Biomechanical Comparison of Flexible Stainless Steel and Titanium Nails with External Fixation Using a Femur Fracture Model

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Abstract: There are several options available for surgical stabilization of pediatric femoral shaft fractures. The purpose of this study was to compare the stability afforded by Ender stainless steel nails, titanium elastic nails, and one-plane unilateral external fixators for the fixation using a synthetic adolescent midshaft femur fracture model. The anterior-posterior (sagittal plane) bending, lateral (coronal plane) bending, torsional, and axial stiffness values were calculated using 6 different fixation configurations. These included pairs of 3.5-mm-diameter Ender nails with and without distal locking, 3.5- and 4.0-mm-diameter titanium elastic nails as well as single- and double-stacked monolateral external fixators. Eight synthetic femur models, 4 each with simulated transverse and comminuted fracture patterns, were sequentially tested for stability afforded by the various fracture fixation configurations.

External fixation exhibited significantly greater control of anterior-posterior angulation compared with all flexible-nailing systems. Although Ender nails were slightly superior to titanium nails in control of sagittal plane angulation, this was not statistically significant. Compared with the external fixation constructs, all 4 flexible nail constructs demonstrated higher torsional stability. For prevention of axial shortening, all fixation methods were similar for the transverse fracture pattern, whereas external fixation was superior to flexible nails in the comminuted fracture model. No significant benefit was demonstrated with double stacking of external fixators. These findings may help guide clinicians choose the optimal fixation method for treatment of pediatric femoral shaft fractures.

Key Words: titanium nails, ender nails, external fixation, biomechanics, pediatric femoral shaft fractures

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During the past decade, the surgical management of femur fractures in adolescent patients has gained popularity over nonoperative treatment. This change in treatment preference is caused by more rapid mobilization and rehabilitation of the patients as well as a decrease in length of hospitalization.[1–8] The operative treatment options include external fixation, flexible nails, plating, and reamed intramedullary nails.[9–22] Although quite effective, these operative treatment modalities differ in the severity and number of their complications. Reamed intramedullary nails have fallen out of favor because of their association with growth arrests of the greater trochanter apophysis and, more importantly, avascular necrosis of the capital femoral epiphysis.[10,23,24] Although there are several reports on the complication rates of both external fixation and flexible nails,[25–28] we currently only have a rudimentary understanding of the mechanical properties of these devices and their comparative advantages and limitations in the management of adolescent femur fractures.

The purpose of this study was to analyze the differences between some of these implants and assess the mechanical effectiveness in both length stable and length unstable midshaft adolescent femur fractures using a synthetic bone model.

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METHODS

Mechanical testing was performed on 8 synthetic adolescent-sized femur models (Pacific Research Laboratories, Vashon, Wash) made of composite epoxy resin simulating cortical and cancellous bone. Each model was 45 cm in length and had a 9-mm canal. A synthetic model was used to minimize the variability between specimens and because pediatric cadaveric bones are expensive and difficult to obtain. Modern synthetic bone models have been shown to simulate physical behavior of cadaveric bone and also reproduce anatomical landmarks with cortical walls and cancellous canals.[29–32]

Transverse and comminuted fracture patterns were created with a custom slotted jig and a handheld saw. The transverse and comminuted fractures were set at 14 cm distal to the tip of the greater trochanter. The comminuted butterfly fracture pattern simulated a medially directed force (Fig. 1). No bone segments were removed. The comminuted fragment was held in place with a single layer of surgical tape (Transpore; 3M, St Paul, Minn) wrapped around the bone.

