**Influence of Locking Bolt Location on the Mechanical Properties of an Interlocking
Nail in the Canine Femur**

A Thesis Presented in Partial Fulfillment of the Requirements for the Degree of Master of
Science in the Graduate School of The Ohio State University

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Abstract

Long bone fractures are common injuries in the canine patient. The aims of this study were to determine whether the fatigue properties of an interlocking nail construct are influenced by metaphyseal or diaphyseal location of the locking bolt and to evaluate fatigue properties of locking bolts in metaphyseal and diaphyseal bone under axial and torsional loading. Paired femora from 20 skeletally mature dogs were implanted with a 6-mm diameter, model 11, interlocking nail (ILN) and locked with a 2.7 mm bolt placed in either the diaphysis or metaphysis. Constructs were tested in axial loading (10 pairs) or torsion (10 pairs) to failure (defined as displacement >2 mm or a total of 500,000 cycles for axial loading, and rotation >45° degrees for torsional loading.) Outcome measures included initial construct stiffness, number of cycles to failure, peak load and peak torque. Microradiography and histology were used to determine the location and nature of construct failure. Metaphyseal bolts failed at higher axial loads than diaphyseal bolts, with bolt failure due to bending at the nail-bolt interface. All metaphyseal constructs were intact after torsional loading with no evidence of fracture of the bone or the bolt whereas 9 of 10 diaphyseal constructs failed catastrophically due to spiral fracture through the adjacent cortical bone. Placement of a locking bolt in metaphyseal bone extends fatigue life under axial loading and decreases the incidence of catastrophic failure under torsional loading. Therefore when inserting an interlocking nail for repair of long bone fractures, efforts should be made to obtain firm seating of at least one locking bolt in metaphyseal bone.

Dedications

To Trish: thank you for making everyday possible. Your love, encouragement, and support have been the wind beneath my wings.

To my Mom, Jason, Adam, Stephanie, and Joey: thank you for always believing in me.

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Field of Study

Major Field: Veterinary Clinical Science

Table of Contents

	Page
Abstract.....	<i>ii</i>
Dedication.....	<i>iii</i>
Acknowledgements.....	<i>iv</i>
Vita.....	<i>v</i>
List of Figures.....	<i>ix</i>
List of Tables.....	<i>x</i>
Chapters:	
1. Introduction.....	1
2. Influence of locking bolt location on the mechanical properties of an interlocking nail in the canine femur.....	6
2.1 Introduction and hypothesis.....	6
2.2 Materials and methods.....	9
2.21 Specimen collection and preparation.....	9
2.22 Biomechanical testing.....	12
2.23 Post-testing evaluation.....	14

2.24	Statistical analysis.....	15
2.3	Results.....	15
2.31	Biomechanical testing.....	15
2.32	Mode of failure analysis.....	20
2.33	Influence of nail position within the medullary canal.....	23
2.4	Discussion.....	25
	References.....	30
	Appendix: Protocol for undecalcified sections.....	35

List of Figures

Figure	Page
2.1 Axial and torsional constructs.....	11
2.2 Biomechanical testing of axial and torsional constructs.....	13
2.3 Gross specimens of torsional constructs.....	19
2.4 Post-testing axial construct montage	21
2.5 Post-testing torsional construct montage.....	22
2.6 Box and whisker plot for centralization ratios of tested constructs.....	24

List of Tables

Table

2.1	Summary of mechanical data from axial test constructs.....	16
2.2	Summary of mechanical test data from torsional test constructs.....	18

Chapter 1: Introduction

Bones are an essential part of every vertebrate animal. They provide the scaffolding for muscle attachments and allow for strength and movement. As such, bones are routinely subjected to physiologic forces and occasionally supra-physiologic forces. Four forces primarily act upon bones during any given moment. These include: axial compression, axial tension, bending, and torsion. Bones may adapt to both physiologic and non-physiologic forces over time, however fractures are more commonly due to an acute episode of non-physiologic forces acting upon a bone, such as during a fall or vehicular accident. These supraphysiologic forces exceed the ultimate strength of the bone, resulting in bone failure, often in a predictable fashion. The fracture configuration and degree of soft tissue trauma are due to the direction and magnitude of the force that is applied to the bone. Ideal methods of fracture repair often depend on the fracture configuration and the biologic environment of the bone. Approximately half of all long bone fractures in dogs and cats involve the femur. Furthermore, femoral fractures reportedly have the highest incidence of nonunion and osteomyelitis of all fractures in canine and feline patients¹.

