Biomechanical Study of Flexible Intramedullary Nails

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Background: Flexible intramedullary (IM) nailing is considered a safe, minimally invasive fixation technique with relatively low complication rates for long-bone fractures in the pediatric population. At our institution, questions have arisen about stability of fixation based on the distance of the nail past the fracture site. Clinically, this question arises with proximal or distal fractures and when the nail is unable to be passed to the desired distance past the fracture site. The purpose of our study was to compare biomechanical resistance with bending forces for fixation constructs whose IM nails are at differing distances beyond the fracture site in different bones.

Methods: This study tested matched pairs of canine radii, ulnas, and tibias in 4-point bending and compared the biomechanical properties of length of nail fixation past the fracture site in relation to bone diameter.

Results: Fixations of 1 or 2 diameters past the osteotomy yielded gross instability. There was no difference found in bending failure force, displacement, stiffness, or energy when comparing 3 versus 5 diameters of fixation past the fracture site.

Conclusions: Flexible IM nails act as internal splints to align the fracture ends. At 3 diameters or more beyond the fracture site, the length does not significantly affect the biomechanical properties of the construct.

Clinical Relevance: Flexible IM nails act as internal splints to align the fracture ends. At 3 diameters or more past the fracture site, the length of the nail does not greatly affect the biomechanical properties of the construct. This knowledge may be helpful in clinical scenarios where there is uncertainty about the expected strength of a shorter fixation. Examples include when the nail cannot be passed completely to the distal metaphysis and in proximal or distal long-bone fractures. Further clinical studies are needed to determine implications in a patient setting.

Key Words: animal model, bone nails, fracture fixation, intramedullary, in vitro, pediatrics, radius fractures, tibial fractures, ulna fractures

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Data from industrialized countries show that fractures constitute 10% to 25% of all injuries sustained during childhood[1,2]; rates have been reported to be as high as 36.1 in 1000 children.[3] Most of the fractures affect the forearm, tibia, femur, or humerus, with forearm fractures accounting for up to 45% of all pediatric fractures.[1,2] Most pediatric fractures can be treated nonoperatively with excellent results.[4–6] Operative indications include open fractures, unstable fractures, loss of reduction, and inability to achieve adequate reduction.[4–8] A variety of fixation methods have been described, including pins and plaster,[9] Kirschner wires,[7,10,11] intramedullary (IM) nails,[12–14] and compression plating.[5,7]

Flexible IM nailing is considered a safe, minimally invasive fixation technique with relatively low complication rates for long-bone fractures in the pediatric population.[8,10,15–21] The approach has had the greatest impact on forearm fractures and femur fractures in children older than 5 years requiring fixation.[4,10,22] Most of today's fixation techniques originate from the elastic, stable IM nail developed in Nancy, France, in the 1980s, using a 3-point fixation technique originally described by Rush.[17,22–25] At our institution, questions have been raised about the stability of fixation based on the distance of the nail past the fracture site. Clinically, the questions arise with proximal or distal fractures and when the nail is unable to be passed to the desired distance past the fracture site, which is typically insertion into the distal metaphysis. To our knowledge, there are no prior studies comparing biomechanics of fracture stability based on the length of nail past the fracture site. The purpose of our study was to compare biomechanical resistance to bending forces for fixation constructs whose IM nails are at differing distances beyond the fracture site, in effect to define and confirm the desired insertion distance. Canine bones were used in this study to simulate pediatric forearm fractures.[7]

METHODS

Specimens and Preparation

Eight pairs of canine radii and 9 pairs of ulnas and tibias that were acquired from previous canine studies were used in the biomechanical analysis, as shown in Figure 1. The sharing of the tissues was approved by the authors' institutional animal care and use committee. All soft tissue was removed from the bones, and they were degreased with acetone. The bones were stored at −12°C and defrosted to room temperature before testing. All bones where then measured with a dial caliper in the anteroposterior and lateral planes at the midpoint of the diaphysis, and the 2 values were averaged to determine the diameter to be used for the length of fixation past the fracture site.

Each pair of radius, ulna, and tibia specimens was labeled with a number and kept as a matched set, then randomized as to whether the right or left bone would be assigned the 3- or 5-diameter fixation length. The bones were then marked with a permanent marker at the appropriate length past the fracture site. These distances were measured to within 0.01

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FIGURE 1. Examples of paired canine radii, ulnas, and tibias used in the study with implanted flexible IM nails.

inches with the dial caliper. Based on the variability of the diameter-length ratio between the different bones, 3 and 5 diameters past the fracture site were chosen so that all bones could be compared (Fig. 2). Because of the large diameters of the tibias, the 5-diameter length was the limit that could be used based on the high diameter-length ratio. Because of the small diameters and diameter-length ratios of the ulnas, the lower limit that could be used was the 3-diameter length. Insertion lengths of 1 or 2 diameters past the fracture site yielded tenuous fixation in the radius and ulna, and anything greater than 5 diameters was too long to allow fixation in the tibia. The 1- and 2-diameter fixations were grossly unstable, losing the important contact point fixation distally and were thus unable to be tested in 4-point bending.