The fractured femur models were stabilized with a total of 6 different types of fixation. These included 2 configurations each of stainless steel flexible nails, elastic titanium nails, and monolateral external fixator. The stainless-steel flexible nail systems used were 3.5-mm-diameter Ender nails (Howmedica, Rutherford, NJ) with or without distal locking of the eyelet of the Ender nail with a unicortical

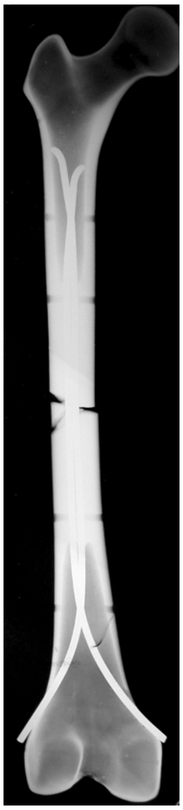

FIGURE 1. Radiograph of comminuted fracture with titanium nails in "C" configuration.

fully threaded 12-mm-long, 2.5-mm-diameter stainless steel screw. The 2 titanium nail configurations tested were a pair of 3.5-mm-diameter and a pair of 4.0-mm-diameter elastic nails (Synthes, Paoli, Pa). Each of the stainless steel or titanium nails was 34 cm in length and was inserted in a retrograde fashion through the metaphysis of the distal femur after precontouring the nail with a 3-point bend. Fluoroscopic imaging was used to place the nails in a divergent "C" configuration (Fig. 1) and to assess nail position and fracture reduction.[33,34] The 2 external fixation configurations were tested, using either 1- or 2-bar unilateral external fixator (Synthes). Four 5.0-mm-diameter stainless steel half-pins were inserted along the sagittal midline of the femur[35,36], 2 proximal and 2 distal to the fracture site. The proximal half-pins were located 6 and 10.5 cm proximal of the middiaphyseal fracture, and the distal pins were located at the same distances distal of the fracture. The carbon rods connecting the 4 half-pins were placed 10 cm from the lateral border of the femur for the single-rod configuration and 9 cm for the more medial of the double-stacked rods. The more lateral rod was placed directly next to the medial rod.

All biomechanical testing was performed using a servohydraulic mechanical testing system (Teststar II; MTS, Eden Prairie, Minn). Each femur was placed into a custom-fit, removable polymethyl methacrylate mold and secured in the MTS machine. Before mechanical testing, each specimen was preloaded to 20 N to ensure complete and reproducible contact between the specimen and loading fixture. Each specimen was subjected to separate anterior-posterior (sagittal plane) bending, lateral (coronal plane) bending, torsional, and axial compression testing conditions. In each testing configuration, 5 trials were performed. The testing sequence was randomized. The specimens were tested for cracks and other defects after each testing. Femurs were mounted vertically for axial compression and torsional testing and loaded through the femoral head (Fig. 2). A 4-point bending model was used for both the anterior-posterior and lateral testing (Fig. 2). In both bending tests, a maximal load of 400 N was applied at 0.1 mm/s. Failure of fixation was set at 20 degrees of angulation for the bending tests. Neither of the external fixator constructs was tested in lateral bending because of interference of the fixator components with the testing system. Torsional testing was performed to a maximal torque of 20 Nm at a rate of 0.3°/s. Failure of fixation was set to 10 degrees of rotation for torsional testing. Angular rotation was measured in degrees, and torsional stiffness was calculated. In axial testing, a maximal load of 400 N was

