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**A Comparative Evaluation of Cadaveric and Composite Femur Models for
Total Hip Arthroplasty**

A Thesis

Submitted to the Faculty

of

Rose-Hulman Institute of Technology

by

Anderson Lynn Adams

In Partial Fulfillment of the Requirements for the Degree

of

Master of Science, in Biomedical Engineering

May 2015

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ROSE-HULMAN INSTITUTE OF TECHNOLOGY

Final Examination Report

Anderson Adams Biomedical Engineering
 Name Graduate Major

Thesis Title A Comparative Evaluation of Cadaveric and Composite Femur Models for Total
Hip Arthroplasty

DATE OF EXAM:

April 23, 2015

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ABSTRACT

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Rose-Hulman Institute of Technology

May 2015

A Comparative Evaluation of Cadaveric and Composite Femur Models for Total Hip
Arthroplasty Biomechanics

Thesis Advisor: Dr. Renee Rogge

Composite bones are often used in testing of orthopedic implants due to their relative ease of use and low inter-specimen variability when compared to cadaveric bones. Tests were run to ensure that the composite bones remained an acceptable model for cadaver bones throughout surgical manipulation. Composite (n=6) and cadaver (n=6) femur specimen were subjected to a total hip arthroplasty (THA). Flexural rigidity, axial stiffness, and axial strain measurements were taken at various stages in the surgical process. The composite and cadaver specimen were not found to behave similarly in either flexural rigidity or axial stiffness tests. The results showed a general inconsistency in the behavior of the specimen, making the composite bones an imperfect model. No residual strains or creep in the axial strain tests were found for either composite or cadaver bones; this supports the use of composite bones to reduce unpredictability in testing results.

Dedication

I would like to dedicate this thesis to my family, friends, and mentors who have supported me throughout my academic career and taught me everything I know. I am blessed to have the support of people who empower and encourage me to chase my dreams.

Acknowledgements

I would like to acknowledge the following people for without their support and guidance this thesis would not have been possible.

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1. INTRODUCTION

When testing new orthopedic implants it is important to have consistent, reliable testing methods to determine the explicit effects of the implant. This allows developers to understand the successes and the flaws of the implant before using it in living patients. Sawbones have created a composite bone that is widely accepted as a good representation of human bone. These bones are advantageous for biomechanical testing due to the consistent size, shape, and composition of the bones. When using cadaveric bones for testing, these properties (size, shape, composition) may vary and the results may be influenced by these differences, rather than the characteristics of the implant. The composite bones have been validated for use in biomechanical testing, but the impact of surgical intervention has not been investigated [1-6]. To test orthopedic implants, such as a femoral stem, the bones must be cut and altered, which in the case of the femoral stem involves reaming out the core of the femur.

The research presented explores how the properties of both cadaveric and composite bone change when the bones are surgically modified. Cadaveric (n=6) and composite femurs (n=6) underwent a total hip arthroplasty and were tested for flexural rigidity, axial stiffness, and axial strain. The bones were evaluated during three stages: intact, implant prep phase (i.e. cut), and implanted. Rigidity, stiffness, and strain results were then compared between the 2 bone models during each stage. Analysis of variance (ANOVA) statistical tests were used to find significant differences between stages and types. P-values were used to identify statistically significant differences between values.

This research project was designed to gather information about the cadaver and composite specimens during surgical manipulation. It was not anticipated that the cadaver and composite specimen would have identical results. However, it was expected that the changes in the composite bone between stages would be comparable to the changes in the cadaver bones.

The intact bone was expected to be stronger in both stiffness and rigidity when compared to the cut and implanted bones. It was also projected that neither the cadaveric nor composite bones would retain residual stresses after testing. This was determined in the axial strain tests.

Following is a brief overview of the hip anatomy, hip replacements, and composite bones. Also included in this thesis are detailed methods, the results from the tests run, a discussion of the results, and a conclusion including recommendations for future testing.

2. BACKGROUND

2.1. Brief Hip Anatomy

The acetabulofemoral joint (i.e. hip joint) is where the head of the femur, attached to the femoral neck, and the acetabular cup of the pelvis articulate [7]. Articular cartilage and synovial fluid in the joint allow for smooth articulation throughout the full range of motion. There are three reinforcing ligaments that meet together to help keep the femoral head in place in the acetabular cup [7]. The acetabular labrum (labeled as capsule in Figure 2.1) is also vital in securing the placement of the femoral head in the acetabular cup. Figure 2.1 below provides a visual representation of the hip joint.

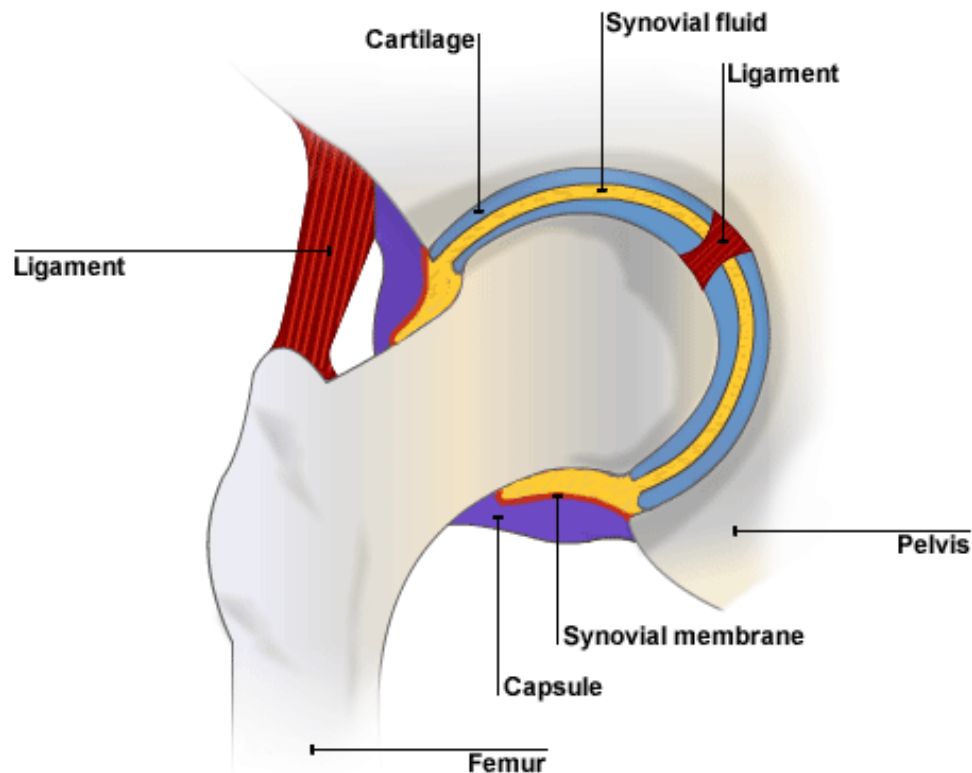


Figure 2.1 Anatomy of hip as a synovial joint [8]

2.2. Hip Replacements

Total hip joint replacement (THR), or total hip arthroplasty (THA), is most commonly a repair for individuals suffering from osteoarthritis (OA). THA is a replacement of the femoral head and the acetabular cup. Hip replacements reduce pain and improve function, improving the patient's overall quality of life.

Overall in the US, there is an average of 285,000 THA per year, with a revision only being necessary in one of every 6 replacements [9, 10]. The average age of patients is 69 years old and women account for over half of the procedures [10]. A THA is recommended for patients with evidence of joint damage and/or moderate to severe persistent pain or disability [10].

2.3. Complications with Hip Replacements

Although it is considered a highly safe and successful procedure, there are still complications of THA. Primary failure mechanisms for THA include: infection, implantation issues (i.e. loosening, instability), implantation wear, dislocation, and bone fracture.

2.4. Biomet Implant

The Echo™ Bi-Metric® (Biomet, Warsaw, IN) is a cementless femoral implant. Its key features include: reduced neck geometry to decrease risk of neck impingement, polished neck to reduce debris in the case of impingement, and a distal tip designed to provide separation from bone cortex and a reduction in distal stresses [11]. Figure 2.2 shows the femoral shaft implant.

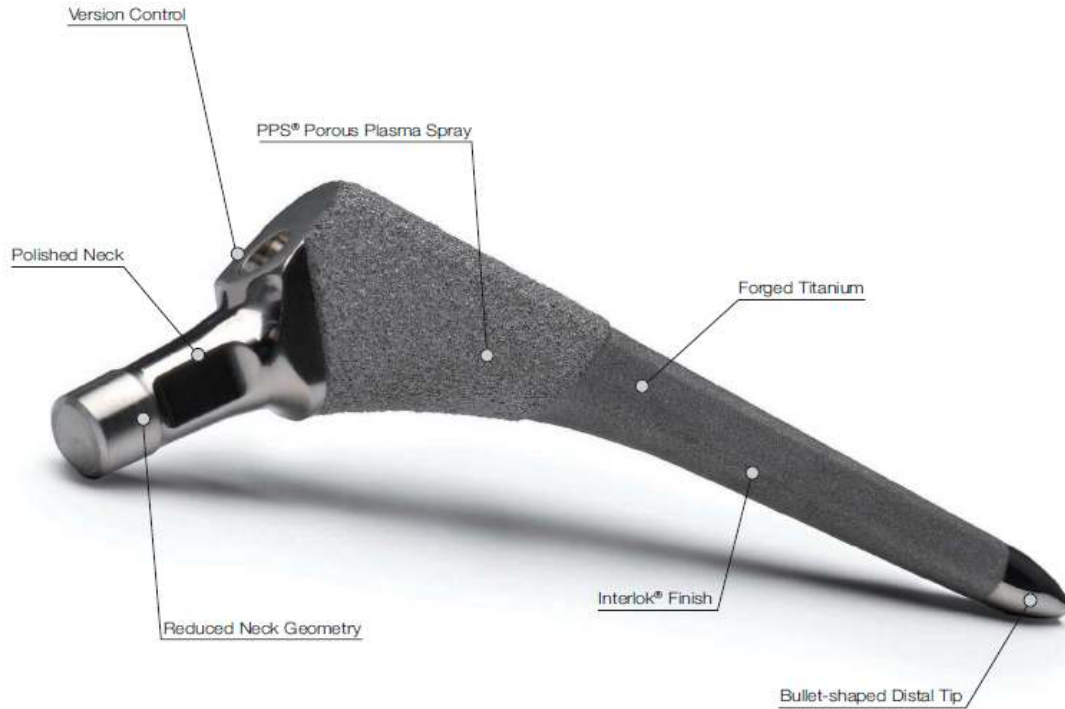


Figure 2.2 Echo™ Bi-Metric® femoral shaft implant with key features identified [11]

2.5. Composite Bone Model

The composite bones used in this research were Sawbones® (Pacific Research Laboratories, Washon Island, WA). The specimens were all fourth generation, size medium, left femurs, foam cortical shell models and one shown in figure 2.3. These models have an inner cancellous material surrounded by a rigid foam shell [12]. The cancellous material is made up of polyurethane foam that the ASTM has verified for use as a medium to test various orthopaedic devices [13]. Multiple studies have shown that the foam has reproducible and consistent mechanical properties that are comparable to a range of trabecular bone properties [14-15]. The rigid foam shell mimics the cortical bone and is made of a short glass fiber reinforced epoxy [4].

Figure 2.4 shows a sagittal cut of the femur which highlights the inner material of the bone. These specimens are ideal for testing joint replacements.



Figure 2.3 Sawbone[®] medium, left, foam cortical shell model [12]



Figure 2.4 Sagittal cut of Sawbone[®] model [12]

2.6. Previous Tests

Cristofolini [1] and Heiner [3-4] both authored various papers that compared the composite and cadaver femurs. Their findings supported the use of composite bones when developing and testing new prostheses. However, Cristofolini cautions that final testing of a design should also include cadaveric specimen to ensure that the prosthesis is not optimized for the composite bone [1]. These studies also report less inter-specimen variability in the composite

bones than in the cadaveric bones [1, 4]. These previous tests were performed on intact composite and cadaver specimen. Heiner reported that the mean stiffness values were comparable between the composite and cadaver bones [3].

2.7. Use of Cadaveric Bones

The obvious advantage of using cadaveric bones in biomechanical testing is the ability to use the results to make direct inferences about the behavior of an implant in a patient. Cadaveric bones allow one to determine how the bone will be affected by the implantation procedure.

Disadvantages to using cadaver bones are numerous. Firstly, it is a biohazard material and ensuring the lab and experimenters stay clean and safe can be problematic and expensive. The cadaver bones are also sensitive to temperature and humidity changes. It is important to keep the bones in conditions that preserve their qualities as long as possible, which can be hard in tests with many cycles or stages. Another disadvantage to cadaver bones is the difficulty in obtaining multiple specimens of the same size, shape, and composition. These bones are coming from a variety of donors who are different heights, weights, and have various lifestyles that can all affect the condition of the bone at the time of donation. These variations in the cadaver specimen could confound results found when testing orthopedic implants. Table 2.1 below highlights the demographics for our cadaveric specimen.

Table 2.1 Cadaveric specimen demographics

	Age	BMI	Gender	Alcohol Use	Tobacco Use	Marijuana Use	Physically Inactive	Malnourishment
MD2675	74	19	Male	+	+			
WV0103	78	23	Male	+	+			
PA1227	63	20	Male		+			
MD1537	63	23	Male	+	+			
GA0618	74	29	Male	+	+	+		
NJ1747	69	16	Male		+	+	+	+

3. METHODS

The methods presented in this section were adapted from Heiner [3]. Composite and cadaver femurs were subjected to a total hip arthroplasty. All cuts and implantations were made by the same, experienced surgeon. EchoTM Bi-Metric[®] (Biomet[®], Warsaw, Indiana) hip implants were used. The same size implant was used for all specimens. These implants were chosen because they were easily available in the lab and were not the focus of this study. The composite bones were Sawbones[®] (Pacific Research Laboratories, Washon Island, WA) and were all medium, left femurs.

3.1. Cadaver Bone Preparation

Cadaveric femurs were received previously dissected. They were further stripped of any remaining soft tissue. While femurs were not being tested, they were kept in a freezer at -20°C. Bones were placed in a refrigerator at 5°C for 24 hours to thaw. To reduce freeze/thaw cycles, bones were tested in both flexural rigidity set-ups consecutively. Axial stiffness and strain tests were also performed consecutively. During testing, bones were kept moist with a 0.9% saline solution.

3.2. Flexural Rigidity

3.2.1. Testing Procedure

A custom built 4-point bending fixture with 62 mm between successive points was used to apply bending to both composite and cadaveric bones. The load was applied using a load cell (2 kN, Instron, Grove City, PA). Bones were loaded in two directions, anterior surface in tension and lateral surface in tension, with the longitudinal midsection aligned with the midsection of the test fixture. The femurs were clamped in the proximal end with rotation constrained in the distal end using a custom mold as shown in Figure 3.1. It is important to restrain rotation about the longitudinal axis and also about the anterior-posterior axis to find the full flexural rigidity.



Figure 3.1 Intact composite bone in lateral in tension loading set-up with rotation constrained by a clamp in the proximal end and a custom mold on the distal end

Specimens were loaded from 50 to 500 N at 0.025 mm/s. The maximum load was held for 30 seconds before the bone was unloaded to 5 N. This protocol was adapted from Heiner [3]. A modification in this study was the additional mold to constrain rotational motion in the distal end of the femur. The schema is shown in Figure 3.2. T_1 shows the start of the test, with a preload of 50 N. T_2 is at the point of maximum load, 500N. T_3 shows the end of the 30 second hold at maximum load and T_4 is at the point where the load returns to 0 and the beginning of the rest period.

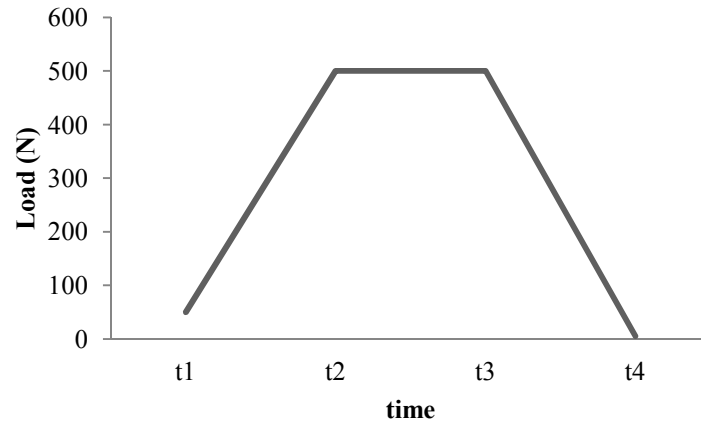


Figure 3.2 Flexural Rigidity loading profile where t1 is the beginning of the test, t2 is when the maximum load is reached, t3 is at the end of the load hold time, and t4 is the end of the test where the load has returned to 0.

