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Biomechanical Evaluation of Two Methods of Humeral Shaft Fixation

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BIOMECHANICAL EVALUATION OF TWO METHODS OF HUMERAL SHAFT FIXATION

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by
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ABSTRACT

Biomechanical evaluations of fracture fixation devices attempt to determine implant performance by approximating the *in vivo* conditions. This performance is affected by many factors and relies on the complex bone-implant interface. Biomechanical tests can be designed in a variety of ways in order to evaluate device performance with respect to any number of these bone-implant interactions. Standardized tests, designed by groups such as the American Society for Testing and Materials (ASTM), are often designed either to determine the performance of a specific type of fixation device or for direct comparison between different devices. Additionally, many biomechanical evaluations are designed for direct comparison between the devices being evaluated. Often times these tests utilize bone analogs in order to eliminate variability. Finally, the method and location of load application greatly influences device performance outcomes. Cyclic tests determine fatigue performance whereas quasi-static tests are used to define device limits (i.e. – Young's modulus, and ultimate/yield properties). Physiologically equivalent loading patterns expose fixation devices to combined loading modalities most closely resembling the *in vivo* conditions.

This paper will explore the variety of ways in which biomechanical testing of fracture fixation devices are performed. Specific focus will be given to the design and application of biomechanical tests which simulate physiologically relevant loading. Physiologically relevant/equivalent loading refers to the simulation of *in vivo* loads with respect to anatomic alignment. This examination will include details regarding the differences in biomechanical test designs between weight-bearing (i.e. – lower limb) and non-weight-

bearing (i.e. – upper limb) fixation devices. These concepts will then be put to use for the purpose of evaluating the biomechanical performance of two methods of humeral shaft fixation. The results of this study have been submitted for publication in the *Journal of Surgical Orthopaedic Advances.*

DEDICATION

I would like to dedicate this manuscript to my family and friends who have helped encourage and support me throughout my academic endeavors and have made this journey an enjoyable one. To my parents, Frank and Carol, I owe you a special thanks for always pushing me to be the best that I can be and for their constant encouragement and understanding. You have provided me the best foundation from which to spread my wings. I would especially like to thank my wife, Lindsey, for her unwavering support, belief and love. You have always been the shoulder I turn to for advice and comfort. Together we have made this journey our own and I cannot wait to see what our future holds. Finally, I dedicate this work to my son, Sawyer, whose innocent smile provides constant motivation.

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CHAPTER ONE

INTRODUCTION

Background of Biomechanical Testing

The *in vivo* performance of fracture fixation devices is influenced by several factors including: (1) the mechanical properties of the implant hardware itself, (2) the interaction between the fixation device and the native tissue (i.e. – bone), and (3) the exposure of this bone-implant construct to physiologic loading (typically a combination of compression, torsion and bending loads). To accurately determine device performance *in vitro* biomechanical tests attempt to recreate these conditions. Biomechanical studies comparing the performance of fracture fixation devices are numerous. However, the procedures employed in these evaluations are as varied as the devices being evaluated, making cross-comparison between devices in different studies extremely difficult. A variety of approaches are commonly used for biomechanical evaluation including: (1) standardized testing, (2) tests using bone models or cadaveric bone, (3) quasi-static testing and/or fatigue testing, and (4) physiologically equivalent loading or loading in a worst-case scenario configuration.

Standardized Tests

The American Society for Testing and Materials has developed a number of test protocols to evaluate the performance of various orthopaedic devices. The standardization of test methods allows for improved reproducibility and direct device comparison. Results from standardized tests are usually required by the FDA when

evaluating new products for market approval. For example, ASTM F1717 defines the "Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model" (setup shown in Figure 1.1). Notice that the vertebral bodies are simulated by ultra high molecular weight polyethylene (UHMWPE) and that all dimensions are defined. These factors aid in the test's reproducibility and the application of a rigorous, relevant load.

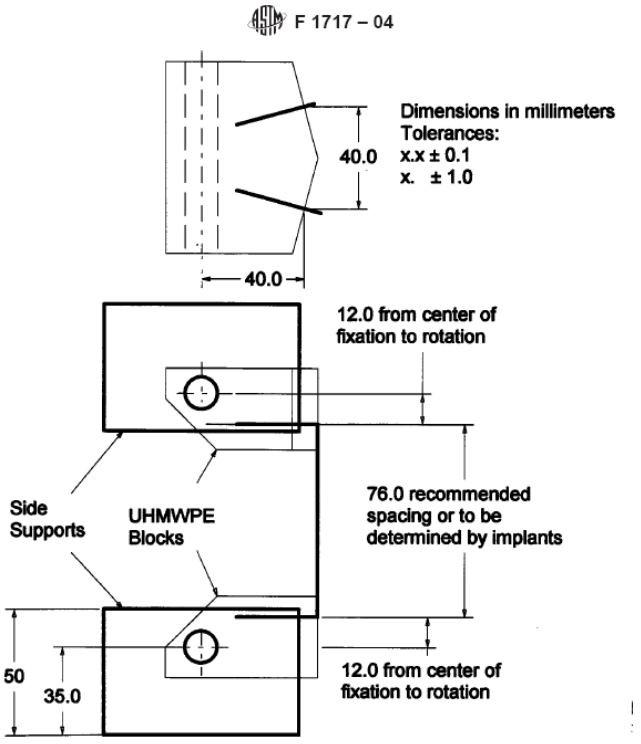

Figure 1.1: Lumbar Bilateral Construct Test Setup for Screws. Reproduced from ASTM F1717-04

While ASTM F1717 allows for the comparison between various fixation methods under physiologically relevant loading for this unique case, most standardized tests are designed to determine the mechanical characteristics of a specific type of device, making

it difficult to compare various types of fixation devices. For example, the standard for testing rods and intramedullary (IM) nails varies from the standard for testing bone plates. ASTM F382 the "Standard Specification and Test Method for Metallic Bone Plates" is intended to provide a reference for bone plates used in internal fixation. The scope of this standard includes:

1.1 "The standard establishes […] performance characteristics of bone plates. […] The standard also presents a catalog of […] standard test methods for measuring […] mechanical characteristics determined to be important to the *in vivo* performance of bone plates."

1.2 "It is not the intention of the standard to define levels of performance or case-specific clinical performance for bone plates, as insufficient knowledge is available to predict the consequences or their use in individual patients for specific activities of daily living."

1.3 "This standard may not be appropriate for all types of bone plates. […]"

Therefore, it is difficult to address clinical questions involving the proper device selection for a given surgical situation, such as comparing bone plates to IM nails for long bone fixation, through some standardized test protocols due to differences in test criteria. This is a limitation of standardized test protocols.

Bone Analogs

In order to determine "case-specific clinical performance" biomechanical tests must incorporate some form of bone analog, such as in the case of ASTM F1717 where the vertebral bodies are simulated as UHMWPE blocks. Many other forms of bone analogs

are utilized in biomechanical evaluations. Geometric models, such as composite cylinders or blocks (Figure 1.2), are often used (Stoffel et al. 2003; Synthes 2003) especially when comparing the biomechanical performance of various construct configurations such as screw density, and bridging length.

