

Protocol for Evaluating the Dynamic Compression of Knee and Ankle Arthrodesis Nails

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Conclusion- Robert Lavado

Future Recommendations- Justin Parker and Robert Lavado

Appendix A- Michael Coutts

Appendix B- Robert Lavado

Appendix C- Michael Coutts

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Abstract

It is important for an arthrodesis nail to maintain compression for successful bony fusion. To test new designs of arthrodesis nails a device and protocol were developed to accurately measure compression within a joint over time. The protocol utilized a uniaxial testing machine to cyclically load the samples 10,000 times at 1 Hz from 0-200 lbs. Using Sawbones as a testing model, a 10% decrease in compression was experienced with a standard locked nail. Using this method, new and old designs of arthrodesis nails can be compared to determine which best maintains compression.

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Chapter 1: Introduction

Many people in the world suffer from joint pain so severe that simple day-to-day tasks, such as walking, become challenging. Current treatments for this pain include medication and bracing (Richardson 2001). Beyond this, complete replacement of the painful joint is necessary. In the knee this is done through total knee replacement surgery (TKR) (McQueen et al. 2005). Still in about one percent of all TKR surgeries, infection or other complications arise. When joint replacement fails, the joint must be completely and permanently removed through a procedure called arthrodesis. Though arthrodesis is a salvage procedure for failed joint replacements, it is also used for patients with severe arthritis in the ankle, due to total ankle replacement surgery not yet being widely accepted (Domingo et al. 2004).

In an arthrodesis procedure, all cartilage is removed from the joint and an intramedullary nail is used to completely stabilize the joint. Doing this causes the bones in the joint to fuse (Domingo et al. 2004). Failure of the bones to fuse could cause the patient to require amputation of the affected limb.

As a result, it is important to strive for the best success rates in this surgery (Tavakkolizadeh et al. 2006). Surgeons hypothesize that the main reason for failure of arthrodesis is that current nails fail to maintain compression in the affected joint over time (Papachristou et al. 2003). It is known that bone remodels and becomes denser when placed under compressive stresses, therefore it can be concluded that arthrodesis nails designed to maintain compression within the joint can improve fusion (Miesse et al. 2004).

To add dynamic compression within the joint and thus maintain compression within the joint over time, Dr. Wixted, an orthopedic surgeon at UMass Medical Center, has developed a prototype of an intramedullary nail which uses a ratcheting device. In theory, in current nails, the majority of the compression is transferred from the bone to the nail, otherwise known as stress shielding. The ratcheting design is intended to allow the nail to shorten should compression be reduced, thus transferring the majority of the compression back to the bone. This has the ability to maximize the bone on bone compression in the joint, minimizing stress shielding. In this way, compression could be reestablished without revision surgery (Wixted and McCormick 2003).

To gain a better understanding of the advantages of his new arthrodesis nail and to prove its marketability, Dr. Wixted requires a device and method in which he can compare his design to those currently available. The goal of this project is to develop the device and protocol that would be used to measure the compression in the arthrodesis joint over time and compare Dr. Wixted's nail to those currently available on the market.

Sawbones have proved useful in many previous orthopedic device tests. Since this study requires that the sawbones have similar creep properties to that of real bone, the research team will conduct a comparison test to prove the usefulness of the Sawbones. The project team will develop a protocol to cycle the samples using an available uniaxial testing machine while recording compression data from a load cell placed within the joint.

If the device functions according to its specifications, any researcher will be able to use the method to compare the loss of compression exhibited in standard arthrodesis

nails. The device will also be able to be re-programmed for use in other loading and testing situations involving arthrodesis nails.

Chapter 2: Background

2.1 Arthrodesis

It is known that bone is strengthened and remodeled along the lines of stress acting in the bone (Richardson 2001). Because of this, in fracture healing, surgeons use a means of fixation that applies compression over the fracture site. Occasionally, two or more bones need to be fused together for permanent immobilization in a procedure called arthrodesis. Similar to what is done in fracture healing, an intramedullary nail is used to stabilize and apply compression to the joint, promoting bony union (Miesse et al. 2004).

2.1.1 Ankle Arthrodesis

Ankle arthrodesis surgery is performed on patients experiencing tremendous pain in the ankle joint, which is incurable by any other method. Degenerative arthritis, post traumatic arthritis, neuropathic arthropathy, talar osteonecrosis and collapse, inflammatory arthritis, or failed total ankle arthroplasty are just some of the many reasons which may cause this tremendous pain. For many of these patients, failure of the procedure would require below the knee amputation (Tavakkolizadeh et al. 2006).

In the hindfoot and ankle, arthrodesis is performed by fusing the tibiotalar (where the tibia and talus meet) and talarcalcaneal (where the talus and calcaneous meet) joints, known as tibiotalocalcaneal (TTC) fusion (Berson et al. 2002). These bones can be seen below, in Figure 2.1.

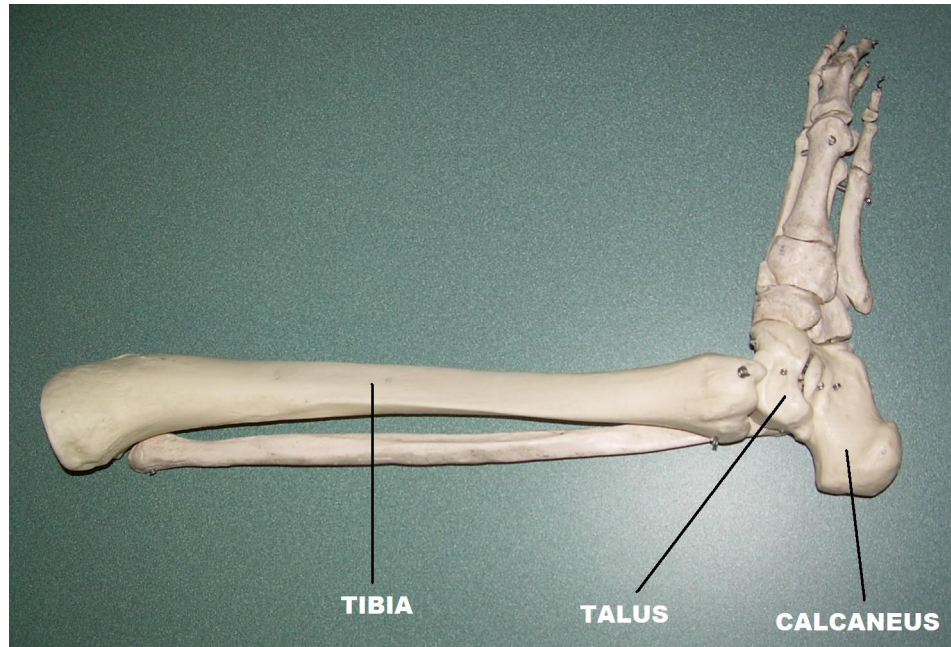


Figure 2.1: Bones of the tibiotalocalcaneal joints

In this procedure, the surgeon first removes the fibula and all the cartilage from the patients, tibiotalar and talarcalcaneal joints. Then saw cuts are made on the tibia, talus, and calcaneus such that maximal contact between the bones can be achieved. The surgeon then drills a hole for the intramedullary nail starting from the calcaneus and moving up through the talus, into the intramedullary canal of the tibia. The nail is then hammered into place in the hole. Next, the nail is locked into place with the proximal screws. At this point, the compression screw can be tightened to provide compression over the fusion site. Finally, the entire nail can be locked into place with the distal screws (Quill and Miller 2002). An implanted tibiotalocalcaneal fusion nail can be seen below, in Figure 2.2.

There are various different tibiotalocalcaneal fusion nails available on the market today. All of these nails can be divided into two categories, first generation nails and second generation nails. First generation nails, such as the Smith & Nephew ReVision Nail, are simple nails in which all compression within the ankle joint must be achieved by



Figure 2.2: An X-ray of the tibiotalocalcaneal joint with an implanted fusion nail. (Wixted, J. Personal collection of radiographs, 2006)

either the surgeon or an external fixator device (Smith & Nephew 2006). Once compression is achieved using the fixator device, the surgeon inserts the locking screws into the nail, holding the nail in place at the set amount of compression (Smith & Nephew 2006). Second generation nails include a nail-mounted compression device. In many nails, this is either a screw or nut which can be tightened to shorten the implanted nail. In this way, additional compression can be added to the joint after the nail is locked in place (Quill and Miller 2002).

In two clinical studies done using second generation nails, the success rates of Tibiotalocalcaneal fusion were examined. One study of 29 patients used a nail manufactured by Stryker. Of these patients, 22 or about 76%, showed successful fusion across the ankle (Goebel et al. 2006). In a similar study done with the Depuy Ace nail manufactured by Johnson and Johnson, 26 patients underwent ankle arthrodesis with only 15 patients, or 57%, showing successful fusion (Tavakkolizadeh et al. 2006).

2.1.2 Knee Arthrodesis

Knee arthrodesis is a procedure very similar to ankle arthrodesis. This procedure is typically undergone after a failed TKR. Again, knee arthrodesis is done as a salvage procedure to prevent above-the-knee amputation (McQueen et al. 2005).

The failure of a total knee replacement is most often due to loosening of the prosthesis or infection (Fidler 1983). There are several methods for knee arthrodesis; these include external fixation, plate and screw osteosynthesis, and intramedullary nails (Domingo et al. 2004). This investigation will only focus on the use of intramedullary nails for knee arthrodesis. Similar to the intramedullary nails used for ankle arthrodesis, the nail is inserted into the intramedullary canals of the tibia and femur, linking them together at the knee joint with the intention of fusing the two bones together (McQueen et al. 2005). The principle of maintained compression remains the same between both knee and ankle arthrodesis (McQueen et al. 2005).

Currently, the Wichita Fusion Nail (WFN) is the intramedullary nail typically used in knee arthrodesis operations (Domingo et al. 2004; Fidler 1983; McQueen et al. 2005). The WFN is implanted through a procedure that requires minimal surgical experience. First, the intramedullary canals are reamed and bone blocks are removed from the femur and tibia, providing access to the compression nut. The tibia and femoral rods are then inserted and secured in place with locking screws. Next, the connecting shaft of the tibial rod is then inserted into the femoral rod and the compression nut is tightened. The procedure is finished by replacing the bone blocks and closing the incision (Domingo et al. 2004).

The WFN is unique in that it provides dynamic compression after the surgery by allowing the tibial shaft to move. When load is applied, the proximal end of the tibial shaft is allowed to move up into the femoral shaft. This could limit the amount of stress shielding seen during normal walking. This compression cannot be maintained, as when the load is removed the tibial shaft is allowed to return to its original position (McQueen 2005).

