ABSTRACT

Title of Document: HUMERAL FRACTURE FIXATION

TECHNIQUES: A FEA COMPARISON OF

LOCKING AND COMPRESSION TECHNIQUES WITH CADAVERIC

PULLOUT COMPARISON OF CORTICAL COMPRESSION AND INTERNAL LOCKING

SCREWS.

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2007

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Engineering

Locking and non-locking humeral repair techniques provide different mechanical constructs for securing fractures, and consequently could generate different strain fields at the callus. The purpose of this study was to investigate the strain field callus, and to compare to determine if one construct offers a healing advantage over another. An FEA analysis was conducted using ABAQUS, with all contact surfaces modeled as friction interfaces; additionally, a pretension was applied to the non-locking construct to simulate the effect of installation. The models were subjected to axial tension loads, and results were compared with existing cadaveric and synthetic experimental loading. Additional validation involved screw pullout testing conducted on cadaveric humeri. Results showed that the strain fields at the fracture site showed no significant variation in distribution, shape, or magnitude, therefore concluding that the locking plate offered no biomechanical healing advantage.

HUMERAL FRACTURE FIXATION TECHNIQUES: A FEA COMPARISON OF LOCKING AND COMPRESSION TECHNIQUES WITH CADAVERIC PULLOUT COMPARISON OF CORTICAL COMPRESSION AND INTERNAL LOCKING SCREWS.

By

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Thesis submitted to the Faculty of the Graduate School of the University of Maryland, College Park, in partial fulfillment of the requirements for the degree of Masters of Science,

Mechanical Engineering

2007

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Acknowledgements

Thanks to all those who helped in the process of completing the research associated with this thesis:

Morrigan Johnson, for her sample polishing and general support

Gilad Sharon and Nathan Blattau for modeling advise and assistance with FEA

David Ryan for help with experimental design and testing

Robert O'Toole, MD and Adam Hsieh for orthopedic, medical, and biomechanical guidance while developing the models contained herein.

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Introduction

Reasons for Study

The long-term goal of this ongoing research project is to investigate the biomechanics of locking versus non-locking screw use in the surgical repair of fractures, specifically humeral fractures. Recently, large shock trauma centers, such as the University of Maryland R. Adams Cowley Center, have started using more costly Locking Compression Plates over the more traditional non-locking plates. Due to the recent adoption of this hardware, there are few guidelines to guide physicians in implementation of these plates, as well as little evidence of a biomechanical advantage of using one type of plate over another.

Preliminary experimental testing has already been conducted by a team led by Robert V. O'Toole, M.D., in Shock Trauma, and experimental results have been generated. The initial goal of this project is to elaborate on the results obtained through the preliminary testing using Finite Element (FE) Analysis. Using the FE technique, a computer simulation of the system (in this case a fractured humerus joined by either a locking compression plate, or a non-locking compression plate) will be developed that will allow the investigators to accurately predict the effects of varying parameters that are not practical to vary through a lab experiment such as that already conducted. Through the data previously collected through lab experiments, and further testing to be conducted for this study, the investigators have a baseline to calibrate and validate the computer simulation that will be generated by FE.

After a successful model has been validated, various parameters (described in detail later) will ultimately be varied to determine their effect on commonly accepted parameters that determine successful bone healing. While analyzing these details, it is important to remember that the overall goal of this project is to aid in the biomechanical characterization of locking compression plates, and their effectiveness in comparison to traditional, less-expensive, non-locking compression plates.

Background

It has been successfully shown that mechanical strain (bone deformation in response to external loading) has a profound affect on bone remodeling. [9], [13] More recent studies exist analyzing the strain development in vivo in bones after application of non-locking compression plates. [7] According to O'Toole, (et al in a white paper presented this spring for publication), there is "little data" analyzing advantages of locking screws over non-locking screws in compression fixation of fractures for load bearing. While they report that there are numerous studies "demonstrating potential advantages of locking plates over other constructs, these have focused on metaphyseal bone...there [have] been no biomechanical studies demonstrating an advantage of locking screws for humeral shaft fractures." [12]

Consequently, the research conducted to date by O'Toole has been in an effort to determine if there is a definite biomechanical advantage to using locking compression plates for humeral fractures. The finite element studies proposed here will be a continuation and extension of the work already completed by him.

Finite Element analyses are commonly used in many disciplines. Although it is commonly used as an analysis tool for engineers, it is also widely used and accepted in scientific research, as can be seen from one example in the special issue of Anatomical Record in 2005 that was completely devoted to Finite Element Analysis in Vertebrate Biomechanics. [15] For the purposes of this study, FE will be the primary investigational method, and will be used to augment results already obtained from both cadaver and synthetic bone experiments conducted by RV O'Toole at UMMC R Adams Cowley Shock Trauma Center.

The main means of comparison of the two models in this application will be the direct numerical comparison of strains measured at the callus site. Both strain distribution and max strain will be measured from the simulation, in order to compare the mechanics of the two systems, and to evaluate if there is a significant difference between the two plating methods.

<u>Purpose</u>

The purpose of this research was to generate and validate a working Finite Element model of compression and locking fracture fixation techniques of humeral shaft fractures. This paper will outline the techniques used to create the model, the validation of the model based on previous research, pullout studies conducted on non-osteoporotic bone, and further work to be done after validation.