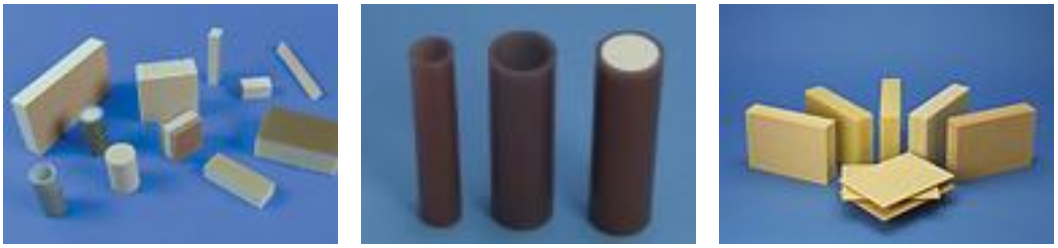

Figure 1.2: Geometric biomechanical test blocks for use as bone analog. Reproduced from <http://www.sawbones.com>

Again, the purpose of using a bone analog is to eliminate variations in geometry and material properties such as bone mineral density. However, these geometric bone analogs can even be made to approximate various degrees of bone quality. For example, osteopenic bone has been simulated using 15 lb/ft^3 foam whereas 40 lb/ft^3 foam represents good quality bone (Synthes 2003). In this way, the biomechanical performance of a particular fixation device can be evaluated with respect to bone quality.

Geometric models work well for simple implants (i.e. – straight plates and nails), however implants are becoming increasingly anatomically specific, often with designs utilizing anthropometric libraries to determine optimal shaping. For example, the proximal tibia Peri-Loc plating system (Smith and Nephew Inc., Memphis, TN, USA) was designed using the osteological collection at the Cleveland Museum of Natural

History as well as from cadaveric specimens at the Medical Education Research Institute (Gerlach 2004). Furthermore, biomechanical analysis of fracture fixation systems involves simulating *in vivo* geometry and structural properties (Burstein and Wright 1994). The use of composite bone substitutes eliminate variability in bone quality and size as a source of high standard deviations in biomechanical results. Satisfactory results for mechanical testing of orthopaedic devices have been reported using a composite bone substitute (Cristofolini and Viceconti 2000; Heiner and Brown 2001; Szivek and Gealer 1991), and these composite models have demonstrated similar mechanical properties to that of human long bone. Composite bone models have even been used to simulate poor quality bone by over-drilling screw holes before insertion (Gardner et al. 2006; Jazrawi et al. 2000).

The main drawback for composite bones is that they do not mimic the screw/bone interface strength of cadaveric specimens, which is a significant factor in the fatigue behavior of bone/device constructs and tends to deemphasize differences in mechanical behavior between various implant configurations, for example between locked and non-locked screw-plate constructs. Therefore the only way to fully appreciate the biomechanical performance of a device at the bone-implant interface is by using bone, either from cadaveric specimens or animal models. The use of cadaveric specimens presents numerous challenges when performing biomechanical evaluations, which include: (1) high variability in both geometric and material properties, (2) larger required sample size, and (3) increased costs associated with procurement and tissue handling procedures. Animal models provide their own unique set of advantages and challenges.

One distinct advantage to the use of animal models is the ability to evaluate the *in vivo* influences on fracture healing for a given device. In this case it is important to use a model in which the biologic response closely resemble that of human bone, a common choice for this application is the sheep model (Moroni et al. 2008; Zeiter et al. 2004). For *in vitro* biomechanical analyses, the use of animal bones provide a reliable, low cost, highly accessible alternative to human cadaver tissue (Esenkaya et al. 2007). However, problems arise from disparities in material and geometric properties. For example, differences in the amount and distribution of cortical and trabecular bone exist between calf tibias, which have been used to evaluate fixation plates for use in tibial osteotomies (Esenkaya et al. 2007), and those of humans which can influence biomechanical test results. These differences can be discounted if the aim of the investigation is only to compare the relative biomechanical properties of the evaluated devices.

Application of Loads

In addition to the mechanical properties of the fixation device and the bone-implant interface, the type of loading as well as how the loads are applied are vital in evaluating biomechanical performance. The type of loading will determine what measureable results can be obtained. Cyclic testing can be used to determine fatigue performance. Since the bone-implant interface is highly susceptible to fatigue and therefore it is beneficial to use a cadaveric test model when evaluating fatigue performance. Fatigue performance is important for quantifying the "duty cycle" of a given implant, in other words, the lifespan of the implant given its ability to withstand a given repetitive load. In addition, load-to-failure tests and fatigue tests can be used to establish mode of failure.

Again, this is largely influenced by the bone-implant interface and therefore it makes sense to use a cadaver model to fully understand the failure mechanisms. Static (or quasi-static) loads and load-to-failure tests are useful in determining device limits. For example, the load vs. deformation curve can be used to obtain the elastic and plastic properties including stiffness, yield load, deformation at yield, ultimate load, deformation at ultimate load.

While the type of loading determines which measureable results are obtained, it is how the loading is applied which determines the absolute value of these parameters. This leads into the discussion of physiologic versus worst-case or "case-specific" load application. Given an identical fracture pattern (Figure 1.3), simulating a multifragmentary fracture of the meta-diaphyseal junction (a commonly tested fracture pattern for evaluating proximal tibia fixation devices (Peindl et al. 2004)), load A would provide a worst-case scenario for the given implant whereas load B more closely approximates a physiologically equivalent axial load. Load A would provide a more rigorous test of the implant construct and should result in gap closure at a lower load than if applied at load B. Both setups will provide valuable data regarding device performance. However, if we are concerned about how the device will perform *in vivo* during partial weight bearing, then load B would be a more appropriate test setup. Figure 1.4 shows several experimental setups evaluating proximal tibia fixation devices through various points of load application.

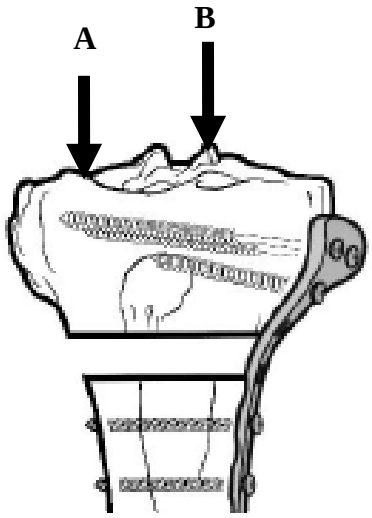

Figure 1.3: The location of physiologic and "case-specific" loading for an identical fracture pattern. Load A represents a worst-case load scenario for a lateral fixation device. Load B represents a physiologically equivalent loading scenario. Modified from Peindl et al. 2004

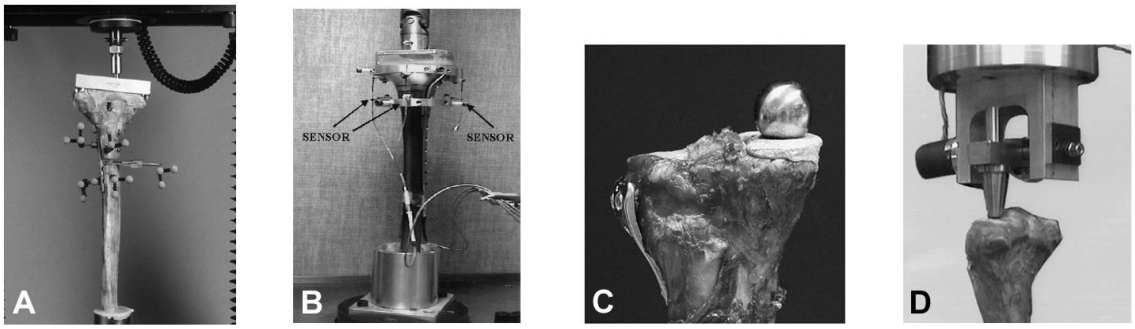

Figure 1.4: Load application setup from various proximal tibia fixation device evaluations depicting both physiologic and "case-specific" load conditions. A-B) Point of load application approximates physiologic load application during weight-bearing. C-D) Point of load application is "case-specific" relative to tested implant and fracture pattern. Reproduced from (left to right) Mueller et al. 2005, Peindl et al. 2004, Ratcliff et al. 2007, and Karunaker et al. 2002

In the case of bending loads, physiologic bending is either the result of cantilever loading, typically in the upper extremities, or due to an anatomic offset in the application of a load, as is the case in the proximal head of the femur (Figure 1.5).