There are four main principles of fracture repair set forth by the *Arbeitsgemeinschaft für Osteosynthesefragen* (AO): anatomical reduction, stable fixation, preservation of the blood supply, and early active pain-free mobilization^{2,3}. There have been numerous methods described for treating femoral fractures in dogs including: bone plate and screws, pin and cerclage wire, external skeletal fixation, and the interlocking nail, among others. The ideal method of fixation for fracture repair is controversial among orthopedic surgeons.

A minimally invasive or ‘open but do not touch’ technique may be utilized for long-bone fracture repair with several fixation types. This limited approach to the fracture site is referred to as biologic osteosynthesis. Biologic osteosynthesis is the preferred approach for long-bone fracture management in human and veterinary patients^{4,5}. The main goals of biologic osteosynthesis are to obtain alignment and stabilization of primary fracture fragments through a minimally invasive approach in order to preserve blood supply and minimize disruption of the fracture hematoma^{6,7}. Advantages of biologic osteosynthesis include decreased blood loss, shorter surgical time, lower infection rates, reduced hospitalization times, shorter healing time, decreased non-union rate, and early return to function⁷⁻⁹.

Gerhard Küntscher developed the first locking intramedullary nail, named the Detensor nail, during the Second World War, and used it to treat femoral fractures in soldiers. Intramedullary interlocking nailing is the preferred surgical technique for management of long bone fractures in humans^{8,10-13}. Several modifications of the original nail described by Küntscher have occurred over the past several decades. The interlocking nail (Innovative Animal Products, Rochester, Minn) most commonly used in

the United States of America is a modified intramedullary pin with 2-4 transverse cannulations in the shaft which can accommodate locking screws or bolts; these are available in a variety of diameters and lengths. The nail acts as an internal splint for fractured long bones and effectively counteracts bending, axial compression, and torsional forces. The interlocking nail is ideally suited for minimally invasive applications. Most fracture configurations are amenable to interlocking nail stabilization and repair has been associated with high union rates as well as low complication rates¹⁴⁻¹⁸. Complications reported with interlocking nail stabilization for long-bone fractures include nail breakage, screw or bolt deformation or breakage, misplaced screws or bolts, delayed or nonunion, bone fracture, and sciatic neuropathy^{8,14,19,20}.

The location of the interlocking nail within the medullary canal provides a biomechanical advantage over repair techniques^{8,9,12} which are applied to the outside of the bone, because the interlocking nail is positioned along the neutral axis of the bone-nail construct. Resistance to bending forces depends on the diameter of the nail, and therefore the largest nail diameter that fits into the medullary canal should be selected. *In vitro* studies of canine femoral fractures stabilized with an interlocking nail found them to be strongest under bending loads and weakest in torsional loading. Torsional strength of the construct was approximately 5-20% of intact bone²¹.

In veterinary surgery, interlocking nails are used for fracture repair in a static nailing technique, in order to provide the greatest possible stability at the fracture site. Static nailing refers to insertion of locking screws or bolts in both the proximal and distal fragments to prevent fracture collapse and rotation. In comparison, dynamic nailing refers to the insertion of locking screws or bolts in both the proximal or distal fracture

fragments at the time of surgery and later removal of these locking screws or bolts (dynamization) in order to allow increased load transmission across the fracture site. Dynamic nailing is more frequently utilized in humans, whereas difficulty with post-operative exercise restriction has limited the use of this technique in veterinary patients²¹⁻²³.

During femoral fracture repair, interlocking nails are routinely placed in a normograde fashion, initiating in the trochanteric fossa. However, due to the cranial curvature of the femoral diaphysis, adequate placement of the nail in the distal fracture fragment may be difficult. In human patients, retrograde placement of an interlocking nail through the intercondylar notch facilitates stabilization of distal femoral fractures and has become the method of choice in polytraumatized patients with complex femoral fractures^{10,24,25}. This technique has several advantages which include stabilization of multiple fractures simultaneously through the same incision (ipsilateral fractures of the femur and tibia), decreased soft tissue dissection compared to plate application therefore decreased blood loss, reduced surgical time and lower infection rates, as well as decreased soft tissue dissection in obese patients. This modified technique of nail insertion facilitates distal femoral fracture repair in patients with proximal femoral implants or severe coxofemoral osteoarthritis, which may make normograde insertion difficult. Additionally, retrograde insertion allows adequate seating of the interlocking nail within the medullary canal of the distal femur, increasing the ability to place two locking screws or bolts in the distal fracture fragment^{10,24-26}.