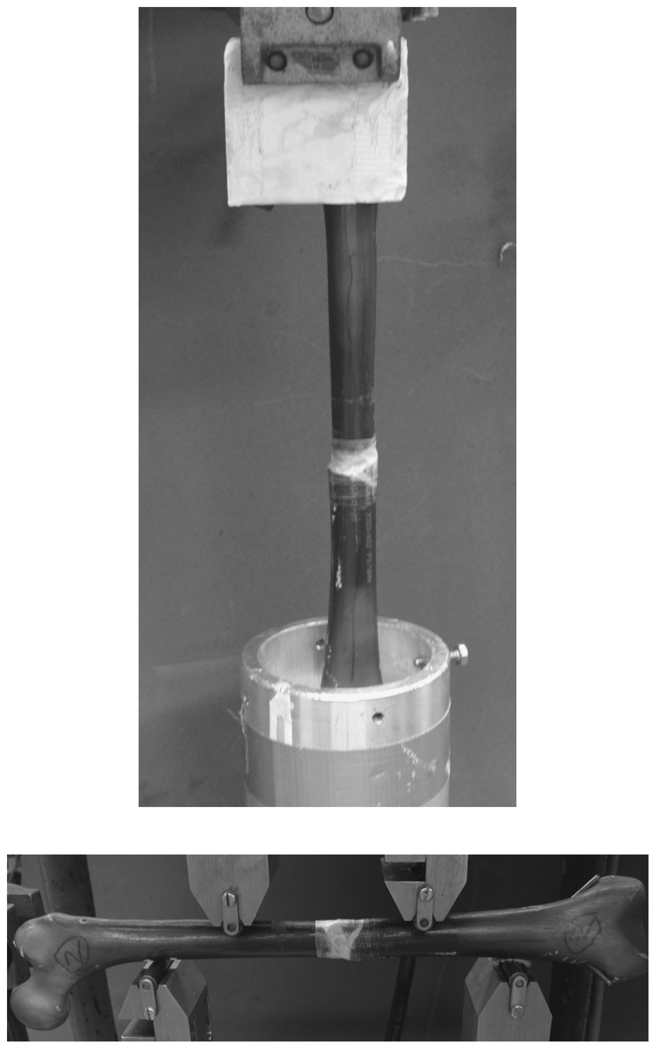

FIGURE 2. Testing apparatus. Servohydraulic MTS machine with potted synthetic bone model testing axial compression (A) and lateral bending (B).

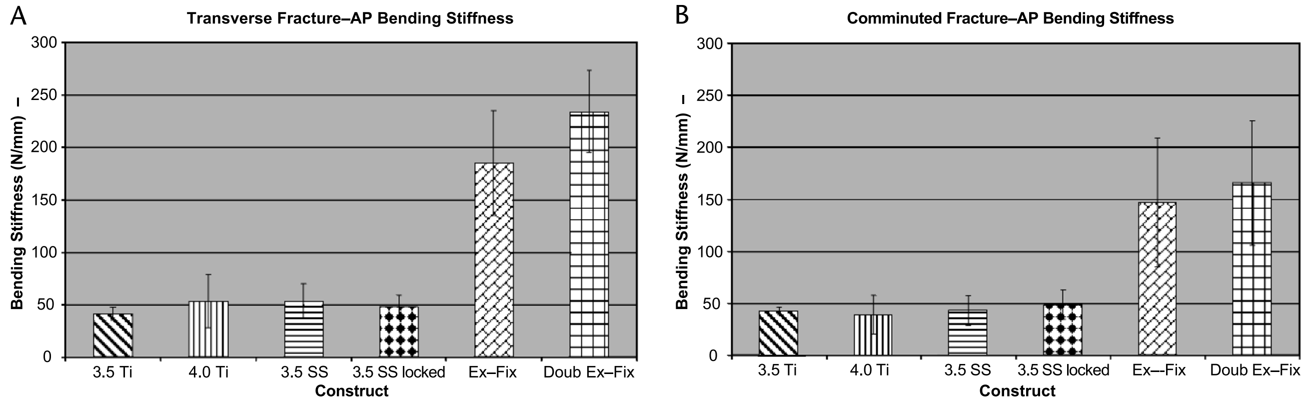

FIGURE 3. Graph demonstrating anterior-posterior (sagittal plane) bending stiffness for transverse (A) and comminuted (B) fracture patterns.

applied at a rate of 0.1 mm/s, and vertical displacement was measured to calculate axial stiffness. Fixation failure for axial testing was set at 10 mm of shortening at the fracture site. None of the specimens were loaded to failure.

Data were collected for both transverse and comminuted fracture patterns stabilized with the 6 different fixation techniques. Bending, torsional, and axial stiffness patterns were compared using analysis of variance. Significance was set at P less than or equal to 0.05. Values were presented as mean ± SD.