2.2 Dynamic Compression

In a study conducted by Berson et al. (2002), it was shown that arthrodesis procedures performed with second generation nails show between four and ten times greater compression across the fusion site than first generation nails. The larger compression found in second generation nails is due to their nail-mounted compression devices. The greater rates of fusion among surgeries using second generation nails are attributed to the extra compression.

Cunningham et al. (1989) suggests that fusion devices should be designed as to limit reduction of compression with time. Dynamic compression decreases fusion time which reduces time for infection, thus increasing union successfulness.

Non-union in the joint often occurs due to lack of compression within the ankle or knee joint. It has been shown that fractured bones heal faster when put under dynamic loading. In a study published in 2003, patients with tibia fractures were encouraged to begin walking as soon as possible after pins or screws were placed in the fracture enhancing the dynamic compression in their ankles. All patients recovered successfully, and regained all motion in their extremities (Papachristou et al. 2003). The success of the

procedures in Papachristo et al's study supports the conjecture that greater compression within the joint will yield a higher rate of bone fusion in arthrodesis.

In a study presented in 2006, the Biomet and Depuy Ace nails were tested uniaxially for 10,000 cycles. It was found that after this time only 40-60% of the initial compression remained (Eichhorn et al. 2006). In a 1989 study, Cunningham et al. found that the levels of compressive load across the joint fell rapidly in the joints of 11 patients who had undergone ankle arthrodesis surgery. The compressive load on the ankle had to be increased daily to return to the 500 Newton load which had initially been applied within the joint (Cunningham et al. 1989). The studies conducted by Berson et al., Eichhorn et al., and Cunningham et al. demonstrate the cause of some patients' delayed healing times and nonunion within the joints. Increase of compression within the joint, the joint is more likely to have successful fusion at an increased rate (Berson et al. 2002; Cunningham et al. 1989). A nail that could maintain dynamic loading, within the fusion joint would be ideal for increasing the success rates and recovery times of arthrodesis patients.

2.3 The Hindfoot Fusion Nail

John Wixted, M.D. at UMass Medical School has developed his own design for an arthrodesis nail which utilizes a ratcheting design to apply maintained dynamic compression to the fusion site. The nail was originally designed for use in ankle arthrodesis procedures, however its size can be scaled up for use in knee arthrodesis.

The ratcheting nail consists of a proximal (closest to the origin of the limb) and a distal (furthest from the origin of the limb) part. The overall diameter of the device varies so that it may fit inside an intramedullary canal from 9 – 14mm. The length of the

device also varies to fit inside an intramedullary canal from 140 – 340mm. The distal most section of the device possesses one or more holes across its diameter that allow for the 5mm interlocking screws to secure the rod within the intramedullary canal, as seen in Figure 2.3. The distal rod has a series of ratchet teeth machined into the top portion, with the tooth spacing being 2mm. The teeth allow for interlocking of the upper and lower ends of the device.

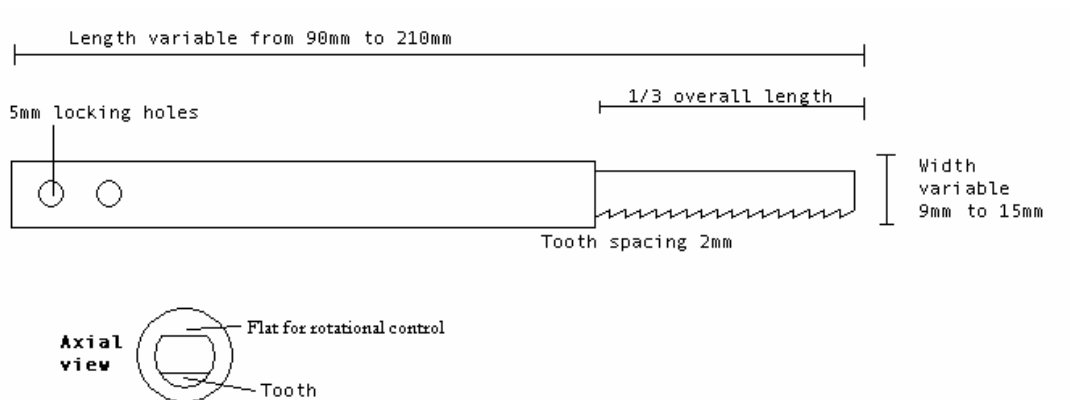


Figure 2.3: Distal part of the ratcheting fusion nail

The proximal part of the device, which can be seen below in Figure 2.4, has one or more holes across its diameter to allow for the 5mm interlocking screws used to secure the proximal section within the intramedullary canal. The distal 1/3 of the proximal end is hollow, with the radius of the hollow portion being 3mm less than the overall radius of the rod. This offers space for the distal and proximal parts to interlock. The flat portion of both the distal and proximal parts of the device ensures rotational alignment and stability; this flat portion was left out for ease of machining and use on the prototype nail. The length of the cantilever may vary based on the clinical application and necessary stiffness.

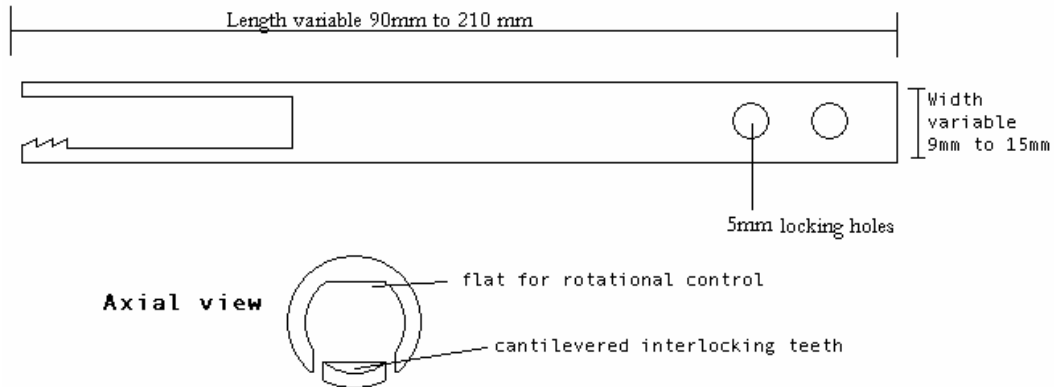


Figure 2.4: Proximal part of the ratcheting fusion nail

The ratcheting nail allows for dynamic compression similar to that seen in the Wichita Fusion Nail. The ratcheting design allows for the distal end of the nail to compress into proximal end as shown in Figure 2.5. Once this compression is achieved, the distal end is not allowed to return to its original position, maintaining prolonged compression in the joint.

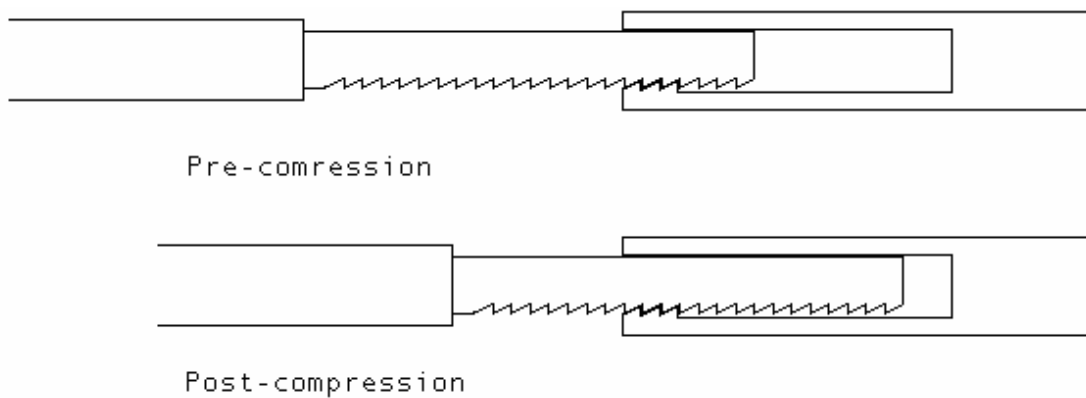


Figure 2.5: Schematic of the interlocking, ratcheting teeth of the ratcheting fusion nail

2.4 Bone Models

To test many orthopedic devices, it is important to have an anatomically correct bone model. Often in orthopedic testing, cadaveric bone samples are used. Cadaveric samples however, often prove to be very costly, difficult to obtain, handle, prepare, and preserve. Biological samples, such as cadavers, also often have a high degree of

variability, requiring the researcher to run many samples in order to be able to validate their conclusions (Cristofolini et al. 2000).

Pacific Research Labs manufactures many different anatomically correct bone models which can be used for orthopedic testing, called Sawbones. In a study conducted by Cristofolini et al. (2000), the mechanical properties of cadaveric bones were compared with those of the manufactured models from Pacific Research Labs. The researchers discovered that the mechanical moduli received for the bone models, in bending and compression, were statistically similar to those of the cadaveric samples. However, the torsional stiffness of the models was found to be twice as great as that of real bone. Because of this, the researchers determined the bone models can be useful for testing in only certain types of loading conditions. Though the researchers noted that the loading curves for the samples seemed to follow a linear path, no real work on the viscoelastic properties was completed.

Chapter 3: Project Approach

The overall goal of this project is to produce a protocol and device for evaluating the dynamic compression of various arthrodesis nails. Orthopedic surgeon, Dr. John Wixted of UMass Medical School, has invented a ratcheting arthrodesis nail that he believes could maintain dynamic compression better than nails currently used in arthrodesis procedures. By comparing his newly designed ratcheting nail to other nails, Dr. Wixted will be able to determine the usefulness and marketability of his design. Details for the design of the ratcheting fusion nail can be found Appendix A.

The project team will design a device which can cyclically load specimens with arthrodesis nails implanted within them. Cyclic loading will be done using a force-controlled uniaxial testing machine. A load measuring device will be used to evaluate the reduction in compression in the joint over time.

To achieve this goal, the project was divided into two specific aims. The first specific aim was to develop a test protocol that will ultimately result in comparative data for different arthrodesis nails. It was to be designed so that it could easily be performed by any lab technician or researcher. The second specific aim was to determine if the developed protocol was capable of evaluating dynamic compression generated by various arthrodesis nails. This was done based on data obtained through mock tests run with the protocol.