Chapter 2: Methods

Material Properties and Model Dimensions

The finite element model (Figure 1), made of three dimensional brick elements, was created using ABAQUS 5.0. The structure was a half symmetry model, with symmetry taken around the fracture site. The shaft of the humerus was approximated as a cylinder to simplify calculations and to minimize computational time, while providing acceptable results [4] [22] [23]. All dimensions were modeled after the experiment conducted by O'Toole, et. al for comparison purposes to validate the model. The gap size in the experiment was a 1 cm transverse gap, with a 1mm plate offset in the locking scenario, and 0 offset in the compression scenario.

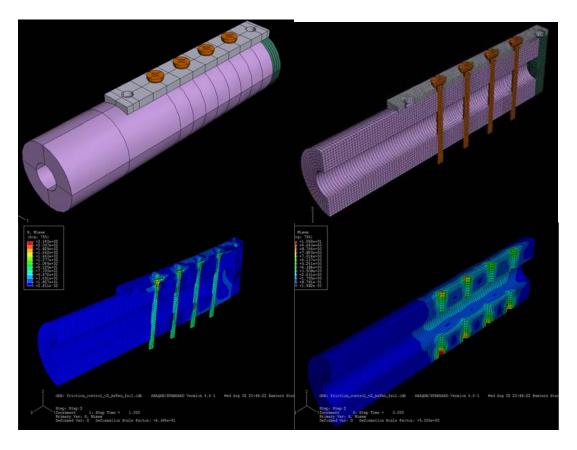


Figure 1. Finite element humeral model. Top left: complete solid model; top right: half section of model with meshing. Bottom left: half section under axial load; bottom right: stress field in bone after loading.

Material properties for the bone were taken from both standard references (Bone Mechanics Handbook, [4]) and published research papers completing similar studies [22] [23]. Dimension for the humerus were taken from the synthetic sawbones used in experimental studies by O'Toole. The material properties for the callus were taken from Gomez-Benito, in a paper that addressed this issue. Ultimately the material properties of the callus can be approximated as a percentage of healing, with the greatest deformation occurring with the least healing (approximated with 1% of healthy bone properties) [9] [9].

The plate used in the experiment was a Synthes Combi 3.5 mm locking/non-locking plate. The plate measured 20 cm in length, 11 mm width, and 3.4 mm thickness, with screws placed every 13mm. The plate as modeled consisted of a rectangular bar, with appropriately sized and spaced holes. The inferior aspect of the plate was contoured to the shape of the bone (Figure 2). The locking screw dimensions were 2.9mm core diameter, 4mm head; the dimensions of the non-locking compression screws were 2.4mm core diameter, with 6.0 mm head (Figure 3). The construction material of the screws and plate was 316L Stainless Steel, with a Young's modulus of 186,000 MPa, Ultimate Tensile Stress of 860 MPa, and .2% Yield Stress of 690 MPa, and Poisson's ratio of 0.3 (figures from Synthes metallurgist John Disegi).

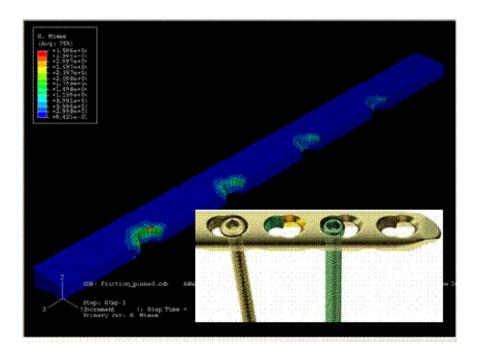


Figure 2. Plate model, with Synthes combi plate inset.

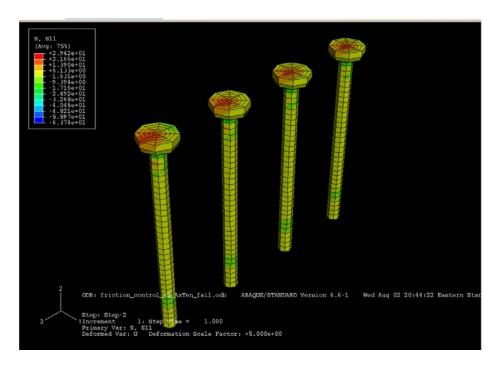


Figure 3. Compression screw model.

Modeling Assumptions

For the compression plate model, several assumptions were made. First, it was assumed that the plate was completely in contact with the bone. Although in surgical scenarios, this is not 100% accurate (as the plate must be conformed to fit the contours of the bone), for the purposes of the model, it is sufficient to assume complete contact. For this application, the friction between the bone and plate plays a critical role. While a friction coefficient of 0 would allow total slippage between the plate and bone, a friction coefficient of 1 would not allow any motion between the plate and bone. In a real life application, this friction coefficient will play a role, along with the degree of contact between the plate and bone, in repetitive loading, cyclical failure of the construct. Since the purpose of this study is to determine the strain at the callus site, it is not critical that the frictional coefficient exactly match

real-life scenarios; rather it is imperative that the friction coefficient be sufficient to allow the construct to hold together during loading.