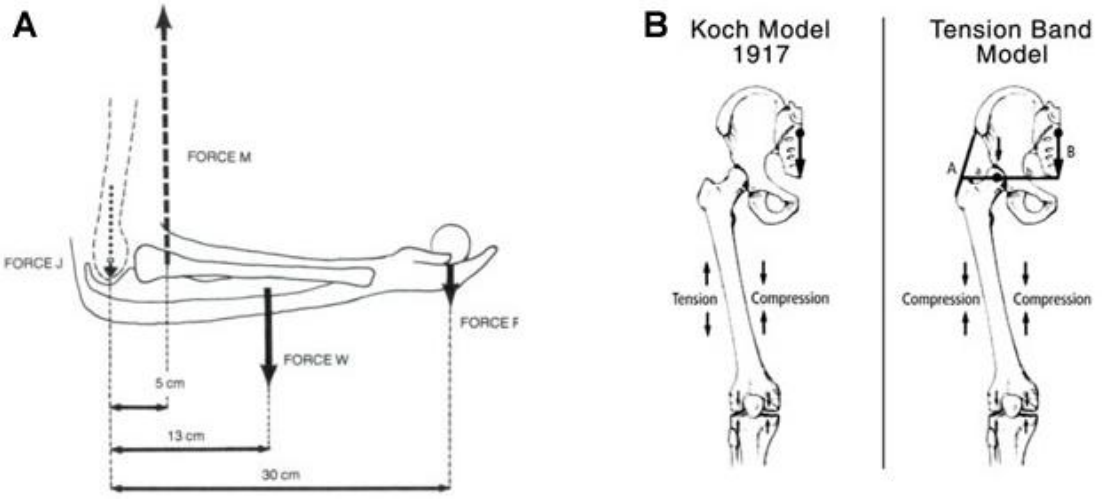

Figure 1.5: Generation of bending loads either as a result of cantilever loading (A) or eccentric loading (B) due to anatomical load application. Reproduced from A) <http://www.soe.uoguelph.ca/webfiles/mleuniss/Biomechanics/biomechanics_page_3.htm> and B) <http://www.djosurgical.com/products/hip/revelation/index.htm>

In the former case, bending loads are typically simulated as 4-point bending during biomechanical testing because this configuration allows for the application of a constant moment across the region of interest. Figure 1.6 shows a 4-point bending setup for a humeral fixation device. A moment diagram is overlaid to show that a constant moment is applied across the fracture site. In the latter case, since the femur is a weight bearing bone, proper physiologic application of the axial load will also simulate the appropriate bending loads.

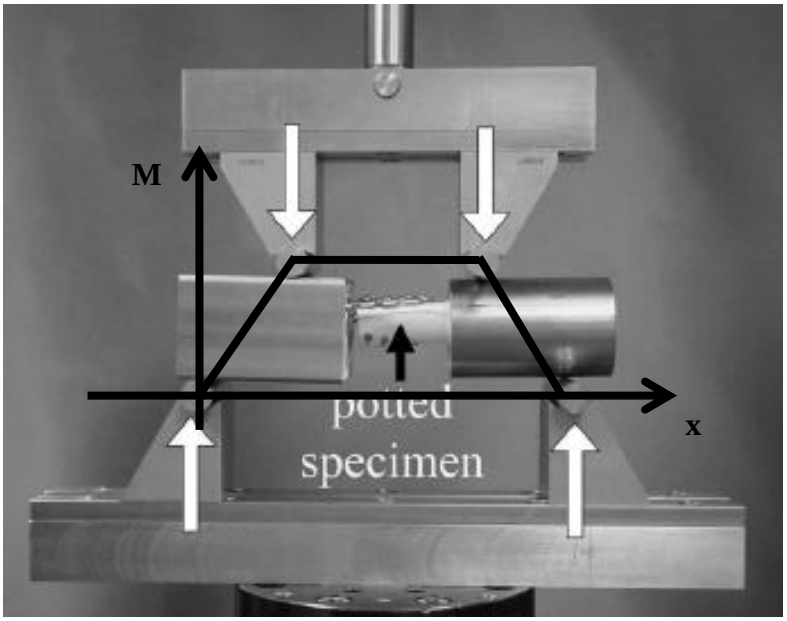

Figure 1.6: Four-point bending setup creates a constant moment across the region of interest. Modified from Korner et al. 2004

The Hypothetical Biomechanical Evaluation of a Fracture Fixation Device

Now that we have examined the various ways in which the biomechanical performance of fracture fixation devices can be evaluated, let us consider when each of these methodologies should be applied. Assuming that we are given a newly designed internal fixation plate to be used for diaphyseal fractures in both the upper and lower extremities, how would we test the biomechanical performance of such a device as compared to existing devices?

The first series of tests would likely involve simple tests to determine the mechanical properties of the plate alone. These tests would probably include: uniaxial tension and/or compression; torsion applied along the central axis of the plate; and both through

thickness and through width cantilever or 4-point bending. Next, since plates are applied to the surface of the bone and not the neutral axis we want to investigate how this eccentricity affects performance. For this we could use a geometric (tubular or rectangular) bone analog (Stoffel et al. 2003). Alternatively, a composite bone model could be used to investigate "case-specific" performance, such as in the case of proximal humerus(Korner et al. 2004; Lill et al. 2003) or tibial fractures (Mueller et al. 2005; Mueller et al. 2003; Peindl et al. 2004). Either of these approaches would be useful for determining factors such as optimal screw density, screw spacing, and working length, etc. Furthermore, the use of a composite bone model would allow for the evaluation of device performance with respect to physiologically equivalent loading. For example, a similar plate-screw configuration and fracture pattern tested in physiologic axial compression for mid-shaft humeral factures will perform significantly differently when compared to its use in a mid-shaft femur fracture. This is due to the fact that axial physiologic loading of the femur results in significant bending loads along the mid-shaft region (see Figure 1.5). Fatigue performance could also be tested the "case-specific" setup using composite bones. However, since the performance of the plate is also influenced by the screw-bone interface, and since this interaction varies based on plate design (i.e. locking versus non-locking) and bone quality, we could perform the test using cadaveric specimens to test performance over a range of bone quality. The combination of physiologically equivalent loading applied to cadaveric specimens will produce the closest approximation to the *in vivo* conditions.