One preconditioning load cycle was administered to rid the bone of any memory from a previous loading. This ensured that the results seen were due to the applied bending load, rather than a previous test. The preconditioning test was exactly the same as the data collection tests, however the data were not analyzed. Preconditioning was followed by five data collection load cycles, with a 5 minute rest between each cycle for the composite specimen. The rest period was incorporated to allow the bone to fully relax and to remove any residual effects of the previous test. A period of 5 minutes had been used in previous testing and was determined to be sufficient in bone recovery. To preserve the cadaver specimen, only three data collection cycles were run. Flexural rigidity during the loading period ($t_2 - t_3$) was found using the following equation:

$$EI = \frac{23 P}{24 y} c^3 \quad (1)$$

where E is the elastic modulus, I is the moment of inertia, P is the load, y is the maximum deflection (assumed at the midpoint) and c is the distance between two successive supports [16]. The derivation of this equation is shown in Appendix C. Flexural rigidity (EI) is reported in Nm². The applied load is a known 450 N and the c is set to be 62 mm. The deflection, y, was

found by identifying the greatest displacement during the maximum load, which was during the $t_2 - t_3$ period.

3.3. Axial Stiffness

3.3.1. Bone Preparation

Composite and cadaveric bones were potted distally at approximate depths of 8.5 cm. The femurs were potted so that the femoral shaft was 11° from the vertical in the direction of adduction, to mimic the physiological arrangement of the femur in vivo. After each stage of testing, the potting on the bones was removed to prepare for the flexural rigidity tests.

3.3.2. Testing Procedure

The load was applied on the head of the femur, in the anatomically correct position using a load cell (10 kN, Instron, Grove City, PA). For the intact bones, a custom mold was made to cover the head of the femur and mimic the acetabular cup. With the implanted bones, the acetabular cup implant was used to cover the femoral head. The load was applied to mimic a single-legged stance [17]. A ball bearing was used to allow for free rotation, which allows variations in component alignment without over constraining the system [18]. The set-up is shown in Figure 3.3.



Figure 3.3 Implanted composite femur in axial stiffness loading set-up

Specimens were loaded in compression from 60 to 600 N at 60 N/s. The maximum load was held for 30 seconds before being unloaded to 10 N. The loading schema is shown in figure 3.4. T_1 is at the beginning of the test, with a preload of 60 N. T_2 is at the point of maximum load, 600 N. T_3 is at the end of the maximum load hold and T_4 is when the bone has been unloaded.

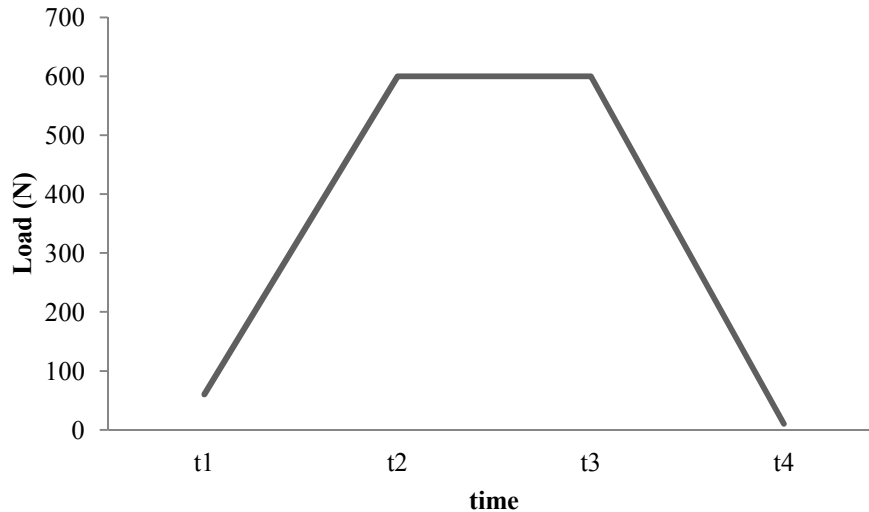


Figure 3.4 Axial stiffness loading profile where t1 is the beginning of the test, t2 is when the maximum load is reached, t3 is at the end of the load hold time, and t4 is the end of the test where the load has returned to 0.

Two preconditioning load cycles were performed to ensure the placement and stability of the bone as well as to remove the loading memory. This was followed by eight data collection load cycles, with a 5 minute rest between each cycle. The rest period was to ensure that the bone had enough time to recover from any residual stresses. Maximum deflection was found during the full load (between t₂ and t₃), a known 550 N. The axial stiffness was found by dividing the load by the deflection and is reported in units of N/mm.

3.4. Axial Strain

3.4.1. Bone Preparation

The potted composite and cadaveric bones were used again for the strain tests. Four rosette strain gauges (KFG-2-120-D17-11L3M3S, Kyowa Electronic Instruments, Tokyo, Japan) were applied at consistent intervals along the medial side of the bones as shown in Figure 3.5. These intervals were chosen to mimic a previous study done in the lab [19]. The “x” marks indicate where the actual gauge is placed and the distances from the first gauge are specified.

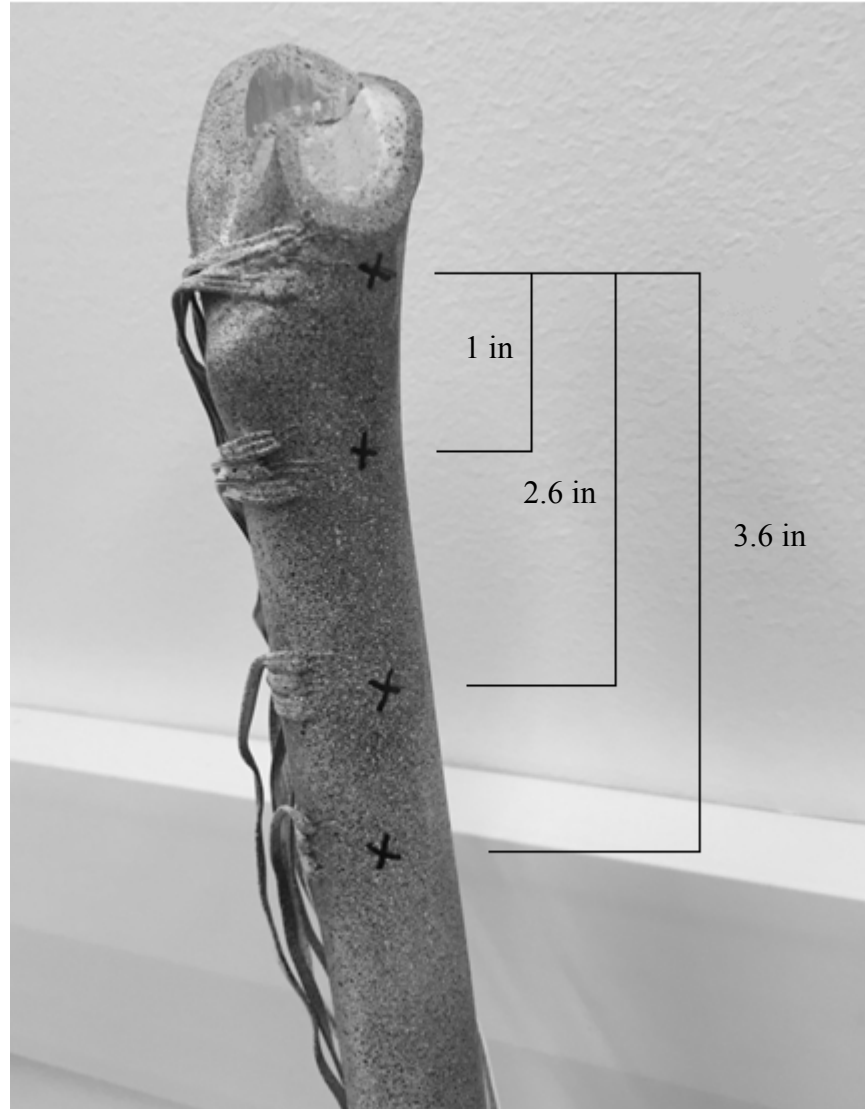


Figure 3.5 Cut composite femur with strain gauges marked by "x" placed along medial side of the bone. Positions are numbered for reference.

To prepare the bones for gauge attachment, they were sanded, rubbed with sterilizing alcohol to remove remaining debris, and coated with glue. The gauge was prepped with glue as well. After being applied to the bone, the gauge and surrounding bone was covered with a protecting coating to ensure adhesion. The adhesive used was M-Bond 200 (Micro-Measurements, Vishay, Raleigh, NC) and the procedure was adapted from the instructions accompanying the product [20]. Before executing this procedure with the cadaveric bones, the periosteum and other remaining soft tissue were removed.

3.4.2. Testing Procedure

The composite and cadaveric bones were loaded in the same set-up used in the axial stiffness test. The minimum and maximum strain values sent from the gauges to the data acquisition system (StrainSmart, Vishay, Raleigh, NC) were used to calculate the Mises strain using the formula below.

$$\text{Mises Strain} = \frac{1}{3} * \sqrt{4 * (\text{max strain} - \text{min strain})^2} \quad (2)$$

The specimens were loaded from 0 to 600 N of compression at 60 N/s and held for 15 minutes. This was followed by an unloading at 60 N/s and held at a zero load for an additional 15 minutes. Recordings of strain were taken before each test (t_1), at the beginning of maximum load hold (t_2), at the end of maximum load hold (t_3), when the load again reached zero (t_4), and at the end of the rest period (t_5). The time of these recordings is shown in the load profile below. This test was only run once per specimen as a means to determine whether the bones were being plastically deformed by the tests.

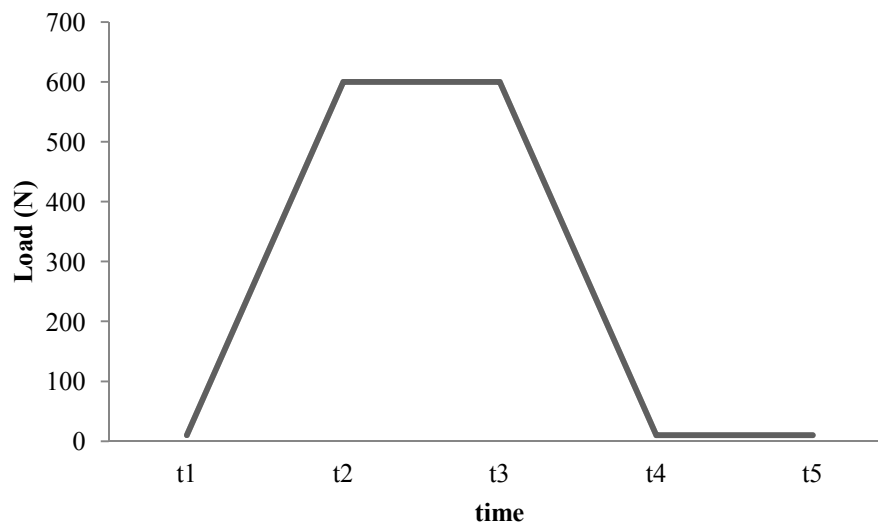


Figure 3.6 Axial stiffness loading profile where t_1 is the beginning of the test, t_2 is when the maximum load is reached, t_3 is at the end of the load hold time, and t_4 is the end of the test where the load has returned to 0, and t_5 is at the end of the rest period.

3.5. Testing Summary

Table 3.1 gives a summary of all tests run on each specimen. The cycles run per test are also specified.

3.6. Statistical Analysis

All statistical analyses were run in Minitab[®] (State College, PA). To assess differences across stages and between types, a repeated measures of analysis of variance (ANOVA) was used. P-values were considered significant if they fell below 0.05. Outliers are identified on boxplots with a *. These outliers are determined by the software during Boxplot formation and were not significant in the analysis. The comparisons made and analyzed are outlined in Table 3.2. The purpose for the comparison is also given and the key is in Table 3.3.

Table 3.1 Testing summary table indicates each test and number of cycles run on each specimen

	Flexural Rigidity						Axial Stiffness		Axial Strain		Total Cycles
	Lateral in Tension			Anterior in Tension			Intact Cycles	Implante d Cycles	Intact Cycles	Implante d Cycles	
	Intact Cycles	Cut Cycles	Implante d Cycles	Intact Cycles	Cut Cycles	Implante d Cycles					
Composite 1	5	5	5	5	5	5	8	8	1	1	48
Composite 2	5	5	5	5	5	5	8	8	1	1	48
Composite 3	5	5	5	5	5	5	8	8	1	1	48
Composite 4	5	5	5	5	5	5	8	8	1	1	48
Composite 5	5	5	5	5	5	5	8	8	1	1	48
Composite 6	5	5	5	5	5	5	8	8	1	1	48
MD0645	3	3	3	3	3	3	8	8	1	1	36
WV0103	3	3	3	3	3	3	8	8	1	1	36
PA0100	3	3	3	3	3	3	8	8	1	1	36
MD1537	3	3	3	3	3	3	8	8	1	1	36
GA0618	3	3	3	3	3	3	8	8	1	1	36
NJ1747	3	3	3	3	3	3	8	8	1	1	36

Table 3.2 List of statistical comparisons between types and stages made and analyzed. Purpose key is included in table 3.2

Flexural Rigidity	Statistical Comparison	Purpose
Composite	Intact vs Cut	A
Composite	Intact vs Implanted	B
Composite	Cut vs Implanted	B
Cadaver	Intact vs Cut	A
Cadaver	Intact vs Implanted	B
Cadaver	Cut vs Implanted	B
Intact	Cadaver vs Composite	C
Cut	Cadaver vs Composite	C
Implanted	Cadaver vs Composite	C
Difference between Intact and Cut	Cadaver vs Composite	C
Difference between Intact and Implanted	Cadaver vs Composite	C
Difference between Cut and Implanted	Cadaver vs Composite	C
Axial Stiffness		
Composite	Intact vs Implanted	B
Cadaver	Intact vs Implanted	B
Intact	Cadaver vs Composite	C
Implanted	Cadaver vs Composite	C
Difference between Intact and Implanted	Cadaver vs Composite	C
Axial Strain		
Composite Intact	Time 1 vs Time 5	D
Composite Intact	Time 2 vs Time 3	E
Composite Implanted	Time 1 vs Time 5	D
Composite Implanted	Time 2 vs Time 3	E
Cadaver Intact	Time 1 vs Time 5	D
Cadaver Intact	Time 2 vs Time 3	E
Cadaver Implanted	Time 1 vs Time 5	D
Cadaver Implanted	Time 2 vs Time 3	E
Difference between Time 1 and 5 - Intact	Cadaver vs Composite	C
Difference between Time 2 and 3 - Intact	Cadaver vs Composite	C
Difference between Time 1 and 5 - Implanted	Cadaver vs Composite	C
Difference between Time 2 and 3 - Implanted	Cadaver vs Composite	C

Table 3.3 Key for Comparison Purpose

A	Determine change due to cutting bone
B	Determine change due to implantion
C	Determine if the composite and cadaver response is similar
D	Determine whether there are residual stresses in bone
E	Determine whether there is creep in bone response

Factors of interest were identified as factors that were used to make comparisons and identify changes in the specimen as they were altered. Factors of interest used in each model are identified in the Table 3.4. Specimen was also included in each test and position was included in the axial strain tests, but these were not considered “factors of interest”. Specimen and position were used to ensure changes between each bone were captured between the stages.

Table 3.4 Factors of interest used in each statistical model to make comparisons are marked with "+"

Tests	Type		Stage			Time				
	Cadaver	Composite	Intact	Cut	Implanted	1	2	3	4	5
Flexural Rigidity	+	+	+	+	+					
Axial Stiffness	+	+	+		+					
Axial Strain	+	+	+		+	+	+	+	+	+

The specimen factor was considered to be a random (observational) variable because the specimens represent a random sample of bones from their respective populations. In the strain test, position was also considered a random variable because those specific sites are just a sample of the strain throughout the bone.

Interaction of type and stage was included in all models to ensure that the effects of the alterations made to the specimens are noted between the different types. In the strain model an interaction between type, stage, and time was also included.

3.6.1. Iterated Reweighted Least Squares

When the ANOVA model was first run with the axial strain data, it was found that there were unequal variances in the axial strain raw data. The fan shape in Figure 3.7 illustrates that as the Mises strain values increase, there is more variance in the data.

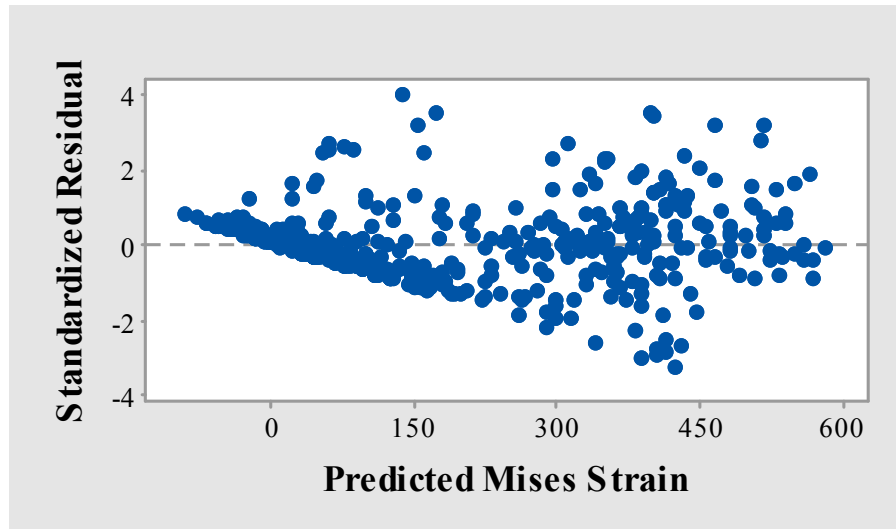


Figure 3.7 Residuals versus fits graph showing unequal variance in the axial strain model

To compensate for the unequal variances an iteration process called iteratively reweighted least squares was used [21]. This process uses the residuals and the fits from the initial ANOVA analysis to estimate the variance function. The logarithms of squared residuals were regressed in a simple model using the fits as the predictors. Then the fits from that model were used to determine the weights ($1/\text{fits}$). The weights are then plugged into the original ANOVA model to find new regression coefficients.

