The Biomechanics of Varied Proximal Locking Screw Configurations in a Synthetic Model of Proximal Third Tibial Fracture Fixation

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Objective: To determine if 1) angularly stable devices created by compressing ("locking") proximal locking screws to intramedullary nails using end caps or compression screws or 2) increasing the number of proximal screws from two to three increases the stiffness of intramedullary constructs that stabilize proximal third tibia fractures in a nonosteopenic bone model.

Methods: Four proximal locking screw configurations were examined in a synthetic composite tibia model with a 2-cm gap simulating a comminuted proximal third tibia fracture with no bony contact: 1) two proximal screws not compressed to the nail; 2) one of two proximal screws compressed to the nail; 3) two proximal screws compressed to the nail; and 4) three proximal screws with only the most proximal screw compressed to the nail. An 11-mm tibial nail with two distal locking screws was used. Stiffness was measured in axial and torsional loading. An analysis of variance was performed to compare results of the screw configurations for each testing mode.

Results: Compressing two screws to the nail produced 22% to 39% greater ($P \leq 0.01$) axial and 16% to 29% greater ($P \leq 0.03$) torsional stiffness than securing neither or only one of the screws. Adding a third proximal transverse locking screw increased the axial stiffness by 28% ($P = 0.005$) and the torsional stiffness by 15% to 28% ($P \leq 0.04$) compared with using two oblique proximal screws.

Conclusions: "Locking" two proximal locking screws to the nail through compression or adding a third proximal screw increases the axial and torsional stiffness of intramedullary nails used to fix unstable proximal third tibia fractures.

INTRODUCTION

Stabilization through intramedullary (IM) nailing is a successful method for treating tibial fractures.[1–5] However, IM fixation of proximal tibia fractures is challenging. Although these fractures can be treated with IM nailing successfully,[6,7] proximal tibia fractures have been found to have a high incidence of malalignment.[8–10] Apex anterior, valgus malalignment, and anterior displacement of the proximal fragment are the most common deformities. Several reasons for this issue have been hypothesized, including the anteriorly directed pull of the patellar tendon on the tibial tubercle, the mismatch between the internal diameter of the proximal fragment and the diameter of the nail, the short working length of the nail, misplaced starting points, and the pull of the muscles of the lateral and posterior compartments.[8–13]

To use IM nailing successfully for the treatment of proximal third tibia fractures, adjustments to the "standard" nail insertion technique as well as mechanical modifications have been proposed. The "standard" IM nailing technique may be modified by nailing with the knee in an extended position,[14] using blocking screws,[8,11,12] a lateral entry starting point,[9,13] and use of a temporary femoral distractor.[13] Mechanical alterations to the "standard" nailing technique include the use of blocking screws to provide an increase in mechanical stability,[8] the addition of two oblique locking screws in addition to the usual two transverse medial to lateral screws to increase construct stability,[15] and cement augmentation of the proximal locking screws to increase stability for osteoporotic fractures.[16] In addition, IM tibial nails are now available with three rather than two proximal screws, the option for transverse or oblique screw paths, and the ability to "lock" one or more of the locking screws to the nail using various techniques, including end caps or compression screws, to form angle stable devices.

Prior studies have demonstrated that changing the number and orientation of the proximal locking screws affects the stiffness and strain at the fracture site.[15,17,18] In addition, securing the locking screws to the nail to create an angle stable device has been shown to decrease interfragmentary motion in an animal model examining midshaft diaphyseal fractures.