The optimal number of locking screws or bolts placed in the interlocking nail remains controversial among surgeons; it is often determined by fracture location and stability. Several human and veterinary studies have reported conflicting results regarding the placement of one or two locking screws or bolts in the distal fracture fragment^{10,13,22,27-31}. According to Lin et al. one distal screw is sufficient for stable fractures¹³. The closer the fracture is to the distal locking screw, the less cortical contact the nail has, which leads to increased stress on the locking screw. Furthermore, the fracture becomes more rotationally stable the farther the distal locking screw is from the fracture site because of friction of the nail within the medullary cavity²⁸. Wu et al. described the incidence of interlocking nail failure based on fracture location within the femur: 4.9% failure in the proximal one-third, 1.9% failure in the mid-diaphysis, and 8.2% failure in the distal one-third of the femur²⁹. Factors which may increase the incidence of failure in the distal femur include stress concentration around screw hole and nail slot, nicking of the nail during drilling of the screw holes, the “fracture-locking hole” distance is decreased, and longer loading over the proximal femur^{13,22,27,29}. Nicking the nail by drilling around the hole weakens the strength of the nail holes and increases stress. In 2006, Bhat et al. reported approximately 55% of failed repairs in humans were located in the distal femur²². Although there are no veterinary reports evaluating failure of interlocking nails based on fracture location, similar results may be expected. Therefore, further investigation into the optimal conditions for the application of the interlocking nail in the femur is needed.

Chapter 2: Influence of Locking Bolt Location on the Mechanical Properties of an Interlocking Nail in the Canine Femur

2.1 Introduction and hypotheses:

The development of innovative techniques to enhance the rate of fracture healing and minimize post-operative morbidity continues to be an area of intense research activity in both human and veterinary orthopedics. Over the past two decades, there has been a paradigm shift from using maximally invasive surgical approaches and anatomic fracture reduction towards a more biologic approach to fracture treatment with smaller incisions and minimal to no disruption of the fracture site itself.^{2,32,33}

Interlocking nails (ILN) provide a viable option for minimally invasive fracture repair and may be an attractive alternative to the use of standard bone plates for the repair of comminuted diaphyseal fractures. The use of interlocking nails in dogs was initially described in 1986 by Johnson and Huckstep³⁴ and later by Dueland and colleagues.⁸ Good to excellent clinical results have been reported with the use of ILNs for the management of humeral, femoral and tibial fractures in dogs and cats.^{7,14,15,21} More

recently, an hourglass-shaped interlocking nail designed to be easier to insert accurately and to provide greater mechanical stability was developed.³⁵

The ILN is a modified intramedullary pin with two to four transverse holes in the shaft to accommodate passage of a locking screw or bolt that passes through the adjacent bone cortices and locks into either the cis- cortex (bolt) or both cortices (screw) as it is tightened. ILN have a number of potential biological advantages as compared to other fixation methods. Standard bone plates, which are placed directly on the periosteal surface and require compression against the cortex for stability, have been shown to interfere with the periosteal blood supply.³⁶⁻³⁸ From a biological perspective, use of an ILN that is inserted into the intramedullary canal allows for better preservation of the periosteal blood supply. However, studies in sheep³⁹ and dogs⁴⁰ have shown that reamed ILNs cause transient decrease in cortical blood flow due to disruption to the endosteal blood supply. As a result, there has been a move away from reamed ILNS towards unreamed ILNs, particularly for open or complex fractures that have significant periosteal or soft tissue trauma.⁴¹