With this data, the coefficients from the weighted regression differed largely from the original model. This led to multiple iterations and revised weights until the coefficients were stabilized. Figure 3.8 illustrates the convergence of the coefficients through 5 iterations. The goal is for the coefficients to reach a consistent value through multiple iterations. The fifth iteration was performed due to the slight increase in the stage variable from iteration three to four.

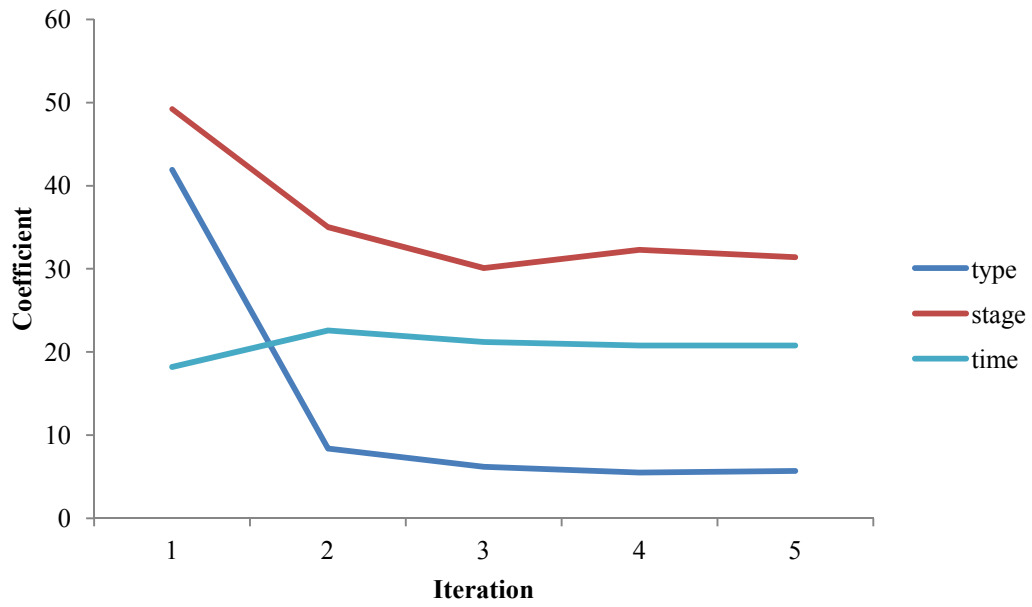


Figure 3.8 Graph showing the convergence of the coefficients through multiple iterations using the iterated reweighted least squares procedure

4. RESULTS

4.1. Composite Bones

In this section the results from the composite bone tests will be presented. Comparisons will be made between each stage to determine whether the modifications made to the bone affect its mechanical properties. Significant differences between stages are highlighted with a p-value less than 0.05. The raw data for these tests can be found in Appendix A.

4.1.1. Flexural Rigidity

The flexural rigidities of the composite femurs were tested in all three stages; intact, cut, and implanted. The composite bones underwent 5 data collection cycles in each test. A repeated measures ANOVA test was used to compare the composite femur flexural rigidity data because it allows the differences for each bone between the stages to be analyzed without correlating the differences between the specimens.

4.1.1.1. Lateral-in-Tension

For composite bones in the lateral-in-tension set up, there was a statistically significant decrease in the flexural rigidity from the intact bone to the cut and implanted bones (p-value < 0.001 in both). There was no evidence of a significant difference between the cut and implanted femurs (p-value = 0.867). The boxplot in Figure 4.1 provides a visual of the comparisons between the stages. In this figure it is clear that the intact femur has a higher flexural rigidity than the cut and implanted bone.

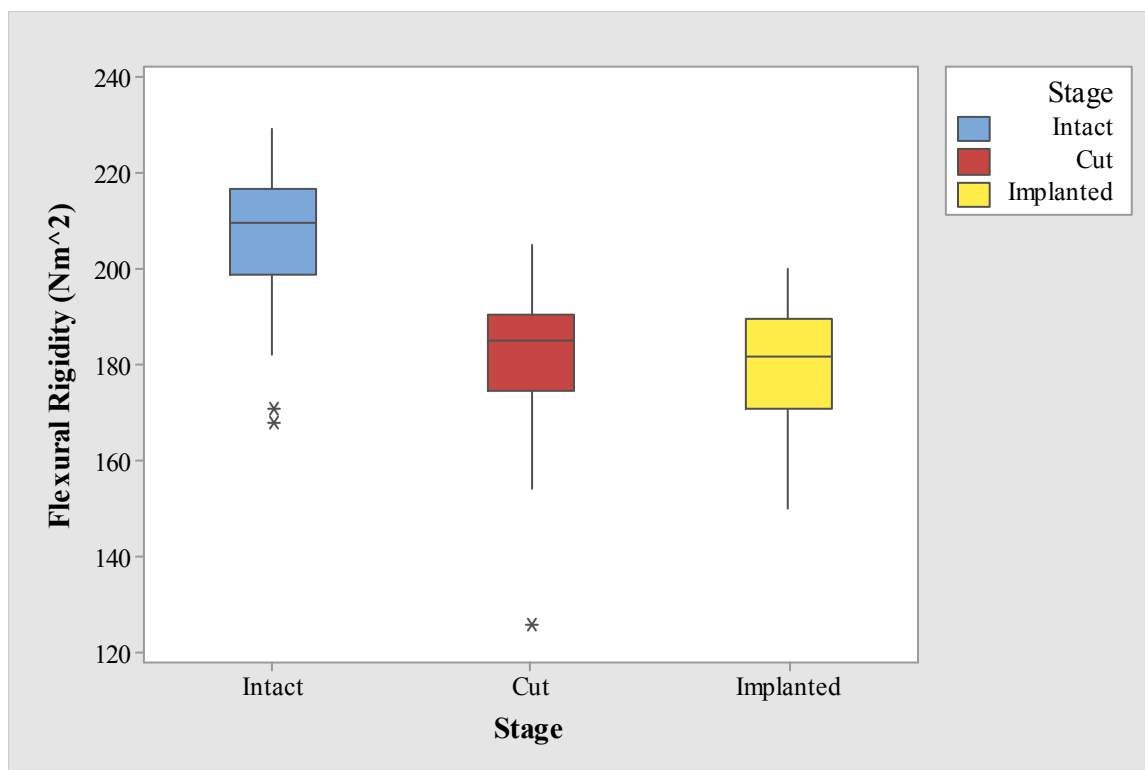


Figure 4.1 Boxplot of flexural rigidity – lateral in tension shows average flexural rigidity for the composite femurs at each stage. Outliers are indicated by *.

4.1.1.2. Anterior-in-Tension

In the anterior-in-tension set up, a difference between the intact bones and the cut and implanted bones was found to be significant with a p-value < 0.001 in both cases. There was no evidence of a significant difference between the cut and implanted bones (p-value = 0.208). Figure 4.2 shows the differences between the means of flexural rigidity between the stages. The differences aren't as pronounced as those associated with the lateral-in-tension but it is still clear that the intact bone has a higher flexural rigidity than the cut and implanted bone.

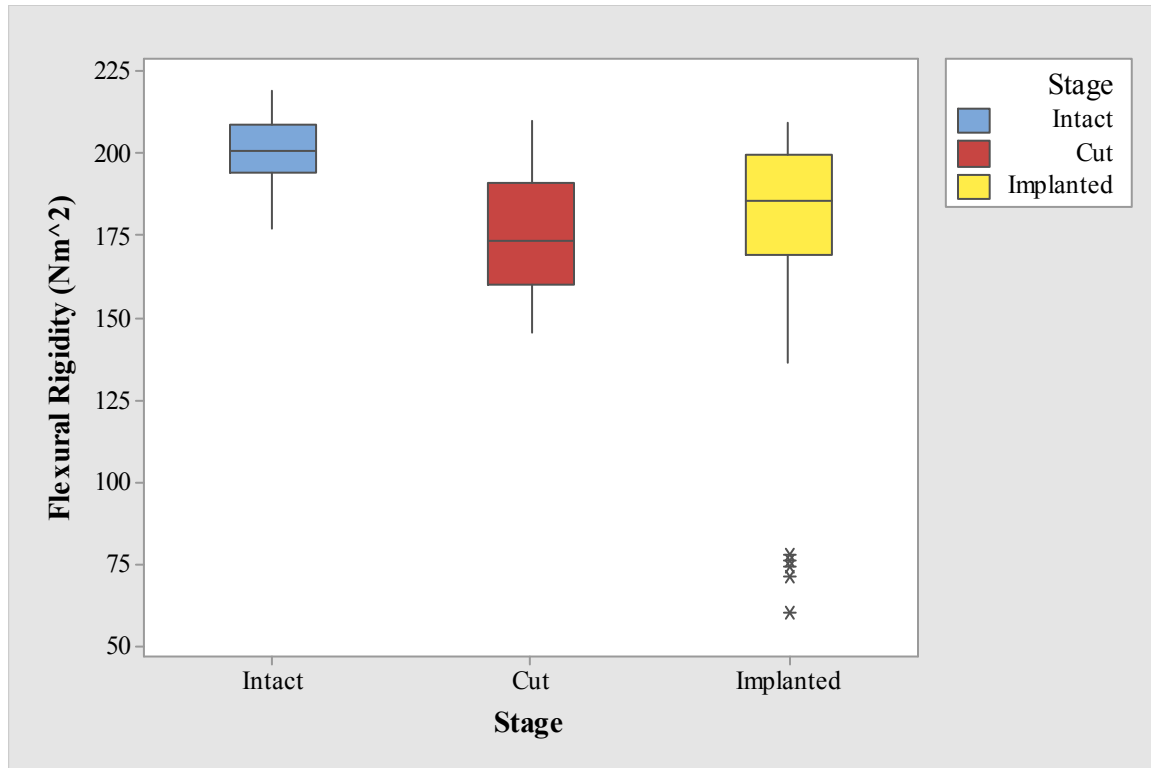


Figure 4.2 Boxplot of flexural rigidity – anterior in tension shows average flexural rigidity for the composite femurs at each stage. Outliers are indicated by *.

4.1.2. Axial Stiffness

The axial stiffness tests were performed at the intact and implanted stages. It was not possible to apply an axial load on the cut femurs because they lacked a femoral head. This test included 8 data collection cycles per bone. It was expected the means for both the intact and implanted femurs would be similar because the implant is designed to undergo normal physiological loading and mimic the natural femur design. It was found that there was no evidence of a significant difference in the axial stiffness between the intact and implanted femur (p -value = 0.159). Figure 4.3 shows how similar the stiffness is between the intact and implanted stages.

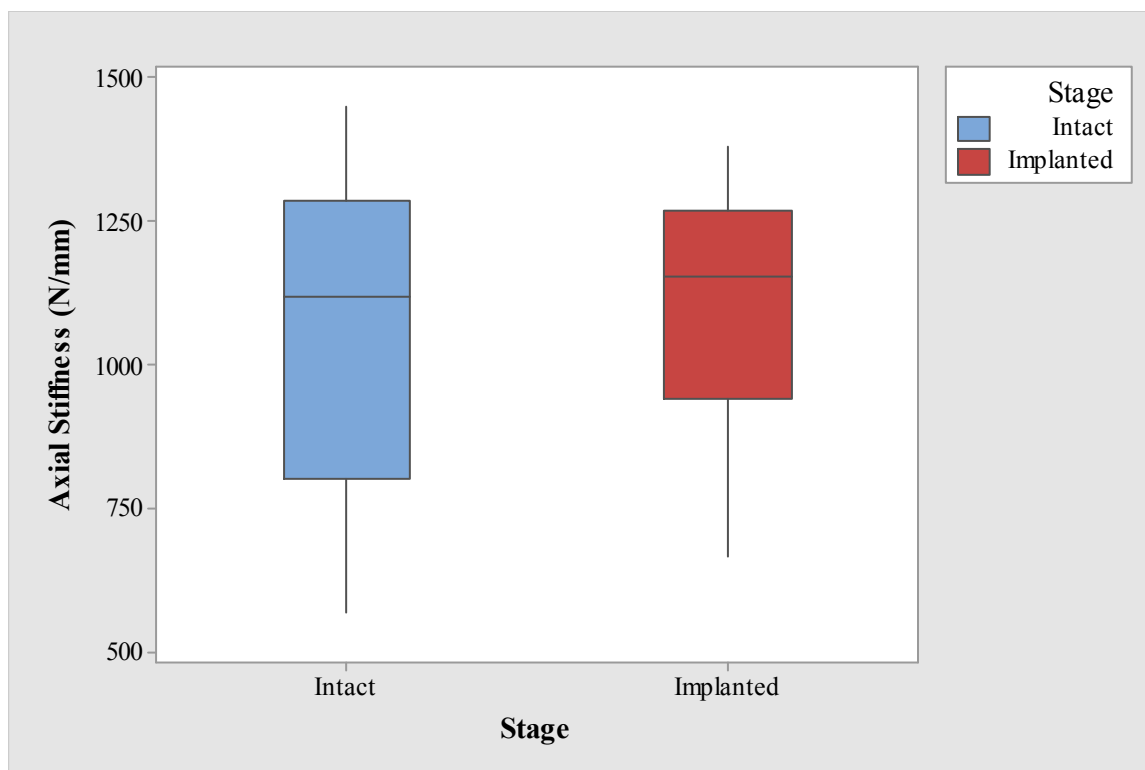


Figure 4.3 Boxplot of axial stiffness shows average stiffness for the composite femurs at each stage.

4.1.3. Axial Strain

In the strain test, Mises strain was compared between time points 1 and 5, and 2 and 3, to ensure that the tests were not permanently deforming the bone. As shown in Table 4.1, in both the intact and the implanted composite femurs there was no significant difference between the strain values at time points 1 and 5, across all positions. Also, there is no significant difference observed between time points 2 and 3 in either intact or implanted bones. This is also shown visually in Figures 4.4 and 4.5.

Table 4.1 Axial Strain ANOVA composite results; significant differences are indicated with a p-value less than 0.05.

Intact	Difference in Mises Strain	95% CI		P-value
Time 1 vs Time 5	-8.3	-36.8	20.2	0.568
Time 2 vs Time 3	28	-181	236	0.793
Implanted	Difference in Mises Strain	95% CI		P-value
Time 1 vs Time 5	14.1	-13.8	42	0.320
Time 2 vs Time 3	99.5	-95.4	294.5	0.316

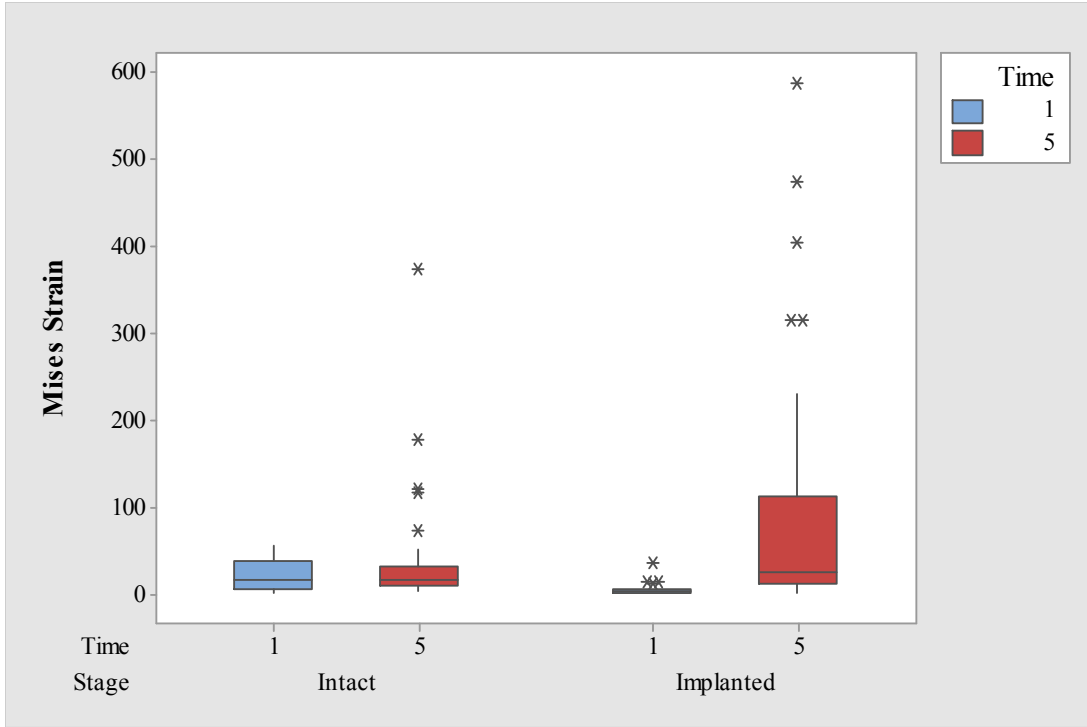


Figure 4.4 Boxplot comparing average Mises strain between times 1 and 5 for both intact and implanted composite femurs. Outliers are indicated with *.