Insertion Technique

For IM nail insertion, an entry hole was made at the appropriate entry site by using an electric drill. The standard retrograde nail metaphyseal insertion site was used for the radii. Antegrade entry points through the olecranon were used in the ulnas, and antegrade medial metaphyseal entry points were used in the tibias.[5,11,19,21,23] Synthes titanium flexible IM nails (Synthes Inc, West Chester, Pa) were measured and marked according to the distance from the entry hole to the appropriate test diameter past the fracture site. Synthes 2.0-mm, flexible IM nails were used for the radii and ulnas and Synthes 2.5-mm, flexible IM nails were used for the tibias. The bones were then placed in a vise with padded jaws and an oblique, 30-degree osteotomy was made with a saw at the middle of the diaphysis. The osteotomy was midshaft in all bones, and we choose 30 degrees instead of straight transverse to help with alignment and to simulate a fracture. The fractures were then reduced in the vise, and using the 3-point bending technique, the flexible nails were inserted to their corresponding distances past the osteotomy site. The distance past the osteotomy was referenced by the midpoint of the osteotomy.

Biomechanical Testing–Cyclic Testing

Biomechanical testing was performed using a 4-point bending setup mounted to an MTS 848 Mini-Bionix (MTS Corp, Eden Prairie, Minn) materials testing system. Initial cyclic testing was performed on each intact specimen before osteotomy and instrumentation to ensure repeatable placement and a normal baseline measure, then repeated for all instrumented cases. The fracture site was centered between the upper supports spaced 4 cm apart and 4 cm from each of the bottom supports. The bottom supports were 12 cm apart. The radii and ulnas were tested in the anteroposterior plane, and the tibias in the medial-lateral plane, which provided the optimal and most consistent bone placements with respect to the natural contours of the canine bones.

All cyclic testing was performed in displacement control, and the loading parameters for each test were determined by selecting the end points that would generate forces within 10% of the yield force, measured by prestudy failure testing of canine long bones. This helped ensure that no permanent deformity occurred as a result of this first, bending-only stage of testing. Displacement control was preferred in this application because the signal fidelity of the load cell

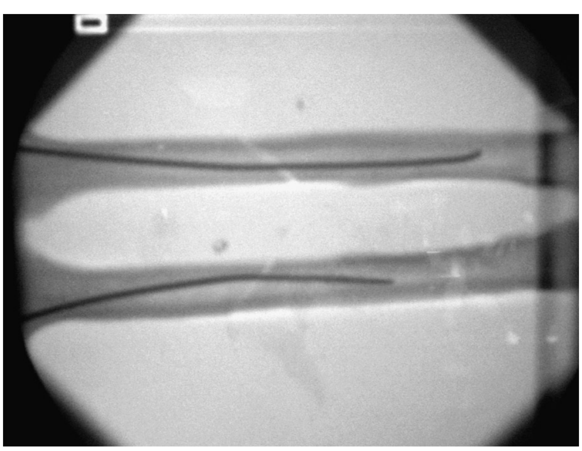

FIGURE 2. Radiographs of canine radii comparing 3- and 5-diameter insertion lengths and illustrating the 3-point bending fixation technique.

TABLE 1. Mean (SD) Values for Stiffness, Force, and Energy After Cyclic Testing for the 3 Bone Types for 3- and 5-Diameter Insertion Lengths

	Stiffness, N/mm	Max Force, N	Energy, N · mm
Radius (n = 16)			
3-Diameter insertion (n = 8)	9.08 (2.96)	10.0 (3.44)	28.80 (10.81)
5-Diameter insertion (n = 8)	8.89 (4.75)	10.51 (5.35)	39.26 (22.95)
Ulna (n = 12)			
3-Diameter insertion (n = 6)	6.08 (1.57)	5.98 (1.68)	20.30 (8.60)
5-Diameter insertion (n = 6)	6.29 (2.54)	7.54 (2.79)	19.00 (7.97)
Tibia (n = 18)			
3-Diameter insertion (n = 9)	13.42 (5.72)	15.30 (7.64)	33.63 (11.88)
5-Diameter insertion (n = 9)	9.54 (2.34)	10.97 (3.89)	28.68 (8.01)