From a biomechanical perspective, locked ILN provide greater resistance to torsional forces than plates and standard intramedullary pins.^{8,12} They also provide superior fatigue resistance and bending stiffness compared with standard plate fixation.⁴² Resistance to bending depends on the area moment of inertia (AMI), a structural property describing the geometric distribution of material within a given implant design.⁵ The AMI of a solid 6-mm diameter ILN is almost four times that of a 3.5 mm dynamic compression plate when the neutral axis is defined in a plane perpendicular to the holes in the ILN.^{5,43} Since they are positioned along the neutral axis of the bone-implant

construct, ILNs are less susceptible than a conventional plate to failure from cyclic axial, torsional, and bending loading.¹⁹ This effect is magnified when complete anatomic reconstruction of the fracture is not possible, making ILNs particularly well suited for comminuted diaphyseal fractures of the humerus, femur and tibia.²

The AMI is reduced by the presence of unfilled holes in either the bone plate or the ILN; additionally, unfilled screw holes serve as a potential stress concentrator and have been associated with failure of the ILN failure when the empty hole is located close to the fracture line.²¹ The decrease in AMI associated with screw holes can be minimized by decreasing the size of the hole in the ILN; for example, reduction of the hole from 3.5 mm to 2.7 mm increases the fatigue life by a factor of approximately 52.⁴² However, it is important to note that the use of smaller diameter screws may itself be problematic since the bending stiffness of a screw is determined in part by its core diameter.⁵ Size-for-size, locking bolts are stiffer and stronger than screws because they have a larger core diameter; additionally, recent data indicate that nails locked with bolts experienced approximately significantly less deformation than if locked with screws.⁴⁴ Under axial loading, locking bolts are subjected to four-point bending forces¹⁰ and the principal mode of failure is by bolt bending or complete breakage. The loads to which locking bolts are exposed depend in part on the diameter of the nail and the location of the fracture. For a transverse mid-diaphyseal femoral fracture, there is usually significant contact between the nail and the cortex at the level of the isthmus and this will tend to unload the distal interlocking bolt. In contrast, the stability of comminuted or oblique mid-femoral fractures, or fractures that involve the proximal or distal metaphysis, will depend more on the locking bolt.

Given the significant role of the locking screws or bolts in determining the mechanical performance of the bone-ILN construct, we previously performed an investigation into the fatigue properties of 2.7 mm locking screws in a 6-mm diameter ILN construct.⁴⁵ This study identified an inverse relationship between the diameter of the bone and the fatigue life of the locking bolt under axial loading. Furthermore, for a given bone diameter, eccentric loading of the locking screw resulted in an increase in fatigue life as compared with central loading of the screw. In the current study, we sought to extend these observations to locking bolts. The purpose of the current study was therefore to evaluate the fatigue life of 2.7-mm-diameter cortical bone locking bolts used in a 6-mm-diameter interlocking nail placed in the canine femur. We hypothesized that the location of a locking bolt would have a significant influence on its fatigue life. Specifically, we hypothesized that bolts placed in the narrower diaphysis would show improved fatigue properties compared to bolts placed in the wider metaphysis. Additionally, we hypothesized that nails placed eccentrically within the medullary canal would exhibit improved fatigue properties under axial loading.

2.2 Materials and Methods:

2.2.1 Specimen Collection and Preparation

Twenty pairs of femora were harvested from skeletally mature dogs that were euthanatized for reasons unrelated to this project. The soft tissues were removed and the femora wrapped in saline-soaked towels for storage at -20°C . Femora were thawed to

room temperature prior to testing and the bones were kept moist with saline irrigation throughout testing.

Craniocaudal radiographs of the bones were obtained before interlocking nail insertion in order to confirm physeal closure and to document the length of each femur (measured from the articular surface of the lateral condyle to the most proximal extent of the greater trochanter). Standard 6-mm diameter ILN with 4 holes (Model 11; Innovative Animal Products, Rochester, MN) were inserted into each femur retrograde to the predetermined distance. The nail was then locked using a single bicortical 2.7 mm diameter bolt located in either metaphyseal or diaphyseal bone. The location in the distal femur was determined as a percentage of length of each femur: 72% for the diaphyseal bolt and 86% for the metaphyseal bolt. The ILN was secured to a custom alignment device and the proximal end of the femur was then potted in epoxy resin (Bondo Body Filler; Bondo Corporation, Atlanta, GA) taking care to ensure that the ILN was aligned axially (Figure 2.1).