In order to achieve the first specific aim, several assumptions had to be made. It had to be assumed that Sawbones would compress proportionally to human bones so that they could be used as an adequate model. This assumption was tested by the researchers to prove its accuracy. It was also assumed that the test parameters for this investigation

could be based on those of a similar study conducted by Eichhorn et al., in which the reduction of compression was compared between the Stryker T2 Femur Nails and the Biomet Merck Arthrodesis Nail (Eichhorn et al. 2006). Lastly, it was assumed that compression within pinned ankle and knee joints occurs in uniaxial loading, which was to be mimicked in the testing procedure.

To accomplish the second specific aim, it was assumed that a mock nail designed by the researchers would mimic the function of first generation nails. If a reduction in force within the joint was seen at the conclusion of the test, the device and protocol will have functioned according to its specifications.

Chapter 4: Design

This project consisted primarily of engineering design. The main focus of the project was to develop a testing apparatus and protocol to compare a newly designed fusion nail for knee and ankle arthrodesis to other nails. The newly designed nails are meant to maintain greater compression over time within their respective joints when compared to currently available nails. Dr. John Wixted currently holds the patent for the new nail design and is providing the funding for the project through a grant provided by UMass Medical Center. For this reason, he was considered to be the primary stakeholder in this project. The protocol and apparatus must be built such that it can be utilized to validate or invalidate the ratcheting concept utilized by the new nail design.

4.1 Problem Statement

To compare the compression maintained by Dr. Wixted's ratcheting fusion nail to currently available nails, a device must be developed which can measure compression in the affected joint over time. The device must use an analogous bone model and cyclically load the affected sample to mimic the typical in-vitro loading of the joint. The device and protocol for running the test must be clearly defined and easy to use, such that research can continue to be done by lab technicians far into the future. A grant of \$20,000 has been procured to cover the costs of designing the apparatus and completing the necessary tests.

4.2 Project Needs Analysis

For this project, Dr. Wixted and his resident Jeremy McCormick were considered to be the sole clients. They provided the design team with the following three constraints for the project:

1. Measure the reduction of compression within a joint
2. The costs of developing the protocol, as well as the costs of conducting the tests, must fall under the \$20,000 budget.
3. The protocol must be able to be used by future lab technicians.

These constraints gave us an initial client statement of:

Develop a testing device and protocol that can be used to assess the compression within a joint after an arthrodesis procedure. The cost of developing the device and running the protocol must not exceed \$20,000 and the protocol must be able to be used by future lab technicians.

With the primary objective of the project being to develop a method to test arthrodesis nails, the design team took the constraints given and developed a list of objectives. The first two objectives for the project strictly concerned making the device capable of completing the intended research. The design team decided to add the objective of “easy to use” to insure the device could be used by any lab technicians the client might hire. Since future testing might be necessary to gain FDA approval or to sell the patent, a goal was added to make the device capable of completing a multitude of different tests. These future tests could include but are not limited to cadaver or torsional testing. These objectives were then weighted in order of importance with the opinion of the client weighted at 70% and the opinion of the design team weighted at 30% (Appendix B). The following is a list of objectives in order of importance:

1. The device should compare the ratcheting fusion nail with currently available nails.
2. The device should measure compression within the joint over time.

3. The device should be easy to use.
4. The device should be adaptable to multiple additional tests, such as cadaver or torsion testing.

From these weighted objectives, a final client statement was derived.

The goal of this project is to determine a method for testing various arthrodesis nails against each other dynamically. This includes the design of an easy to use test apparatus and method. The device should be adaptable to conduct tests beyond the initial testing parameters. The cost of the test apparatus and testing must not exceed the \$20,000 grant.

4.3 Test Design

4.3.1 Determining Testing Parameters

The first step that had to be completed in designing the test protocol and apparatus was to determine the parameters under which the test was to be conducted. This included determining the proper number of cycles for a test, the frequency of these cycles, the force under which the test was to be conducted, and if the test should be designed to mimic gait.

Through research and discussions with the orthopedic surgeons, it was determined that currently available arthrodesis nails, as well as the ratcheting nail, can only handle compression along its mechanical axis. This mechanical axis is the same as the mechanical axis of the bones in which it is inserted. Because of this, it was determined that it is only necessary that the testing device be uniaxial in nature

A previous study conducted by Eichhorn et al. (2006), was similar in nature to the problem presented to the design team. This study showed that compression loss was noticeable at 10,000 cycles. Because of this, the design team decided that by running tests for the same length of time, the results will then be directly comparable to this study. To mimic the reaction the implant would have in-vitro, it was decided to run the test at a

speed and force similar to the average person. Thus it was decided that each cycle would run to 200 lbf of compression at a speed of 1 Hz.

4.3.2 Determining a Proper Testing Apparatus

Since the WPI campus has multiple mechanical testing machines, and the client has access to the WPI campus, the design team decided to employ the use of one of these machines to apply the cyclic loading forces to the sample. Since the sample was to be loaded cyclically, a hydraulic machine would be preferable. Also, the machine would have to be able to handle the 200 lb compressive load force. To account for any overshoot of this force that the machine might encounter, the design team decided to apply a factor of safety of at least two to all decisions regarding force recording equipment. Thus, the machine had to be able to handle at least 400 lb compressive load force. Also, the ease of access to the machine for both the design team and the client was considered in the evaluation. The available machines were then compared using a pairwise comparison as shown in Table 4.1.

Table 4.1: Pairwise Comparison of available mechanical testing machines on the WPI campus

	BME	ME/Biomechanics	Civil/Impact	Civil/Tinus	Civil/Instron	Total
BME	x	0	1	1	0	2
ME/Biomechanics	1	X	1	1	1	4
Civil/Impact	0	0	X	0	0	0
Civil/Tinus	1	0	0	x	0	1
Civil/Instron	1	0	1	1	x	3

From this comparison, it was determined that the best machine to use would be the MTS 858 Mini-Bionix owned by the Mechanical and Biomedical Engineering Departments.

4.3.3 Determining a Bone Model

To run the test, a suitable bone model had to be determined. The most ideal model to use for these samples would be cadaver specimens. However, these would be expensive and difficult to obtain. Because of this, an analogous bone model had to be determined. Animal specimens were considered, but rejected, because their anatomical differences when compared to humans would not allow for proper arthrodesis nail insertion.

Sawbones are currently used in a variety of orthopedic tests. For this procedure, it would be important that the Sawbones be able to mimic the viscoelastic properties of real bone, as this is what is believed to be the cause of compression loss in arthrodesis procedures. The team was unable to find study in which the viscoelastic properties of Sawbones were tested. These properties were thus tested by the team through cyclic tests, comparing Sawbone plastic cortical shell (available only in knee joints), and Sawbone foam cortical shell (available in ankle joints) to bovine samples obtained from a butcher. The stress within all samples was kept the same and the strain per cycle was measured. The initial strain in both the plastic and foam Sawbones happened abruptly. After this point, the peak strain data followed a linear curve. Because of this and the fact that the MTS machine took 50 cycles to achieve a repeatable cycle, the first 50 cycles were eliminated from analysis. The slopes of the linear curves were then calculated and compared. Figure 4.1 shows the averages of all the samples run. The data for each sample can be found in Appendix C.

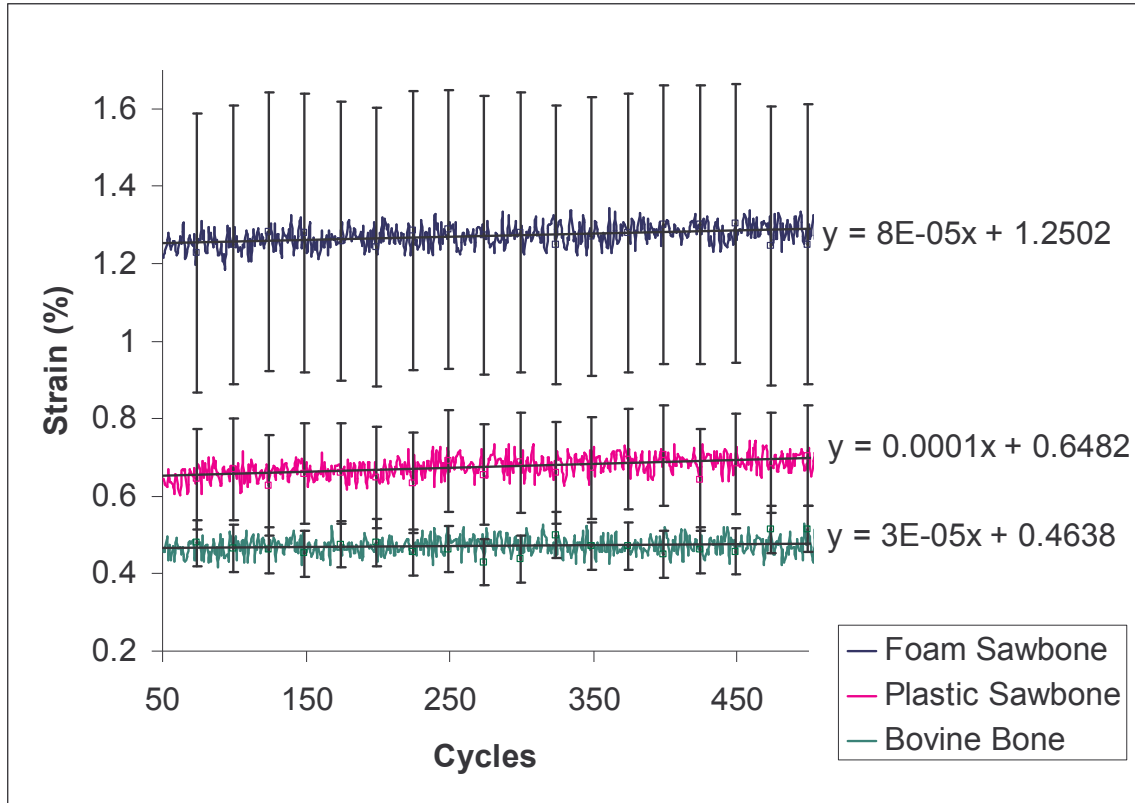


Figure 4.1: Strain versus cycles graph showing the linear increase of the strain in each bone sample used.

All of the data shows that both the Sawbones and the bovine bones demonstrate a linear increase in strain over time. Because of the similar slopes it was deemed that both foam and plastic Sawbones will act with similar viscoelastic properties compared to real bone after the initial strain. As the mechanical properties of plastic cortical shell Sawbones are closer than foam to real bone, when possible, it is recommended that plastic Sawbones be used.

4.3.4 Determining Proper Machine Mounts

To mount the Sawbone samples to the MTS machine, a set of specialized grips had to be developed. When doing testing on the knee, only the proximal end of the femur and distal end of the tibia need to be supported. To do the same testing on an ankle joint, the proximal end of the tibia needs to be supported in the grip as well as the entire foot.