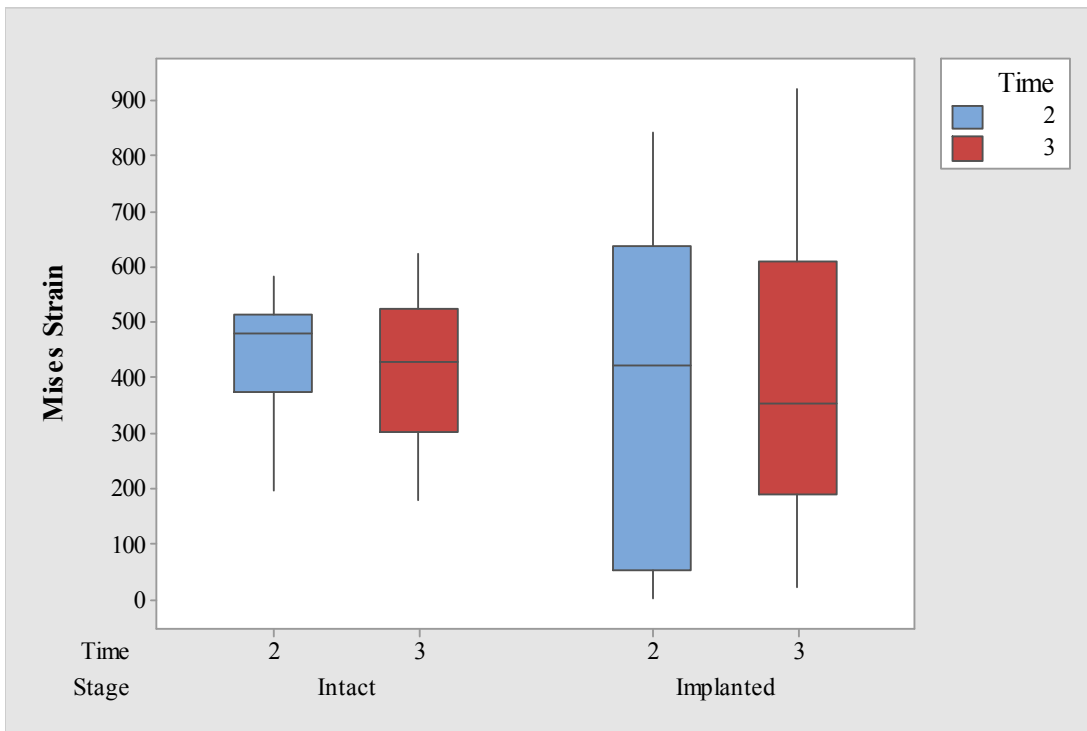


Figure 4.5 Boxplot showing comparison of average Mises Strain between times 2 and 3 for both intact and implanted composite femurs.

4.2. Cadaver Bones

In this section the results from the cadaver bone tests will be presented. Comparisons will be made between each stage to determine whether the modifications made to the bone affect its mechanical properties. Significant differences between stages are highlighted with a p-value less than 0.05. The raw data for these tests can be found in Appendix A.

4.2.1. Flexural Rigidity

The flexural rigidities of the cadaver femurs were tested in all three stages; intact, cut, and implanted. The composite bones underwent 3 data collection cycles in each test. A repeated measures ANOVA test was used to compare the cadaver femur flexural rigidity data because it allows the differences between the stages for each bone to be analyzed without correlating the differences between the specimens.

4.2.2. Lateral-in-Tension

In the lateral-in-tension set-up, a significant change in flexural rigidity from intact to cut bone was found in the cadaver femurs ($p\text{-value} < 0.001$). The flexural rigidity of the cut bone was greater than the intact bone. A p-value of 0.032 indicates a significant difference in flexural rigidity of the intact femur and the implanted femur. These results indicate that the cadaver bone is more rigid after it is cut but then becomes less rigid with the implant. To support this, is a significant difference in the flexural rigidity between the cut and implanted femur ($p\text{-value} < 0.001$). A decrease in rigidity from cut to implanted shows that the bone becomes considerably less rigid when implanted. The average flexural rigidity for the cadaver femurs at each stage is shown in Figure 4.6.

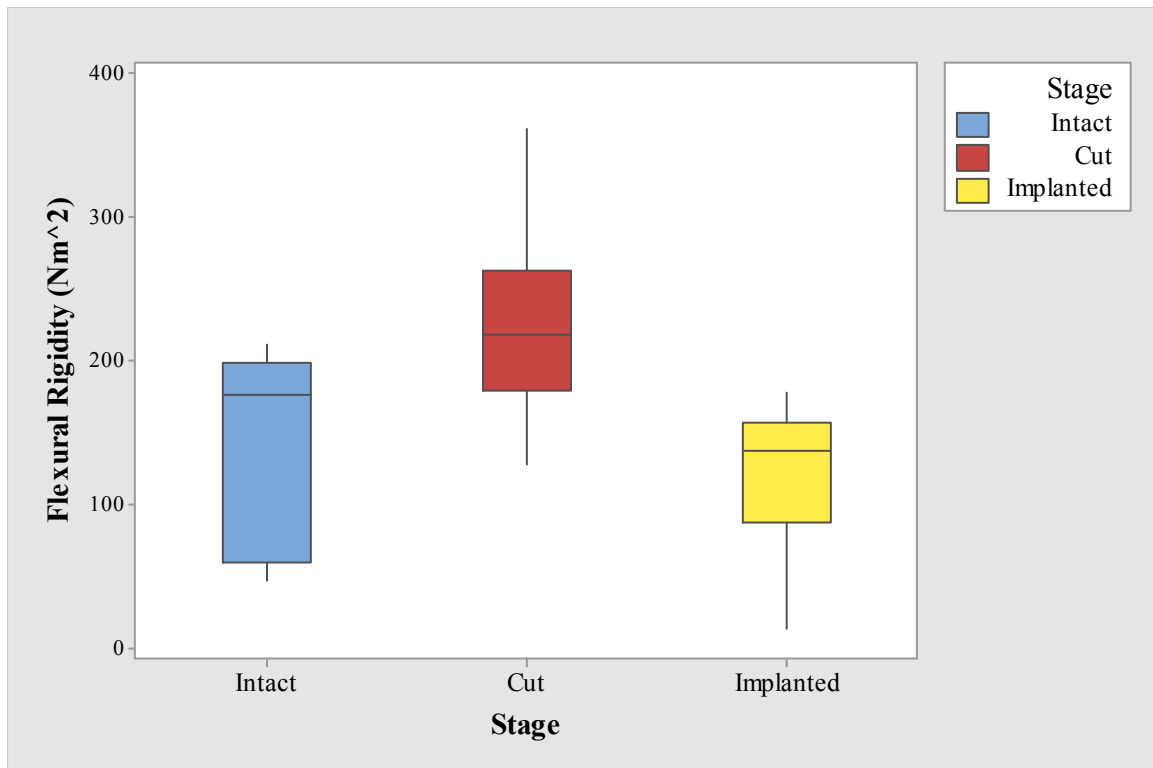


Figure 4.6 Boxplot of flexural rigidity – lateral in tension averages for cadaver specimen at each stage.

4.2.2.1. Anterior-in-Tension

The anterior-in-tension results also showed that the intact and cut bone were statistically different ($p\text{-value} < 0.001$). This is expected with such a drastic cut. However, between the intact bone and the implanted bone there is no evidence of a statistical difference ($p\text{-value} = 0.067$). When comparing the cut bone to the implanted bone, a $p\text{-value}$ of 0.039 indicates a significant difference. The average flexural rigidities for the cadaver femurs at each stage are shown in Figure 4.7.

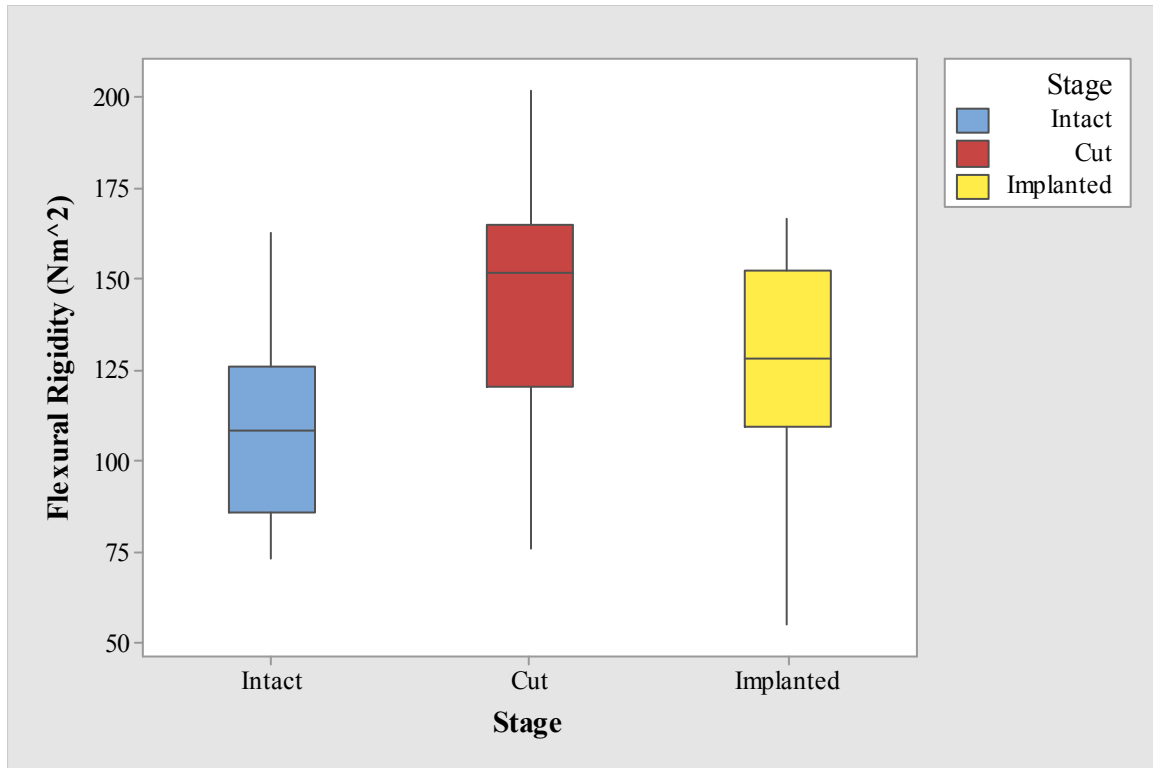


Figure 4.7 Boxplot of flexural rigidity averages for cadaver specimen at each stage

4.2.3. Axial Stiffness

The axial stiffness tests were performed at the intact and implanted stages. It was not possible to apply an axial load on the cut femurs because they lacked a femoral head. This test included 8 data collection cycles per bone. It was found that there was a statistical difference in the stiffness between the intact femur and the implanted femur (p -value < 0.001). The axial stiffness in the implanted femur is higher than in the intact femur. The average axial strains for the cadaver femurs at each stage are shown in Figure 4.8.

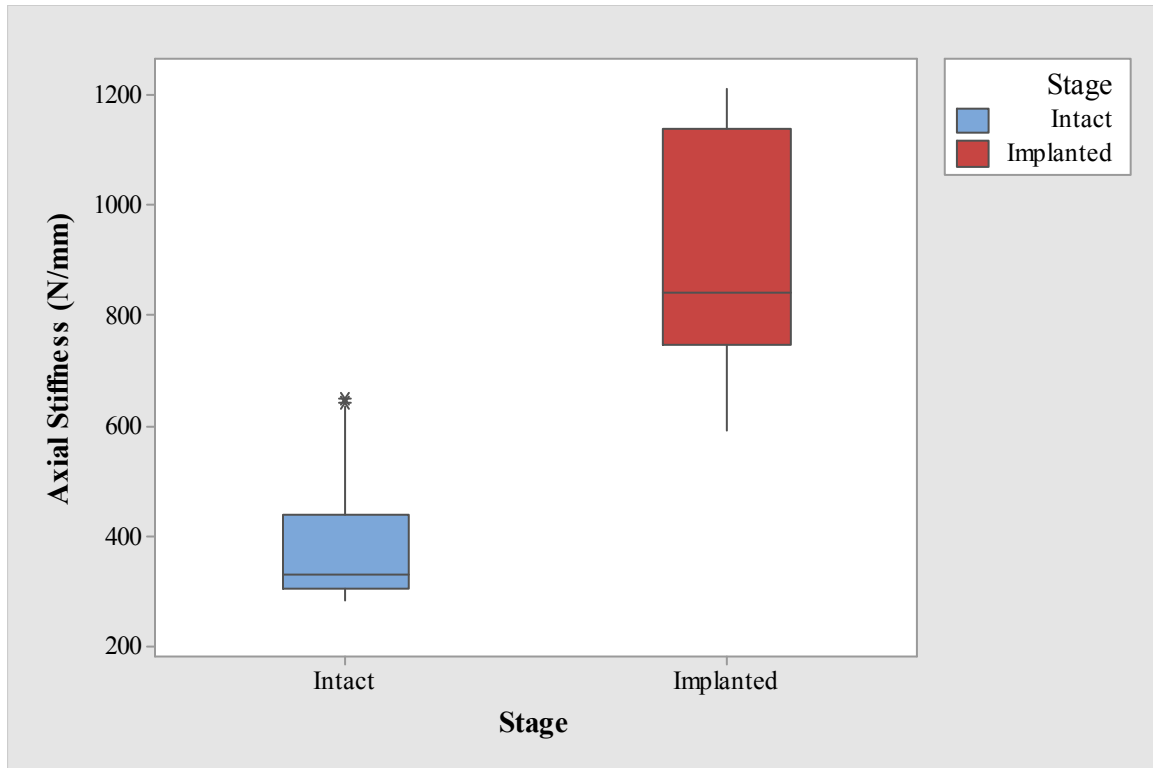


Figure 4.8 Boxplot of axial stiffness averages for cadaver specimen at each stage. Outliers are indicated with *.

4.2.4. Axial Strain

Table 4.4 shows the difference in axial strain in both intact and implanted cadavers between time points 1 and 5, and 2 and 3. These comparisons are shown visually in Figures 4.9 and 4.10. It is clear that in the both stages, there is no significant difference in the strain between time 2 and 3. However, in the implanted femur, there is a significant difference between time 1 and time 5. In Figure 4.9, it appears that the Mises strain values at times 1 and 5 are similar. The significant difference found is due to the weighting used in the ANOVA model.

Table 4.2 Axial Strain ANOVA cadaver result; significant differences are indicated with a p-value less than 0.05

Intact	Difference in Mises Strain	95% CI		P-value
Time 1 vs Time 5	28	-3.8	59.7	0.084
Time 2 vs Time 3	-29.6	-170	110.9	0.679
Implanted				
	Difference in Mises Strain	95% CI		P-value
Time 1 vs Time 5	73.6	32.2	115	0.001
Time 2 vs Time 3	-1.8	-105.9	102.3	0.973

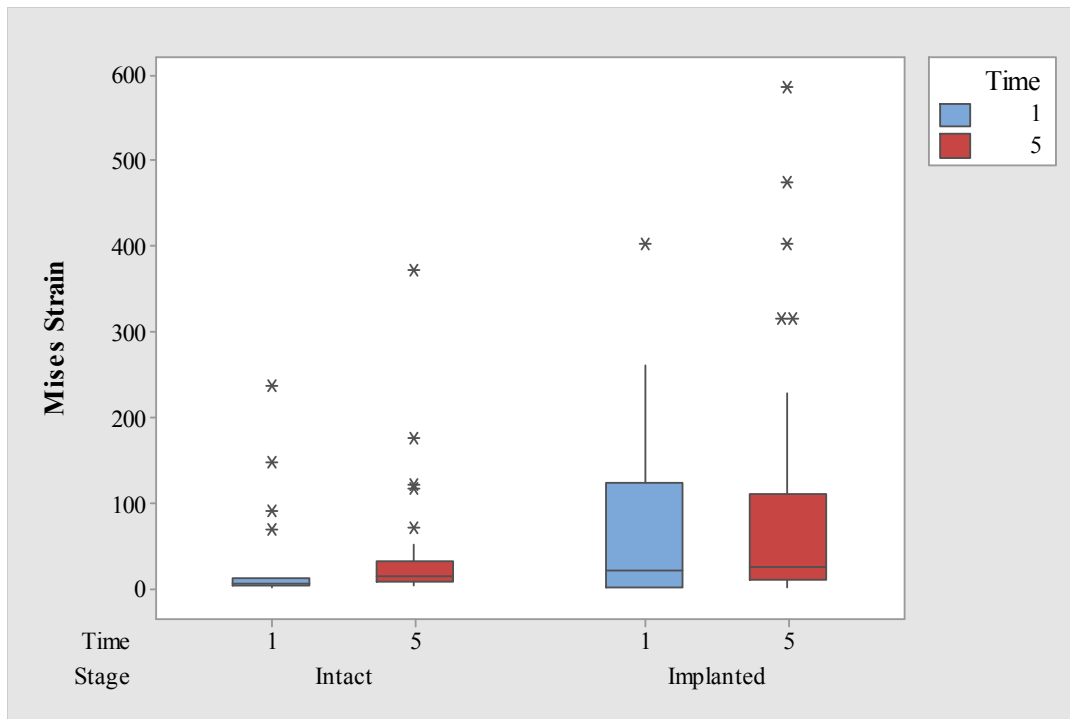


Figure 4.9 Boxplot comparison of average Mises strain between times 1 and 5 for both intact and implanted cadaver femurs. Outliers are identified with *.