Figure 2.1. Overview of the preparation of test specimens. Paired canine femora were used to make direct comparisons between ILN locked with a metaphyseal bolt (left) or a diaphyseal bolt (right).

2.22 Biomechanical Testing

For torsional testing, the proximal end of the nail was secured to the crosshead and a compressive pre-load of 10N was applied to remove the initial compliance (“slack”) associated with slight mismatch between the bolt and the hole in the nail (Figure 2.2a). The nail was then externally rotated under displacement control at a rate of 5°/second and continued to failure, defined as angular displacement of 45 degrees or catastrophic failure of the implant or the adjacent bone. *Torsional stiffness* was determined as the slope of the initial linear portion of the torque versus angular displacement curve. *Peak torque* was recorded at specimen/construct failure or when there was a sudden and significant (>35%) drop in the torsional moment. Finally, the torque required to induce 20 degrees of external rotation was calculated for each specimen.

For axial testing, the proximal end of the ILN was secured to the crosshead of a servohydraulic materials testing system (Model 858 Bionix servohydraulic materials testing frame; MTS Systems Corp, Eden Prairie, MN) using a Jacob’s chuck. The potted end of the specimen was secured to the base of the materials testing frame (Figure 2.2b). The ILN was then axially loaded throughout the range from 70N to 700N, at a rate of 10 Hz. The number of cycles to failure was recorded, with failure defined as 2 mm of axial displacement. For constructs that did not fail, testing was concluded after a total of 500,000 cycles.

Figure 2.2. Overview of test constructs in the MTS machine. Paired canine femora were used to make direct comparisons between ILN locked with a metaphyseal bolt or a diaphyseal bolt under torsional loads (A) and axial loads (B).

2.23 Post-Testing Evaluation

Craniocaudal and mediolateral radiographs were obtained immediately after testing. The bone was then sectioned transversely to isolate a cylindrical bone specimen containing a short length of ILN and the locking bolt. The bone specimens were fixed in neutral buffered formalin, dehydrated through an alcohol series and embedded in polymethyl methacrylate (Appendix), then sectioned in either the coronal plane (for bones subjected to axial loading) or the transverse plane (for specimens subjected to torsional loading) using a diamond band saw (Model 340CP; Exakt Technologies, Oklahoma City, OK). The resulting sections (approximately 500-700 μm) were ground to a final thickness of 150-200 μm , microradiographed (Model LX-60; Faxitron Corporation, Wheeling, IL) and stained with 1% toluidine blue for morphometric analysis.

The following parameters were measured under the light microscope: bone diameter, cortical thickness, diameter of the medullary canal, and the maximum and minimum lengths of unsupported bolt within the medullary canal. The maximum and minimum unsupported lengths were then used to calculate a “*Centralization Ratio*” to describe the relative position of the nail along the span of the locking bolt. A centralization ratio >0.80 was considered to be representative of a well centered nail and a centrally loaded bolt, whereas ratios <0.80 were representative of an off-center nail and an eccentrically loaded bolt.

2.24 Statistical Analysis

Number of cycles to failure, torsional stiffness, peak torque and torque to 20 degrees were compared in diaphyseal versus metaphyseal constructs using a paired Student's t-test. Failure rates in the axial fatigue test specimens were compared with the Fisher's exact test. Differences in fatigue life for centrally and eccentrically loaded bolts were determined using an unpaired Student's t-test. A significance level of $p < 0.05$ was used throughout.

2.3 Results:

2.31 Biomechanical Testing

Axial tests: Data from one axial loading specimen was lost due to technical problems associated with the MTS machine, leaving a total of nine paired specimens for analysis. The mean number of cycles to failure was significantly greater for specimens that were locked with a metaphyseal bolt ($p = 0.03$) (Table 2.1). Overall, eight of nine diaphyseal specimens failed before 500,000 cycles in the cyclic testing, compared with seven of nine metaphyseal specimens ($p > 0.05$; Fisher exact test).