The mounting grip for femurs and tibias could be the same. The group brainstormed a few initial designs as shown in Figure 4.2.

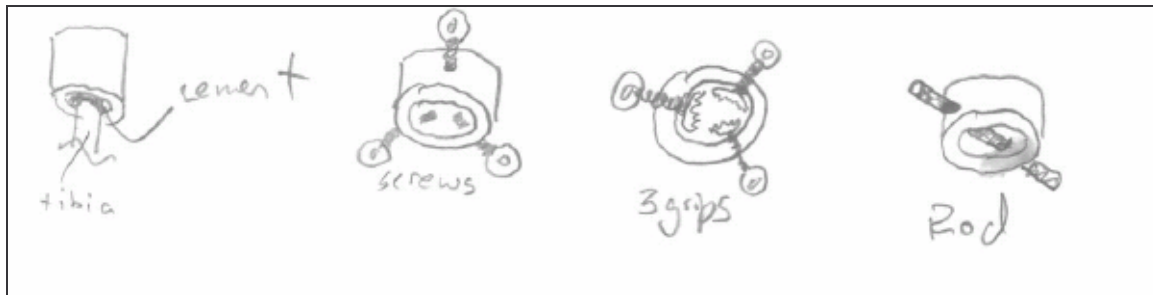


Figure 4.2: Initial designs for mounts of the tibia and femur.

After reviewing these initial designs it was determined that a similar mount had already been developed for a previous study done by Eli Wilson. The device, as shown in Figure 4.3, will mount directly to the MTS machine and requires that the tibias and femurs be potted with cement in 3" PVC endcaps.

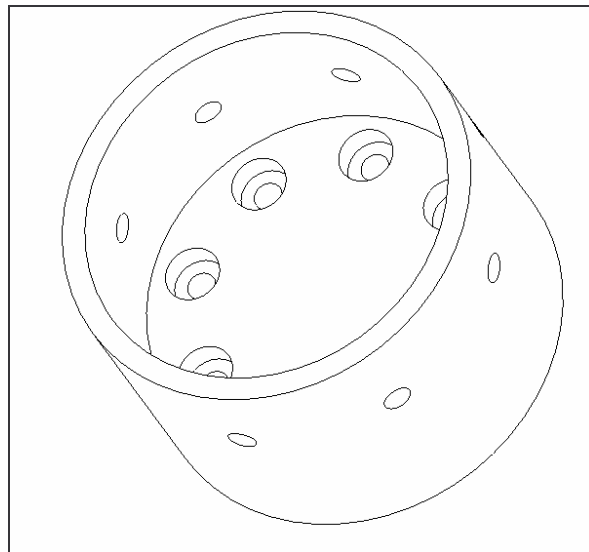


Figure 4.3: Mount for tibia and femur designed by Eli Wilson.

To help facilitate the potting of the bones in the cement the design team built a simple device to hold the tibias and femurs in proper alignment while the cement cured. This can be seen in Figure 4.4.

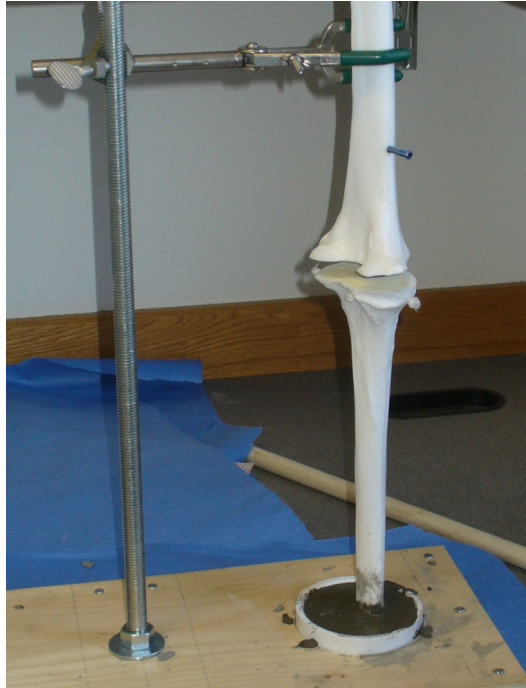


Figure 4.4: Alignment device for potting bones in cement

The group brainstormed many ideas for mounting the foot to the MTS machine. These original designs all included a bottom plate with a different medium to hold the foot in place such as rods, screw, or straps. In the end, the team opted to use a combination of straps and screws to hold the foot in place as shown in Figure 4.5.

Appendix D contains the professional drawings of all the mounting devices.

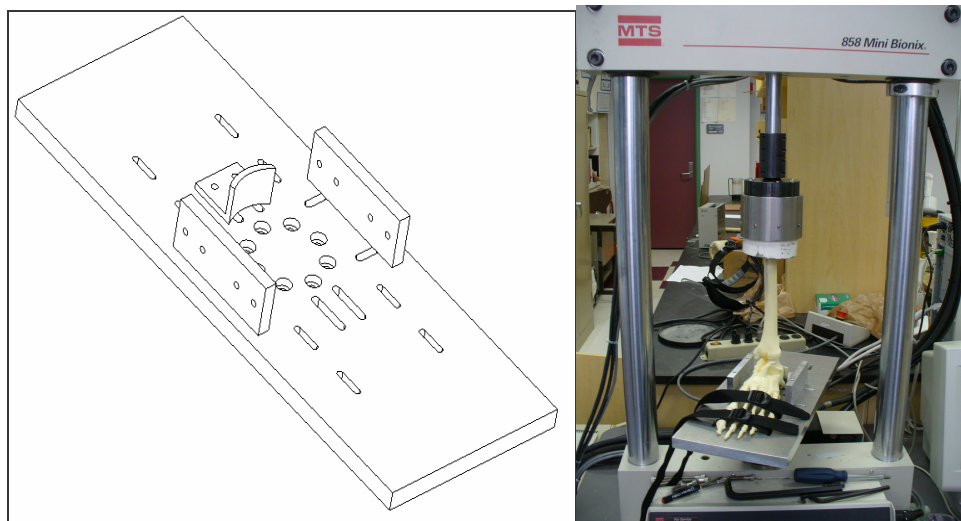


Figure 4.5: Footplate mount for ankle testing. On the left is the isometric view of the CAD drawing for the mount. On the right is the foot held in place using the mount.

4.3.5 Determining a Proper Pressure Measurement Device

Lastly, the team needed to determine a method for measuring the reduction of compression within the ankle and knee joints. Three different methods were examined, Fuji pressure sensitive film, Tekscan pressure mapping pads, and Futek doughnut load cells. These options are compared in Table 4.2, via a morphological chart.

Table 4.2: Morphological chart comparing different methods for measuring compression within a joint.

Function	Possible Means		
Measure Force Across the Fusion Site	Load Cell	Pressure Film	Tekscan Pad
Acquire Dynamic Data	Tekscan	Load Cell	
Allow for Insertion of an intramedullary rod	Load Cell	Pressure Film	
Connect to MTS for Data Acquisition	Load Cell		

Fuji pressure sensitive film was eliminated because it could only measure the maximum load applied. Though the thin nature of this film would have been perfect, it is impossible to determine a compression loss.

Tekscan pressure mapping pads were ideal and thin. They also would have provided a nice image as to where exactly in the joint the pressure is being lost. However in order to insert the arthrodesis nails through the pad, a custom designed pad would have had to be manufactured. These custom designs would have cost more than the budgeted cost of \$2000 for this part of the project. Since the image was not a necessity for the client, this method was also eliminated

This left doughnut load cells. These load cells measure the force applied on them in compression as well as already having a hole in which the arthrodesis nail can pass through. These made them the ideal candidate for use in this design. Due to the differing

sizes of the ankle and knee joints, the team purchased a separate load cell for each joint. The Futek LTH-400 was purchased for use in the ankle, and the LTH-500 was purchased for use in the knee. These load cells can measure up to 1000 lbf and 2000 lbf respectively. They were chosen on the criteria that their diameters fit the sawbones that were selected, and that they were capable of measuring the expected compressive joint forces, plus a factor of safety of at least two.

After making all of the necessary decisions, the finalized testing parameters were:

1. The test will cycle to 200lbf compression 10,000 times at a frequency of 1Hz.
2. Uniaxial testing will be done using the MTS 858 Mini-bionix machine and the specially designed grips.
3. The specimens will be Sawbone models.
4. Loss of compression in the joint will be measured using Futek doughnut load cells.

Chapter 5: Methodology

The goal of this project was to design a device and test protocol for comparing the dynamic compression of various arthrodesis nails. The device needed to be suitable for testing both ankle and knee arthrodesis nails. It was required that the test apparatus be easy enough to use so that the client could conduct future tests. These issues were investigated by first designing a test apparatus, followed by creating a test protocol to be used with the device. After testing the device and test protocol, instructional material was created for using the apparatus.

5.1 Specific Aim One

The first specific aim required that a test protocol and apparatus be developed such that any researcher or lab technician could perform the necessary tests.

5.1.2 Determining a Suitable Test Protocol

A test protocol is needed in order to achieve comparative data for different arthrodesis nails. It is believed that force across the arthrodesis site will decay with time using the existing arthrodesis nails, as shown in Figure 5.1. Using the ratcheting nail in the joint, it is believed that this decay will not occur as shown in Figure 5.2. Therefore, the testing protocol would need to measure the force across the site dynamically.