This allowed the animals to bear full weight earlier and produced superior bone healing when compared with nails that had conventional locking screws.[19]

The purpose of this study was to test and analyze the mechanical characteristics of four different proximal locking screw configurations of IM nails used to fix an unstable proximal third tibial fracture using a nonosteopenic bone model. Our hypotheses were that 1) proximal screws "locked" to the nail using compression through either an end cap or compression screw would produce a stiffer construct than those with proximal locking screws not compressed against the nail; and that 2) constructs with three proximal locking screws, even if the third screw is not "locked" to the nail, would be stiffer than those configurations with two proximal screws.
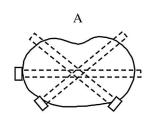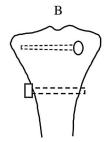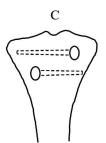
MATERIALS AND METHODS

Constructs

Forty third-generation composite tibiae (Sawbones; Pacific Research Laboratories, Inc, Vashon, WA) were instrumented with 11 mm T2 tibial nails (Stryker Orthopaedics, Mahwah, NJ). Although using synthetic tibiae may not accurately simulate conditions in vivo, composite specimens were chosen for this study because their use in mechanical studies has been well established, they have been shown to exhibit similar properties to cadaveric specimens, and they significantly reduce the variability found in cadaveric bones.[20,21] Use of synthetic tibiae allowed for a direct comparison of the fixation methods examined in this study. To insert the nail, an entry hole was made in the proximal tibia using a guidewire and an opening reamer. After placing a guidewire down the canal, flexible reamers were used to ream the canal to 12.5 mm. The nail was then inserted and two distal locking screws were placed using the freehand technique with C-arm imaging.

The tibiae were randomly divided into four groups of 10 for insertion of the proximal screws (Fig. 1A), which were placed using an outrigger guide. The sample size for the groups was estimated from our preliminary test results of IM devices and a previous study from the literature.[15] The first two configurations examined were instrumented with two proximal screws with neither (Group 1, Fig. 1B) or one (Group 2, Fig. 1C) screw compressed to the IM nail (Table 1). The proximal screws in Group 3 (Fig. 1B) were the same configuration as those in Group 1, but both were placed in a "locked" fashion through compression against the IM nail (Table 1).

TABLE 1. The Four Screw Configurations Examined

Group	Proximal Screw Configuration (each are 5.0 mm locking screws)
1	First screw: oblique, not compressed ("locked") to the nail
	Second screw: transverse, not compressed to the nail
2	First screw: oblique, compressed against the locking hole of the nail with an end cap
	Second screw: oblique, not compressed to the nail
3	First screw: oblique, compressed to the nail with an end cap
	Second screw: transverse, compressed to the nail with a compression screw placed in the center of the nail
4	First screw: oblique, compressed to the nail with an end cap
	Second screw: oblique, not compressed to the nail
	Third screw: transverse, not compressed to the nail

Group 4 (Fig. 1D) consisted of the same configuration as Group 2 with the addition of a third screw that was not compressed to the nail (Table 1).

After insertion of the implant and screws, a 2 cm gap was cut into the proximal tibia 8 cm below the tibial plateau to simulate a comminuted proximal third tibial shaft fracture (Orthopaedic Trauma Association/OA 41-A3) and to ensure no bony contact during testing.

Testing Protocol

The stiffness of each fixation technique was evaluated in axial loading and torsion. All testing was performed in an Instron 5800R (Instron, Canton, MA) materials testing machine. The order in which specimens were tested was randomized within each loading mode. Loading rates and magnitudes were chosen to allow for measurements of stiffness within the linear elastic range of the construct while preventing plastic deformation, which was confirmed by observation of the load-deformation or torque-angle plots.

For axial testing, a ramped load to a maximum of 2000 N at a rate of 5 mm/min was applied to the tibial plateau and directed along the long axis of the tibia through a custom mold (Fig. 2). The distal end of the tibia was also placed in a custom mold during testing. Both custom molds were supported in the materials testing machine by ball bearings to reduce unwanted torque and bending during the axial test.