RESULTS

Anterior-posterior bending (sagittal plane) stiffness for the transverse and the comminuted femur fracture model was significantly higher with external fixation compared with all the nail systems ($P < 0.0001$; Fig. 3). The means for external fixation were nearly 400% higher than the means for the flexible nail systems. The 3.5-mm-diameter Ender nails with and without distal locking screws were similar in anterior-posterior bending to the 3.5- and 4.0-mm-diameter titanium nails for both the transverse and the comminuted fracture models.

In determining lateral bending (coronal plane) stiffness, no statistical difference for transverse ($P = 0.8143$) and comminuted ($P = 0.8201$) fracture models was noted between the Ender and titanium nail systems (Fig. 4). Lateral bending stiffness with external fixation was unable to be carried out because of the instrumentation abutting the jig mounted on the MTS.

The flexible nail systems demonstrated significantly more torsional stiffness for transverse ($P = 0.0070$) and comminuted ($P < 0.0001$) fracture patterns compared with the 2 external fixator constructs (Fig. 5). The flexible nail systems had 500% or greater mean torsional stiffness when compared with that of the external fixators.

During compressive loading, the transverse fracture model revealed no significant differences between any of the 6 fixation methods ($P = 0.9386$). The comminuted fracture models also showed no statistical difference in the axial compression stiffness between the titanium and stainless steel nail systems ($P = 0.0981$). On average, the external fixators had a mean compressive stiffness that was 41% greater than the average compressive stiffness of all flexible nail constructs tested. However, the difference was not statistically significant (Fig. 6).

DISCUSSION

Successful operative treatment of adolescent femoral shaft fractures involves identifying associated injuries, assessing fracture patterns, understanding the stability afforded by different fixation techniques, and anticipating complications associated with adolescent fractures. Nonoperative treatment of adolescent femur fractures requires longer

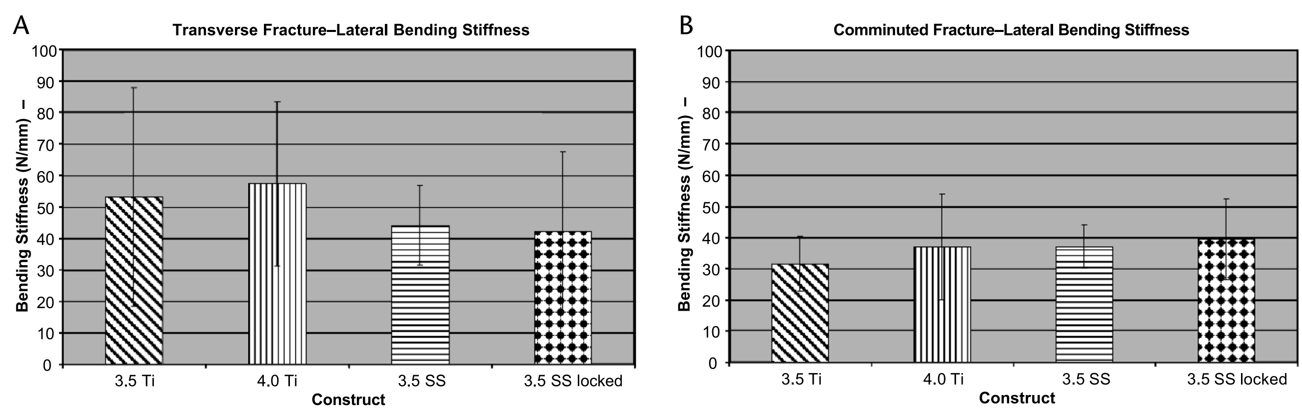

FIGURE 4. Graph demonstrating lateral (frontal plane) bending stiffness for transverse (A) and comminuted (B) fracture patterns.