In order to begin testing arthrodesis nails, models of both the knee and ankle joints needed to be achieved. Sawbones are used in many mechanical and surgical applications. These composite bones provide an anatomically correct framework in

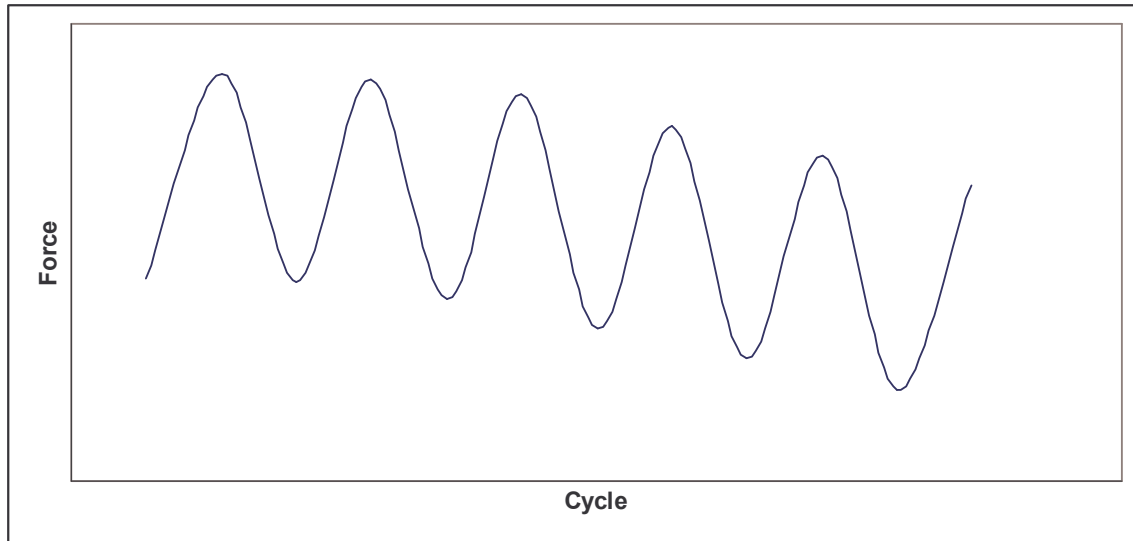


Figure 5.1: Prediction of data for existing arthrodesis nails. The force along the fusion site will decrease with time.

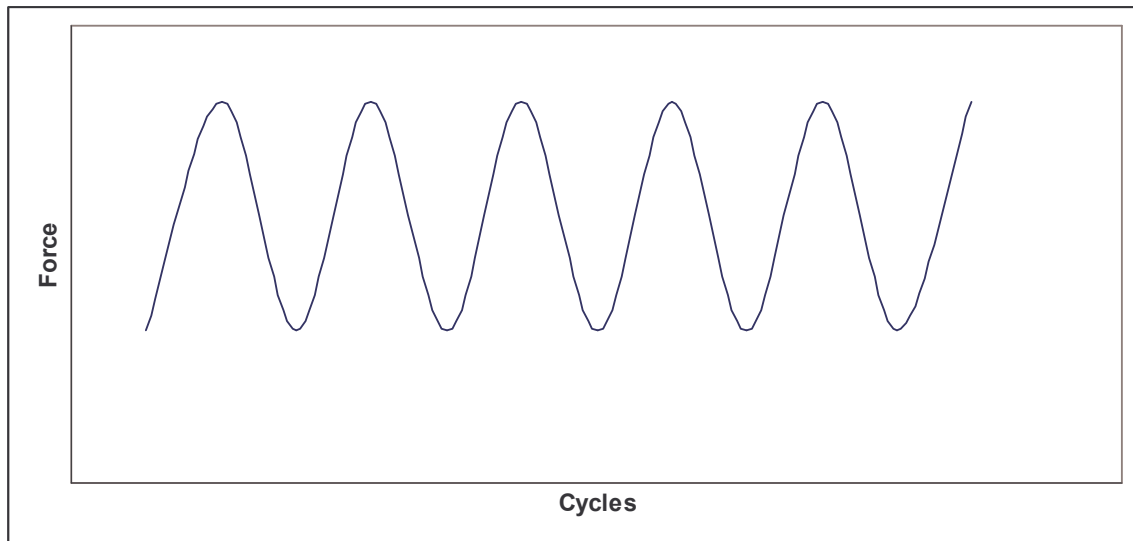


Figure 5.2: Prediction of data for ratcheting nail. The force along the fusion site remains constant with time.

which testing can be conducted. Sawbones are composed of materials that have similar mechanical properties to bone under certain loading conditions.

The testing protocol cyclically loads the sample, thus any reduction in compression in the joint will be due to bone creep. As discussed in the previous chapter, the team conducted tests to prove that the creep of the Sawbones is similar to that of real bone, thus making Sawbones a suitable material for the proof-of-concept testing desired

by the client. If it is determined that future testing would be useful, the testing apparatus and protocol could then be used with cadaver samples.

Since arthrodesis nails only allow for compression in the axial direction, a uniaxial 858 Mini Bionix MTS machine was used to apply a 200 lb load on the sample at a rate of one hertz. An additional load cell, purchased from Futek, was placed within the joint to measure bone on bone compression.

A step by step lab protocol was then produced. This protocol can be found in Appendix E.

5.1.2 Designing the Testing Apparatus

To use the MTS Mini-bionix 858 for this test, specialized grips needed to be made. A previous WPI study produced grips which could be used for testing the knee arthrodesis nail samples. However, in order to test ankle arthrodesis, a specialized foot plate was designed. Professional drawings of this part can be found in Appendix C. This plate is designed to mount directly to the MTS machine while holding the foot in place using a series of clamps and straps.

The previously created grip for the MTS machine required that the sample be cemented into place in PVC end caps. To hold the bone in proper alignment while the cement cures, an alignment device was created. The device was made from a 5/8" rod and a piece of wood with two 4" holes drilled into it. The rod had two clamps attached to it to hold the bone pieces vertically while the cement cures. The clamps on this device can be adjusted to allow the mechanical axis of the bones to align vertically as is necessary for the MTS machine.

5.2 Specific Aim Two

To verify that all parts of the device were working properly and to insure accuracy of the written protocol, a practice test was run. To do this a $\frac{5}{8}$ " steel rod with locking holes drilled into it, as shown in Figure 5.3, was placed in the intramedullary canal of a Sawbone sample. The test procedure was then executed. This nail was a simple rod with a hole drilled at the top and bottom, such that it could be locked in the femur and tibia of the knee without the ability to allow for dynamic compression. This design was based on those of first generation arthrodesis nails. For this practice test, the rod was only locked in the femur to allow for maximum dynamic compression to occur on the load cell. This was to assure the design team that the load cell would give readings fast enough for the speed under which the test was being run. It was found that all components of the device, including data acquisition device and grips were all working properly. A few of the steps in the original testing procedure were out of order, which might have caused confusion in upcoming tests. These steps were re-arranged into the correct order and the finalized protocol was written and used for further testing.

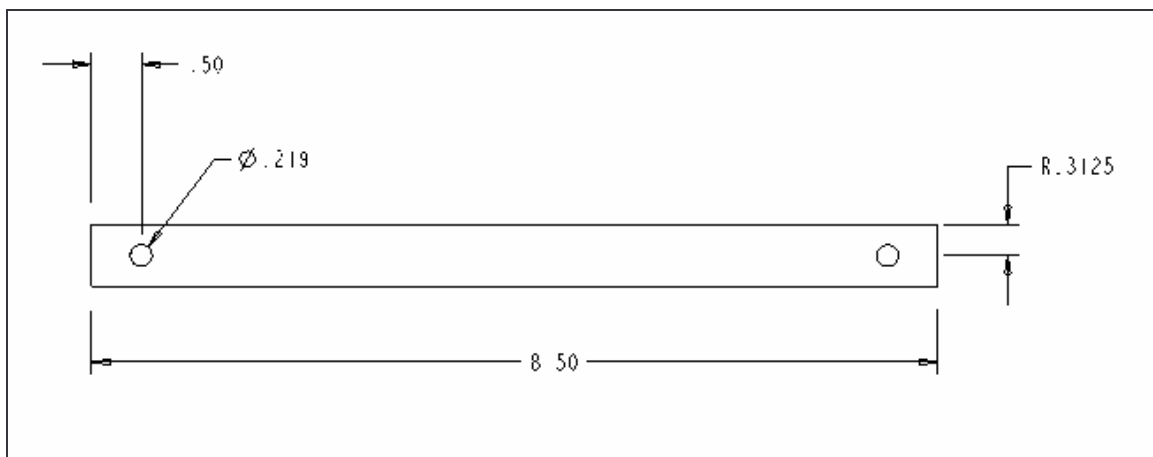


Figure 5.3: Dimensions of the steel rod used for the validation tests

It was next important to show that the device and protocol will show the loss of compression that is believed to occur in standard locked nails. Since currently available

nails were not available to the design team, the mock nail shown in Figure 5.3 was used, locked in place in both the tibia and femur.

Initial compression was placed on the joint using the MTS machine as an external fixator, similar to clinical application. This was done using a compress and hold function on the machine while the final locking screw was placed across the bone. The sample was then tested using the developed testing protocol. Three of these samples were tested and analyzed to see if they measured a compression loss in the joint over the 10,000 cycles. It was assumed that if loss was seen, then the protocol would be good for testing the clients newly designed nail. It was also assumed that if this protocol worked for testing in the knee joint, then it would also be useful for testing in the ankle joint.

Final testing of the device was done using the ratcheting nail. The nail was inserted into the knee joint, and manual compression was applied. The test was then run and data was analyzed to see if the ratcheting nail would maintain compression over time, and to see if a ratchet would be noticeable during the test.

A priori power analysis using power analysis software (GPower v. 2.0) was then completed to determine a recommended sample size. The approximate differences in the average loss of compression between the locked nail and the ratcheting nail were unknown. Because of this, the effect size (d) for the program was calculated assuming the difference in the loss of compression to be 50%. Alpha was valued at 0.05 with a power of 0.95. This calculation led to a minimum sample size of four. Since the values for the average loss of compression used were just assumptions, it was recommended that the client run a post hoc power analysis after testing to determine the actual power achieved. If the desired power is not achieved, more samples can be run.

5.3 Deliverables: Design of Training Materials

Since the researchers will not be the end users of the test apparatus and protocol, it was determined that it would be necessary to create proper training materials. These materials could be given to future lab technicians to teach them how to properly conduct the desired tests.

Aside from the written lab protocol, the test procedure was animated through the use of digital video and Camtasia (v3.1.2, TechSmith), computer-recording software. Digital videos were created for demonstrations of how to mount the grips and samples to the MTS machine and for demonstrations on how to use the alignment devices. Camtasia was used to provide video tutorials on how to operate the MTS software and analyze the retrieved data.

Chapter 6: Results and Discussion

The purpose of this section is to present the results from the procedures followed in the methodology chapter of this report. The results that are presented first make up the protocol that was developed for this project. The protocol describes how to properly evaluate the loss of compression in a joint locked with an arthrodesis nail over time. The second part of this chapter presents the data collected by using the protocol that was developed.

6.1 Testing Protocol

The testing protocol was developed to meet *Specific Aim One* of this project, which required the development of a test protocol and apparatus to compare the new ratcheting nail design to other arthrodesis nails. The procedure is based on the use of Sawbones as models of human bone.

6.1.1 Sawbone Preparation

For knee joint, use Sawbones' *Large Left Knee*: Item number 1107-2.

For ankle joint, use Sawbones' *Large Left Foot/Ankle*: Item number 1132-3.