Torsional testing was performed in a custom test fixture by holding the distal end of the specimen in a custom mold while the proximal end was secured in a chuck (Fig. 3). The test setup was similar to a previous study examining subtrochanteric femur fractures[22] with the positioning such that the tibial axis was aligned with the axis of rotation during

FIGURE 1. Top view (A) showing the screw orientation for the two oblique screws and one transverse screw used in the study. The configurations tested included (B) one oblique screw proximal to one transverse screw, (C) two oblique screws, and (D) two oblique screws proximal to one transverse screw.
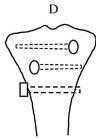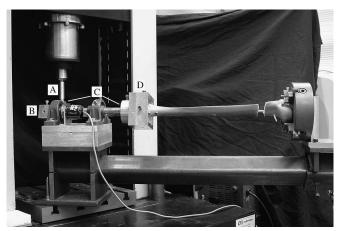
FIGURE 2. Experimental testing of a tibia–implant construct in axial loading.

testing. A lever was inserted into a swivel pin within a loading assembly mounted to the Instron crosshead on one end. On the other end, the lever was attached to a shaft and bearing system mounted to the distal mold (Fig. 3). This allowed the Instron crosshead to impart a force to rotate the distal end of the specimen while the proximal end remained fixed. Each specimen was loaded in external rotation to a torque of 20 Nm at an angular displacement of 1 degree/min.[23]

Data Analysis

Axial stiffness values were calculated from the linear portion of the plots of load versus deformation. Torsional stiffness values were calculated from the linear portion of the torque versus angle curves. A one-way analysis of variance was used to determine statistical significance for each testing protocol between the four screw configurations. This was then followed by a Fisher protected least significant difference post hoc analysis to evaluate the pairwise comparisons between each group when appropriate. A P value <0.05 was considered significant.

FIGURE 3. Experimental testing of a tibia–implant construct in torsion. (A) Loading assembly; (B) mount for lever; (C) shaft and bearing assembly; (D) distal mold fixture.

RESULTS

Axial Stiffness

Compressing ("locking") two proximal locking screws to the nail (Group 3) produced a construct with an axial stiffness that was 22% greater ($P = 0.01$) than Group 1 in which neither screw was compressed to the nail and 39% greater ($P < 0.001$) than Group 2 in which only the most proximal screw was "locked" to the nail (Table 2). Also, adding a third transverse proximal screw that was not compressed to the nail (Group 4) significantly increased the axial stiffness of the construct by 28% ($P = 0.005$) compared with the configuration of Group 2 in which only two oblique proximal screws were used (Table 2). For axial testing, no other comparisons produced significant differences.

Torsional Stiffness

The torsional stiffness of "locking" both proximal screws to the nail (Group 3) was 16% greater ($P = 0.03$) than

TABLE 2. Axial and Torsional Stiffness (Mean ± Standard Deviation) of the Four Intramedullary Fixation Methods Examined

	Axial Stiffness (N/mm)	Torsional Stiffness (Nm/°)
Group 1 (neither proximal screw compressed to the nail)	937 ± 225	1.20 ± 0.15
Group 2 (one proximal screw compressed to the nail)	824 ± 141	1.08 ± 0.19
Group 3 (both proximal screws compressed to the nail)	1146 ± 197*	1.39 ± 0.16†
Group 4 (one proximal screw compressed to the nail, third screw added)	1058 ± 126‡	1.38 ± 0.24§

*Significantly different than Group 1 ($P = 0.01$) and Group 2 ($P < 0.001$).
†Significantly different than Group 1 ($P = 0.03$) and Group 2 ($P < 0.001$).
‡Significantly different than Group 2 ($P = 0.005$).
§Significantly different than Group 1 ($P = 0.04$) and Group 2 ($P = 0.001$).

when neither screw was compressed against the nail (Group 1) and 29% greater ($P < 0.001$) than when only one proximal screw was "locked" to the nail (Group 2). Similarly, adding a third proximal screw (Group 4) significantly increased the torsional stiffness by 28% ($P = 0.001$) compared with "locking" only one screw to the nail (Group 2) and by 15% ($P = 0.04$) compared with Group 1, which did not have either screw compressed to the nail (Table 2). No other comparisons produced significant differences for torsional testing.