	Metaphysis (n=9)	Diaphysis (n=9)	p-value
Cycles to failure	209,207 ± 159,576	80,143 ± 205,316	0.03
Cortical diameter, cm	2.12 ± 0.21	1.89 ± 0.18	<0.001
Cortical thickness, cm	0.26 ± 0.10	0.48 ± 0.10	0.0002
Medullary diameter, cm	1.86 ± 0.19	1.32 ± 0.12	<0.001
Minimum unsupported bolt length, cm	0.56 ± 0.1	0.27 ± 0.1	<0.001
Maximum unsupported bolt length, cm	0.70 ± 0.13	0.46 ± 0.1	0.002
ILN centralization ratio	0.62 ± 0.30	0.80 ± 0.16	0.16
Failure incidence	7 of 9 (78%)	8 of 9 (89%)	0.50

TABLE 2.1. Summary of mechanical test and morphometry data (mean ± standard deviation) from axial test constructs. Tests were conducted to either failure, defined as 2mm bolt displacement, or a total of 500,000 cycles. Significance values are based on two-tailed Student's paired t-tests tests. The failure incidence was compared with Fisher exact test.

Torsional Tests: There was no significant difference between the initial stiffness of specimens locked with diaphyseal versus metaphyseal bolts ($p=0.17$) (Table 2.2). The torque required to generate 20 degrees of angular displacement was greater in the diaphyseal specimens ($p<0.05$). All ten of the metaphyseal constructs were intact after torsional loading, compared with only 1 of 10 diaphyseal specimens ($p<0.0001$). The nine diaphyseal specimens that failed all did so as a result of a spiral fracture through the drill hole, typically through the hole in the trans-cortex (Figure 2.3).

	Metaphysis (n=10)	Diaphysis (n=10)	p-value
Stiffness, N-mm/degree	565.63 ± 91.07	506.22 ± 154.68	0.17
Torque to 20 degrees, N-mm	7689.5 ± 828.5	8704.2 ± 1392.7	0.045
Peak torque, N-mm	ND	13961.7 ± 2595.56	ND
Cortical diameter, cm	2.17 ± 0.16	1.79 ± 0.14	<0.001
Cortical thickness, cm	0.21 ± 0.08	0.45 ± 0.12	0.0001
Medullary diameter, cm	1.74 ± 0.14	1.34 ± 0.17	<0.001
Minimum unsupported bolt length, cm	0.49 ± 0.07	0.27 ± 0.05	<0.001
Maximum unsupported bolt length, cm	0.65 ± 0.10	0.47 ± 0.13	<0.01
ILN centralization ratio	0.80 ± 0.13	0.58 ± 0.12	0.046
Failure incidence	0 of 10 (0%)	9 of 10 (90%)	0.000060

TABLE 2.2 Summary of mechanical test and morphometry data (mean ± standard deviation) from torsional test constructs. ND = not determined.

FIGURE 2.3. Photographs illustrating gross findings following axial testing (a) and torsional testing of ILN constructs locked with bolts in metaphyseal (b) and diaphyseal (c) locations. Both bolts bent in the coronal plane under axial loading (a). Under torsional loading, the metaphyseal bolt deformed in the transverse plane (b) whereas the diaphyseal construct failed catastrophically due to bone fracture through the hole in the trans-cortex (c).

2.32 Mode of Failure Analysis

Axial tests: None of the specimens failed catastrophically but there was evidence of bolt deformation consistent with three-point loading of bolt through the nail for constructs with a metaphyseal bolt (Figure 2.4a to 2.4c) or a diaphyseal bolt (Figure 2.4d to 2.4f).

Torsional tests: All 10 of the specimens locked with a metaphyseal bolt had evidence of deformation at the nail-bolt interface (Figures 2.5a to 2.5c). All of the bolts bent, but none pulled out of bone and none of the bolts broke. Nine of the diaphyseal specimens failed catastrophically as a result of a spiral fracture through the drill hole for the bolt (Figures 2.5d to 2.5f).

FIGURE 2.4. Effects of cyclic axial loading on ILN. Radiographs, microradiographs and stained transverse sections illustrating bending of both the metaphyseal bolt (a to c) and, to a lesser extent, the diaphyseal bolt (d to f).

FIGURE 2.5. Effects of acute torsional loading on ILN. Radiographs, microradiographs and stained coronal sections illustrating slight bending of the metaphyseal bolt (a to c). In stark contrast, note the catastrophic failure of the bone around the diaphyseal bolt in Figures d to f. Nine of ten diaphyseal constructs failed in this manner whereas none of the metaphyseal bolts failed secondary to bone fracture.