Another assumption that was made was the preload of the screw. This is a result of tensioning the screw as it is inserted into the plate. Because this is a matter of objectivity based on the surgeon, this is a difficult value to quantify for simulation purposes. Beaupre, et al, [1] addressed this issue, and the value taken for preload was assumed to be 100 N per screw. Figure 4 shows the method used to generate the preload: compressive forces are applied to the screw head, to simulate the effect of tightening the screw into the bone, effectively compressing the plate to the bone. Figure 5 shows the strain field seen at the callus site during preload from the screw tightening. The significance of this is that, as expected, the strains shown are symmetrical about the midpoint, and indicate that the method used to approximate preload effectively produced strains at the callus site.

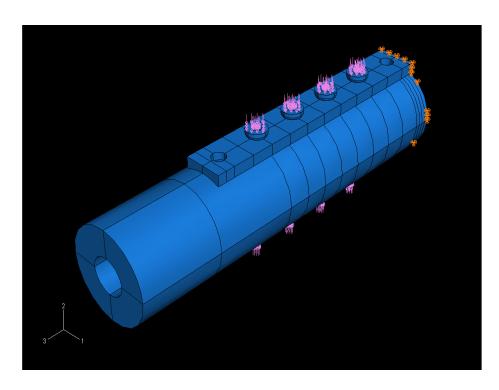


Figure 4. Preloading of compression plate.

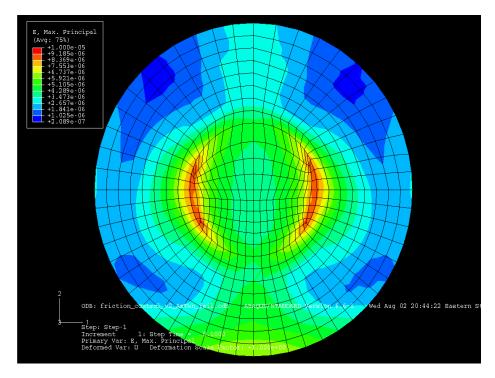


Figure 5. Strains in callus seen at preload of compression plate.

The interface between the screw and bone is approximated to be a rigid interface. This assumes that there is no slippage, and no pullout of the screw. Pullout testing was conducted and will be discussed later. The angle of screw insertion was assumed to be perpendicular to the axis of the humerus. This is a critical value, and Robert, et al show that the strongest bone/plate interface occurs when the screws are inserted at 90 degrees relative to the longitudinal axis of the bone [17].

The theory of locking plate constructs is that the plate should produce shearing stress at upper shaft of the screw, near the screw head. Figure 6 shows that the dominant forces in the screw head are in shearing, and thus correlate with the theory, in that the screws in compression plating should experience shear stress. This is one aspect of validation for the compression model: that it follows the expected theory that screws should experience shearing stress.

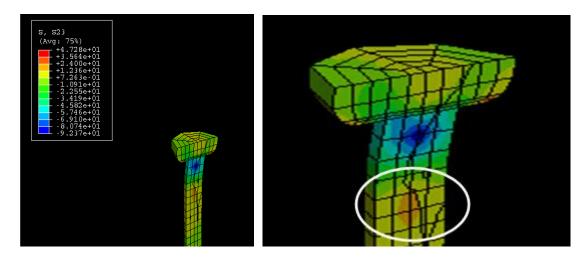


Figure 6. Shearing at the compression screw head. Right shows close-up of screw, indicating areas of high shearing stress.

There are fewer assumptions in the locking plate model, as the assembly is a more constricted construct. Due to the nature of the plate, the screws must be inserted at an

angle of 90 degrees to the plate, otherwise cross-threading will occur and the screw will not hold. Additionally, friction is not a factor since this is not a critical part of the construct, and the construct is based on the theory of the external fixator and can be modeled with an offset from the bone.

The main mechanism of stress in the screws should be bending stress. Figure 7 clearly shows the screw head in the locking model to be experiencing bending stress under load. This correlates with the theory of the locking fixator, that the main mode of stress in the screw should be shearing, and is an initial step validating the mechanics of the locking-plate model.

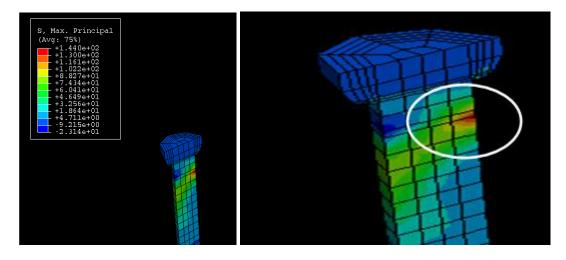


Figure 7. Bending stress in locking screw head. Picture at right shows close-up of areas indicating high bending stress.

A reported claim by proponents of locking-plate manufacturers' is that the locking construct can be used with only one screw applied on each side. Based on the theory of the two applications, this should be true. With the compressive fit plate, the holding power of the plate is due to the friction force between the plate and the bone. If there is only one screw on either side of the fracture, then the construct should fall

apart due to insufficient degrees of freedom to generate this friction force.