1. Separate Tibia and Femur by cutting elastic ligaments.
2. Using a 5/8" drill bit and a power drill, drill a hole in the Posterior Intercondyloid Fossa of tibia.
3. Using a table saw, flatten the proximal end of the tibia, keeping the Medial Malleolus pressed against the push arm.
4. Make the Distal Femoral Osteotomy Cut by setting the blade to 5° posterior slope and the push arm to 6°, keeping the Femoral Head pressed against the push arm.
5. Using a band saw, cut the tibias and femurs to 7 7/16" long.

6.1.2 Potting the Sawbones

1. Place 3" PVC endcaps into the holes in potting device.
 2. In the proximal end of the femur and distal end of the tibia, plug the intramedullary canal with Play-Doh®.
 3. Insert a 5/8" rod into the intramedullary canal on the distal end of the femur.
 4. Place proximal end of the femur into the PVC endcap and clamp it in place.
 5. Using a level, adjust the clamp screws until the bone is centered in the PVC cap and the rod is perfectly vertical.
 6. Using Quickrete Anchoring Cement, mix the amount of concrete necessary to fill the endcaps to a putty-like consistency (when potting two samples at a time the amount of concrete and water needed is approximately 3 full endcaps of mix and about 300mL of water).
 7. Scoop the mixed concrete into the endcaps.
 8. Tap endcap and top of concrete mixture for 30 seconds to 1 minute to remove any air bubbles.
 9. Let the cement set for approximately 4 hours or until hardened.
 10. Place the tibia on top of femur and flip the system over.
 11. Put new endcaps in potting device.
 12. Using a straightedge and a level, align the top and bottom endcaps.
 13. Repeat steps 6-9
 14. Let all concrete cure for 24 hours before doing any testing
- *Note that when performing an ankle test, the only pot that needs to be done is to the proximal end of the tibia

6.1.3 Running the Test

1. Mount the appropriate specialized grips to MTS machine (2 collets for a knee test, and one collet on the top and foot plate on the bottom for an ankle test).
2. Connect and screw load cell input and output wires into the amplifier.
3. Insert the nail according to manufactures instructions with load cell in between joint (be sure to make sure bottom and top washers are in place).
4. Connect the load cell BNC connector to slot in back of controller unit (J78 for 2K load cell used in the knee, J77 for 1K load cell used in the ankle)
5. Plug in load cell power source.
6. Log onto TestStar using the tibianail configuration (username: mts, password: mts).
7. Apply initial compression to joint (to insure compression in each joint is the same, be sure to monitor the load cell meters in the TestStar software).
8. Power on MTS machine components in the following order: Cooler, hydraulics turned to high, reset the interlocks on control arm, turn HPS control to high, turn HSM control to low then high, then turn Actuator Positioning Control on.
9. Unlock the cross head and raise it all the way up, and raise the actuator to midway.

10. Place the sample in bottom grip.
11. Zero the MTS load cell.
12. Lower the cross head into place so as to only put a small force on the sample (this can be anywhere between 1 and 100 lbf compression).
13. Lock cross head in place and tighten the top and bottom grips.
14. In TestStar, go to “Adjust-Tuning”. Insert tuning parameters if you have them, or run tuning procedures. For plastic sawbones, P=22.056, I=5.175, D=.0085, F=0.
15. Open TestWare.
16. Open the appropriate testing template (“kneetest” for testing knee nails, “ankle test” for testing ankle nails).
17. Execute procedure (it will ask you to name the data file, give the data file a name and click ok). Before doing this step make sure Actuator Positioning Control is turned off.
18. When the test is complete, loosen the grips and raise the crosshead to remove the sample.
19. Re-lock the cross head.
20. Shut off the hydraulics by hitting the red “Stop” button on hydraulic unit.
21. Shut off the power to the cooling unit.
22. Close all of the test ware windows.
23. Open the TSCX folder on desktop.
24. Locate the data file and copy it to 3 ½” floppy or USB drive (Note: when using a USB drive to remove data, the drive must be safely removed using the safely remove hardware wizard in order for files to be saved on the drive).

Along with this step by step protocol, video tutorials were produced to aide the end user. These tutorials used screen capturing software (Camtasia), as well as digital video camera, to walk the user through each one of the steps described above. The video tutorials can be found in Appendix G with the hard copies of this report.

6.2 Verification of Testing Protocol

To verify the testing protocol, a practice test was done on the knee joint with three plastic Sawbones samples. The arthrodesis nail used for the practice test was a “mock” nail designed by the team to mimic first generation arthrodesis nails. Its details were discussed previously in Section 5.2 of this report. The data produced demonstrates both the compressive force within the joint and the force produced by the MTS machine. The

data were gathered in a force vs. cycles graph, such as in the graph for “Sample 1” shown below in Figure 6.1. The graphs for the remaining samples can be found in Appendix G.

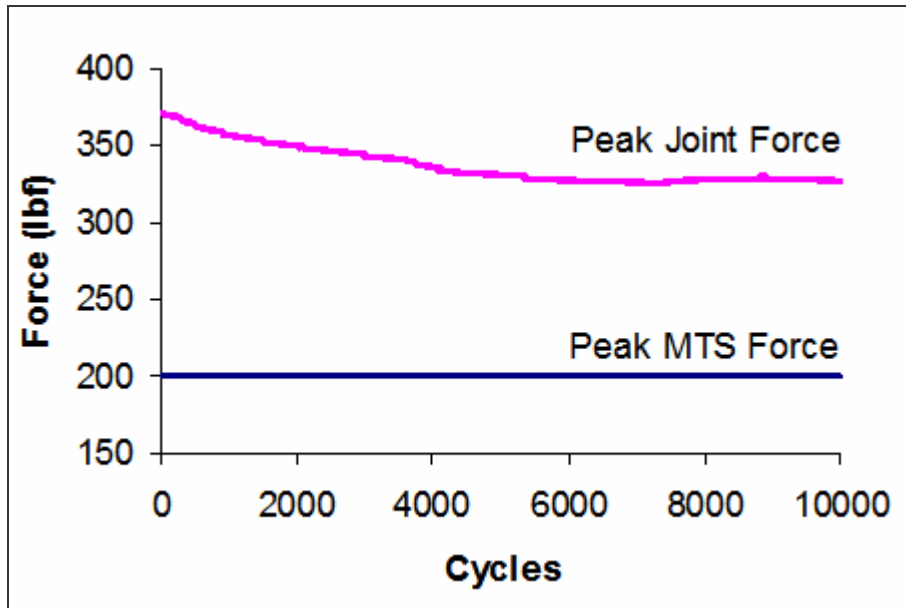


Figure 6.1: Force versus cycles curves for MTS produced compressive force and compressive force existing within the joint; the joint was preloaded to 300-370 lbf using the MTS machine to create the compression.

The data for all three samples is represented in Table 6.1 below. The table shows the difference between both the MTS and in-joint forces at both 1 and 10,000 cycles. It also demonstrates the percent of compressive force lost within the joint after 10,000 cycles of 200 lbf uniaxial loading.

Table 6.1: Demonstration of reduction of compressive force within the knee joint.

	Sample 1	Sample 2	Sample 3	Average
Initial Joint Force (lbf)	371.7	302.3	341.9	338.6
Final Joint Force (lbf)	327.1	277.8	303.9	302.9
% Loss of Joint Force	12.0	8.1	11.1	10.4

The validation test shows that after 10,000 cycles, the compressive force within the knee joint decreases by an average of 10.4 %. This is a significant loss of compression considering that 10,000 cycles equates to just 2.8 hours of constant walking at one step per second. The design team noted that the initial compression obtained using a locked nail was much greater than reported in literature, approximately 112 lbs, for

similar nails (Cunningham et al. 1989). The design team believes that this was due to the difference in equipment available to surgeons and the design team. When trying to place the second locking screw in the tibia the design team did not have an external fixator available. Thus to apply the compression, an MTS machine was utilized, which is capable of exerting much larger forces than an external fixator. Also, the lack of a fluoroscope required that a desired displacement be achieved despite how much force it took to reach the displacement. The design team did not find this to be of major concern because the point of these tests were not to determine the amount of force lost with a locked nail, but rather if the device would record and measure such a loss of compression. This proves that the device works to the specification of measuring dynamic compression across a joint.

The test was then run with the ratcheting nail implanted in the specimen. Initially it was noted that the force exerted on the joint post insertion was much lower than mock nails. However, this is difficult to compare analytically because of the difference in insertion techniques.

After running the test for 10,000 cycles it was noticed that compression within the joint remained constant, however the nail never ratcheted. The test was then extended to 30,000 cycles to see if a single ratchet could be achieved. Though compression continued to remain constant as seen in Figure 6.2, the ratchet was never achieved.

To properly evaluate the ratcheting nail, it would be important to view at least one ratchet while testing each sample. It was decided to run a monotonic loading test, where the sample would continuously be subjected to higher and higher loads. Doing this will

force the nail to ratchet and would provide information as to how much force would be required to compress the Sawbone specimen enough to force one ratchet. As can be seen

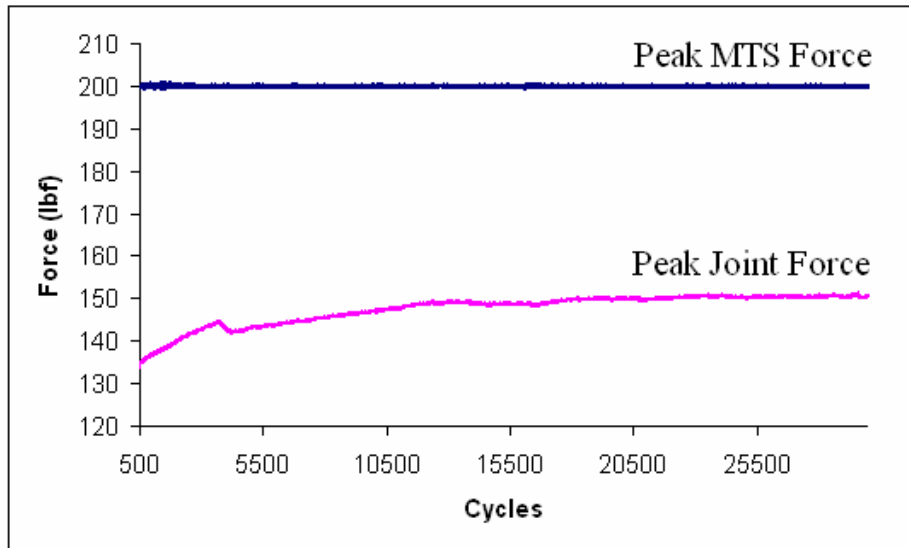


Figure 6.2: Peak MTS force vs. Peak joint force for 30,000 cycle tests. No ratcheting was seen during this test.

in Figure 6.3, the ratchet occurred at 4.5 mm of compression, or about 1200 lbf of compression applied to the specimen.

