64 mm for the femurs fixed with the TAN nail, and 2.09 mm for those fixed with the FAN nail (Table 1). The difference was not significant when analyzed with repeated measures analysis of variance or with paired t-tests.

Cyclical Loading
None of the specimens failed at 100, 1000, or 10,000 cycles. There was no statistically significant difference in inferior head displacement after 100 or 1000 cycles. After 10,000 cycles, the mean inferior head displacement of the FAN-fixed femurs was 2.02 mm, whereas the mean inferior head displacement of the TAN-fixed femurs was 3.03. Although these differences were not significant by repeated measures analysis of variance, the values at 10,000 cycles were significantly different ($p < 0.05$) when analyzed by a paired t-test (power 60%).

Table 1

<table>
<thead>
<tr>
<th></th>
<th>FAN Nail</th>
<th>TAN Nail</th>
<th>t-test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strain 750 N(mm/mm)</td>
<td>-133</td>
<td>-214</td>
<td>$p &gt; 0.05$</td>
</tr>
<tr>
<td>Displacement 750 N (mm)</td>
<td>1.98</td>
<td>1.44</td>
<td>$p &gt; 0.05$</td>
</tr>
<tr>
<td>Strain 1000 N(mm/mm)</td>
<td>-176</td>
<td>-293</td>
<td>$p &gt; 0.05$</td>
</tr>
<tr>
<td>Displacement 1000 N (mm)</td>
<td>2.09</td>
<td>2.64</td>
<td>$p &gt; 0.05$</td>
</tr>
</tbody>
</table>

Load to Failure
There was no statistically significant difference between the loads to failure for the trochanteric nails and the standard antegrade nails. The average ultimate load for the FAN and TAN nails were 3010 N and 2830 N respectively. Nine of the ten femurs from each group failed by extension of the fracture through the lesser trochanter area (Fig. 4). The other femur from each group failed by head fracture. These two femurs were from the same matched pair.

Discussion
During static loading, there was no significant difference between the FAN and TAN nails. It is likely that any differences in strain were too small to detect with the sample size used in this study. The only significant difference found between the two nails was a 1 mm difference in the mean inferior head displacement after 10,000 cycles. This may have been due to toggling of the TAN nail within the canal, as there is slightly more space medially between the nail and the medial cortex with the trochanteric insertion. This 1 mm difference may not be clinically significant. We found no significant differences in the strain readings between the two nails. Several femurs were found to have an approximately 1 mm to 2 mm gap in the medial cortex above the strain gauge after fracture fixation. This probably more closely approximates the position of fracture fragments when fixed in vivo, as the reduction of the medial cortex cannot be visualized intraoperatively to ensure anatomic reduction. This gap usually closed down with loading, but the strain readings did not significantly differ for the loads when the gap was closed. The TAN reconstruction screws may be expected to be slightly longer due to the bend in the nail, but this difference was not noticed in this study, perhaps because the screw lengths are provided in increments of 5 mm. Since deflection is proportional to the length of the reconstruction screw, this might be a source of difference in deflection and possibly medial strain, but the difference would be too small to detect in this study.

This study had several limitations. Although the number of femurs in each study group was large compared to other studies, it was still small enough to limit the power of the study. Despite this, the difference in head displacement after 10,000 cycles was statistically sig-
significant, with 60% power. A four-part unstable intertrochanteric fracture pattern was chosen for this study. Other fracture patterns could have been used in this study, and these might have yielded different results. However, some fracture patterns require an abductor force, which is too technically difficult to reliably reproduce when cycling the load for 10,000 cycles. Also, the more unstable fracture pattern would be more likely to reveal differences in stability of fixation between the two nails.

The ultimate loads to failure for the FAN-fixed and TAN-fixed femurs were 3010 N and 2830 N, respectively, compared to the values found for three other intramedullary devices by Wheeler and colleagues. These values were 3870 N for the Richards reconstruction nail, 3110 N for the Zimmer reconstruction nail, and 2500 N for the Synthes spiral blade reconstruction nail. It may be inappropriate, however, to compare these values, as the study by Wheeler and colleagues used a different fracture pattern, a different testing protocol, and a different selection of femurs.

These two nails performed very similarly throughout our testing. In this study, the entry point had no effect on fixation stability, proximal load transmission, or failure strength. The 1 mm difference after 10,000 load cycles is probably clinically insignificant. As both nails used two proximal reconstruction screws, the entry portal appeared to be the primary difference between the groups.

It is unclear how these nails will compare to other second-generation short intramedullary nails, such as the Gamma (Stryker, Howmedica-Osteonics, Rutherford, NJ), and IMHS (Smith & Nephew, Memphis, TN). The Gamma has a 10° bend, and has been suspected of having a higher fracture rate due to three-point loading. The IMHS has a 4° bend, which allows it to align itself more anatomically in the intramedullary canal. The TAN nails in this study have a 5° bend, which may be expected to fit more like the IMHS, but the TAN has two proximal reconstruction screws instead of the one large lag screw with a screw sleeve construct. This difference was not evaluated in this study. Perhaps a future study comparing the TAN and FAN nails with the Gamma and IMHS devices may be indicated.

References