Conversely, the locking plate will hold – in theory – because the screws themselves lock into the plate, thereby preventing rotation of the plate around the fracture site with as few as two screws installed. If our model correctly simulates the theoretical biomechanics of the constructs, then this phenomenon should be seen when only one screw is inserted on either side. Subsequently, although the forces were calculated to be extremely high, the locking plate model did hold rigid under loading, while the compression-fit model failed to converge due to insufficient fixation and degrees of freedom.

Finally, previous investigators have investigated the strain field in the bone callus for various fractures in the past, while not necessarily applying it to the same application as this study. Therefore, our strain field distributions should be similar to those previously reported. Strain fields from the finite element model are seen in Figure 9 and Figure 10. Figure 8 shows strain fields in a plated sheep radii subject to loading, and calculated by Beaupre, et. Al [1]. As can easily be seen by comparison, the strain fields calculated by our experiments match well with those shown previously by other investigators. (It should also be pointed out that the loadings are of different values, so that while the values are not comparable, the distribution of the strain field can be compared.)

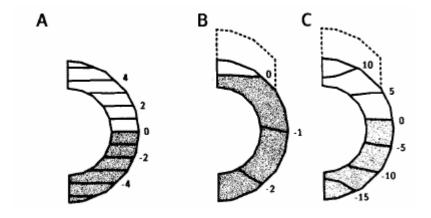


Figure 8. Strain field reported by Beaupre, et. al.

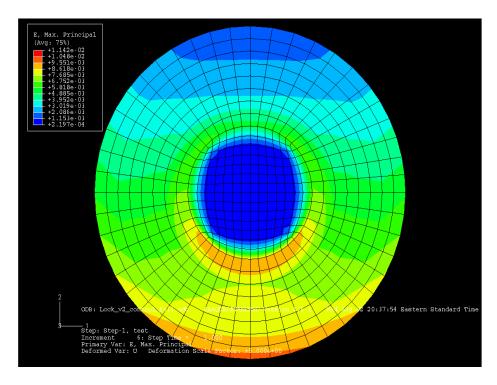


Figure 9. Strain field in callus, locking plate fixation.

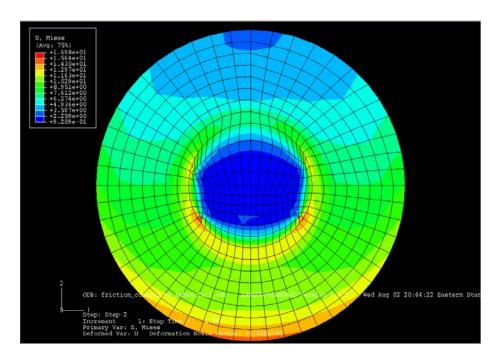


Figure 10. Strain field in callus, compression plate fixation.

Model loading

In O'Toole's experiment, the constructs were all exposed to three loading mechanisms: axial tension, bending, and torsion. For the purposes of this study, only axial tension were directly examined, the results of which will be presented later.

Further studies will discuss and address the further loadings of bending and torsion.

Chapter 3: Model Validation

Including Cadaveric bone screw pullout experiment

Introduction

The first validation of the model was to compare the failure stiffness of the plate to the failure stiffness measured by O'Toole in experiments. The mean failure force measured was 4,200 N in both locking and non-locking, with a minimum failure at 2,500 N.

In order to validate the FE model with the completed experiments, these values were used as loadings to generate stresses. In the experiments, the constructs were axially loaded until the entire construct failed by tensile fracture. While this gives a good measure of overall stiffness of the construct, it tells us little about the mechanics of what is occurring at the fracture site. Therefore, if the FE model correlates with the experimental model, it will allow us to analyze the constructs on a more local level—at the fracture/callus site—in order to give a more accurate account for the biomechanics of the two systems as they relate to fracture healing.

Cadaveric bone screw pullout

Introduction

For a local validation measure, screw pullout was selected. Although in experiments by Berkowitz [2], screw pullout was not identified as a major means of construct

failure during cyclical loading, it provides a numerical value that can easily be measured, and compared against forces calculated from the model. Experiments in literature were conducted with various screw types inserted in blocks of synthetic bone, but few have been conducted with cadaveric bone.

Internal fracture fixation is a common surgical fracture union technique. There is current debate over the use of cortical compression screws and internal fixator techniques, and their respective applications. Each of these methods uses a different screw design, with the commonly held belief that a larger screw pitch and wider thread depth lead to higher strength. The purpose of this experimental study was to evaluate the normal strength (pullout strength) differences between cortical compression screws and locking internal fixator screws by isolating and assessing the screw-bone interface strength.

Background

Limited numbers of studies have been conducted addressing the pullout strength of internal fixator screws in cadaveric bone. While there have been several studies approximating screw-bone interface strength by experimental design consisting of simulated saw-bone studies, no cadaveric studies have been published specifically addressing the comparative strength of cortical compression screws vs. locking internal fixator screws. Any studies existing to date have focused on evaluation of the strength of the bone itself during pullout, rather than the effective max load that the pullout strength would convey to the specific screw being applied.

The purpose of a paper published in 1941 was to prove that finer pitched screws failed by pullout at lower tensile loads on the screw than coarser pitched screws [15]. The only advantage that was found in this study was an advantage of coarser screws to grip the bone better, regardless of the size of the predrilled hole (none of the screws used in this 1941 study were self tapping). The general result was little difference in loading strength of the coarse versus fine pitched screws, while the coarse screws did offer a practical advantage. No mention was made of specifically addressing osteoporotic versus well mineralized bone.