DISCUSSION

Our study found that "locking" two proximal screws to an IM tibial nail through compression to create an angle stable device significantly increases the stiffness of the construct in axial and torsional loading by 16% to 39% compared with constructs with two proximal screws in which only one or neither of the screws are compressed to the nail. In addition, supplementing two proximal screws with an additional proximal screw, although it is not "locked" to the nail by compression, significantly increases the stiffness of the construct by up to 28% in both axial loading and torsion. Hansen et al[24] also examined the biomechanical effects of adding a third proximal screw to fix proximal tibial fractures and demonstrated in a cadaveric model that a construct with three proximal oblique screws increased axial stiffness by 61% compared with fixation with only two oblique screws. Similarly, Laflamme et al[15] found that supplementing standard IM fixation of high proximal tibia fractures with two oblique screws significantly increased construct stability 18% to 50% in various loading modes. Although it is not known if an increase in stiffness across the fracture site will significantly enhance bone healing, the ability to improve the stiffness at the fracture site for these difficult fractures may help improve the stability in this region and lessen the chance for loss of fixation or alignment during healing.

Angle stable locking IM nails also have been found to improve fixation stability and stiffness when used for tibial fractures other than that examined in this study. Hansen et al[25] compared fixation methods for extra-articular proximal tibial fractures and demonstrated that fixation of an IM nail using three proximal oblique locking screws, with the most proximal compressed to the nail with an end cap, produced similar axial stiffness as a construct with dual nonlocking plates and increased stiffness compared with an external fixator or lateral plating with the Less Invasive Stabilization System (LISS; Synthes, West Chester, PA). Their study also found that torsional stiffness for the angle stable nail was greater than that for a combined nail–plate construct and similar to all other fixation methods examined. Angle stable and compressed angle stable locking IM nails also have been shown to demonstrate superior biomechanical stability compared with statically locked nails in a retrograde tibiocalcaneal arthrodesis model.[26] In addition, fixation with angle stable locking nails significantly increased axial stiffness or decreased interfragmentary motion compared with conventional locked nails in midshaft and distal tibia fractures.[19,27]

Fracture reduction is an important part of bone–implant stability when fixing fractures. Although our gap model with no bony contact does not simulate the clinical situation, it removes the influence of fracture reduction on testing and allows for a more direct evaluation of the different fixation methods. In addition, the stiffness measurements performed in this study were conducted across the entire bone–implant construct length in the direction of loading (axial or torsion) rather than specifically at the fracture site. This method tends to reduce differences in stiffness measurements among the constructs compared with those observed locally at the site of fracture and, thus, may have diminished the relative extent of variability in construct stiffness at the point of interest in this gap model.

The synthetic bones used in this study also have fairly dense cancellous bone in the metaphysis and are representative of patients with healthy, nonosteopenic bone. The dense cancellous bone surrounding the nail in this model may create relatively stable fixation for the constructs when compared with the "empty" proximal tibia in older patients who are more osteopenic. This does not accurately reflect the clinical situation of fixation for proximal third tibia fractures in osteopenic bone, especially those in the metaphysis, which lack a tight fit between the nail and bone because of the differences between the nail diameter and the canal of the bone resulting from the paucity of cancellous bone. However, in the current study, we reamed the synthetic bone 1.5 mm in diameter over the diameter of the inserted nail, allowing the nail room to translate slightly within the canal. Even in this model in which "healthy," nonosteopenic bone surrounds the nail, we found that either "locking" two proximal screws to the nail through compression or adding a third proximal locking screw adds significant axial and torsional stiffness to the constructs. Whether similar results would be obtained in a model in which less cancellous bone surrounds the IM nail would need to be tested in future studies.

Adequate reduction and stability of the fracture are necessary for successful healing of proximal third tibia fractures. With several options existing for the proximal screw configurations in treating proximal third tibia fractures with IM nails, our results suggest that either 1) "locking" two proximal locking screws to the nail through compression applied with end caps and compression screws or 2) adding a third proximal locking screw, even if it is not secured against the nail with a compression screw, provides increased fixation stiffness for the fracture.

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