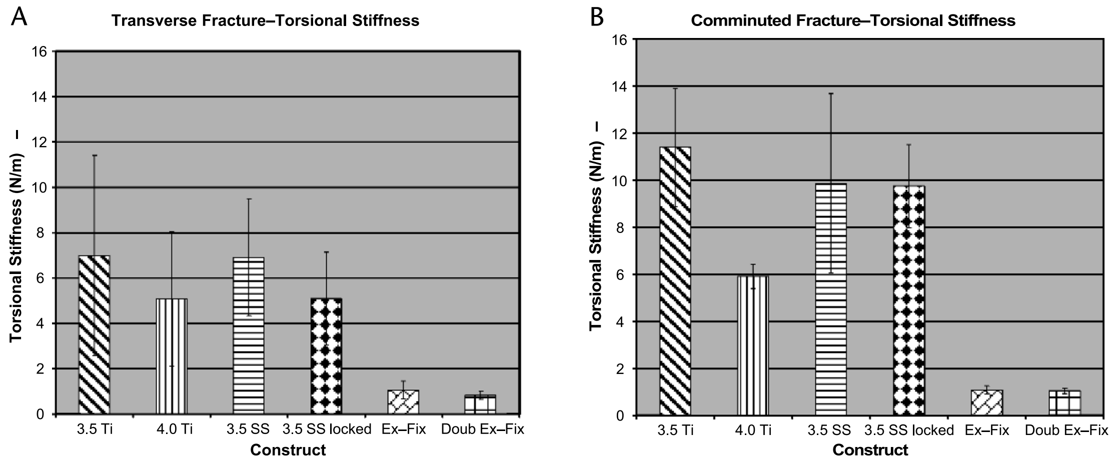

FIGURE 5. Graph demonstrating torsional stiffness for transverse (A) and comminuted (B) fracture patterns.

hospitalization and may have a negative psychological and social impact on patients and their families.[5–7] Each operative option for the management of adolescent femoral shaft fractures has advantages and limitations. A low but unpredictable incidence of avascular necrosis and growth disturbances of the proximal femur after reamed intramedullary nailing has largely eliminated this treatment option.[10,23,24] Open reduction and plating do allow anatomical alignment, but it leaves unsightly scars and is associated with refractures upon implant removal.[1,12,27,28] External fixation is a good option for the treatment of adolescent femur fractures, particularly in open fractures and in polytrauma patients. However, fixators are associated with pin tract infections and refracture after device removal.[11,14,25,27,28] Both stainless steel and titanium flexible nails have shown superior long-term results with low rates of malunions, nonunions, refractures, and no reports of avascular necrosis.[13,16]

It was the purpose of this study to compare the mechanical properties of external fixation and flexible stainless steel and titanium nails—currently the most popular stabilization methods for midshaft adolescent femur fractures. All devices were tested for transverse and comminuted fractures, by submitting them to different loading modes: anterior-posterior bending, lateral bending (except external fixators), torsion, and axial compression.

We found that external fixators provide a significantly higher bending stiffness than do the nails for both the transverse and comminuted fracture patterns. Although not statistically significant, compared to the 3.5 mm titanium nails, the stainless steel (Enders) nails provided better control of sagittal plane angulation for both fracture models and better control of coronal plane angulation for comminuted fracture models. These tested results correlated well with a recent retrospective clinical study[37] which compared outcomes of titanium and stainless steel flexible nails for the stabilization of 38 femoral shaft fractures in children aged 5 to 15 years. There was a statistically significant difference in angular deformity with the titanium nails demonstrating greater angulation on lateral radiographs (sagittal plane) compared with the stainless steel Ender nails. Luhmann et al[38] reported the results of titanium elastic nailing for pediatric femoral shaft fractures. They also found that heavier patients with smaller diameter titanium nails had more sagittal plane angulation. Our results corroborate with some of the findings noted in these clinical studies.[37,38]

There was no statistical difference noted for axial compression stiffness between the nail systems for either fracture pattern. However, there was a significant difference between the 3.5-mm-diameter titanium nails and the external fixators for the comminuted fracture pattern (Fig. 6B). This