In 1970, Koranyi, et, al [12] investigated the effect of bone thickness on holding power of coarse versus fine pitched screws. Experiments performed on canine tibia and fibia concluded that pullout strength varies linearly with cortical thickness of bone. This conclusion is justified by the results seen in the graph reproduced in Figure 1. This "linear" approximation is supported by a linear best fit line of R² ~ 0.5. While this hardly justifies a good linear fit, some current pullout studies still reference pullout failure loads in terms of load per length of bone in which the screw is inserted. In our pullout study, we will attempt to offer a better analysis of the pullout failure data using Weibull statistical distributions and screw design theory.

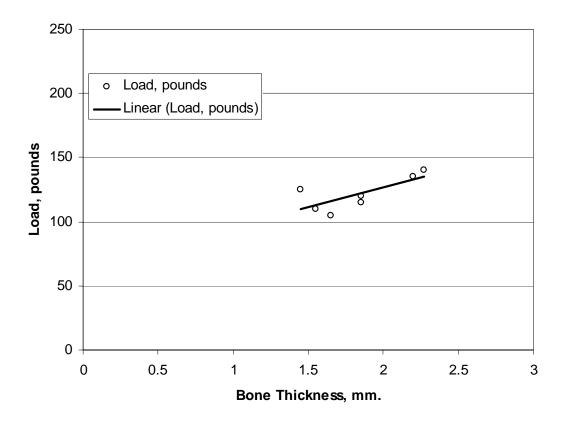


Figure 11. "Holding power of orthopedic screws" as reported by [12].

Berkowitz, et. al analyzed the effects of insertion depth and insertion angle of 3.5 mm Synthes self-tapping cortical screws in synthetic saw bone. [2] This study found that the greatest strength was observed when the screw was inserted through two cortices, but greater insertion depth offered no significant advantage.

Kearny, et. al. investigated the effect of divergent screw placement on pullout strength. Their results found that as the angle from normal increased from 0 to 20 degrees, the pullout strength was weakened. Again, though, this study was conducted with synthetic saw bone models. [10]

The most recent paper discussing mechanical pullout stresses was published in 2007 by Zdero, et. al. This paper addresses 3.5mm and 4.5 mm cortical screws inserted into synthetic bone, and compares the results to previously published values obtained from insertion into human and canine tibia and femurs. The results were determined as a range of shearing loads over which the samples failed. These ranges were compared to previously published ranges. In general, the synthetic bone tended to fail on the lower end of the range presented from cadaveric failures, although the authors concluded that the synthetic bones were a "satisfactory" analog.

One major problem with using synthetic bone models is the lack of variation in material properties and failure modes between samples. By analyzing cadaveric bone, this study will address the failure mechanisms of cortical and locking screw pullout, and will determine the statistical likelihood of screw pullout for a given loading in human humeri.

Additionally, the purpose of this study is to address the commonly held assumption that cortical compression screws (which have a larger thread pitch and larger thread thickness) have greater normal strength than locking internal fixator screws in screws that have the same major diameter [15] [12]. One practical application of this is seen in patients with osteoporosis. Greater normal stresses are required for the compression plating technique during preloading; if a compression screw strips during installation, a locking internal fixator is used instead, because there are no normal stress preload demands placed on the bone-screw construct.

No existing studies provide adequate statistical analysis of the data. Some provide mere averages of the failure data with excessively large standard deviations, while others provide ranges over which the samples fail. This study will provide a statistical analysis of the failure data to more accurately characterize the data, rather than present a range over which samples fail. Additionally, studies frequently will assess the failure load by calculating the load per mm of screw that is inserted into bone (as discussed above). According to machine screw theory, as long as the appropriate length of engagement has been reached, there will be a stress concentration in the outer few threads during axial loading, as is experienced during pullout [20]. Thus, although normalizing the failure load by insertion depth has no practical meaning for pullout strength, that doesn't exclude insertion depth as a factor affecting strength of the construct during physiological loadings in vivo.

Consequently, for the analyses here the linear insertion depth will not be considered, other than that all screws were inserted through both cortical thicknesses.

For this study, the two methods of fixation for a Synthes combi plate were assessed for their comparable strength: 3.5mm compression screw and 3.5 mm locking screw. These are two alternatives for the same plate, and will serve as a basis for comparison between the two plating techniques.

Methods

For this procedure, Synthes 3.5 mm locking and 3.5 mm cortical screws were used for comparison, as these would be the two (connector) options available while using a Synthes 3.5 mm Combi Plate. Dimension details for the screws are given in Table 1.

Table 1. Screw Dimensions

	3.5 mm Locking	3.5 mm Cortex
Thread Diameter	3.5 mm	3.5 mm
Thread Pitch	0.8 mm	1.25 mm
Core diameter	2.9 mm	2.4 mm

Core diameter	2.9 mm	2.4 mm

Four cadaver humeri (two matched pair) were obtained for testing. These humeri were selected to be non-osteoporotic via DEXA testing. The humeri were sectioned into several samples of uniform length, depending on overall length of each humerus (Figure 12).