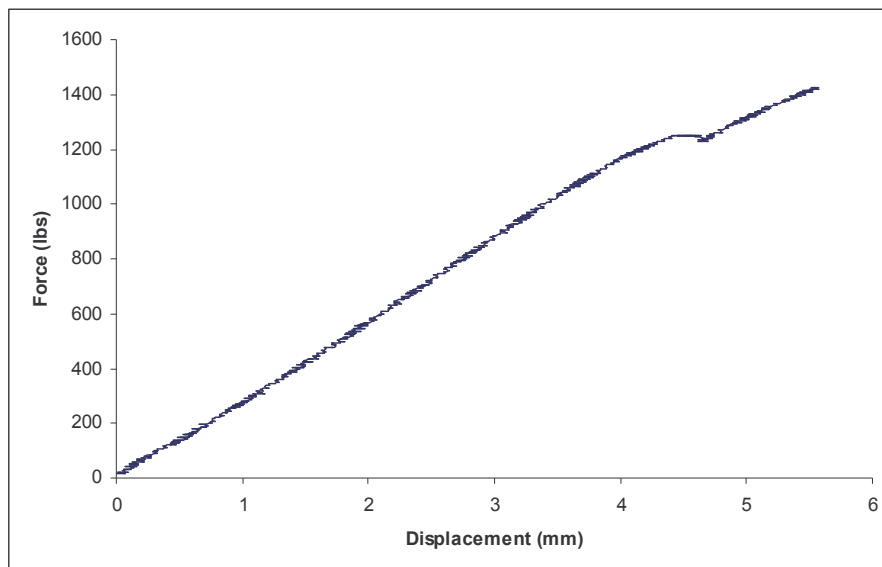


Figure 6.3: Applied force vs. displacement to force the ratcheting nail to compress “one click.”

A portion of the ratcheting design was confirmed in that, as shown in Figure 6.4, the nail experienced minimal stress shielding. Since so much force is required to create a

ratcheting point, Dr. Wixted must re-design his nail. However, this still represents that the device designed meets the specification of being adaptable as it was able to be reprogrammed for a greater number of forces, as well as the monotonic load testing.

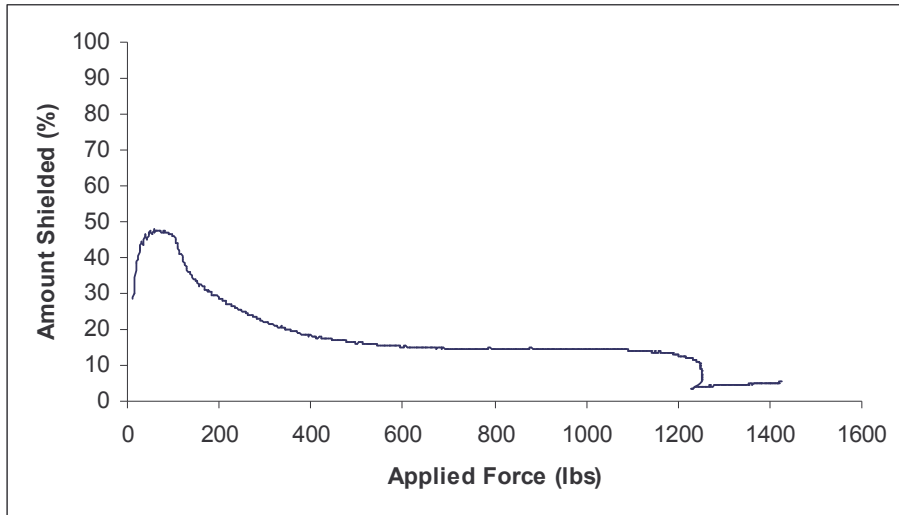


Figure 6.4: Percentage of force shielded by the ratcheting nail during monotonic testing.

The priori power analysis shows that the tests should be run with a minimum sample size of four. This assumes that the difference in the average compression reduced between different nails will be at least 50%. This may prove to be incorrect and a post hoc analysis should be run.

Chapter 7: Conclusions

The testing device and protocol are capable of measuring compression dynamically across a fusion site. Using a locked nail, the device measured an average reduction in compression of about 10%. A 10% reduction in force is significant considering the small number of cycles (10,000) through which the test runs. Therefore, it was determined that the device will suit the needs of the client in comparing the reduction of compression in multiple arthrodesis nails.

As shown by the monotonic load testing, the device is capable of being reprogrammed to test in many different types of loading situations beyond the parameters originally developed by the design team. These include, but are not limited to monotonic load testing, torsional load testing, or an increased number of cycles. The specially designed grips for the MTS machine are large enough that they will fit human cadaver samples as well, should cadaver testing be necessary.

Chapter 8: Recommendations

The testing completed only provided the client with an appropriate protocol and device to achieve his desired results. To compare Dr. Wixted's ratcheting arthrodesis nail to other nails the procedure needs to be run with the following recommendations.

8.1 Recommendations for Arthrodesis Nail Comparisons

It is recommended that testing of at least 4 samples with each nail be completed. A priori power analysis was first run to see what sample size should be used to statistically validate the difference between two nails. However, since the difference between the compression averages of a locked nail and a ratcheting nail were unknown, the four samples were determined to be the minimal sample size necessary to achieve 95% accuracy.

After running these samples it is recommended to complete a post hoc power analysis. A post hoc power analysis shows the actual power achieved in the testing. This can be done using G-Power, a free power analysis software tool available online. If the power is not of a desired level, then the achieved average compression values can be used to run a more accurate priori power analysis. From this, the correct number of samples can be determined. A good p-value for this power analysis would be a value greater than 0.8.

It is recommended that the basic knee test procedure be followed to test compression in the ankle joint. To test the arthrodesis nail on the ankle joint, the same procedures for testing on the knee can be used with a few minor changes. First, only the tibia needs to be potted as the foot will be mounted to the MTS machine using the

designed “ankle mount.” Also, simply use the smaller load cell so that it will fit in the joint and the testing protocol “ankletest” to allow the computer to record data from the correct load cell. The Sawbone preparation protocol for the ankle will have to be developed by the researcher.

It is recommended that tests be done on both knee and ankle nails. It is recommended that the tests for both the knee and the ankle be completed if possible. Testing on the knee alone will allow for proof-of-concept for Dr. Wixted’s ratcheting nail. However, it is important that tests also be conducted in the ankle to prove that the design would be a viable alternative to currently available arthrodesis nails for both the knee and the ankle.

It is recommended that the comparison nails be the Biomet and Wichita arthrodesis nails. The Biomet and Wichita nails are the leading arthrodesis nails for the ankle and the knee respectively. Because of this it is recommended that these nails be used for the comparison with the ratcheting fusion nail.

It is recommended that the given template be used to compare the results. The design team has provided the client with an Excel template for comparing the results of the tests. The template is set up such that pasting the received data into the template will automatically adjust the graphs and mathematics. This insures that all tests are analyzed in the same manner.

8.2 Further Areas of Investigation

The current testing device is adaptable for different types of testing, such as testing on cadavers or testing the nails in torsion. However, one major assumption the design team made was that it was only necessary to test the arthrodesis nails under

uniaxial compression. However, should this testing prove that the ratcheting design is superior to the currently available arthrodesis nails, orthopedic device companies may require that the nail be tested in a device mimicking gait. This further research would require a new type of mounting apparatus and possibly a different machine to perform the tests.

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Glossary

Arthritis - Chronic inflammation of a joint, causing pain.

Arthrodesis - Medical procedure in which two or more bones are together.

Bovine bone - Bone from a cow.

Cortical bone - Compact bone. Primary load bearing tissue in long bones; Sawbones attempt to mimic this.

Distal - Situated away from the point of origin.

Dynamic compression - Compression occurring over a period of time. Results from normal physiological loading.

First generation nail - An arthrodesis nail which does not have a nail mounted compression device.

Intramedullary nail - Orthopedic implant which is inserted into a bone's intramedullary canal.

MTS – A company that produces various types of mechanical testing machines.

Power Analysis - Statistical calculation used to estimate sample size or confidence of a test.

Proximal - Situated near the point of origin.

Sawbones - Composite bone models which can be used for orthopedic testing.
Developed by Pacific Research Laboratories.

Second generation nail – An arthrodesis nail that has a nail mounted compression device.

Stress shielding – Stress caused by normal loading is absorbed by an implant instead bone.

TKR - Total Knee Replacement Surgery; a surgical procedure in which the knee joint is removed and replaced with an artificial joint.

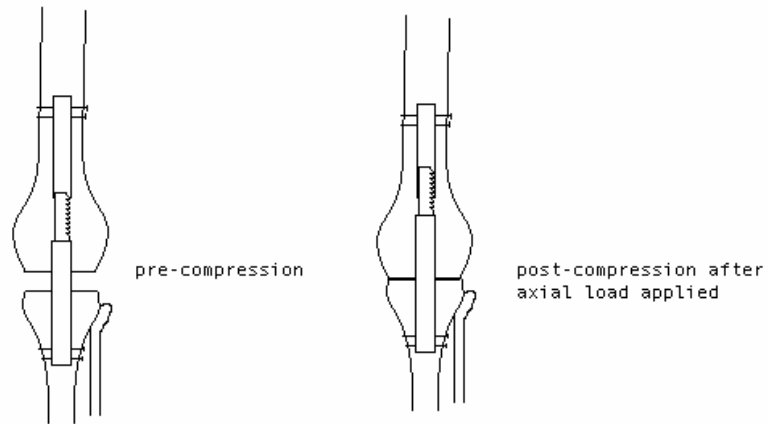
TTC - Tibiotalocalcaneal; the tibiotalar and talocalcaneus joints in the ankle.

UMass - University of Massachusetts; the institution providing the funding for this study.

