The maximum displacements and rotations for each specimen were statistically analyzed using a repeated measures ANOVA design and respectively (SynthesAO/ASIF), on the tibiae previously tested with osteotomy located 8 cm from the proximal articular surface to simulate a worst-case scenario proximal third tibial fracture. Screws were removed in the holes. Proximal fixation was achieved using four 4.2 mm diameter screws, a screw-hole tolerance of 0.5 mm. Distally, the nail was secured under fluoroscopy with 3 interlocking screws (2 transverse, 1 anterior/posterior, 4.5 mm diameter). Specimens were potted and testing was conducted on a digitally controlled servohydraulic testing machine (MTS Bionix 858, Eden, MN). Specimens were tested in varus/valgus, flexion/extension, and torsion for a displacement rate of 0.5 mm/sec, and in rotation to a maximum torque of 7 Nm at an angular rate of 0.5 °/sec. Tibiae were tested with a 2 cm gap towards increased stability were observed in the 0.1 mm tolerance group in varus/valgus (29%, 5.4 °, p < 0.05). Trends towards increased stability were observed in the 0.1 mm tolerance group for both the varus/valgus (36%, 5.8 mm, p = 0.093) and flexion/extension (14%, 2.15 mm, p = 0.135) loading configurations (Figure 1).

**Materials and Methods:**

Soft tissues and fibulae were dissected from 12 pairs of fresh-frozen human cadaveric tibiae (80±14 years, range 62 to 100 years, 9 male, 3 female). Each tibia was instrumented with a reamed, stainless steel IM nail with four 5.0 mm diameter proximal screw-holes (2 transverse, 2 oblique) (M/DN Zimmer, Warsaw, IN). Screw-hole tolerance is defined as the difference in diameter between the screw-hole and screws inserted in the holes. Proximalfixation was achieved using four 4.2 mm diameter screws on one tibia from each pair resulting in screw-hole tolerances of 0.8 mm, while the contra-lateral tibia was fixed with four 4.5 mm diameter screws, a screw-hole tolerance of 0.5 mm. Distally, the nail was secured under fluoroscopy with 3 interlocking screws (2 transverse, 1 anterior/posterior, 4.5 mm diameter). Specimens were potted and testing was conducted on a digitally controlled servohydraulic testing machine (MTS Bionix 858, Eden, MN). Specimens were tested in varus/valgus and flexion/extension to a maximum bending moment of 12 Nm at a displacement rate of 0.5 mm/sec, and in rotation to a maximum torque of 7 Nm at an angular rate of 0.5 °/sec. Tibiae were tested with a 2 cm gap osteotomy located 8 cm from the proximal articular surface to simulate a worst-case scenario proximal third tibial fracture. Screws were removed and 2 transverse screws were inserted to compare screw-hole tolerances of 0.5 mm and subsequently 0.1 mm (4.5 mm and 4.9 mm screws, respectively) (SynthesAO/ASIF), on the tibiae previously tested with four 4.5 mm screws.

Trabecular bone cores were removed from the distal tibia to obtain a physical measurement of bone density (BD). Displacement data were statistically analyzed using a repeated measures ANOVA design and linear regression (SPSS/PC, Version 10.0).

**Results:**

The maximum displacements and rotations for each specimen were measured for the different tolerances (0.1 mm to 0.8 mm) in two construct configurations (Table 1).

**Table 1: Maximum Displacements of Tibia Under Loading**

<table>
<thead>
<tr>
<th>Screw-hole Tolerance (mm)</th>
<th>Varus/Valgus (mm)</th>
<th>Flexion/Extension (mm)</th>
<th>Torsion (deg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.8 mm</td>
<td>18.96±14.4 *</td>
<td>14.76±25.8 *</td>
<td>18.83±26.6 *</td>
</tr>
<tr>
<td>0.5 mm</td>
<td>8.65±2.6 *</td>
<td>9.57±5.8 *</td>
<td>13.90±24.3 *</td>
</tr>
<tr>
<td>0.5 mm</td>
<td>16.06±113 *</td>
<td>15.44±210.3 *</td>
<td>18.58±26.5 *</td>
</tr>
<tr>
<td>0.1 mm</td>
<td>10.3±6.6 *</td>
<td>13.29±10.4 *</td>
<td>13.15±5.7 *</td>
</tr>
</tbody>
</table>

Comparison of Screw-hole Tolerances of 0.5 mm and 0.1 mm (2 Proximal Screws): A significant increase in stability was observed when loading the 0.1 mm tolerance group in torsion (29%, 5.4 °, p < 0.05). Trends towards increased stability were observed in the 0.1 mm tolerance group for both the varus/valgus (36%, 5.8 mm, p = 0.093) and flexion/extension (14%, 2.15 mm, p = 0.135) loading configurations (Figure 1).

**Discussion:**

Intramedullary nail screw-hole tolerance is a design parameter that may be underestimated when fixing proximal third tibia fractures. Previously, surgical technique, bone quality and nail design relating to orientation and number of fixation screws have been investigated as potential explanations for malalignment. The results of this study demonstrate trends which may indicate that tighter screw-hole tolerances can serve to improve the stability of IM nailed high proximal tibia fractures in all loading directions.

Low bone density has been shown to affect biomechanical stability of the IM nail construct. However, no correlation was observed between bone density and stability in the constructs with the greatest screw hole tolerances. This suggests that the governing factor for construct stability may switch from the bone-screw interface to screw-hole tolerance as bone density then becomes the weak link in stability. Historically, larger screw-hole tolerances may have been necessary in historical cases where bone density was poor. However, as bone density increases, the bone-screw interface becomes the weak link in stability due to the flared geometry of the superior medullary cavity. Thus screw-hole tolerances may be an important factor influencing the biomechanical stability of IM nail fixation of proximal third tibia fractures. In examining presently available IM nail designs, tolerances of up to 0.8 mm have been found to exist between the screws and screw-holes, however, no prior studies have been conducted to determine the effect of screw-hole tolerance on the biomechanical stability of the fixation. While trabecular bone screw fixation has previously been shown to affect the stability of the construct, potential instability due to screw toggle within the nail may also affect initial clinical stability and alignment.

The purpose of this study was to assess the impact of proximal screw-hole tolerance on the stability of IM nail constructs in the treatment of high proximal tibial fractures. The following two questions were posed: 1) Does the screw-hole tolerance of the IM nail have an effect on its ability to stabilize high proximal tibia fractures? and 2) Is the impact of screw-hole tolerances influenced by bone density in assessing the stability of these constructs?

**Conclusion:**

Screw-hole tolerance should be considered an important parameter in the design of IM nails in the fixation of proximal third tibia fractures. Improving proximal screw-hole tolerances may improve construct stability and the clinical outcome of proximal tibia fractures treated with IM nail fixation.

**References:**


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