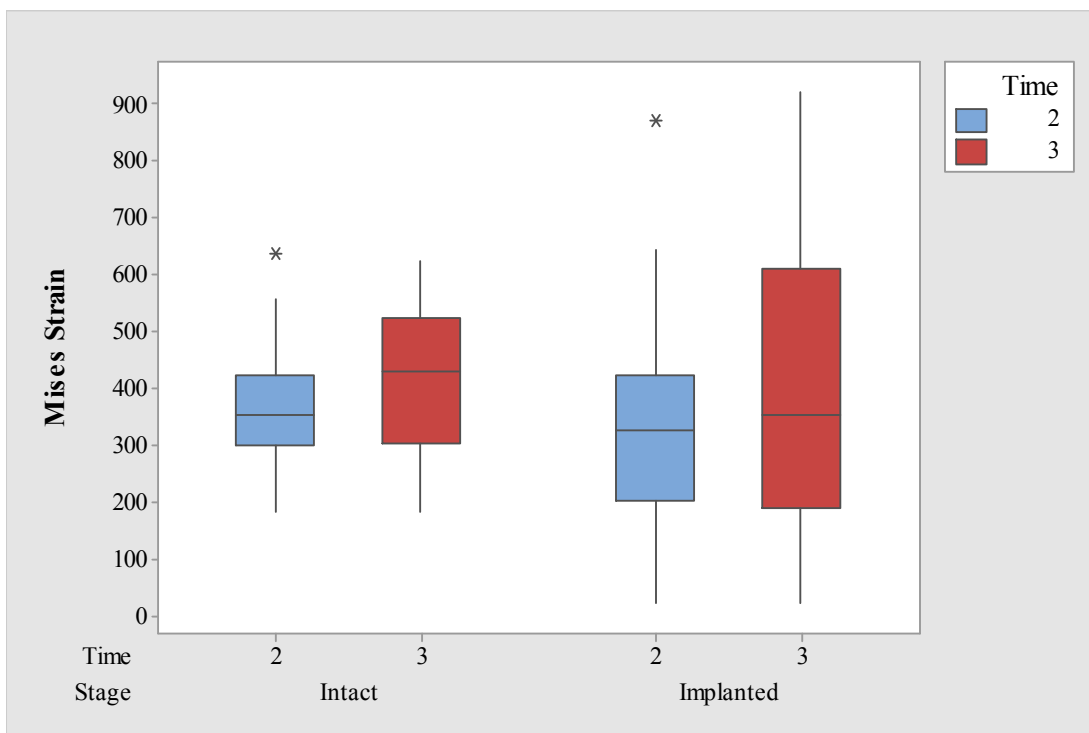


Figure 4.10 Boxplot comparison of average Mises strain between times 1 and 5 for both intact and implanted cadaver femurs. Outliers are identified with *.

4.3. Comparison Between Composite and Cadaver Femurs

In this section comparisons will be made between each type to determine whether the composite and cadaver bones react differently to the modifications made. Comparisons will be made between types at each stage as well as between the changes from stage to stage. Significant differences between types are highlighted with a p-value less than 0.05.

4.3.1. Flexural Rigidity

4.3.1.1. Lateral-in-Tension

When comparing the stages across the type of specimen, the composite bones and cadaver bones are significantly different at each stage, as shown in Table 4.5.

Table 4.3 Comparison of flexural rigidity between types at each stage. Statistically significant differences indicated with a p-value less than 0.05.

Intact	Difference in Flexural Rigidity	95% CI		P-value
Cadaver vs Composite	42.8	0.5	85.2	0.047
Cut				
Cadaver vs Composite	-62.7	-105	-20.4	0.004
Implanted				
Cadaver vs Composite	43.7	1.4	86	0.043

However, it is not so important that the composite and cadaver bones have exactly the same values, but that they react to the alterations in the same fashion. Table 4.6 shows the differences between the stages for each type. The clear difference is the statistically significant difference between rigidity of the cut and implanted stages in the cadaver bone while there is no difference between these stages in the composite bone.

Table 4.4 Flexural rigidity ANOVA results for both composite and cadaver specimen in the lateral in tension set-up

Statistically significant differences indicated with a p-value less than 0.05.

Composite	Difference in Flexural Rigidity	95% CI		P-value
Intact vs Cut	-24.2	-43.03	-5.37	0.012
Intact vs Implanted	-25.8	-44.63	-6.97	0.008
Cut vs Implanted	-1.6	-20.43	17.23	0.867
Cadaver				
Intact vs Cut	81.3	57	105.6	0.000
Intact vs Implanted	-26.7	-51	-2.4	0.032
Cut vs Implanted	-108	-132.3	-83.7	0.000

4.3.1.2. Anterior-in-Tension

In this set-up, the intact and implanted stages were statistically different, but at the cut stage there was no difference between the types. This is shown in Table 4.5.

Table 4.5 Comparison of flexural rigidity between types at each stage. Statistically significant differences indicated with a p-value less than 0.05.

Intact	Difference in Flexural Rigidity	95% CI		P-value
Cadaver vs Composite	75	47.6	102.6	0.000
Cut				
Cadaver vs Composite	18.9	-8.7	46.4	0.178
Implanted				
Cadaver vs Composite	28.1	0.5	55.7	0.046

In this set-up, the cadaver specimens' flexural rigidity increased from intact to cut, but then decreased from cut to implanted. In the composite specimens, the flexural rigidity decreases from intact to cut, as well as cut to implanted.

Table 4.6 Flexural rigidity ANOVA results for both composite and cadaver specimen in the anterior in tension set-up

Statistically significant differences indicated with a p-value less than 0.05.

Composite	Difference in Flexural Rigidity	95% CI		P-value
Intact vs Cut	-24.63	-36.9	-12.37	0.000
Intact vs Implanted	-32.1	-44.37	-19.38	0.000
Cut vs Implanted	-7.47	-19.73	4.8	0.231
Cadaver				
Intact vs Cut	31.5	15.67	47.33	0.000
Intact vs Implanted	14.78	-1.06	30.61	0.067
Cut vs Implanted	-16.72	-32.56	-0.89	0.039

4.3.2. Axial Stiffness

In both the intact and the implanted stages, there were significant differences between the composite and cadaver bones. However, in the intact stage, the composite specimens had a higher stiffness and in the implanted stage the cadaver specimens had a higher stiffness.

Table 4.7 Comparison of axial stiffness between types at each stage. Statistically significant differences indicated with a p-value less than 0.05.

Intact	Difference in Axial Stiffness	95% CI		P-value
Cadaver vs Composite	254.9	155.6	354.2	0.000
Implanted				
Cadaver vs Composite	-230.6	-329.9	-131.3	0.000

When comparing the change between the stages across the types, it is clear that there is more variability in the cadaver specimen. This is expected because of the variation between the cadaver specimens. They are not all the same size or shape and they also have variations in their quality.

Table 4.8 Axial stiffness ANOVA results for both composite and cadaver specimen; statistically significant differences indicated with a p-value less than 0.05.

Composite	Difference in Axial Stiffness	95% CI		P-value
Intact vs Implanted	39	-14.1	92.1	0.149
Cadaver				
Intact vs Implanted	524.5	131.2	329.9	0.000

4.3.3. Axial Strain

When comparing the changes in axial strain across the specimen, the confidence intervals given in the ANOVA tests can be evaluated to show differences in variation. When comparing times 1 and 5, in both intact and implanted stages, the cadaver specimens have a larger confidence interval than the composite specimens. The cadaver specimens also have a larger difference from time 1 to 5. However, when comparing times 2 and 3, the cadaver has a tighter confidence interval in both stages and a significantly smaller difference in the implanted stage.

Table 4.9 Comparison of axial strain difference across times for both types and stages. Significant differences are indicated with a p-value less than 0.05.

Composite Intact	Difference in Mises Strain	95% CI		P-value
Time 1 vs Time 5	-8.3	-36.8	20.2	0.568
Time 2 vs Time 3	28	-181	236	0.793
Cadaver Intact				
Time 1 vs Time 5	28	-3.8	59.7	0.084
Time 2 vs Time 3	-29.6	-170	110.9	0.679
Composite Implanted				
Time 1 vs Time 5	14.1	-13.8	42	0.320
Time 2 vs Time 3	99.5	-95.4	294.5	0.316
Cadaver Implanted				
Time 1 vs Time 5	73.6	32.2	115	0.001
Time 2 vs Time 3	-1.8	-105.9	102.3	0.973

5. DISCUSSION

5.1. Composite Bones

The composite bones behaved as expected in all testing set-ups. The flexural rigidity was compromised after the cut but remained stable when implanted. The axial loading tests showed that the cut and implantation did not affect the stiffness or strain in the bone.

5.1.1. Flexural Rigidity

In the composite bones, it was found that flexural rigidity decreased after the femur was cut and was not regained after implantation. However, there was no difference in flexural rigidity found between the cut and implanted femurs.

5.1.1.1. Lateral-in-Tension

It was found that there was a significant difference in the flexural rigidity between the intact femur and the cut and femur with implant when loaded with the lateral-in-tension. This change in bone properties was anticipated after a dramatic cut such as this. It was also expected that the flexural rigidity would decrease when the bone is altered. The analysis showed that difference between the cut and femurs with implants was not significant. As the major changes to the bones structure had already occurred, this is a projected outcome. Implanting the composite femurs did not change the flexural rigidity after the cut had been made.

5.1.1.2. Anterior-in-Tension

A significant difference was found between the intact femur and the cut and implanted femurs when loaded with the anterior-in-tension. There was no evidence of a significant difference between the cut femur and the femur with implant. These results mirror those from the lateral in tension set up and confirm the conclusion that the initial cut has an effect on the flexural rigidity of bone but inserting the implant does not.

5.1.2. Axial Stiffness

No evidence of a significant difference of axial stiffness between the intact femur and the femur with implant was found. This was anticipated because the implant is designed to mimic the natural bone as it supports an axial load. The cut does not affect the bone's ability to support an axial load because the bone is loaded at the femoral head rather than the shaft, where the cortical bone analog has been compromised.

5.1.3. Axial Strain

In the axial strain time comparisons between times 1 and 5, there were no statistical differences found in either the intact bone or the implanted bone. This indicates that the composite bone is not carrying any residual stress after being loaded. No evidence of a statistical difference of the strain between times 2 and 3 indicates that there is no creep in the femur during the 15 minute loading time. The implant does not affect the ability of the composite bone to undergo a load without plastically deforming.

5.2. Cadaver Bones

The cadaveric specimen produced results that were puzzling, such as increased flexural rigidity after the cut was made. However, axial stiffness increased with implantation which could be anticipated. Residual strains were found in the femurs with implants, which is expected after extensive testing such as this.

5.2.1. Flexural Rigidity

The flexural rigidity test results in the cadaver specimen were more varied than those in the composite specimen. There were differences found between the intact bones and the cut and implanted bones but also between the cut and implanted bones, which was not found in the composite specimen. The results show that the cadaveric bones become more rigid after they have been cut, but then lose the increased rigidity when they are implanted. A possible

explanation for this could be the variations in the cadaveric bones. These bones have inconsistent curvatures as well as cross-sections. A small variation in set-up between stages could have an impact on the flexural rigidity.

5.2.1.1. Lateral-in-Tension

It was found that the flexural rigidity increased from intact to cut femur in the cadaver specimen in the lateral set-up. This is unexpected, especially when compared to the composite specimen reaction. There was a significant difference found between the intact femurs and the femurs with implants; however the rigidity decreased from the intact to the implanted femur as expected. The largest difference was a decrease in rigidity from the cut femurs to the femurs with implants. This supports the idea that implantation is damaging to the cadaveric bone.

5.2.1.2. Anterior-in-Tension

In the anterior set-up, it was found that the rigidity increased from the intact to the implanted femurs, which mimics the lateral results. However, there was no significant difference between the intact and implanted femurs. In this set-up, the implanted bone mimics the intact bone results, which is the desired outcome for the implant. There was a significant difference found between the cut and implanted femurs, however it was not as large as in the lateral set-up.

5.2.2. Axial Stiffness

A significant difference was found between axial stiffness of the intact and implanted cadaveric femurs. The stiffness actually increased in the femurs that were implanted when compared to the intact. The implant appears to be able to withstand the loading better than the cadaveric bone. This is anticipated due to the poorer bone quality of the cadaveric bones used in these tests.

5.2.3. Axial Strain

In the axial strain tests, times 1 and 5 were compared in both the intact bones and the implanted bones. No significant difference was found in the intact bones, showing that there are no residual strains in the bone, which is expected. However, in the implanted bone there was a significant difference. The strain in the bone at time 5 was higher than at time 1. This can be attributed in part to the implant but also to the volume of cycles these bones were put through. This was the last test performed on these bones and deterioration of the bone is expected after testing of this quantity. There was no significant difference found between times 2 and 3 in either the intact or the implanted bone. This shows that there is no creep in the cadaveric bone during the 15 minute load hold.

A substantial number of outliers in the strain data for the cadaver tests is concerning. Some of this may be due to only one cycle of this test being performed for each specimen; it could also be due to zeroing issues when preparing the test. However, it could also be an indication of residual stresses in the bones. This can only be determined with further testing.

5.3. Comparison Between Composite and Cadaver Femurs

The important comparisons between the composite and cadaver specimen is made when analyzing the change in the material properties after the cut is made. In fact, the only result that was not statistically different when directly comparing the composite and cadaver specimen was flexural rigidity in the anterior at the cut stage. This section will focus on the comparison of the changes between the stages for composite and cadaver specimen.

5.3.1. Flexural Rigidity

5.3.1.1. Lateral-in-Tension

For the intact versus cut comparison, both composite and cadaver specimen had a significant change, but the composite rigidity decreased while the cadaver rigidity increased.

While the cut is harmful to the composite bone, it increased the rigidity in the cadaver bone. This difference in response between the cadaver and composite bones is unexpected. The repeated thawing and refreezing cycles the cadaver bones underwent, as well as the potting and unpotting procedures could have had a residual effect on the mechanical properties of the cadaveric bones.

Between the cut and implanted stage, it is found that there is no significant difference in the composite femurs but there is a significant decrease in the flexural rigidity of the cadaver femurs. The composite femurs are not affected by the installation of the implant while the cadaver femurs are. This is a more anticipated result. The cadaveric bone is more sensitive to changes in structure and has a higher probability of plastic deformation than the composite bones. This result supports the idea that composite bones are more stable to use for implant testing, but sheds light on the loss of bone response to implantation when cadavers are not used.

5.3.1.2. Anterior-in-Tension

The change from intact to cut was significant in both the composite and cadaver specimen; however the rigidity increased in the cadaver femurs while it decreased in the composite femurs. This mirrors the results found in the lateral in tension set up and confirms the idea that the cadaveric bones are affected by factors external to this experiment.

No significant difference was found between the intact and implanted cadaver specimen, while a significant difference was found in the composite specimen. This indicates that the implanted cadaver will behave similarly to the intact femur, which is the ultimate goal of the implant.

As in the lateral set-up, there was no significant difference found between the cut and implanted composite specimen and a significant difference in the cadaver specimen. This can again be attributed to the increased sensitivity of the cadaver specimen.

5.3.2. Axial Stiffness

When comparing axial stiffness, the composite specimen did not have a significant difference but the cadaver specimen did. From this it can be inferred that the composite bones are better equipped to deal with structural changes than the cadaver bones. This would support the use of composite bones in testing in scenarios such as micro-motion but not when looking at the effect of implantation on the shaft of the bone.

5.3.3. Axial Strain

When comparing axial strain at times 1 and 5, it was found that the composite intact and implanted femurs did not have a significant difference, but the implanted cadaver did. This can be attributed to the degenerative nature of the cadaver bones. At the point in which they were implanted, the cadaver specimens had gone through various thaw/refreezing phases as well as the repeated loadings. The composite bones are not in danger of “drying out” or losing their natural properties. The larger variation in the cadaver Mises strain data is expected due to the varied sizes, shapes, and quality of the cadaver bones.