Application of Physiologic Loading

Overview

Physiologic loading typically results in a combination of compression, torsion, and bending loads. The application of physiologic loading in biomechanical testing varies between weight-bearing (lower extremities) and non-weight-bearing (upper extremities) bones.

CASE 1: Lower Extremity

For tests involving the lower extremity, physiologic loads are most commonly associated with supporting body weight during double leg stance and normal walking activities. Simulating these physiologic loads *in vitro* requires proper anatomic alignment of the bone under investigation and the application of proper load constraints to eliminate unwanted forces. In the case of evaluating intramedullary nail designs used in the reconstruction of subtrochanteric fractures of the proximal femur the alignment of the femur is determined in the following manner:

1. Bone references axes (Figure 1.7) are established according to Ruff and Hayes (1983). The femur is placed dorsal side down on a supporting surface and the proximal end is raised until the anterior-posterior (A-P) midpoint just distal to the lesser trochanter and just proximal femoral condyles are equidistant above the supporting surface. The frontal plane is then defined as being parallel to the supporting surface equidistant from the A-P centers of the condyles. The sagittal plane is perpendicular to the frontal plane containing both the deepest point in the intercondylar notch

and the medial-lateral midpoint of the shaft at the same proximal location used to define the frontal plane. The intersection of these two planes forms the longitudinal axis of the femoral diaphysis. Next the line running through the center of the femoral head and neck and intersecting the longitudinal axis of the diaphysis is defined as the cervical axis. The superior-inferior plane (defined the antetorsion plane) contains the cervical and longitudinal axes. The A-P plane of the femoral neck is defined as the plane perpendicular to the superior-inferior axis, which also contains the cervical axis.

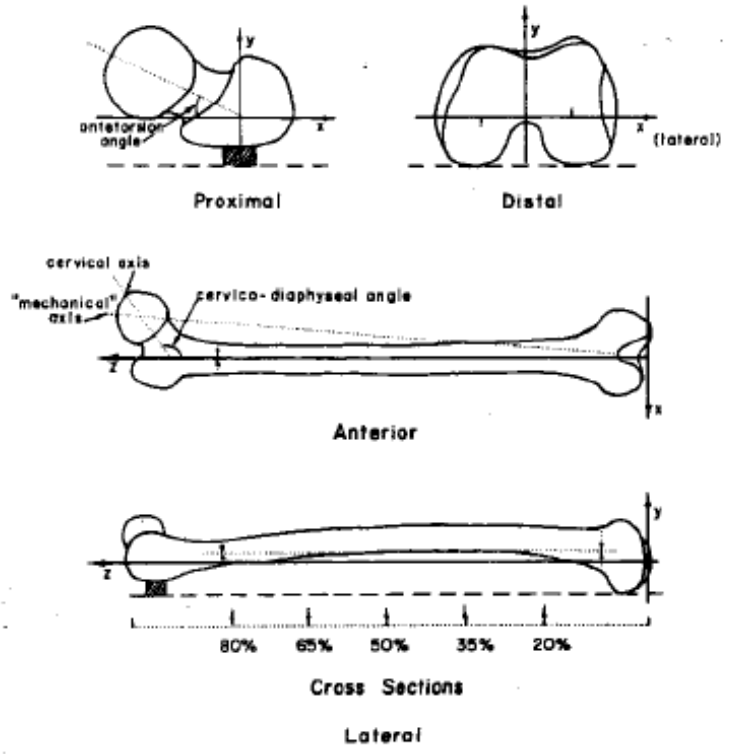

Figure 1.7: Reference axes in the femur. Reproduced from Ruff and Hayes 1983

2. The next step is to determine the mechanical axis, or line of load application. The line of load application at the distal femur (Figure 1.8) is: (1) centered between the two condyles within the frontal plane, and (2) tangential to the dorsal outer cortex at the meta-diaphyseal junction in the sagittal plane (Cordey et al. 1999; Cristofolini et al. 1996; Pugh et al. 1998). The use of a ball-bearing prevents unwanted torque or bending due to horizontal forces.

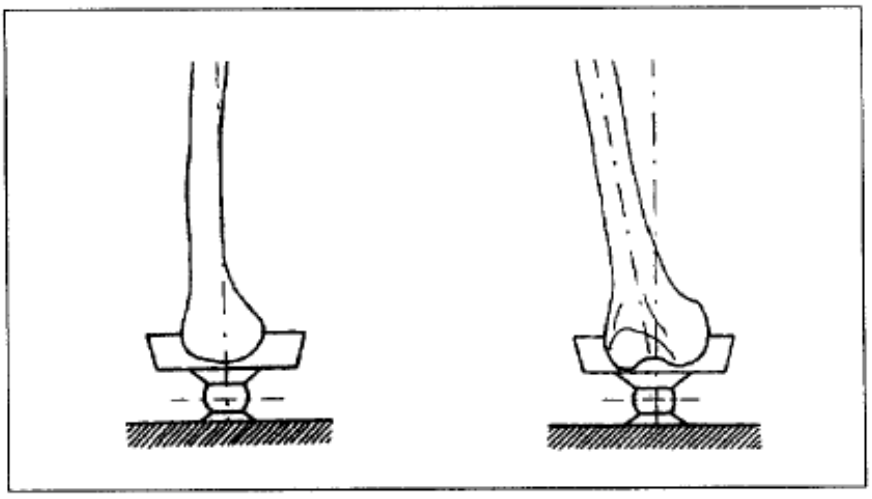

Figure 1.8: Load application at the distal femur. Reproduced from Cordey et al. 1999

Cordey et al. (1999) developed a femoral loading model which accounts for the tension band effect of the ilio-tibial tract based on *in vivo* strain. The line of load application at the femoral head was evaluated at three loading positions: (1) directly over the center of the femoral head (modeled according to (Koch 1917) without tension at the trochanter), (2) moderate

eccentricity with a line of load perpendicular to the condylar surface, and (3) large eccentricity with the distance between the femoral head and externally applied load equal to that of distance between the tension band on the trochanter and the femoral head. The loading condition used by Koch produced adequate results as compared to the moderately eccentric model with tension applied at the greater trochanter. A drawback to this model is that application of trochanteric tension can lead to stripping of the fixation screw. Additionally its exact value has remained undetermined. Therefore, the line of load application at the femoral head is directed over the center of the femoral head for the presented case. This configuration has been used in previous biomechanical tests of the femur (Cristofolini et al. 1996; Pugh et al. 1998) and results in approximately 11° in adduction when using composite femora, as shown in Figure 1.9 (Cristofolini et al. 1996).

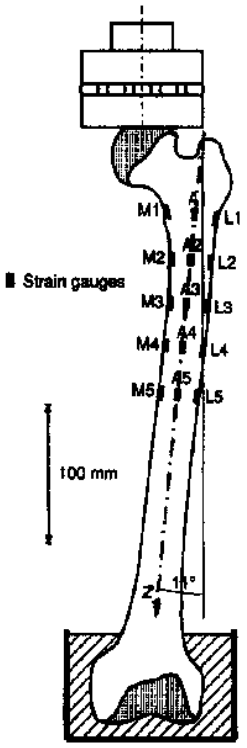

Figure 1.9: Anterior view of the femur with the longitudinal axis Z 11° adducted. Reproduced from Cristofolini et al. 1996

As shown in the sample case, the application of physiologic loading in weight-bearing bones can be determined through a combination of anatomic alignment and constraints. It is obvious that the most physiologically relevant loads are associated with normal weight-bearing activities such as walking. As a result it is easy to define the physiologic scenario which must be recreated *in vitro*. Furthermore, the loads associated with normal gait have been studied at length and are readily available within the literature.