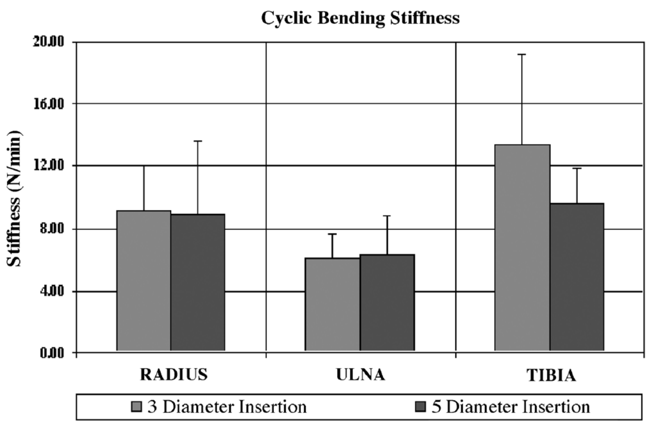

FIGURE 3. Graphical results from the cyclic bending tests showing the elevated stiffness of the radii and tibias over the ulnas. No differences were found between 2- and 3-diameter insertions within the bone groups.

would be less in force control owing to the small size of the specimens and the small forces in effect. The load rate was 2.0 mm/s, and the actuator cycled between 0.5 and 1.5 mm of deflection for a total of 20 cycles. Load versus displacement curves were generated, from which bending stiffness was determined from the slopes of the linear portion of the final cycle. The results from these tests were compiled and compared per pair, based on the 3- or 5-diameter insertion length.

Biomechanical Testing–Failure Testing

Failure testing was next performed on all the instrumented canine bones. Each specimen was deformed to failure at 2 mm/s in displacement control. Failure data were recorded and used to generate load versus displacement curves, from which stiffness, failure displacement, and failure force were determined and compared for each matched set of bones. In all cases, stiffness was calculated as the slope of a linear regression of the elastic portion of the load versus displacement curve. Failure load was considered the highest load attained before permanent ductile deformation of the implanted bone construct began; failure displacement is the deflection value at failure, and failure energy is the area under the curve up to that failure point.

Statistical Methods

Statistical analysis was performed using 2-way analysis of variance in PC-SAS (SAS Institute, Cary, NC) to determine differences in bone type (radius, ulna, tibia), side (right, left), and insertion length (3 diameters, 5 diameters). A $P \leq 0.05$ was considered statistically significant. Values are reported as the mean (SD).

RESULTS

Cyclic Testing

The results for cyclic testing of the 3 bone groups for each insertion length are shown in Table 1. For the ulna group, only 6 pairs were tested in the cyclic condition. The tibias significantly showed the highest values for stiffness over ulnas ($P = 0.0006$) and failure load over ulnas ($P = 0.0013$). Figure 3 shows the cyclic stiffness for each bone group and the insertion length. The radii and tibia significantly absorbed more energy than the ulnas (P = 0.0072 and P = 0.0254). There was no significant difference between right and left bones within each group. There were no significant differences between the condition of 3- and 5-diameter insertions for stiffness (P = 0.1715), peak force (P = 0.4388), or cyclic energy (P = 0.7553).

Failure Testing

The results for the failure testing of the 3 bone groups for each insertion length are shown in Table 2. There was a significant difference overall between bone types ($P < 0.001$), with the tibias having the highest values for stiffness, failure displacement, failure load, and energy to failure. Figure 4 shows the failure stiffness for each bone group and the insertion length. There was no significant difference between right and left bones within each group. There were no significant differences between 3- and 5-diameter insertions for stiffness (P = 0.1970), failure displacement (P = 0.3220), failure load (P = 0.1414), or energy to failure (P = 0.8475).

DISCUSSION

An IM nail is an internal splint that stabilizes long-bone fractures. The length of a nail that transmits load from one fragment of a fractured bone to the other is known as the working length. Stiffness is related to working length of the

TABLE 2. Mean (SD) Values for Stiffness, Displacement, Force, and Energy After Failure Testing for the 3 Bone Types for 3-Diameter and 5-Diameter Insertion Lengths

	Stiffness, N/mm	Displacement, mm	Max Force, N	Energy, N · mm
Radius (n = 16)				
3-Diameter insertion (n = 8)	6.49 (1.75)	18.75 (3.27)	92.22 (13.78)	995.20 (231.35)
5-Diameter insertion (n = 8)	7.34 (1.71)	18.71 (3.29)	82.65 (9.43)	834.62 (227.74)
Ulna (n = 18)				
3-Diameter insertion (*n* = 9)	8.34 (1.87)	15.15 (2.65)	80.60 (8.40)	695.18 (159.28)
5-Diameter insertion (*n* = 9)	7.84 (1.29)	15.91 (3.15)	82.35 (8.72)	801.57 (200.16)
Tibia (n = 18)				
3-Diameter insertion (n = 9)	15.18 (4.69)	19.54 (3.15)	176.06 (17.59)	2202.11 (486.69)
5-Diameter insertion (n = 9)	12.13 (1.61)	21.67 (4.55)	167.01 (16.42)	2311.91 (759.90)