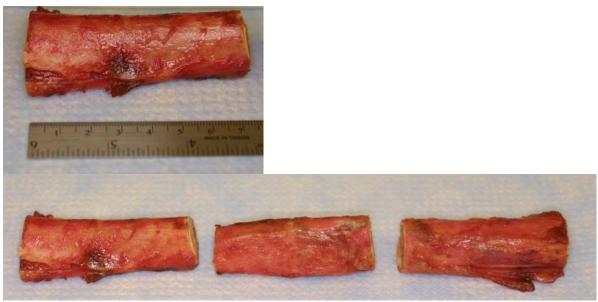


Figure 12. Humeri sample sections.

Using standard surgical procedures and tools, each test sample was first pre-drilled to the appropriate diameter for either locking or cortical screw (randomly decided). The screw was then inserted through both cortices, with the connection plate attached (used to attach the sample to the MTS for loading). No preload was added to the screw as the primary aim of this study was to assess the strength of the bone-screw interface.

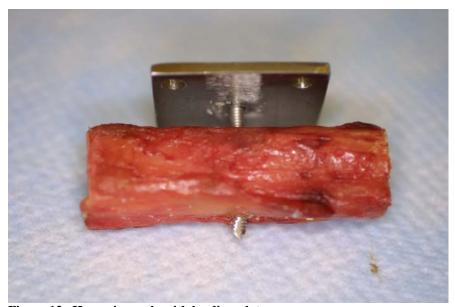


Figure 13. Humeri sample with loading plate

After the sample was prepped, the lower portion was then potted in bone cement in the experimental channel (Figure 15). Vacuum grease was applied to the portion of the screw protruding below the lower cortex to prevent binding to the bone cement. Samples were then mounted to the (MTS) and loaded in displacement-control until failure (Figure 16) at 0.01 mm/s . Load and displacement were measured during experiment, and a sample profile is shown in Figure 14. The largest value observed during testing was taken to be the pullout force.

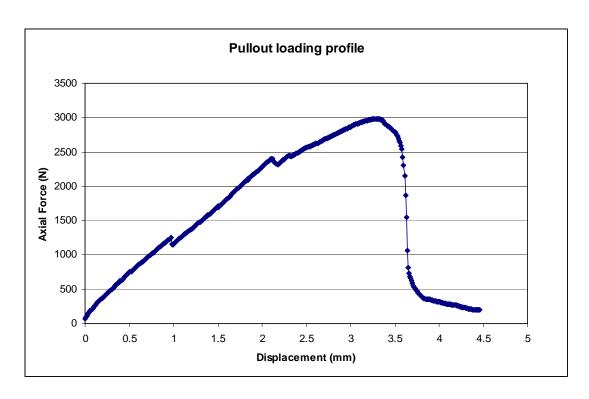


Figure 14. Sample loading profile.

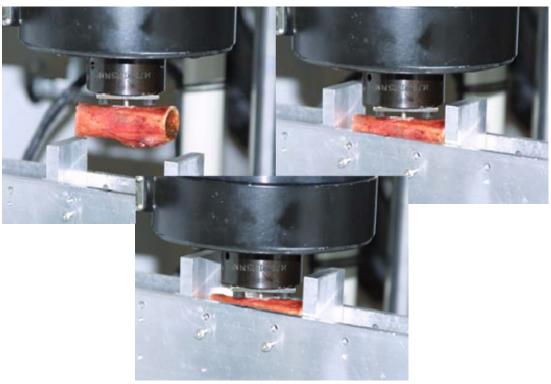


Figure 15. Potting sample into experimental channel.

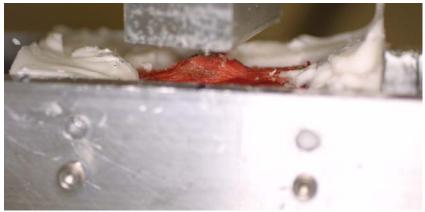


Figure 16. Sample seen at failure.

Data / Results

Using machine design theories, it is possible to calculate the stresses in the screw and bone (which is analogous to the nut in machine theory) using a few basic calculations. By calculating the tensile stress area and shear stress area of the screw using the following equations, it is possible to calculate the stress seen in the bone at the time of failure.

$$A_{t,screw} = \frac{\pi}{4} (D - 0.938194 \cdot p)^2$$

$$L_e = \frac{S_{ut,screw}(2A_{t,screw})}{S_{ut,bone} \cdot \pi \cdot OD \cdot 0.5}$$

$$A_{sN} = \pi \cdot L_e \cdot OD \cdot 0.5 = \frac{2 \cdot A_t \cdot S_{ut,screw}}{S_{ut,bone}}$$

 $S_{ut,screw}: Ultimate\ strength\ of\ screw$

 $S_{ut.bone}$: Ultimate strength of bone

 $OD: major\ diameter\ of\ screw$

 $p:pitch\ of\ screw$

[20]

	At	L _e	A _{sN}
3.5mm	5.94 mm ²	14.95mm	82.22 mm ²
Locking			
3.5 mm	4.25 mm ²	10.7mm	58.90 mm ²
Compression			

On cross-sectional inspection of the samples, it was found that there were two different failure mechanisms: some samples failed by bone stripping, while some failed via bone fracture (maintaining cut threads in fractured surface, as seen with arrows in Figure 18. For visualization, samples were first potted in epoxy, and cross-sections were cut along the longitudinal direction of the sample along the centerline where the screw was installed (Figure 17). (Note that the bone was set in epoxy post-failure, and that all spaces will be filled or lined with epoxy in photographs.) The purpose of the cross sectioning is to visualize the region of bone immediately surrounding the bone-screw interface.