CASE 2: Upper Extremity

For tests involving the upper extremity, physiologic loads are not as easily definable as in the case of the lower extremities. While the lower extremities are subject to the loads associated normal weight-bearing activities, typical loads associated with upper extremities are harder to define and vary according to the specific activity and the anatomic positioning of the upper extremity during these activities. For example, the act of carrying an object can apply tension, compression, or bending about any number of axes depending on the anatomical positioning of the upper extremity. This presents a unique challenge regarding the reproducibility of test methods and cross comparison between biomechanical tests.

Axial compression, torsion, and 4-point bending in both anterior-posterior and medial-lateral planes are the most common loading conditions for humeral fixation studies (Chen et al. 2002; Damron et al. 1999; Elfick AP 2003; Jazrawi et al. 2000; Korner et al. 2004; Rubel et al. 2002; Schemitsch et al. 1994). However, no consistent loading condition has been used to investigate the fatigue performance of humeral constructs. A few investigations have evaluated cyclic axially compression (Chen et al. 2002), while others have focused on torsion (Fulkerson et al. 2006; Jazrawi et al. 2000). Still others (Korner et al. 2004; Lill et al. 2003) have chosen to apply cyclic anterior-posterior bending. According to Jazrawi et al specimens were cycled in torsion to simulate upper extremity use during the early postoperative period. However, no justification for this statement was presented. In fact, retrospective case studies evaluating the treatment of humeral shaft fractures have indicated that rehabilitation

focuses on the recovery of activities of daily living and on strengthening of the extensor and flexor muscles of the upper arm (Rommens et al. 2008). Furthermore, no rotational movements are allowed until callus formation is radiographically visible. This suggests that cyclic anterior-posterior bending would most accurately simulate upper extremity loading during postoperative rehabilitation. While no consistent modality for testing the fatigue performance of humeral implants exists, a majority of the reviewed articles agree that the biomechanical axis of the humerus corresponds to the long axis. Loading conditions within the humerus have been defined by Korner et al. to apply near-physiologic loads based on determinations of the muscle and joint forces through the elbow.

Summary

Physiologically equivalent loading can be applied to both weight bearing and non-weight bearing fracture fixation devices. When defining physiologic loading for the lower extremities it is important to recreate the anatomic alignment which corresponds to weight bearing activities. Also, the point of load application and the type and magnitude of this loading is well defined by the normal activities associated with gait. Conversely, for defining physiologic loading in the upper extremities the point of load application and the type and magnitude of loading vary greatly with specific activities and are therefore not well defined and must be determined based on the anticipated usage. As with the lower limb, loading constraints must carefully be considered when designing biomechanical tests for the upper extremity so as to avoid inducing unwanted loading.

The following article has been submitted to the *Journal of Surgical Orthopaedic Advances*. The biomechanical considerations presented above regarding the application of physiologically equivalent loading have been applied to the design of this study. The current study is designed to evaluate the performance of two methods of humeral shaft fixation.

CHAPTER TWO

BIOMECHANICAL EVALUATION OF TWO METHODS OF HUMERAL SHAFT FIXATION

Abstract

This study compared the biomechanical performance of 4.5-mm limited-contact dynamic compression plates and 3.5-mm locking compression plates for the fixation of unstable humeral shaft fractures. Composite humeri were divided into two groups: 3.5-mm LC and 4.5-mm LCDC plates. Osteotomy gaps of 5-mm, simulating diaphyseal comminution, were created. Stiffness tests were performed in anterior-posterior bending, medial-lateral bending, torsion, and axial compression. Results showed that while construct stiffnesses in ML bending and torsional loading are significantly higher for 4.5 LCDC plates ($p < 0.05$), no statistically significant differences were observed in AP bending or axial compression. Fatigue characteristics under cyclic AP bending conditions were also evaluated, although no failures occurred. Data from the literature suggest that stiffness results for the LC plate constructs perhaps afford sufficient fixation strength capable of supporting the physiologic loads most commonly applied during postoperative rehabilitation. However, results indicate that the 4.5 LCDC plating system is mechanically advantageous for stabilizing diaphyseal comminuted fractures.

Key Words: humerus; fracture fixation; biomechanics; Locking Compression Plate; Limited-Contact Dynamic Compression Plate

Introduction

While a majority of humeral diaphyseal fractures can be successfully treated by non-operative means (Gregory and Sanders 1997), some situations warrant surgical treatment. Surgical stabilization is considered the treatment of choice for open, segmental and pathological fractures, fractures with vascular damage, the so called "floating elbow", patients with multiple injuries to allow early weight bearing, and those patients expected to remain recumbent for extended periods.

Various methods of internal fixation by rod or plate have been described. Arguably, open plating remains the gold standard for operative fixation (Gregory 2001; Gregory and Sanders 1997; Rommens PM 2000). Previous studies have thoroughly documented the successes of plate fixation using 4.5-mm and 3.5-mm conventional plates for humeral shaft fractures (Bell et al. 1985; Dabezies et al. 1992; Livani and Belangero 2004; Vander et al. 1986). Conventional plating consistently yields 96-98% union rates with complication rates below 5%, as well as significantly faster healing rates than intramedullary nailing (Niall et al. 2004). The ideal choice of plate, however, remains controversial. Researchers have argued for, and successfully implemented fixation with 4.5 broad and narrow limited-contact dynamic compression (LCDC) plates, 3.5 LCDC plates, as well as 4.5 and 3.5 locking compression (LC) plates. Furthermore, a clinical review of small fragment locking plates for the treatment of humeral shaft fractures recently reported no failures in 21 patients with humerus fractures treated with 3.5 mm locking plates (Sheerin DV 2004). These results suggest that smaller plate fixation, namely 3.5 mm locking plates, provide sufficient fixation for humeral shaft fracture

(Morgan SJ 2001). Specifically, with a recent shift towards biologic fixation (Frigg 2003) and minimally invasive plate osteosynthesis methods, there has been renewed interest in the subject of optimal plate selection.

In this study, we compared the biomechanical characteristics of the 4.5 narrow LCDC plate with the 3.5 LC plate. There currently exists limited biomechanical data comparing locked versus conventional plates used for diaphyseal humeral bone defects. Multiple clinical studies have documented the successful use of 3.5 locking and conventional compression plates in diaphyseal humeral fractures, but none have elucidated the biomechanical characteristics. It's smaller size, ability to place more screws per unit length, easier fit onto the humeral diaphysis, and need for less soft tissue dissection when compared to a 4.5 plate, makes the 3.5 LC plate a viable option for humeral shaft fixation. We hypothesize that the 3.5 LC plates will demonstrate biomechanical equivalence under functional loading regimes to the traditionally used 4.5 LCDC plates. Equivalent biomechanical performance would tend to suggest a biologically advantageous, surgical preference for use of the 3.5 LC plates.

The purpose of this study was to demonstrate biomechanical similarity between 4.5 LCDC plates and 3.5 LC plates of similar lengths under a variety of loading circumstances.