2.33 Influence of Nail Position within the Medullary Canal

On the basis of previous work that documented improved fatigue properties when locking screws are loaded eccentrically²⁴ we were interested to see whether a similar relationship was evident in the axial fatigue tests that were performed with these locking bolts. In diaphyseal specimens, centralization ratios of <0.8 , indicative of an eccentrically loaded bolt, were associated with increased fatigue life ($p<0.01$) compared with centrally loaded specimens with centralization ratios of >0.8 . In metaphyseal specimens, the situation was reversed, with centrally loaded bolts exhibiting significantly increased fatigue life than eccentrically loaded bolts ($p<0.05$) (Figure 2.6).

FIGURE 2.6. Effects of nail centralization ratio on the fatigue life of locking bolts placed in diaphyseal or metaphyseal locations. Whisker plot depicts third quartile (upper line), median (thick middle line) and first quartile (lower line). The upper and lower whiskers represent maximum and minimum scores. For each location (metaphyseal or diaphyseal), asterisks indicate statistically significant differences ($p < 0.05$) between specimens with centralization ratios less than or greater than 0.8.

2.4 Discussion

Predictably successful fracture healing depends on the development and maintenance of biological and mechanical conditions that favor new bone formation. Traditional concepts of rigid internal fixation seek to control the mechanical environment at and around the fracture site on the basis that excessive interfragmentary motion delays bone healing.^{2,11} However, it has also been shown that controlled micromotion stimulates new bone formation and enhances the healing of long bone fractures.^{46,47} Completely rigid fixation might not therefore always provide the optimal biological environment for healing and subsequent remodeling. Biologic fracture repair, whether achieved through truly minimally invasive approaches or a more traditional open approach, focuses on engaging the patient's innate reparative potential with the goal of accelerating bone healing.^{33,48} In many cases, this approach involves trading off the overall strength and stiffness of the repair construct against the ability to preserve the viability of the bone fragments and surrounding soft tissues. These concessions in overall device strength or stiffness can usually be made without any significant negative effect on clinical outcomes because the material properties of modern implant alloys far exceed those of intact bone, at least in the setting of single-cycle loading. However, concerns remain about the potential for fatigue damage and implant failure. Clinical reports from both the human and veterinary literature highlight the potential significance of fatigue failure mechanisms, particularly with respect to failures of the locking screws or failures at the screw-nail interface of ILN.^{15,21}

In an earlier study, we determined that the location in which a locking screw is placed (metaphyseal vs. diaphyseal) affects the fatigue properties of the screw.⁴⁵ The

current study sought to determine whether a similar effect held for locking bolts. We hypothesized that bolts placed across the relatively wider metaphysis would exhibit reductions in fatigue life. However, the results from the current *in-vitro* study clearly demonstrate that locking bolts placed in metaphyseal bone provide greater resistance to failure in acute torsional loading and improved fatigue life in axial loading. These data do not support the original hypothesis. The most likely explanation for this outcome is that the initial *in-vitro* tests reported by Aper *et al.*⁴⁵ were performed using hollow aluminum tubing as a bone surrogate. While this set-up likely provided a reasonable model of a cylinder of cortical bone (as in the diaphysis) it may be less representative of metaphyseal bone, which is rich in cancellous bone. If the earlier observation of an inverse relationship between bone diameter and fatigue properties holds true, then the current finding of increased fatigue properties for bolts in the metaphysis suggests that the nature of the bone is more significant than bone diameter *per se* as a determinant of mechanical performance under axial loading. There was a significant difference between cortical thickness in diaphyseal and metaphyseal specimens ($p=0.0002$ for axial-loaded specimens; $p=0.0001$ for torsional-loaded specimens). The increased cortical thickness of the diaphyseal specimens may result in a stiffer construct with a lower yield point leading to catastrophic failure of the bone.