Figure 17. Schematic of cross sectional views.

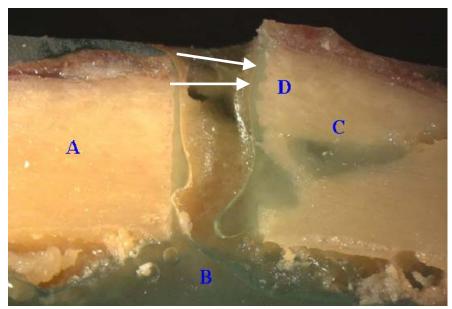


Figure 18. Bone fracture failure. A. Bone; B. Interior lumen of bone, with epoxy fill; C. Fracture site; D. Thread spaces (arrows).



Figure 19. Bone stripping. As seen in Figure 19, no thread cuts can be seen in the remaining bone material,

indicating that the failure occurred because of bone material stripping failure between screw threads, rather than gross failure of the bone itself. This indicates a weakening of the bone modulus. As the ratio of stiffness between the screw and bone increases, the likelihood of stripping increases.

A failure in stripping indicates that there has been a decrease in the strength ratio between the screw and the bone [20]. Since osteoporosis results in decreased density of bone, and subsequently decreased bone strength, it could be possible to conclude that samples that stripped did so as a result of osteoporotic bone decreasing the strength of the material. Additional studies with more samples would be necessary to definitively confirm this, but this agrees with anecdotal discussions with clinicians regarding inserting screws into osteoporotic bone. It is usually found that upon insertion of cortical compression screws into osteoporotic bone, stripping occurs.

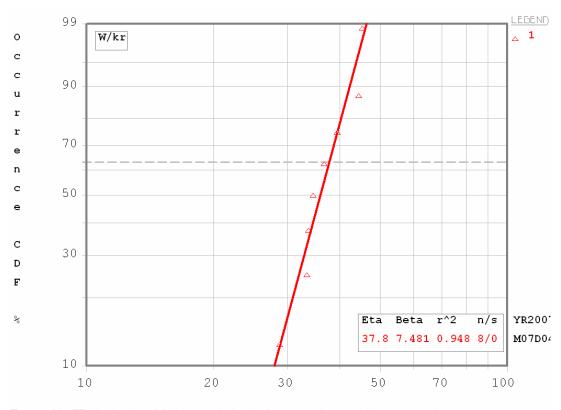


Figure 20. Weibull plot of failure probability for screw-bone pullout strength.

Because failure occurs strictly in the bone, the results have been grouped based upon what type of bone failure occurred. Therefore, all pullout failures that failed in

fracture were analyzed with the characteristic value taken as the calculated shear stress based on screw design parameters and external loading. As is seen in Figure 20, the shear stresses at failure, regardless of whether locking or non-locking screws were used, correspond to the Weibull plot with r^2 =.948, and B=7.481. Both values indicate a strong likelihood that the failures observed were not due to chance. The formula used to calculate shear stress are given as follows:

$$A_{sN} = \pi \cdot L_e \cdot OD \cdot 0.5 = \frac{2 \cdot A_t \cdot S_{ut,screw}}{S_{ut,bone}}$$

$$\tau_{\mathit{fail}} = \frac{P_{\mathit{failure}}}{A_{\mathit{sN}}} = \frac{2 \cdot P_{\mathit{failure}} \cdot A_{\mathit{t}} \cdot S_{\mathit{ut,screw}}}{S_{\mathit{ut,bone}}}$$

 $P_{failure}$: failure load

 $S_{ut.screw}$: Ultimate strength of screw

 $S_{ut\ hone}$: Ultimate strength of bone

 A_{sN} : shear stress area

Figure 20 supports the claim that all bones that fail in brittle fracture (Figure 18), and not by stripping (Figure 19), do so via the same brittle fracture mechanism. The Weibul plot is a plot of probability of failure at a given stress. Therefore, one can extract what percentage of the population can be expected to fail at a given loading value. Additionally, the Weibull shape parameter (beta) is found to be 7.481, which indicates that the probability of failure increases with increasing load, and additionally the failure rate also increases with increasing stress. With the above data, 1% of the population can be expected to fail at a shear stress of 20.44 MPa.

An additional factor to consider here is the concept of stress concentrations. According to machine design [20], stress concentrations are seen at the outer few threads due to screw loadings. This is due to increased pitch in the screw, and decreased pitch in the bone. As seen in

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Table 2, the value of the shear yield stress approximated using the stress concentration is within 12% of the yield shear stress as reported by Kemper et. al. [11].