Materials and Methods

Specimen Preparation

Eight Sawbones third generation, composite resin humeri models (Pacific Research Labs, Vashon, WA) were used in order to limit inter-specimen anatomical and

mechanical variability (Heiner and Brown 2001). The humeri were randomly divided into two groups: the 8-hole 3.5-mm LC plates or the 6-hole 4.5-mm LCDC plates (Synthes, Inc, Paoli, PA). Plate selection was based on comparable length. Constructs were assembled by an orthopaedic surgeon on intact composite humeri using standard surgical techniques and instrumentation. To simulate diaphyseal comminution (type 12-C3.3 according to AO classification) (1996), 5-mm osteotomy gaps were created after plating, using parallel saw cuts at the center of the plate. Plates were placed on the antero-lateral surface of the humerus. All screw holes were filled on either side of the osteotomy, producing screw purchase in a total of six cortices per fragment for the 4.5 LCDC plates, and eight cortices for the 3.5 LC plates. Each locking screw was placed in the threaded portion of the plate combination holes.

Both the proximal and distal ends of the humeri were potted in a two component polyurethane resin (FastCast, Goldenwest Manufacturing, Cedar Ridge, CA). Specimens were centered into proximal and distal potting fixtures in order to assure proper biomechanical alignment along the longitudinal axis of the humerus.

Mechanical Testing

Testing was conducted on a universal biaxial servohydraulic test system (8874 Table Top Biaxial Servohydraulic Testing System, Instron Corp., Canton, MA). Non-destructive stiffness tests were performed sequentially in the following order: axial compression, torsion, 4-point anterior-posterior (AP) bending, and 4-point medial-lateral (ML) bending (Figure 2.1). Loading levels, based on several previous studies (Bell et al. 1985; Chen et al. 2002; Dabezies et al. 1992; Elfick AP 2003; Gregory 2001; Gregory

and Sanders 1997; Korner et al. 2004; Livani and Belangero 2004; Morgan SJ 2001; Niall et al. 2004; Rommens PM 2000; Rubel et al. 2002; Schmidt 2001; Sheerin DV 2004; Vander et al. 1986), were chosen to avoid plastic deformation. Constructs were cycled to 250 N at a rate of 45 N/sec in compressive loading. Under torsion, 15º of internal rotation was applied to the distal humerus at a rate of 3º/sec while maintaining zero load in axial compression. A constant bending moment of 4.5 Nm was applied across the implant at a rate of 1.4 Nm/sec for both 4-point bending configurations. AP bending was performed in a gap opening orientation, with the plate parallel to the bending plane. ML bending was performed with the plate at a right angle to the plane of bending. The outer support rollers for bending were set 210 millimeters apart. Inner load rollers were centered at 130 millimeters apart to avoid any direct contact between the rollers and the plate. All stiffness tests were carried out for 10 cycles at a constant load ratio (R= min load / max load) greater than or equal to ten. Reported stiffness values were measured from the fifth cycle, which was determined to represent steady state conditions.

Following stiffness testing, sinusoidial cyclic loading was performed under 4-point AP bending to 4000 cycles, simulating approximately 3 months of *in vivo* loading (Helfet and Hotchkiss 1990; Self et al. 1995), at a maximum bending moment of 4.5 Nm and a frequency of 1 Hertz. A constant load ratio, R (R = min load / max load), greater than or equal to ten was maintained. During loading, changes in maximum and minimum displacement values were tracked to determine the onset of plastic deformation. Construct failure was defined as plastic deformation, implant breakage, screw pullout, or

bone fracture. Following cyclic testing, displacement controlled strength testing was performed in 4-point AP bending for all constructs that did not exhibit fatigue failure. Load to failure as well as the failure modes were recorded.

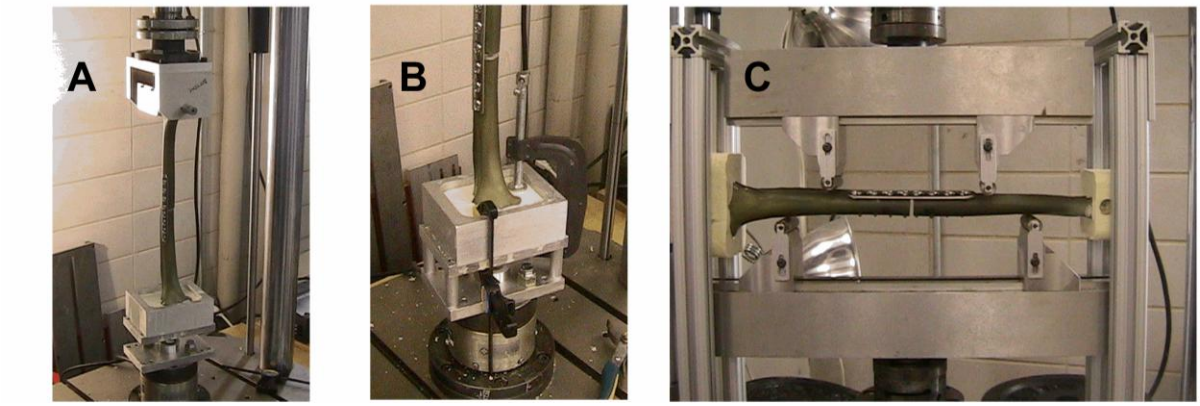

Figure 2.1: Mechanical test set-up for each loading mode. A) For axial compression the humeri were inverted, with the proximal end free to rotate about a universal joint at the base of the fixture. B) The torsion fixture was identical to compression except that the proximal end fixture (base) was constrained to prevent rotation. C) The 4-point bending setup provided a constant bending moment at the fracture site in anterior-posterior (shown above) and medial-lateral bending as well as cyclic loading and strength testing. During 4-point bending the humeri were constrained about the long axis by two sets of rails, preventing longitudinal rotation while permitting vertical translation.

Data Analysis

Data was acquired from the Instron using *MAX* © (Instron Corp., Canton, MA) software. Cyclic AP bending data were evaluated to determine the onset of plastic deformation by monitoring changes in displacement over the course of loading. Load to failure data was determined at 2% offset yield . Stiffness and load to failure results were

analyzed using Student's t-test and statistically significant differences were identified at the 95% confidence level.

Results

Stiffness and load-to-failure results for the LCP and LCDC plates are summarized in Table 1. The two plates performed similarly in axial compression and AP bending. Overall, the LCDC plates were stiffer than the LC plates in all loading modes except axial compression. Statistically higher stiffness values for the LCDC plates were observed in torsion ($p=0.0051$) and ML bending ($p=0.0022$). Additionally, the LCDC plates demonstrated statistically higher load to failure ($p=0.0212$). Bending stiffness values are reported in a similar fashion as previous studies (Korner et al. 2004), using the applied axial load instead of the bending moment. Similarly, load to failure data represents the axial load applied to the 4-point bending apparatus which resulted in failure. The reported maximum axial loads correspond to moments of 21.96 Nm and 27.70 Nm for the 3.5 LC plates and the 4.5 LCDC plates respectively. These moments are calculated based on the experimental setup previously described.

Failure during cyclic loading was not observed for any of the constructs. Load to failure was significantly higher in the LCDC plates than the LC plates ($p < 0.05$). Load to failure data was only available for three constructs of each type. LCDC plates failed as a result of fracture of the composite bone through the screw holes. Conversely, LC plates underwent plastic deformation adjacent to the osteotomy and failures of the composite humeri were not observed (Figure 2.2).