A comparison of times 2 and 3, shows no significant difference in either type or stage. Despite the heavy load and many cycles each specimen was put through, there was no creep in the strain throughout the hold period. This supports the results from the testing done and the assumption that there is no plastic deformation. There was greater variation in the composite specimen at this comparison. This indicates that the composite bones have some variances when subjected to a sustained load. However, this is not considered a significant issue because there was no statistical evidence of a change in the strain or residual strains in the bone.

5.4. Comparison to Heiner Results

To evaluate the execution of the methods, results were compared to Heiner [4]. The averages for each bone type (intact stage) in each study are presented in Table 5.1. This

comparison shows that the results obtained are of the same order of magnitude as those found previously. The marginally higher flexural rigidity in this study can be attributed to the additional mold restraining rotation at the distal end of the femur during testing. The extreme difference in the axial stiffness could be due to poorer bone quality of specimen in this study, or due to a discrepancy in loading set-up (i.e. alignment or positioning). Heiner removed the specimen after each test cycle, while in this study femurs were set-up once and subjected to each cycle.

Table 5.1 Averages for flexural rigidity and axial stiffness of intact femurs in this study and Heiner. AT = anterior surface in tension; LT = lateral surface in tension

Study	Bone Type	Flexural Rigidity (Nm ²), AT	Flexural Rigidity (Nm ²), LT	Axial Stiffness (N/mm)
Heiner	Cadaveric	317	290	2480
Heiner	Composite	241	273	1860
Adams	Cadaveric	253	329	388
Adams	Composite	449	460	1044

6. CONCLUSION

At every stage, differences in the behavior of the cadaver and composite specimen were shown. However, the goal of this thesis was to determine if the changes in the composite specimen between the stages successfully mirrors the changes in the cadaver specimen. In the flexural rigidity tests, there was not much continuity between the composite and cadaver specimen. In both the lateral and anterior set-up, the cadaver specimens had increased flexural rigidity from the intact to the cut stages, while the composite specimens exhibited a decreased rigidity. When comparing the cut to implanted stages there was a consistent decrease in the flexural rigidity but it was only statistically significant in the cadaver specimen. The results showed that the implant has an effect on the specimen, but the composite bone had a more predictable reaction to the surgical modifications.

In the axial tests, the composite bone did not have much change from the intact to the implanted stage, but the cadaver bone had a significant change. It is expected that the bone would be affected adversely by an implant like this being driven down the shaft. These tests show that the composite axial stiffness is not affected by the implant in the same manner as the cadaver. Part of this difference may be due to the inconsistencies of the cadaver bones. The increased cycles in this test may have contributed to the variable reactions of the cadaver bones.

The axial strain is a good test to encourage the use of composite bones because of their consistency and resistance to negative influences of testing. When comparing the strain at time points 1 and 5, the lasting effects of the test are shown. The composite specimens did not have a significant difference in strain between times 1 and 5 in either stage, while the implanted cadaver was found to have residual strains. However, the implanted cadaver showed the least resistance to increased strain over time when comparing times 2 and 3.

The results presented support the use of the composite femurs in testing. The composite bones are not compromised during repeated testing and exposure time. The results of the composite bones throughout testing are also more predictable. Composite bones also provide a means to control for size, shape, and composition that cadaver bones do not.

6.1. Future Work

Future work could include increased specimen testing. While 6 specimens per type was robust enough for this initial testing, to make more conclusions about the true differences between the composite and cadaver bones more data is required. It would also be beneficial to maintain the same number of cycles between the cadaver and composite specimen. To determine whether the outliers in the strain data are indicative of residual strains in the femurs, more cycles of the axial strain test are required. This would be advantageous in determining how bones are reacting to the many cycles of testing. Additionally, strain measurements could be taken during flexural rigidity tests.

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APPENDICES

1. Appendix A: Test Data
2. Appendix B: ANOVA Test Results
3. Appendix C: Flexural Rigidity Equation Derivation

APPENDIX A: Test Data

1. Flexural Rigidity – Composite

Lateral in Tension		Flexural Rigidity (Nm ²)		
		Intact	Cut	Implanted
Composite 1	Preconditioning	244	331	281
Composite 1	Test 2	386	416	414
Composite 1	Test 3	419	426	432
Composite 1	Test 4	435	455	449
Composite 1	Test 5	458	465	453
Composite 1	Test 6	458	472	460
Composite 2	Preconditioning	246	221	311
Composite 2	Test 2	455	354	400
Composite 2	Test 3	490	382	414
Composite 2	Test 4	508	398	421
Composite 2	Test 5	518	412	423
Composite 2	Test 6	524	423	423
Composite 3	Preconditioning	248	331	317
Composite 3	Test 2	460	290	423
Composite 3	Test 3	497	426	442
Composite 3	Test 4	501	432	451
Composite 3	Test 5	522	449	455
Composite 3	Test 6	527	455	460
Composite 4	Preconditioning	207	368	251
Composite 4	Test 2	435	393	354
Composite 4	Test 3	462	419	380
Composite 4	Test 4	481	430	396
Composite 4	Test 5	497	435	407
Composite 4	Test 6	501	442	414
Composite 5	Preconditioning	288	308	212
Composite 5	Test 2	465	403	345
Composite 5	Test 3	483	435	368
Composite 5	Test 4	483	437	377
Composite 5	Test 5	485	432	386
Composite 5	Test 6	485	437	393
Composite 6	Preconditioning	99	239	290
Composite 6	Test 2	393	366	393
Composite 6	Test 3	455	393	412
Composite 6	Test 4	469	414	423
Composite 6	Test 5	476	414	430
Composite 6	Test 6	485	442	435

Anterior in Tension		Flexural Rigidity (Nm ²)		
		Intact	Cut	Implanted
Composite 1	Preconditioning	117	248	67
Composite 1	Test 2	407	359	380
Composite 1	Test 3	428	389	396
Composite 1	Test 4	437	407	403
Composite 1	Test 5	446	421	409
Composite 1	Test 6	455	428	414
Composite 2	Preconditioning	382	276	340
Composite 2	Test 2	428	368	419
Composite 2	Test 3	435	393	432
Composite 2	Test 4	451	403	442
Composite 2	Test 5	446	414	449
Composite 2	Test 6	449	419	455
Composite 3	Preconditioning	340	150	237
Composite 3	Test 2	469	391	421
Composite 3	Test 3	485	421	451
Composite 3	Test 4	497	437	465
Composite 3	Test 5	501	446	476
Composite 3	Test 6	504	455	481
Composite 4	Preconditioning	368	308	124
Composite 4	Test 2	439	384	138
Composite 4	Test 3	449	384	163
Composite 4	Test 4	455	384	170
Composite 4	Test 5	460	361	175
Composite 4	Test 6	462	366	179
Composite 5	Preconditioning	400	163	271
Composite 5	Test 2	465	334	313
Composite 5	Test 3	476	338	391
Composite 5	Test 4	481	359	414
Composite 5	Test 5	490	368	439
Composite 5	Test 6	488	386	458
Composite 6	Preconditioning	393	370	363
Composite 6	Test 2	460	453	446
Composite 6	Test 3	469	462	460
Composite 6	Test 4	476	474	465
Composite 6	Test 5	478	478	472
Composite 6	Test 6	478	483	476

2. Flexural Rigidity – Cadaver

Lateral in Tension		Flexural Rigidity (Nm ²)		
		Intact	Cut	Implanted
MD2675	Preconditioning	290	106	145
MD2675	Test 2	412	292	301
MD2675	Test 3	451	412	340
MD2675	Test 4	462	449	368
WV0103	Preconditioning	81	124	101
WV0103	Test 2	110	412	117
WV0103	Test 3	124	527	294
WV0103	Test 4	106	612	334
PA1227	Preconditioning	83	150	170
PA1227	Test 2	138	340	343
PA1227	Test 3	150	412	380
PA1227	Test 4	129	437	407
MD1537	Preconditioning	377	205	225
MD1537	Test 2	329	476	331
MD1537	Test 3	377	566	357
MD1537	Test 4	396	598	375
GA0618	Preconditioning	306	271	0
GA0618	Test 2	460	628	30
GA0618	Test 3	485	773	78
GA0618	Test 4	474	830	55
NJ1747	Preconditioning	400	110	154
NJ1747	Test 2	430	446	225
NJ1747	Test 3	446	527	242
NJ1747	Test 4	455	566	253

Anterior in Tension		Flexural Rigidity (Nm ²)		
		Intact	Cut	Implanted
MD2675	Preconditioning	64	104	168
MD2675	Test 2	168	260	301
MD2675	Test 3	205	285	338
MD2675	Test 4	228	299	354
WV0103	Preconditioning	340	209	253
WV0103	Test 2	347	308	336
WV0103	Test 3	366	354	368
WV0103	Test 4	375	368	384
PA1227	Preconditioning	147	48	177
PA1227	Test 2	191	350	248
PA1227	Test 3	200	380	285
PA1227	Test 4	184	407	294
MD1537	Preconditioning	354	140	170
MD1537	Test 2	262	283	253
MD1537	Test 3	258	350	276
MD1537	Test 4	260	382	292
GA0618	Preconditioning	131	170	120
GA0618	Test 2	186	370	294
GA0618	Test 3	212	414	350
GA0618	Test 4	242	465	359
NJ1747	Preconditioning	150	113	37
NJ1747	Test 2	267	175	127
NJ1747	Test 3	285	193	145
NJ1747	Test 4	306	202	147

3. Axial Stiffness – Composite

Axial Stiffness (N/mm)		Intact	Implanted
Composite 1	Preconditioning	512	765
Composite 1	Preconditioning	617	982
Composite 1	Test 3	632	1033
Composite 1	Test 4	629	1074
Composite 1	Test 5	623	1094
Composite 1	Test 6	622	857
Composite 1	Test 7	568	1333
Composite 1	Test 8	628	1164
Composite 1	Test 9	617	1164
Composite 1	Test 10	593	1352
Composite 2	Preconditioning	1141	1006
Composite 2	Preconditioning	1233	1136
Composite 2	Test 3	1251	1149
Composite 2	Test 4	1265	1164
Composite 2	Test 5	1271	1161
Composite 2	Test 6	1282	1151
Composite 2	Test 7	1285	1152
Composite 2	Test 8	1291	1151
Composite 2	Test 9	1292	1150
Composite 2	Test 10	1294	1158
Composite 3	Preconditioning	836	966
Composite 3	Preconditioning	1022	1213
Composite 3	Test 3	1085	1232
Composite 3	Test 4	1103	1245
Composite 3	Test 5	1117	1251
Composite 3	Test 6	1116	1258
Composite 3	Test 7	1129	1261
Composite 3	Test 8	1136	1266
Composite 3	Test 9	1143	1268
Composite 3	Test 10	1150	1268

Axial Stiffness (N/mm)		Intact	Implanted
Composite 4	Preconditioning	643	914
Composite 4	Preconditioning	941	944
Composite 4	Test 3	1038	954
Composite 4	Test 4	1073	967
Composite 4	Test 5	1095	936
Composite 4	Test 6	1107	937
Composite 4	Test 7	1118	938
Composite 4	Test 8	1128	944
Composite 4	Test 9	1146	946
Composite 4	Test 10	1144	949
Composite 5	Preconditioning	1096	821
Composite 5	Preconditioning	1240	1226
Composite 5	Test 3	1284	1274
Composite 5	Test 4	1313	1308
Composite 5	Test 5	1325	1323
Composite 5	Test 6	1447	1337
Composite 5	Test 7	1339	1343
Composite 5	Test 8	1345	1363
Composite 5	Test 9	1355	1378
Composite 5	Test 10	1356	1369
Composite 6	Preconditioning	312	456
Composite 6	Preconditioning	548	659
Composite 6	Test 3	656	668
Composite 6	Test 4	734	670
Composite 6	Test 5	789	671
Composite 6	Test 6	791	672
Composite 6	Test 7	829	673
Composite 6	Test 8	852	673
Composite 6	Test 9	871	673
Composite 6	Test 10	868	675

4. Axial Stiffness – Cadaver

Axial Stiffness (N/mm)		Intact	Implanted
GA0618	Preconditioning	499	969
GA0618	Preconditioning	613	790
GA0618	Test 3	623	672
GA0618	Test 4	649	1026
GA0618	Test 5	640	1106
GA0618	Test 6	631	1148
GA0618	Test 7	634	1170
GA0618	Test 8	625	1190
GA0618	Test 9	629	1202
GA0618	Test 10	635	1209
MD1537	Preconditioning	331	593
MD1537	Preconditioning	336	663
MD1537	Test 3	328	599
MD1537	Test 4	316	743
MD1537	Test 5	309	767
MD1537	Test 6	307	786
MD1537	Test 7	304	798
MD1537	Test 8	299	793
MD1537	Test 9	284	816
MD1537	Test 10	284	830
MD0645	Preconditioning	284	464
MD0645	Preconditioning	315	670
MD0645	Test 3	330	718
MD0645	Test 4	327	762
MD0645	Test 5	332	786
MD0645	Test 6	330	800
MD0645	Test 7	335	814
MD0645	Test 8	328	824
MD0645	Test 9	331	835
MD0645	Test 10	332	843

Axial Stiffness (N/mm)		Intact	Implanted
NJ1747	Preconditioning	244	1027
NJ1747	Preconditioning	321	1071
NJ1747	Test 3	338	1106
NJ1747	Test 4	330	1121
NJ1747	Test 5	329	1131
NJ1747	Test 6	329	1137
NJ1747	Test 7	325	1145
NJ1747	Test 8	327	1150
NJ1747	Test 9	330	1151
NJ1747	Test 10	330	1154
PA0100	Preconditioning	356	322
PA0100	Preconditioning	423	594
PA0100	Test 3	440	600
PA0100	Test 4	444	604
PA0100	Test 5	436	607
PA0100	Test 6	439	592
PA0100	Test 7	442	593
PA0100	Test 8	430	596
PA0100	Test 9	430	598
PA0100	Test 10	433	600
WV0103	Preconditioning	263	667
WV0103	Preconditioning	298	950
WV0103	Test 3	303	980
WV0103	Test 4	295	1056
WV0103	Test 5	293	1055
WV0103	Test 6	290	1049
WV0103	Test 7	286	1074
WV0103	Test 8	290	1140
WV0103	Test 9	291	1154
WV0103	Test 10	289	1157

5. Axial Strain – Composite

T	P	FEMUR 1			FEMUR 2			FEMUR 3			FEMUR 4			FEMUR 5			FEMUR 6		
		MAX	MIN	MISES	MAX	MIN	MISES	MAX	MIN	MISES	MAX	MIN	MISES	MAX	MIN	MISES	MAX	MIN	MISES
1	1	14	-25	26	6	-5	7			0	4	-20	16	-4	-83	53	3	-8	7
	2	16	-28	29	4	-7	7	8	3	3	5	-20	17	-8	-77	46	2	-7	6
	3	25	-32	38	7	-7	9	16	11	3	9	-26	23	7	-77	56	1	-6	5
	4	28	-30	39	5	-3	5	14	6	5	12	-27	26	17	-56	49	0	-1	1
2	1	145	-634	519	142	-732	583			0	118	-692	540	144	-634	519	118	-649	511
	2	136	-633	513	128	-576	469	112	-640	501	112	-639	501	85	-625	473	91	-560	434
	3	216	-574	527	177	-584	507	175	-556	487	164	-554	479	136	-496	421	139	-498	425
	4	125	-250	250	141	-421	375	145	-402	365	110	-296	271	46	-247	195	88	-240	219
3	1	162	-729	594	156	-780	624			0	128	-711	559	122	-663	523	128	-695	549
	2	146	-710	571	144	-610	503	127	-700	551	121	-649	513	91	-651	495	98	-589	458
	3	246	-651	598	194	-616	540	195	-615	540	173	-552	483	139	-504	429	146	-525	447
	4	144	-302	297	153	-453	404	168	-465	422	105	-268	249	39	-231	180	93	-246	226
4	1	23	-64	58	22	-55	51			0	9	-39	32	-6	-68	41	8	-35	29
	2	16	-56	48	22	-42	43	23	-38	41	18	-38	37	-14	-54	27	7	-16	15
	3	35	-43	52	22	-37	39	43	-23	44	19	-36	37	-2	-45	29	1	-7	5
	4	25	-13	25	22	-41	42	23	-21	29	14	-16	20	-14	-33	13	19	-2	14
5	1	11	-26	25	22	1	14			0	4	-2	4	-10	-31	14	3	-19	15
	2	5	-19	16	22	-1	15	18	-3	14	9	-6	10	-11	-25	9	6	-11	11
	3	17	-6	15	22	-1	15	37	5	21	7	1	4	-9	-13	3	2	-12	9
	4	25	2	15	22	0	15	17	3	9	6	1	3	5	-38	29	7	-4	7