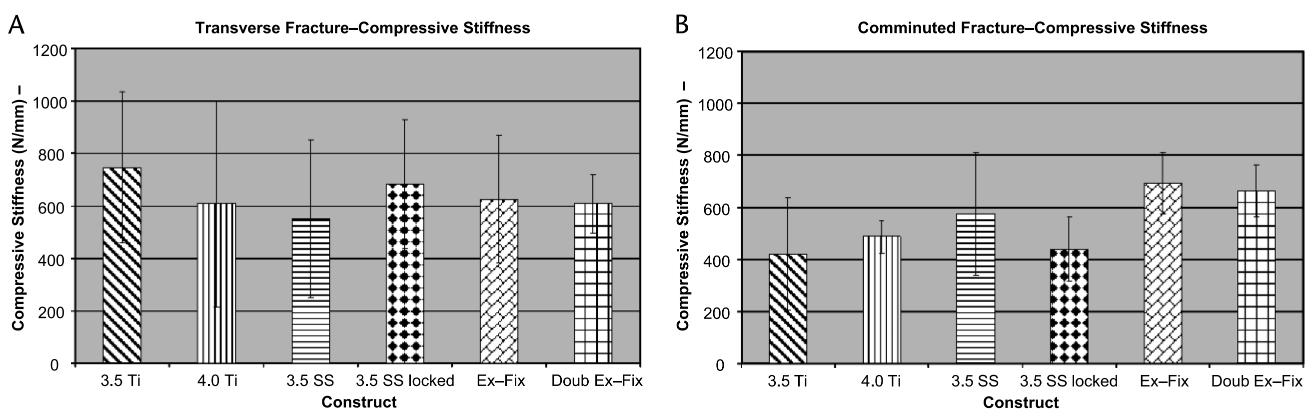

FIGURE 6. Graph demonstrating axial compressive stiffness for transverse (A) and comminuted (B) fracture patterns.

finding reinforces the fact that it is easier to maintain length in comminuted fractures with external fixation. There was no statistical difference between the locked and unlocked 3.5-mm-diameter Ender nails with respect to axial compression stability.

As with all such undertakings, this biomechanical study has limitations. For obvious but unavoidable reasons, synthetic bone models had to be supplanted for adolescent cadaver femora. However, these synthetic models provide less variability between specimens and simulate the physical properties of cadaver bone with respect to modulus of elasticity and their deformation responses to mechanical testing when compared with cadaver bone.[29–32]

A potential criticism of our surgical technique for insertion of the elastic nails is that they were not advanced far enough proximally into the flare of the medial femoral neck and greater trochanter, as is often done clinically. This variation in nail insertion technique may have underestimated the stability afforded by the elastic nails. Another limitation was the application of rather small forces, particularly in axial compression. Although this preserved specimen for sequential implant use, it may have underestimated the stability attained in comminuted fractures, particularly with flexible nails. The relatively small sample size may have caused a β error in some testing modes.

When compared with flexible nails, external fixators, by and large, have superior capability to resist most loading modes, particularly in comminuted fractures. While pin tract infections and refractures after early fixator removal have limited the use of external fixators,[9,11,14,25,27,28] it is possible that the recently introduced hydroxyapatite-coded pins will largely remedy both problems.[39]

In all loading modes, the 3.5-mm, stainless steel, flexible nails (Ender) were equivalent or superior to the 3.5-mm titanium nails. This suggests that 3.5-mm titanium implants should be used cautiously in large patients with a relatively wide intramedullary canal. There was no shortening in the presence of comminuted fractures with any of the nails tested. However, this finding may not hold when large axial forces are applied by a heavier or less reliable patient because the threshold to proximal nail migration or locking screw pullout was not addressed in this study. Although not an in vivo study, our findings may help guide clinicians choose the optimal fixation method for treatment of pediatric femoral shaft fractures.

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