Table 2.1: Stiffness results for all test modes, and load-to-failure in 4-point AP bending (mean ± standard deviation; n = 4 except as indicated).

	Compressive Stiffness	* Torsional Stiffness	A-P Bending Stiffness	* M-L Bending Stiffness	** Load-To-Failure
	(N/mm)	(N-m/deg)	(N/mm)	(N/mm)	(N)
3.5 LC	593.3 ± 194	1.02 ± 0.1	410.7 ± 17	524.5 ± 65	1098.2 ± 104
4.5 LCDC	505.2 ± 53	1.30 ± 0.2	461.2 ± 78	847.7 ± 131	1384.8 ± 133

* indicates statistically significant differences between implant groups at $\alpha = 0.05$.
** n = 3

Discussion

The aim of this study was to demonstrate biomechanical similarity between the 3.5 LC plates and the 4.5 LCDC plates. Such a result would provide surgical preference for the LC plates due to the advantages stated previously, namely the lack of soft tissue/osseous blood supply disruption and the potential for minimally invasive techniques. Differences in axial stiffness and AP bending stiffness were not statistically significant, providing evidence of biomechanical similarity. LCDC plates exhibited significantly higher stiffness values in torsion, ML bending, and load to failure. Based on these findings biomechanical equivalence between 4.5 LCDC and 3.5 LC plates of equal length cannot be established. Despite this inability to demonstrate biomechanical equivalence, data from the literature suggests that the stiffness results obtained for the LC

plate constructs perhaps afford sufficient fixation strength capable of supporting the functional loads most commonly applied during rehabilitation.

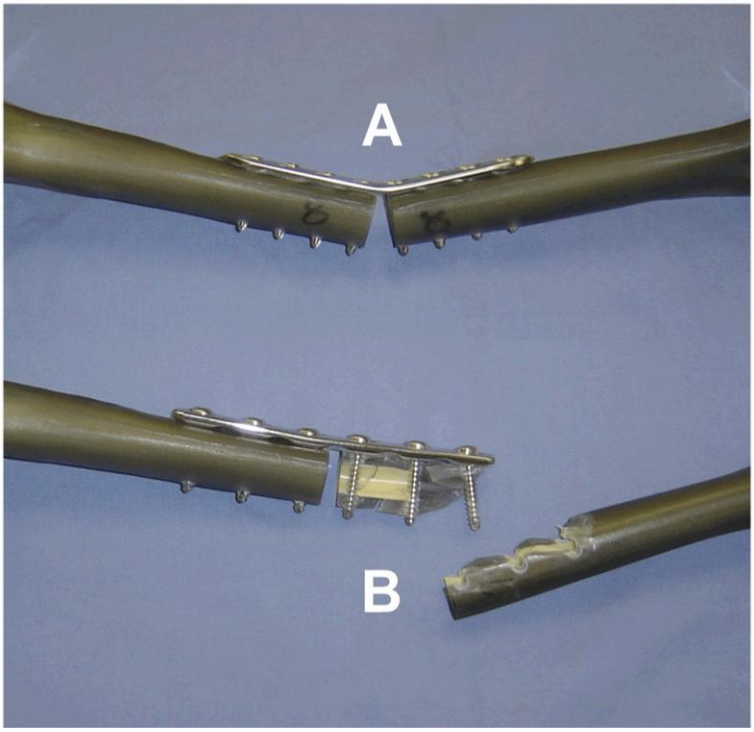

Figure 2.2: Mode of failure under 4-point AP bending for each implant type. A) LC plates failed via plastic deformation. B) LCDC plates failed via bony fracture through screw holes.

Dissimilar to long bones of the lower extremity, the humerus is not subjected to high axial loads such as those associated with weight bearing (Henley et al. 1991). In contrast, torsion and bending loads are the most frequently observed loading patterns for the humerus (ElMaraghy et al. 2001; Jazrawi et al. 2000; Simon et al. 1999). Typical postoperative rehabilitation protocols primarily utilize flexion/extension motions of the elbow joint to impart axial compression and bending (mainly AP) (Rommens et al. 2008;

Schwartz et al. 2006). Furthermore, no rotational movements are allowed until callus formation is radiographically visible. This suggests that cyclic anterior-posterior bending would most accurately simulate upper extremity loading during postoperative rehabilitation. As previously stated, there were no significant differences in construct stiffness between the 4.5 LCDC and 3.5 LC plates under these loading conditions in our study. In addition, cyclic AP bending produced no construct failures in either group. Furthermore, functional rehabilitation involves repetitive, sub-yield loading. Based on loading modes typically seen by the humerus, it can be concluded that LC plates provide sufficient fixation during rehabilitation.

In general, torsional strength of plate fixation devices is proportional to screw number and is less dependent on screw placement (Tornkvist et al. 1996). Biomechanical investigations of locked plates have confirmed this neutrality with regard to screw placement and have further determined that the position of the third and subsequent screws, and the addition of more than four screws per fracture fragment have no significant effect on torsional rigidity (Stoffel et al. 2003). Torsional stiffness results from our study conflict with those of a recently published study on locked versus hybrid and unlocked plates for humeral fractures (Gardner et al. 2006), in which locked plate constructs were significantly stiffer in torsion than unlocked plates. However, these results were obtained using a simulated osteoporotic model in which all screw holes were over-drilled. Poor bone quality has become a major indication for locked plating and bicortical locked screw constructs have been shown to be more stable than conventional

plating techniques in diaphyseal comminuted fractures involving osteoporotic bone (Fulkerson et al. 2006).

Biomechanical studies by Tornkvist et al (Tornkvist et al. 1996) and ElMaraghy et al (ElMaraghy et al. 2001) reveal that wider screw spacing in longer plates results in a more efficient increase in bending strength as compared to increasing the number of screws in shorter plates. Also, out-of-plane (ML) bending represents the best case scenario as compared with in-plane (AP) bending since the applied loading occurs in the same plane as the plate, through its width rather than through its thickness. Therefore, stiffness in AP bending can be expected to be lower than stiffness in ML bending. Results from our study support these trends. Given plates of equal length, increasing screw spacing (LCDC plate with 3 screws per fragment) results in a larger increase in bending stiffness than increasing the number of screws (LC plate with 4 screws per fragment). The efficacy of this increased bending strength due to wider spacing is accentuated during ML bending and is possibly a contributing factor to the significantly higher bending stiffness observed in LCDC plates, given their broader width than LC plates.

It has been proposed that internal fixation strength on the order of 20% of intact bone strength is adequate for healing (Morgan SJ 2001). Reported torsional stiffness values for intact humeri range between 2.02±0.79 and 2.67±0.37 Nm/° (Damron et al. 1994; Damron et al. 1999). Furthermore, 3.5 LCDC plates have been reported to exhibit ML bending stiffness values which exceed that of an intact specimen when greater than 5 cortices of screw purchase is achieved per fragment (ElMaraghy et al. 2001). Given these assumptions and the fact that our bending and torsion results exceed 20% of intact

strength, it is reasonable to assume that the LC construct tested provides sufficient fixation strength despite significantly lower torsional and bending stiffness results as compared to the LCDC plates.