6. Axial Strain – Cadaver

T	P	GA0618				MD1537				MD0645				NJ1747				PA0100				WV0103			
Intact		MAX	MIN	MISES	MAX	MIN	MISES	MAX	MIN	MISES	MAX	MIN	MISES	MAX	MIN	MISES	MAX	MIN	MISES	MAX	MIN	MISES			
1	1	-2	-8	4	9	-10	13	-6	-14	5	113	-25	92	6	-12	12	2	2	-6	5					
	2	2	-18	13	213	-8	147	-5	-11	4	0	-12	8	83	-21	69	10	10	-5	10					
	3	-6	-15	6	306	-49	237	-7	-11	3	-1	-6	3	-1	-6	3	3	3	-3	4					
	4	-3	-18	10	7	-12	13	-7	-9	1	-3	-9	4	-3	-7	3	2	2	-2	3					
2	1	84	-384	312	127	-515	428	75	-690	510	158	-619	518	206	-626	555	84	-417	334						
	2	123	-390	342	228	-184	275	178	-490	445	143	-445	392	185	-424	406	190	-426	411						
	3	133	-314	298	583	-373	637	171	-407	385	126	-327	302	163	-369	355	173	-327	333						
	4	107	-270	251	179	-342	347	162	-399	374	87	-183	180	170	-248	279	160	-261	281						
3	1	70	-407	318	153	-541	463	3	-476	319	140	-503	429	220	-663	589	63	-449	341						
	2	109	-407	344	212	-320	355	88	-268	237	103	-477	387	139	-561	467	319	-390	473						
	3	104	-335	293	393	-423	544	86	-287	249	110	-328	292	146	-406	368	163	-364	351						
	4	78	-310	259	125	-327	301	87	-280	245	91	-180	181	158	-513	447	159	-301	307						
4	1	-12	-46	23	44	-45	59	-33	-55	15	0	-96	64	27	-23	33	-8	-35	18						
	2	-8	-52	29	72	-20	61	52	-38	60	-41	-50	6	-27	-76	33	299	-97	264						
	3	-29	-54	17	60	-42	68	-33	-37	3	-11	-19	5	-16	-32	11	-16	-25	6						
	4	-29	-79	33	143	-189	221	-22	-36	9	17	-36	35	-24	-61	25	-9	-24	10						
5	1			0	53	-20	49	-5	-13	5	65	-43	72	49	-5	36	23	-7	20						
	2	1	-48	33	76	-100	117	32	-25	38	-5	-35	20	37	-39	51	461	-98	373						
	3	-17	-64	31	140	-41	121	-19	-28	6	7	-4	7	-10	-25	10	10	-19	19						
	4	-31	-96	43	115	-149	176	-13	-23	7	17	1	11	-18	-40	15	-9	-14	3						

T	P	GA0618					MD1537					MD0645					NJ1747					PA0100					WV0103				
Implant		MAX	MIN	MISES		MAX	MIN	MISES		MAX	MIN	MISES		MAX	MIN	MISES		MAX	MIN	MISES		MAX	MIN	MISES		MAX	MIN	MISES			
1	1	153	-37	126	0	-2	1	1	-4	3	482	-125	404	70	-1	47	3	-1	3												
	2	68	-39	71	3	-1	3	0	0	0	222	-171	262	176	-188	243	0	-1	1												
	3	40	-132	115	2	-7	6	2	-1	2	127	-229	238	80	0	53	1	0	1												
	4	71	6	43	2	0	1	1	-1	1	26	-263	193	26	-29	36	0	-1	1												
2	1	161	-64	150	-2	-34	21	11	-23	23	488	-148	425	65	-95	106	19	-39	39												
	2	27	-263	193	124	-373	331	90	-336	284	123	-571	463	335	-630	643	96	-309	270												
	3	110	-393	335	164	-426	393	131	-353	323	635	-672	871	321	-551	582	98	-306	269												
	4	137	-202	226	147	-347	329	148	-386	356	126	-500	417	216	-648	576	143	-325	312												
3	1	254	-232	324	9	-91	67	120	-3	82	780	-197	652	71	-113	122	45	-24	46												
	2	31	-251	188	243	-480	482	59	-320	253	66	-415	321	238	-612	567	91	-307	265												
	3	16	-356	248	179	-442	414	107	-377	323	25	-297	215	269	-662	621	97	-287	256												
	4	108	-285	262	135	-377	341	123	-405	352	-65	-316	168	181	-730	608	134	-331	310												
4	1	402	-142	363	10	-59	46	134	-12	97	674	-164	559	106	-74	120	44	-22	44												
	2	116	-129	163	104	-56	107	17	-37	36	108	-306	276	193	-209	268	90	-302	261												
	3	35	-148	122	27	-7	23	-21	-29	5	17	-251	179	103	-12	76	98	-287	257												
	4	66	-15	54	15	-29	29	-22	-26	3	-6	-311	203	41	-107	99	134	-331	310												
5	1	417	-189	404	54	-97	101	131	-17	99	481	-230	474	236	-75	207	49	19	20												
	2	198	-145	229	186	-33	146	35	-40	50	119	-353	315	215	-258	315	24	0	16												
	3	67	-102	112	76	-237	209	2	-8	7	239	-639	586	101	-13	76	42	12	20												
	4	83	-1	56	34	-3	25	11	-20	21	66	-271	224	53	-135	125	13	-1	9												

APPENDIX B: ANOVA test results

1. Anterior Bending

General Linear Model: flexural rigidity versus type, specimen, stage

Method

Factor coding (1, 0)

Factor Information

Factor	Type	Levels	Values
type	Fixed	2	cadaver, composite
specimen(type)	Random	13	GA0618(cadaver), MD0645(cadaver), MD1537(cadaver), NJ1747(cadaver), PA0100(cadaver), WV0103(cadaver), U1(composite), U1 (composite), U2(composite), U3(composite), U4(composite), U5(composite), U6(composite)
stage	Fixed	3	cut, implanted, whole

Analysis of Variance

Source	DF	Seq SS	Contribution	Adj SS	Adj MS	F-Value	P-Value
type	1	109383	41.36%	2347	2347.1	0.78	0.393 x
stage	2	5493	2.08%	8942	4470.8	7.76	0.001
specimen(type)	11	56017	21.18%	56017	5092.5	8.84	0.000
type*stage	2	20378	7.71%	20378	10189.0	17.68	0.000
Error	127	73192	27.68%	73192	576.3		
Lack-of-Fit	22	62179	23.51%	62179	2826.3	26.95	0.000
Pure Error	105	11013	4.16%	11013	104.9		
Total	143	264464	100.00%				

x Not an exact F-test.

Model Summary

S	R-sq	R-sq(adj)	PRESS	R-sq(pred)
24.0066	72.32%	68.84%	93879.3	64.50%

Coefficients

Term	Coef	SE Coef	95% CI	T-Value	P-Value	VIF
Constant	139.02	9.24	(120.73, 157.30)	15.05	0.000	
type						
composite	28.1	13.9	(0.5, 55.7)	2.02	0.046	11.37
stage						
cut	16.72	8.00	(0.89, 32.56)	2.09	0.039	3.56
whole	-14.78	8.00	(-30.61, 1.06)	-1.85	0.067	3.56
specimen(type)						
MD0645(cadaver)	-21.9	11.3	(-44.3, 0.5)	-1.93	0.055	*
MD1537(cadaver)	-13.3	11.3	(-35.7, 9.1)	-1.18	0.241	*
NJ1747(cadaver)	-50.4	11.3	(-72.8, -28.1)	-4.46	0.000	*
PA0100(cadaver)	-17.0	11.3	(-39.4, 5.4)	-1.50	0.136	*
WV0103(cadaver)	15.2	11.3	(-7.2, 37.6)	1.35	0.181	*
U1 (composite)	-2.1	12.7	(-27.1, 22.9)	-0.17	0.868	*
U2 (composite)	5.2	11.6	(-17.7, 28.1)	0.45	0.655	*
U3 (composite)	19.7	11.6	(-3.3, 42.6)	1.70	0.092	*
U4 (composite)	-36.3	11.6	(-59.2, -13.3)	-3.13	0.002	*
U5 (composite)	-0.7	11.6	(-23.6, 22.3)	-0.06	0.954	*
U6 (composite)	23.5	11.6	(0.5, 46.4)	2.02	0.045	*
type*stage						
composite cut	-9.3	10.1	(-29.3, 10.8)	-0.91	0.362	4.22
composite whole	46.9	10.1	(26.8, 66.9)	4.63	0.000	4.22

Regression Equation

```
flexural rigidity = 139.02 + 0.0 type_cadaver + 28.1 type_composite + 16.72 stage_cut
+ 0.0 stage_implanted - 14.78 stage_whole
+ 0.0 specimen(type)_GA0618(cadaver)
- 21.9 specimen(type)_MD0645(cadaver)
- 13.3 specimen(type)_MD1537(cadaver)
- 50.4 specimen(type)_NJ1747(cadaver)
- 17.0 specimen(type)_PA0100(cadaver)
+ 15.2 specimen(type)_WV0103(cadaver)
+ 0.0 specimen(type)_U1(composite)
- 2.1 specimen(type)_U1 (composite)
+ 5.2 specimen(type)_U2(composite)
+ 19.7 specimen(type)_U3(composite) -
36.3 specimen(type)_U4(composite)
- 0.7 specimen(type)_U5(composite)
+ 23.5 specimen(type)_U6(composite)
+ 0.0 type*stage_cadaver cut + 0.0 type*stage_cadaver implanted
+ 0.0 type*stage_cadaver whole - 9.3 type*stage_composite cut
+ 0.0 type*stage_composite implanted + 46.9 type*stage_composite
whole
```

Equation treats random terms as though they are fixed.

Expected Mean Squares, using Adjusted SS

Source	Expected Mean Square for Each Term
1 type	(5) + 5.9341 (3) + Q[1, 4]
2 stage	(5) + Q[2, 4]
3 specimen(type)	(5) + 11.0182 (3)
4 type*stage	(5) + Q[4]
5 Error	(5)

Error Terms for Tests, using Adjusted SS

	Source	Error DF	Error MS	Synthesis of Error MS
1	type	13.23	3008.5840	0.5386 (3) + 0.4614 (5)
2	stage	127.00	576.3155	(5)
3	specimen(type)	127.00	576.3155	(5)
4	type*stage	127.00	576.3155	(5)

Variance Components, using Adjusted SS

Source	Variance	% of Total	StDev	% of Total
specimen(type)	409.882	41.56%	20.2455	64.47%
Error	576.316	58.44%	24.0066	76.44%
Total	986.198		31.4038	

2. Lateral Bending

General Linear Model: flexural rigidity versus type, specimen, stage

Method

Factor coding (1, 0)

Factor Information

Factor	Type	Levels	Values
type	Fixed	2	cadaver, composite
specimen(type)	Random	13	GA0618(cadaver), MD0645(cadaver), MD1537(cadaver), NJ1747(cadaver), PA0100(cadaver), WV0103(cadaver), U1(composite), U1 (composite), U2(composite), U3(composite), U4(composite), U5(composite), U6(composite)
stage	Fixed	3	cut, implanted, whole

Analysis of Variance

Source	DF	Seq SS	Contribution	Adj SS	Adj MS	F-Value	P-Value
type	1	26042	7.33%	11664	11664.3	5.50	0.028 x
stage	2	42258	11.89%	113941	56970.7	41.96	0.000
specimen(type)	11	30497	8.58%	30497	2772.5	2.04	0.029
type*stage	2	84221	23.69%	84221	42110.6	31.02	0.000
Error	127	172422	48.51%	172422	1357.7		
Lack-of-Fit	22	140512	39.53%	140512	6386.9	21.02	0.000
Pure Error	105	31910	8.98%	31910	303.9		
Total	143	355441	100.00%				

x Not an exact F-test.

Model Summary

S	R-sq	R-sq(adj)	PRESS	R-sq(pred)
36.8464	51.49%	45.38%	235337	33.79%

Coefficients

Term	Coef	SE	Coef	95% CI	T-Value	P-Value	VIF
Constant	247.3	14.2		(219.3, 275.4)	17.44	0.000	
type							
composite	-62.7	21.4		(-105.0, -20.4)	-2.93	0.004	11.38
stage							
implanted	-108.0	12.3		(-132.3, -83.7)	-8.79	0.000	3.56
whole	-81.3	12.3		(-105.6, -57.0)	-6.62	0.000	3.56
specimen(type)							
MD0645(cadaver)	-15.8	17.4		(-50.1, 18.6)	-0.91	0.365	*
MD1537(cadaver)	-0.4	17.4		(-34.8, 33.9)	-0.03	0.980	*
NJ1747(cadaver)	-10.8	17.4		(-45.1, 23.6)	-0.62	0.536	*
PA0100(cadaver)	-52.1	17.4		(-86.5, -17.7)	-3.00	0.003	*
WV0103(cadaver)	-56.9	17.4		(-91.3, -22.5)	-3.28	0.001	*
U1 (composite)	-1.6	19.4		(-40.0, 36.8)	-0.08	0.934	*
U2(composite)	-2.4	17.8		(-37.7, 32.8)	-0.14	0.891	*
U3(composite)	4.6	17.8		(-30.6, 39.9)	0.26	0.795	*
U4(composite)	-5.4	17.8		(-40.6, 29.9)	-0.30	0.764	*
U5(composite)	-6.2	17.8		(-41.5, 29.0)	-0.35	0.727	*
U6(composite)	-6.6	17.8		(-41.9, 28.6)	-0.37	0.710	*
type*stage							
composite implanted	106.4	15.5		(75.7, 137.1)	6.85	0.000	4.22
composite whole	105.5	15.5		(74.8, 136.3)	6.79	0.000	4.22

Regression Equation

```
flexural rigidity = 247.3 + 0.0 type_cadaver - 62.7 type_composite + 0.0 stage_cut
- 108.0 stage_implanted - 81.3 stage_whole
+ 0.0 specimen(type)_GA0618(cadaver)
- 15.8 specimen(type)_MD0645(cadaver)
- 0.4 specimen(type)_MD1537(cadaver)
- 10.8 specimen(type)_NJ1747(cadaver)
- 52.1 specimen(type)_PA0100(cadaver)
- 56.9 specimen(type)_WV0103(cadaver)
+ 0.0 specimen(type)_U1(composite)
- 1.6 specimen(type)_U1 (composite) -
2.4 specimen(type)_U2(composite)
+ 4.6 specimen(type)_U3(composite) -
5.4 specimen(type)_U4(composite)
- 6.2 specimen(type)_U5(composite) -
6.6 specimen(type)_U6(composite)
+ 0.0 type*stage_cadaver cut + 0.0 type*stage_cadaver implanted
+ 0.0 type*stage_cadaver whole + 0.0 type*stage_composite cut
+ 106.4 type*stage_composite implanted
+ 105.5 type*stage_composite whole
```

Equation treats random terms as though they are fixed.

Fits and Diagnostics for Unusual Observations

Obs	flexural rigidity	Fit	SE Fit	95% CI	Resid	Std Resid	Del Resid	HI
79	127.0	231.6	14.2	(203.5, 259.6)	-104.6	-3.07	-3.18	0.148148
84	266.0	190.4	14.2	(162.4, 218.5)	75.6	2.22	2.26	0.148148
92	336.0	247.3	14.2	(219.3, 275.4)	88.7	2.61	2.67	0.148148
93	361.0	247.3	14.2	(219.3, 275.4)	113.7	3.34	3.49	0.148148
134	165.0	87.2	14.2	(59.2, 115.3)	77.8	2.29	2.33	0.148148
135	177.0	87.2	14.2	(59.2, 115.3)	89.8	2.64	2.70	0.148148
139	13.0	139.3	14.2	(111.3, 167.4)	-126.3	-3.71	-3.92	0.148148
140	34.0	139.3	14.2	(111.3, 167.4)	-105.3	-3.10	-3.21	0.148148
141	24.0	139.3	14.2	(111.3, 167.4)	-115.3	-3.39	-3.54	0.148148

Obs	Cook's D	DFITS	
79	0.10	-1.32744	R
84	0.05	0.94134	R
92	0.07	1.11321	R
93	0.11	1.45378	R
134	0.05	0.97020	R
135	0.07	1.12797	R
139	0.14	-1.63444	R
140	0.10	-1.33812	R
141	0.12	-1.47721	R

R Large residual

Expected Mean Squares, using Adjusted SS

Source	Expected Mean Square for Each Term
1 type	(5) + 5.9341 (3) + Q[1, 4]
2 stage	(5) + Q[2, 4]
3 specimen(type)	(5) + 11.0182 (3)
4 type*stage	(5) + Q[4]
5 Error	(5)

Error Terms for Tests, using Adjusted SS

Source	Error DF	Error MS	Synthesis of Error MS
1 type	21.83	2119.6452	0.5386 (3) + 0.4614 (5)
2 stage	127.00	1357.6549	(5)
3 specimen(type)	127.00	1357.6549	(5)
4 type*stage	127.00	1357.6549	(5)

Variance Components, using Adjusted SS

Source	Variance	% of Total	StDev	% of Total
specimen(type)	128.409	8.64%	11.3318	29.40%
Error	1357.65	91.36%	36.8464	95.58%
Total	1486.06		38.5495	

3. Axial Stiffness

General Linear Model: axial stiffness versus type, specimen, stage

Method

Factor coding (1, 0)

Factor Information

Factor	Type	Levels	Values
type	Fixed	2	cadaver, composite
specimen(type)	Random	12	GA0618(cadaver), MD0645(cadaver), MD1537(cadaver), NJ1747(cadaver), PA0100(cadaver), WV0103(cadaver), U1(composite), U2(composite), U3(composite), U4(composite), U5(composite), U6(composite)
stage	Fixed	2	implanted, whole

Analysis of Variance

Source	DF	Seq SS	Contribution	Adj SS	Adj MS	F-Value	P-Value
type	1	8218730	34.84%	364717	364717	0.75	0.407 x
stage	1	3810387	16.15%	6602406	6602406	380.19	0.000
specimen(type)	10	5642797	23.92%	5642797	564280	32.49	0.000
type*stage	1	2828523	11.99%	2828523	2828523	162.88	0.000
Error	178	3091182	13.10%	3091182	17366		
Lack-of-Fit	10	2520636	10.68%	2520636	252064	74.22	0.000
Pure Error	168	570545	2.42%	570545	3396		
Total	191	23591619	100.00%				

x Not an exact F-test.