Table 2. Comparison of shear failure stresses

	Calculation from screw	$\tau_{y \lceil 11 \rceil}$
	theory	
Failure stress at site of	61.32	54.46
stress concentration		

For comparison, the FEA model, at experimental failure loads, has generated a max shear stress of approximately 10 MPa in the bone near the bone-screw interface. This falls below the 1% failure stress, and confirms both (1) that at failure in axial loading, pullout is not a dominant failure mechanism (unless the bone is osteoporotic, with weakened material properties, and strips during installation), and (2) the model does not show significant pullout effects at axial failure loadings.

The load that produces this shear stress varies depending on the specific screw used, and for the screws used in this investigation is given in Table 3. (Calculating a mean and standard deviation is not appropriate in this scenario because we are evaluating failure data. It is incorrect to assume a normal distribution with brittle fracture as observed in this scenario. Weibull distribution is specifically designed to analyze failures that correspond to logarithmic distributions.

Table 3. Failure loads for 3.5mm cortical compression and locking screws.

	3.5 mm Locking	3.5 mm Compression
1% Failure Load (N)	1,540	1,010

Discussion

In a practical application, because of variable screw parameters, this means that there are differences in the actual load at which the bone fails between the two screw types. Working backwards from the above equations, assuming both a compression and locking screw-bone interface were to fail in fracture at the same shear stress, the locking screw would be loaded to greater than 1.5 times the load for an equivalent failure stress in the compression construct. While at first this seems to contradict the commonly held concept that coarser threads provide greater strength, it is in fact consistent with machine design theory, and agrees with previous studies conducted in synthetic bone [5].

For this study, spare humeri not suitable for other studies were used. While the exclusion criteria for these other studies was DEXA scanning for osteoporosis, it is apparent from the results here that a portion of one of the samples was osteoporotic, given the stripping failures indicating material weakening. Those results were not used as the purpose of this investigation was to assess pullout failure in non-osteoporotic humeri. Further studies are necessary to characterize the failure pullout strength for osteoporotic loading.

Further studies with larger population sizes would allow for better comparison of subtle differences between different screw types. Doing so could account for effects

such as microdamage in the bone resulting from larger thread size. Insertion of larger screw sizes could induce larger numbers of defects and voids in the bone crystal structure which could help initiate crack propagation (and thus failure in fracture) at lower stresses due to larger initial defect size. It is not practical to make these claims with this study because of limited sample size.

Chapter 4: FEA Results and Discussion

In order to compare the two models, the normal strain at the callus site was compared between the two models. This value of normal strain corresponds to the type of healing, and is the reasoning behind rigid fracture fixation: the lower the strain, the less displacement of the two bones, resulting in greater primary bone healing and less cartilaginous formation during healing. The generally accepted number for primary bone healing is 2% max.

The max strain seen in the callus during failure loading (Figure 9 and Figure 10) is 1.14% with locking fixation, and 1.09% in compression fixation. This difference between these two values is a 4% difference in strains. In future experiments, this value (percent strain difference between the two models) will be used as a measure of relative strain, and the change of this value will used to evaluate the effectiveness of the two different constructs as other variables change.

Ultimately, this model will be extended to include both cadaveric and healthy bone. While the validation was for healthy bone only, only mild amounts of validation and geometric adjustments to the model would be required to extend its' use for osteoporosis. The major result of these simulations was to show and validate that the locking construct offers no biomechanical advantage over the less-costly compression plate in non-osteoporotic individuals. A critical value to identify will be at what point a humerus should be considered "non-osteoporotic" for the purposes of fracture fixation. Currently, if the surgeon inserts a compression screw that does not grip, this

is the main criteria for non-compliance with compression plates. Hopefully this model will allow us to identify a measurable value (cortical thickness to cortical diameter ratio, perhaps) that can be measured prior to surgery, and can ultimately give some sort of guideline for appropriate fixation technique.

Chapter 5: Conclusion and Discussion

While the general loading mechanics of the two fixation methods discussed here have long been understood, this study took a further step in extending the understanding of how the fracture callous is affected during plated-bone loading. An unexpected outcome of this study was the screw pullout data. The results from this testing were contradictory to commonly held beliefs within the orthopaedic community as to the relative strength of each screw type, and hopefully this result can be further exploited to eventually develop a more functional screw for use in patients with osteoporosis. As the mean age of the population continues to increase, fractures due to osteoporosis will continue to rise. An improved fixation method for fractured osteoporotic bone will ultimately have a substantial impact on society.

Future work will consist of the following:

- Application of additional loading mechanisms of torsion and transverse loading to FEA model
- Extension and modification of FEA model to generate results for rat spinal fracture callous modeling
- Complete parametric studies of the following parameters with FEA model:
 - o variable number and placement of screws
 - o unicortical screw placement
 - variable callous thickness

- variable cortical thickness (e.g. in osteoporosis, the outer diameter of the bone increases as a compensatory mechanism for loss of bone density and cortical thickness)
- generate experimental data for osteoporotic plating failures
- experimentally test additional screw types in both normal and osteoporotic
 bone to more fully characterize screw pullout
- generating recommendations for existing screw uses in fracture applications given DEXA values or other measurements taken pre-operatively
- optimize a screw design for osteoporotic bone given failure data derived from existing screws in osteoporotic bone, and failure methods characterized by such data

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