A notable result in this study is the mechanism of construct failure. LCDC plates rely on friction between the plate and bone to maintain stable, rigid fixation. Loads exceeding this frictional force cause plate micromotion and subsequent screw toggle which eventually leads to screw loosening. This micromotion is not shared equally between individual screws and failure of the entire construct can occur after failure of a single screw. In the present study all LCDC failures occurred via bony fracture with the fracture lines extending through all screw holes. This mechanism of longitudinal fissuring has been described and observed by several other studies (Ellis et al. 2001; Sanders et al. 2002; Stoffel et al. 2004). Bony fracture is caused by stress concentrations generated at each screw hole, the greatest concentration of which occurs at the end screws during bending (Cheal et al. 1984) and creates a large stress riser at the transition from the plate end to the un-plated section of bone. Failure initiation is therefore hypothesized to originate away from the simulated fracture at the location of this stress transition and propagate longitudinally though the subsequent stress risers located at each screw hole (Stoffel et al. 2004). Locking plates, on the other hand, do not rely on friction for fixation since all the screws are fixed rigidly to the plate. Instead, the entire load is borne more or less equally by the entire construct and the sum of the pullout strengths of all the screws dictates the pullout strength of the entire construct. When screws have excellent bone purchase, as in our study, this number can be extraordinarily high, and

other mechanisms of failure will occur. Working length, the length of plate unsupported by bone, may become the weak link (Stoffel et al. 2004). This was the method of failure for all of the locking plate constructs tested, which underwent plastic deformation across the fracture gap. Based on these results and similar observations by several other investigators (Korner et al. 2004), the screw-plate fixation provided by LC plates decreases the likelihood of failure at the bone-implant interface during a single overload event.

The clinical implications of this study are difficult to estimate, as the precise amount of weight borne by the upper extremity during postoperative rehabilitation is undefined, and thus the needed strength of fixation cannot be reliably determined. However, clinical studies have repeatedly reported successful humeral fixation using smaller plates suggesting that sufficient fixation strength is achieved despite lower biomechanical performance as compared to larger plates. A recent study showed no failures of humeral fixation or union with either 3.5 LC or LCDC plates while allowing immediate post-op weight bearing (Sheerin DV 2004). Furthermore, retrospective case studies (Ring et al. 2004) have documented successful treatment of osteopenic delayed unions or nonunions of the diaphyseal humerus using locked plating. These findings suggest that smaller plate fixation provide sufficient fixation strength and have altered traditional plate fixation guidelines, especially for patients of poor bone quality.

The current study has several limitations, including the use of synthetic bones. Although results from synthetic systems are limited in their ability to correlate with clinical results, cadaveric specimens were not considered for this study due to anatomic

and mechanical variability concerns. Studies of this nature neglect the effects of soft tissue attachment and bone remodeling. Additionally, the small sample size and inconsistent screw insertion torques (which were not monitored during implant assembly) contributed to high standard deviations. Additionally, lack of intact specimen test data makes normalized data unavailable, further limiting comparison to other published literature. Cyclic testing was performed in AP bending to approximate commonly applied postoperative loading, however cyclic data within the literature is more readily available for torsion, probably because the load configuration is more generic and universally applied (Damron et al. 1999; Elfick AP 2003; Henley et al. 1991; Jazrawi et al. 2000; Morgan SJ 2001; Simon et al. 1999).

Conclusions

Biomechanical results from this current study do not confirm biomechanical equivalence for all loading conditions between the 3.5 LC plates and the 4.5 LCDC of equal length. Results indicate that the 4.5 LCDC plating system has a mechanical advantage over the 3.5 LC plate for stabilizing diaphyseal comminuted fractures. Although biomechanical equivalence could not be established, benefits still exist which make 3.5 LC plates a viable surgical option.

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CHAPTER THREE

CONCLUSIONS AND FUTURE CONSIDERATIONS

In vitro biomechanical tests are designed to evaluate and compare the performance of fracture fixation devices. While not every test is designed to completely mimic the in vivo conditions, each test provides useful information in determine performance. Standardized tests, such as ASTM standards, are performed on the implants themselves and are useful in determining device properties. Other standards, such as ASTM F1717, can be used to directly compare the performance of different devices under similar conditions. The performance of fixation devices is also highly influenced by the properties of the bone itself and the behavior of the bone-implant interface. The use of various bone analog materials, such as geometric foam substitutes or even composite resin bone models, can be used to mimic geometries and serve as a cost effective alternative to cadaveric testing, especially when dealing with static testing. Furthermore, static testing is useful in determining the limits under which a device can perform. Conversely, cyclic testing is used to determine fatigue performance characteristics. Each method provides useful information, but it is necessary to understand how to use this information with regard to device performance. For example, since fatigue characteristics can be highly influenced by the bone-implant interface it follows that fatigue performance can be better determined by using a cadaveric test model instead of a composite bone model. Finally, the method of loading can alter the outcome of biomechanical performance tests. Non-physiologic loads can be applied in order to make analysis simpler. Such is the case between cantilever bending and four-point bending;

the latter provides for a constant moment across the fixation device and is therefore preferential to cantilever bending in certain instances. Testing under physiologically equivalent loading makes sense for implants such as total knee and hip prosthesis and other lower limb fracture fixation devices subject to complex loading resulting from normal walking activities.

The use of biomechanical testing is a valuable tool in predicting the *in vivo* performance of fracture fixation devices. However physiologically equivalent loading is the closest approximation to *in vivo* conditions and therefore should be used especially in determining fatigue performance. Application of physiologically equivalent loading is necessary to fully predict biomechanical performance of fracture fixation device. The combined use of physiologically equivalent loading and the use of cadaveric specimens enhance this predicting capability.

Drawbacks inherent in the current study could be addressed in future work. For example, the use of cadaveric humeri would allow for a more thorough investigation between non-locking and locking plates with respect to bone quality. This is consistent with other humeral studies which used cadaveric specimens(Chen et al. 2002; Korner et al. 2004; Lill et al. 2003). Since bone quality significantly affects the bone-screw interface we would expect that the locking plates may demonstrate either equivalent of superior performance in a population with compromised bone quality. This would also necessitate an increase in sample size, which was one of the largest drawbacks to this study. Finally, it may be beneficial to include new loading regimes to evaluate the humerus in a larger variety of loading conditions. For example, biomechanical

performance under axial tension may prove to be a valuable predictor of *in vivo* performance. It makes sense to evaluate upper extremity fixation devices under tension since activities which involve carrying a load at the side of the body are common. Furthermore, a combined loading pattern, incorporating bending and compression loading may be useful to simulate activities such as weight-transfer during a rise from a seated position.

Several aspects regarding the general application of physiologically equivalent biomechanical testing warrant further refinement. Most biomechanical studies evaluate performance under single axis loading. In weight-bearing applications, such as the hip and knee, it would be beneficial to apply simultaneous biaxial loading to fixation devices in a similar manner as to that which is used in total joint wear testing. Furthermore, kinetic and kinematic studies on gait analysis could be used to determine the appropriate physiologic levels of loading during fracture healing and these profiles could then be used to evaluate fixation devices. Coupling this idea of biaxial loading with the deliberate use of cadaveric specimens which span a range of bone quality would create the closest approximation to the *in vivo* conditions at the bone-implant interface. However biomechanical tests can never fully recreate the *in vivo* conditions since the loading environment exerted on a fixation device is continually changing due to the process of fracture healing.

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