Model Summary

S	R-sq	R-sq(adj)	PRESS	R-sq(pred)
131.781	86.90%	85.94%	3596557	84.75%

Obs	Cook's D	DFITS	
5	0.03	-0.64056	R
8	0.02	-0.58321	R
101	0.07	1.00322	R
102	0.03	0.60410	R
103	0.03	0.60410	R
104	0.07	1.04994	R
145	0.07	-1.03391	R

R Large residual

Expected Mean Squares, using Adjusted SS

Source	Expected Mean Square for Each Term
1 type	(5) + 13.7143 (3) + Q[1, 4]
2 stage	(5) + Q[2, 4]
3 specimen(type)	(5) + 16.0000 (3)
4 type*stage	(5) + Q[4]
5 Error	(5)

Error Terms for Tests, using Adjusted SS

Source	Error DF	Error MS	Synthesis of Error MS
1 type	10.10	486149.2128	0.8571 (3) + 0.1429 (5)
2 stage	178.00	17366.1896	(5)
3 specimen(type)	178.00	17366.1896	(5)
4 type*stage	178.00	17366.1896	(5)

Variance Components, using Adjusted SS

Source	Variance	% of Total	StDev	% of Total
specimen(type)	34182.1	66.31%	184.884	81.43%
Error	17366.2	33.69%	131.781	58.04%
Total	51548.3		227.042	

4. Mises Strain

General Linear Model: Mises Strain versus type, Stage, specimen, position, Time

Method

Factor coding (1, 0)
Rows unused 11

Factor Information

Factor	Type	Levels	Values
type	Fixed	2	Cadaver, Composite
Stage	Fixed	3	Implanted, Intact, whole
specimen(type)	Random	12	GA0618(Cadaver), MD0645(Cadaver), MD1537(Cadaver), NJ1747(Cadaver), PA0100(Cadaver), WV0103(Cadaver), U1(Composite), U2(Composite), U3(Composite), U4(Composite), U5(Composite), U6(Composite)
position	Random	4	1, 2, 3, 4
Time	Fixed	5	1, 2, 3, 4, 5

Analysis of Variance

Source	DF	Seq SS	Contribution	Adj SS	Adj MS	F-Value	P-Value
type	1	2878	0.01%	3269	3269	0.10	0.753 x
Stage	2	179361	0.80%	83579	41789	2.39	0.093
position	3	713648	3.17%	716309	238770	13.64	0.000
Time	4	12300839	54.59%	1155166	288791	16.50	0.000
type*Stage	2	31764	0.14%	22010	11005	0.63	0.534
specimen(type)	10	537884	2.39%	537457	53746	3.07	0.001
type*Time	4	754880	3.35%	646088	161522	9.23	0.000
Stage*Time	8	457075	2.03%	298276	37284	2.13	0.032
type*Stage*Time	8	97242	0.43%	97242	12155	0.69	0.697
Error	426	7457199	33.09%	7457199	17505		
Total	468	22532770	100.00%				

x Not an exact F-test.

Model Summary

S	R-sq	R-sq(adj)	PRESS	R-sq(pred)
132.307	66.91%	63.64%	8805970	60.92%

Coefficients

Term	Coef	SE	Coef	95% CI	T-Value	P-Value	VIF
Constant	-22.5	35.4	(-92.2, 47.1)		-0.64	0.526	
type							
Composite	-20.4	47.2	(-113.1, 72.3)		-0.43	0.666	14.90
Stage							
Intact	0.8	47.6	(-92.7, 94.3)		0.02	0.987	11.16
whole	-99.3	47.6	(-192.8, -5.8)		-2.09	0.037	11.54
position							
2	51.8	17.3	(17.7, 85.9)		2.99	0.003	*
3	135.6	21.4	(93.6, 177.7)		6.34	0.000	*
4	100.9	21.0	(59.6, 142.3)		4.80	0.000	*
Time							
2	253.5	38.2	(178.4, 328.5)		6.64	0.000	6.26
3	234.7	38.2	(159.6, 309.8)		6.15	0.000	6.26
4	76.9	38.2	(1.8, 152.0)		2.01	0.045	6.26
5	83.0	38.2	(7.9, 158.1)		2.17	0.030	6.21
type*Stage							
Composite Intact	54.4	67.4	(-78.2, 186.9)		0.81	0.421	12.61
Composite whole	66.6	66.4	(-63.9, 197.1)		1.00	0.316	13.18
specimen(type)							
MD0645(Cadaver)	-30.5	29.8	(-89.0, 28.1)		-1.02	0.307	*
MD1537(Cadaver)	31.2	29.8	(-27.3, 89.8)		1.05	0.295	*
NJ1747(Cadaver)	99.9	29.8	(41.3, 158.4)		3.35	0.001	*
PA0100(Cadaver)	70.0	29.8	(11.4, 128.5)		2.35	0.019	*
WV0103(Cadaver)	-4.6	29.8	(-63.1, 54.0)		-0.15	0.878	*
U2(Composite)	-24.6	29.6	(-82.8, 33.6)		-0.83	0.406	*
U3(Composite)	-25.4	30.7	(-85.8, 35.0)		-0.83	0.409	*
U4(Composite)	-15.4	29.6	(-73.5, 42.8)		-0.52	0.604	*
U5(Composite)	-47.7	29.6	(-105.9, 10.4)		-1.61	0.107	*
U6(Composite)	-13.8	30.7	(-74.2, 46.5)		-0.45	0.653	*
type*Time							
Composite 2	104.4	54.6	(-2.9, 211.7)		1.91	0.057	7.07
Composite 3	238.6	54.6	(131.2, 345.9)		4.37	0.000	7.07
Composite 4	27.9	54.6	(-79.4, 135.2)		0.51	0.609	7.07
Composite 5	-68.6	54.6	(-175.9, 38.7)		-1.26	0.210	7.07
Stage*Time							
Intact 2	125.4	66.2	(-4.7, 255.4)		1.90	0.059	5.47
Intact 3	127.0	66.2	(-3.1, 257.0)		1.92	0.056	5.47
Intact 4	-53.3	66.2	(-183.4, 76.7)		-0.81	0.421	5.47
Intact 5	-45.7	67.2	(-177.7, 86.3)		-0.68	0.497	5.41
whole 2	57.5	66.2	(-72.5, 187.6)		0.87	0.385	5.69
whole 3	60.9	66.2	(-69.2, 190.9)		0.92	0.358	5.69
whole 4	-64.2	66.2	(-194.2, 65.9)		-0.97	0.333	5.69
whole 5	-69.8	66.2	(-199.8, 60.3)		-1.05	0.292	5.69
type*Stage*Time							
Composite Intact 2	2.8	95.3	(-184.6, 190.1)		0.03	0.977	5.57
Composite Intact 3	-79.9	95.3	(-267.3, 107.4)		-0.84	0.402	5.57
Composite Intact 4	-32.9	95.3	(-220.2, 154.5)		-0.34	0.730	5.57
Composite Intact 5	24.9	96.0	(-163.8, 213.6)		0.26	0.795	5.66
Composite whole 2	-60.2	93.9	(-244.8, 124.3)		-0.64	0.521	5.89
Composite whole 3	-154.5	93.9	(-339.0, 30.1)		-1.65	0.101	5.89
Composite whole 4	-33.2	93.9	(-217.7, 151.4)		-0.35	0.724	5.89
Composite whole 5	45.8	93.9	(-138.7, 230.4)		0.49	0.626	5.89

Regression Equation

```

Mises Strain = -22.5 + 0.0 type_Cadaver - 20.4 type_Composite + 0.0 Stage_Implanted
               + 0.8 Stage_Intact - 99.3 Stage_whole + 0.0 position_1
+ 51.8 position_2
               + 135.6 position_3 + 100.9 position_4 + 0.0 Time_1 + 253.5 Time_2
               + 234.7 Time_3 + 76.9 Time_4 + 83.0 Time_5 + 0.0 type*Stage_Cadaver
Implanted
               + 0.0 type*Stage_Cadaver Intact + 0.0 type*Stage_Cadaver whole
               + 0.0 type*Stage_Composite Implanted + 54.4 type*Stage_Composite Intact
               + 66.6 type*Stage_Composite whole + 0.0 specimen(type)_GA0618(Cadaver)
               - 30.5 specimen(type)_MD0645(Cadaver)
+ 31.2 specimen(type)_MD1537(Cadaver)
               + 99.9 specimen(type)_NJ1747(Cadaver)
+ 70.0 specimen(type)_PA0100(Cadaver)
               - 4.6 specimen(type)_WV0103(Cadaver) + 0.0 specimen(type)_U1(Composite)
               - 24.6 specimen(type)_U2(Composite) - 25.4 specimen(type)_U3(Composite)
               - 15.4 specimen(type)_U4(Composite) - 47.7 specimen(type)_U5(Composite)
               - 13.8 specimen(type)_U6(Composite) + 0.0 type*Time_Cadaver 1
               + 0.0 type*Time_Cadaver 2 + 0.0 type*Time_Cadaver 3
+ 0.0 type*Time_Cadaver 4
               + 0.0 type*Time_Cadaver 5 + 0.0 type*Time_Composite 1
               + 104.4 type*Time_Composite 2 + 238.6 type*Time_Composite 3
               + 27.9 type*Time_Composite 4 - 68.6 type*Time_Composite 5
               + 0.0 Stage*Time_Implanted 1 + 0.0 Stage*Time_Implanted 2
               + 0.0 Stage*Time_Implanted 3 + 0.0 Stage*Time_Implanted 4
               + 0.0 Stage*Time_Implanted 5 + 0.0 Stage*Time_Intact 1
               + 125.4 Stage*Time_Intact 2 + 127.0 Stage*Time_Intact 3
               - 53.3 Stage*Time_Intact 4 - 45.7 Stage*Time_Intact 5
+ 0.0 Stage*Time_whole 1
               + 57.5 Stage*Time_whole 2 + 60.9 Stage*Time_whole 3 -
64.2 Stage*Time_whole 4
               - 69.8 Stage*Time_whole 5 + 0.0 type*Stage*Time_Cadaver Implanted 1
               + 0.0 type*Stage*Time_Cadaver Implanted 2 + 0.0 type*Stage*Time_Cadaver
Implanted 3 + 0.0 type*Stage*Time_Cadaver Implanted 4
               + 0.0 type*Stage*Time_Cadaver Implanted 5 + 0.0 type*Stage*Time_Cadaver
Intact
               1 + 0.0 type*Stage*Time_Cadaver Intact 2 + 0.0 type*Stage*Time_Cadaver
Intact
               3 + 0.0 type*Stage*Time_Cadaver Intact 4 + 0.0 type*Stage*Time_Cadaver
Intact
               5 + 0.0 type*Stage*Time_Cadaver whole 1 + 0.0 type*Stage*Time_Cadaver
whole 2
               + 0.0 type*Stage*Time_Cadaver whole 3 + 0.0 type*Stage*Time_Cadaver
whole 4
               + 0.0 type*Stage*Time_Cadaver whole 5 + 0.0 type*Stage*Time_Composite
Implanted 1 + 0.0 type*Stage*Time_Composite Implanted 2
               + 0.0 type*Stage*Time_Composite Implanted 3
+ 0.0 type*Stage*Time_Composite
Implanted 4 + 0.0 type*Stage*Time_Composite Implanted 5
               + 0.0 type*Stage*Time_Composite Intact 1
+ 2.8 type*Stage*Time_Composite
Intact 2 - 79.9 type*Stage*Time_Composite Intact 3
               - 32.9 type*Stage*Time_Composite Intact 4
+ 24.9 type*Stage*Time_Composite
Intact 5 + 0.0 type*Stage*Time_Composite whole 1
               - 60.2 type*Stage*Time_Composite whole 2 -
154.5 type*Stage*Time_Composite
whole 3 - 33.2 type*Stage*Time_Composite whole 4
               + 45.8 type*Stage*Time_Composite whole 5

```

Equation treats random terms as though they are fixed.

437	841.0	400.5	35.6	(330.5, 470.6)	440.5	3.46	3.50	0.072505
0.02								
438	867.0	515.9	35.6	(445.9, 586.0)	351.1	2.76	2.78	0.072505
0.01								
447	831.0	402.1	36.9	(329.6, 474.6)	428.9	3.38	3.42	0.077670
0.02								
448	921.0	517.5	36.9	(445.0, 590.0)	403.5	3.18	3.21	0.077670
0.02								

Obs	DFITS	
62	-0.56720	R
63	-0.78027	R
67	-0.63258	R
68	-0.85106	R
73	-0.81313	R
77	-0.56414	R
78	-0.83124	R
83	-0.65547	R
88	-0.73746	R
94	0.67702	R
95	0.75488	R
106	0.71314	R
108	0.74264	R
109	0.88733	R
110	0.68434	R
180	0.90261	R
187	-0.75331	R
189	0.70314	R
207	0.63760	R
232	0.63305	R
277	0.78817	R
302	0.57750	R
307	-0.94579	R
309	0.98270	R
317	0.66365	R
347	0.88857	R
350	0.63328	R
427	-0.86502	R
429	1.12485	R
437	0.97919	R
438	0.77639	R
447	0.99176	R
448	0.93158	R

R Large residual

Expected Mean Squares, using Adjusted SS

Source	Expected Mean Square for Each Term
1 type	(10) + 15.7278 (6) + Q[1, 5, 7, 9]
2 Stage	(10) + Q[2, 5, 8, 9]
3 position	(10) + 97.3233 (3)
4 Time	(10) + Q[4, 7, 8, 9]
5 type*Stage	(10) + Q[5, 9]
6 specimen(type)	(10) + 38.9890 (6)
7 type*Time	(10) + Q[7, 9]
8 Stage*Time	(10) + Q[8, 9]
9 type*Stage*Time	(10) + Q[9]
10 Error	(10)

Error Terms for Tests, using Adjusted SS

Source	Error DF	Error MS	Synthesis of Error MS
1 type	21.84	32124.2300	0.4034 (6) + 0.5966 (10)
2 Stage	426.00	17505.1624	(10)
3 position	426.00	17505.1624	(10)
4 Time	426.00	17505.1624	(10)
5 type*Stage	426.00	17505.1624	(10)
6 specimen(type)	426.00	17505.1624	(10)
7 type*Time	426.00	17505.1624	(10)
8 Stage*Time	426.00	17505.1624	(10)
9 type*Stage*Time	426.00	17505.1624	(10)

Variance Components, using Adjusted SS

Source	Variance	% of Total	StDev	% of Total
position	2273.50	10.98%	47.681	33.13%
specimen(type)	929.507	4.49%	30.488	21.19%
Error	17505.2	84.53%	132.307	91.94%
Total	20708.2		143.903	

APPENDIX C: Flexural Rigidity Equation Derivation

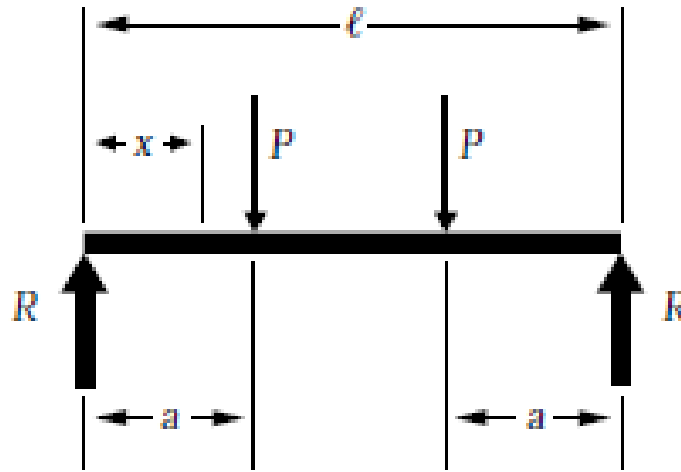


Figure 1 Simple Beam - Two Equal Concentrated Loads Symmetrically Placed [1]

$$y_{max}(\text{at center}) = \frac{Pa}{24EI} (3l^2 - 4a^2) \quad [1]$$

where $l = 3a$

$$y_{max} = \frac{Pa}{24EI} [3(3a)^2 - 4a^2]$$

$$y_{max} = \frac{Pa}{24EI} [27a^2 - 4a^2]$$

$$y_{max} = \frac{Pa}{24EI} [23a^2]$$

$$y_{max} = \frac{23Pa^3}{24EI}$$

$$EI = \frac{23 Pa^3}{24 y_{max}}$$