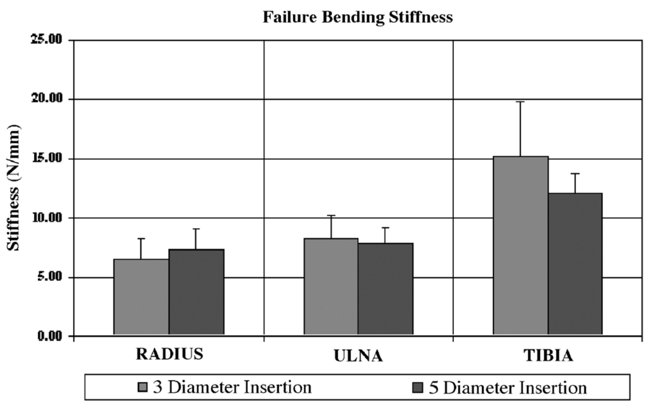

FIGURE 4. Graphical results from the failure tests showing the higher stiffness of the tibias. No differences were found between 2- and 3-diameter insertions within the bone groups.

nail and its moment of inertia.[26] Bending stiffness is inversely proportional to the square of the working length[26]; thus, a greater working length results in less bending stiffness. Overall construct stability is based on IM dynamic pressure exerted by the flexible nail at points of nail-bone contact.[23] Longer nails may have more area of dynamic pressure, but this study showed no difference in construct stiffness when compared with shorter nails (Figs. 3 and 4). The fixation difference may be negligible, or it could be counterbalanced by the decrease in bending stiffness due to increased working length.

The different shapes of the IM canal and bone morphology result in varying degrees of points of interface depending on the bone being tested. Fixation in the distal fragment of bone may be enhanced by placing a straight pin in a curved medullary cavity, placing a curved pin in a straight cavity (3-point fixation), or placing the point obliquely into cancellous bone.[23] The bone-nail interface is essentially determined by the bone morphology in a curved medullary cavity, with the fixation points little influenced by the surgical technique. However, in the 3-point fixation technique, the bone-nail interface is much more technique dependent. In this study, no difference was found between the different fixation lengths past the fracture site when comparing right to left bones from the same dog with the same bone morphology. Our study was limited to the length of fixation. Prebending of the rods and using longer rods can often aid in fracture reduction, but this was not included in our model. It is possible that the predetermined factors of bone morphology and the subsequent fixation technique required for fixation are the major factors determining strength when compared with nail insertion length.

In vitro biomechanical studies using an animal bone model for human surgical techniques have limitations. Although canine bones are of similar size and shape to pediatric human bones,[7] this study does not suppose that the adult canine bone is qualitatively equivalent to pediatric human bone. The actual quantitative biomechanical properties cannot be applied to humans; therefore, the data on intact specimens were not included. The soft-tissue envelope was dissected away from bones; thus, the effects of muscle, tendon, and ligament forces were not considered. Although the presence of soft tissue would certainly simulate a more physiological mechanical response of a limb to fracture fixation, the authors chose to focus solely on the fixation differences in the bone itself with a repeatable fracture model to reduce variability. This study is also limited to diaphyseal fixation, and fixation into cancellous bone may not yield the same results. The amount of canal fill was also not considered in this model. Some variability was also reduced by using matched pairs and limiting comparisons between the 3 bone types used in this study. This study also focused on 4-point bending in a single plane. We tested only single rod fixation in larger bones such as the tibia, and femur often uses 2 rods. Measuring the rotational mechanics of fixation was not practical because of the limited fidelity of the torsional load cell to such small forces. Furthermore, in the clinical setting, rotational control is achieved by casting, and historically, single flexible IM nailing has not been expected to control rotation well.[11]

This study tested matched pairs of radii, ulnas, and tibias in 4-point bending and compared the biomechanical properties of length of nail fixation past the fracture site in relation to bone diameter. Fixation of 1 or 2 diameters past the osteotomy yielded gross instability. We found no difference in bending failure load, displacement, stiffness, or energy when comparing fixation of 3 versus 5 diameters of fixation past the fracture site. Flexible IM nails act as internal splints to align the fracture ends. The length of nail past the fracture site does not greatly affect the biomechanical properties of the construct. This knowledge may be helpful in clinical scenarios where there is uncertainty in the expected strength of a shorter fixation. Examples include when the nail cannot be passed completely to the distal metaphysis and in proximal or distal long-bone fractures. Further clinical studies are needed to determine implications in a patient setting.

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