The second hypothesis behind this study, namely that bolts loaded in an eccentric fashion would support higher loads, was supported by the experimental data from diaphyseal specimens but not for metaphyseal specimens. This difference may reflect the differences in load transfer that likely exist in the two locations. Within metaphyseal bone, loads applied through the nail to the bolt are dissipated into the surrounding

cancellous bone, thereby reducing load transfer from the bolt to the cortex. In contrast, in diaphyseal locations, load is transferred directly from the bolt to cortical bone, leading to stress concentrations and an increased risk of catastrophic material failure of the bone. Eccentric placement of the nail may magnify the risks of catastrophic material failure of the bone by increasing stress concentrations at the cortex and changing the lever-arm of the interlocking nail construct. The degree to which an ILN is centered within the medullary canal can be hard to control and will likely vary depending on the geometry of the bone (femur vs. tibia vs. humerus) and the location at which alignment is measured (for example, an ILN placed centrally along the long axis of the tibial shaft will be positioned to the medial side of the midline within the proximal tibial metaphysis). Nevertheless, the results from this study suggest that failure to centralize a nail within the metaphysis is unlikely to increase the risk of subsequent failure of the locking bolt.

There are a number of limitations with a study of this type. Firstly, the testing was performed on cadaveric specimens and, as such, do not incorporate the potential effects of bone remodeling around the ILN or locking bolt. Our decision to focus on cyclic axial testing was based on the fact that axial compression is recognized as an important component of the mechanical environment to which ILN constructs are exposed *in vivo*^{10,49} and because we wanted to be able to compare data from these whole-bone tests with earlier published data from bone surrogates.⁴⁵ Monotonic torsional tests were used to characterize the acute torsional properties of the ILN construct but cyclic tests were not used because the available clinical data suggest that physiologic torsional loads do not play a significant role in fatigue failure of ILN.^{8,21} In future studies, it would be interesting to investigate the effects of bending loads, as has been reported elsewhere.⁴⁴

The cyclic axial tests were stopped after 500,000 cycles rather than continued to the point of failure, and the mechanical test data from specimens that did not fail should therefore be considered estimates of the minimum fatigue life for a particular specimen, rather than an absolute measure of the maximum fatigue life that might be expected under real-life conditions.

The torsional tests were conducted under displacement control and continued to the point of failure, with continuous monitoring of the applied torque. In each of the tests there was evidence of initial slack due to incongruity between the bolt and the hole in the nail; however, once the bolt engaged with the edges of the hole, load transfer occurred and the extent of angular displacement was linearly related to the applied torque. There was no significant difference in the initial stiffness recorded from the two constructs when tested in torsion. Nine of 10 bones locked with a diaphyseal bolt failed as a result of spiral fracture through the cortical hole (most often originating in the trans-cortex) whereas all of the metaphyseal specimens failed as a result of bolt deformation. Spiral fractures are not a common cause of ILN failure in clinical practice, but screw or bolt bending and breakage is an important cause of failure.^{18,21,50,51} While there is no clear evidence that screw bending or breakage per se has any significant negative impact on fracture healing, the removal of ILN with bent or broken screws can be complicated.⁵¹ In their *in-vitro* studies comparing ILN locked with either one or two distal screws, Reems *et al.*³⁰ showed that the risk of screw failure was higher for the distal locking screw, with 4 of 8 (50%) of the 2-screw constructs and 7 of 8 (87.5%) of the 1-screw constructs exhibiting complete breakage of the distal screw. In a clinical setting, ILN are typically used with two locking bolts but this may not always be possible, particularly for fractures

that are located in the distal diaphysis or metaphysis. Computational models have shown that strains on the distal screw can be reduced if the ILN is inserted into dense subchondral bone since the cancellous bone serves to reduce load transfer to the screws.¹³

In conclusion, the results from this study demonstrate that the fatigue life of bolts used to lock a 6-mm diameter ILN is increased if bolts are placed in metaphyseal rather than diaphyseal bone. Whenever possible, ILN should be placed as distal (or proximal) as possible in order to ensure that at least one distal bolt can engage the metaphyseal bone.

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Appendix: Protocol for undecalcified sections

1. 70% alcohol.....3 days
2. 80% alcohol.....3 days
3. 95% alcohol.....3 days
4. 100% alcohol.....3 days
5. 100% alcohol.....3 days
6. 30% Technovit/70% alcohol.....3 days
7. 50% Technovit/50% alcohol.....3 days
8. 70% Technovit/30% alcohol.....3 days
9. 100% Technovit.....4 days
10. 100% Technovit.....4 days