WPI - Worcester Polytechnic Institute

Appendix A: A Detailed Description of the Ratcheting Arthrodesis Nail Designed by Dr. John Wixted

1. The rod consists of a proximal and a distal part, with the proximal part corresponding to the end of the rod closest to the origin of the limb, and the distal part corresponding to the end of the rod furthest from the origin of the limb. (Figure 1)
2. The overall diameter of the rod varies to fit a particular intramedullary canal from 9mm to 14mm.
3. The overall length of the rod varies to fit a particular intramedullary canal from 140mm to 340mm.
4. The distal most part of the rod has two holes across its diameter to allow for two 5mm interlocking screws to be placed through the holes to secure the rod within the intramedullary canal. (Figure 2)
5. The distal part of the rod changes its diameter such that the upper 1/3 of the distal part has a smaller radius by 3mm than the lower 2/3 of the rod. A series of teeth are machined into the rod along its narrow portion, with the tooth spacing being 2mm (Figure 2). The teeth are machined with the flat portion of the tooth facing the end of the rod, the sloping to the start of the next tooth. This allows for interlocking of the upper and lower ends of the rod.
6. The proximal most part of the rod has two holes across its diameter to allow for two 5mm interlocking screws to be placed through the holes to secure the rod within the intramedullary canal. (Figure 3)
7. The distal 1/3 of the proximal part of the rod is hollow, with the radius of the hollow portion being 3mm less than the overall radius of the rod. This provides space for the two rods to interlock. (Figure 3)
8. The distal 1/3 of the proximal part of the rod has two longitudinal cuts extending from the distal end towards the proximal end designed to create a cantilever in the distal portion of the proximal part. The length of the cantilever varies depending on the clinical application and necessary stiffness.
9. The inside of the cantilever has teeth machined into it, extending toward the center of the rod. This is designed to interlock with the corresponding portion of the distal part of the rod. A flat portion of both the distal and proximal parts assures rotational alignment and stability. (Figures 2,3,4)
10. The rod is inserted either separately or together, into the intramedullary canal and interlocked above and below the intended site of fusion. By means of axial loading, the rod can collapse in a controlled manner. If bony union is not secured by the initial compression, further axial load can be applied as the clinical situation dictates until the proximal and distal ends of the rod are fully engaged. At this point, no further compression is possible. The amount of allowable compression can be adjusted to meet clinical parameters by compressing the rod more or less at the time of insertion, prior to locking the ends into the intramedullary canal of the bone.



Intended site of bony union - knee fusion example

Figure 1. Clinical Application

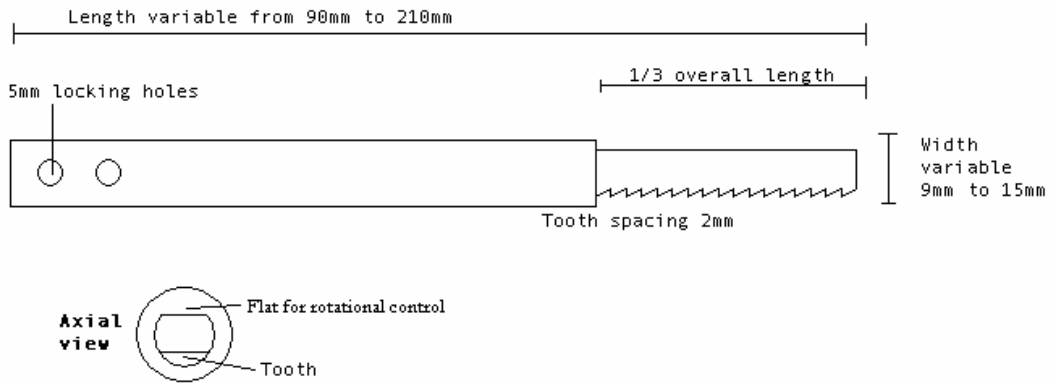


Figure 2. Distal Part of Intramedullary Rod

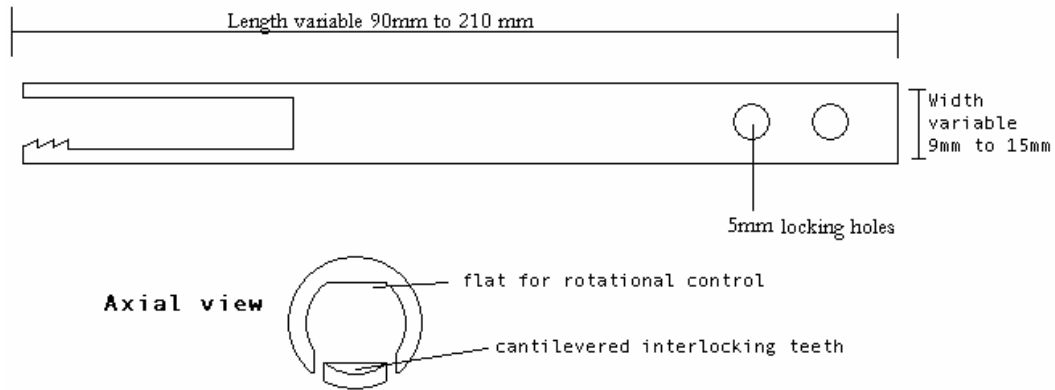


Figure 3. Proximal part of intramedullary rod

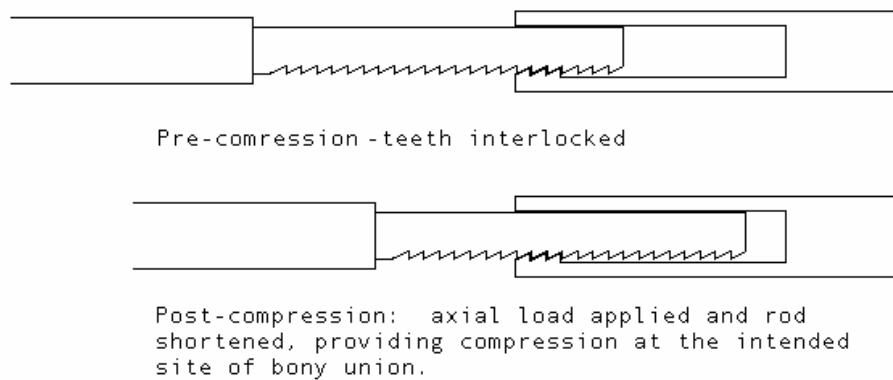


Figure 4. Detail of interlocking teeth

Appendix B: Weighted Objectives List

Objectives (1-least important, 4- most important)	Surgeon 70%	Design Team 30%	Surgeon Total	Design Total
Compare ratcheting fusion nail with other nails	4	4	2.8	1.2
Easy to use	2	1	1.4	0.3
Adaptable to other tests	1	2	0.7	0.6
Measure compression within joint	3	3	2.1	0.9

Combined Totals	
Compare ratcheting fusion nail with other nails	4
Easy to use	1.7
Adaptable to other tests	1.3
Measure compression within joint	3

Weighted Objectives in Order of Importance
Compare ratcheting fusion nail with other nails
Measure compression within joint
Easy to use
Adaptable to other tests

Appendix C: Sawbone vs. Bovine Test Data

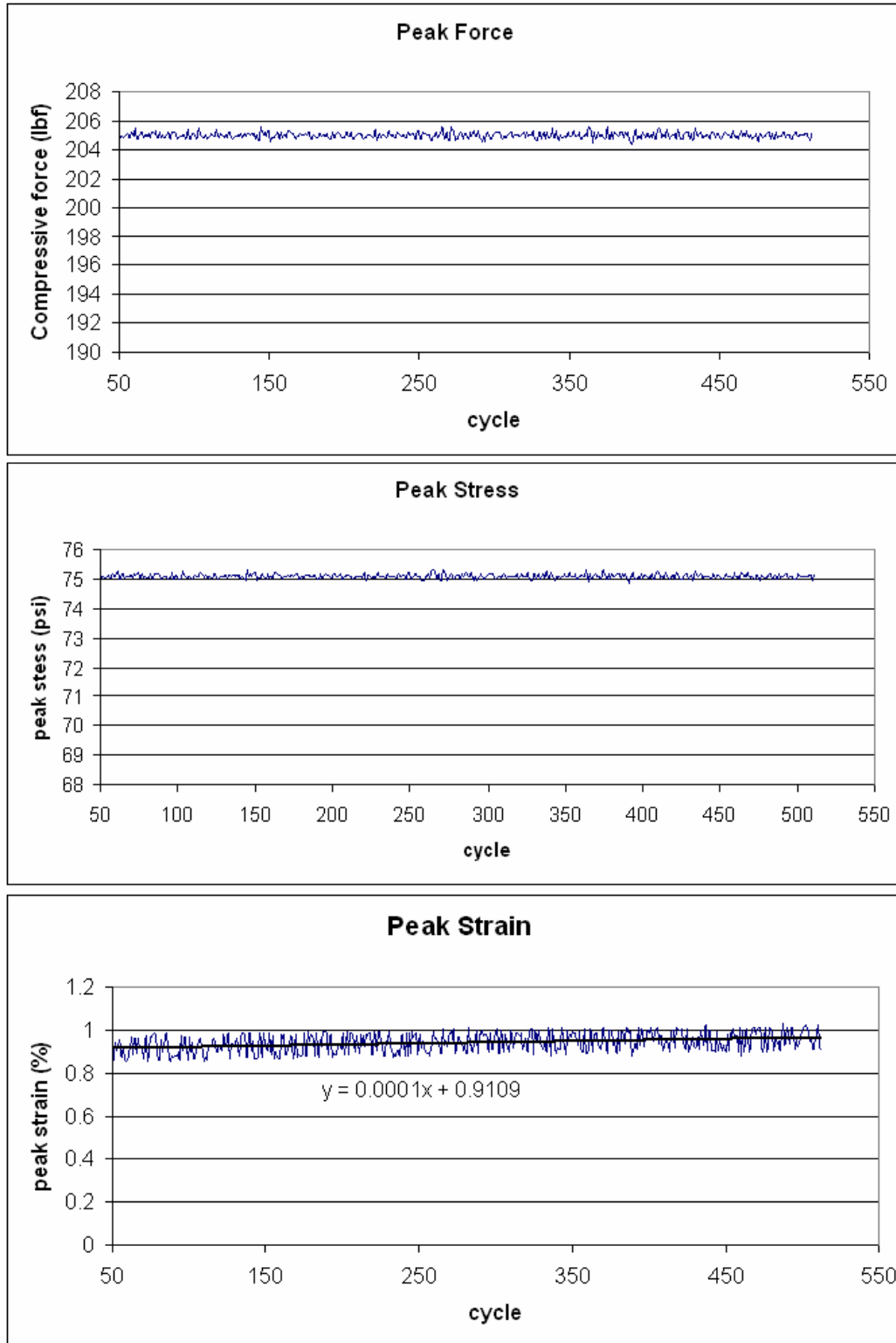


Figure AC.1: Graphs displaying peak force, stress, and strain versus cycles for foam-cortical shell sample #1.

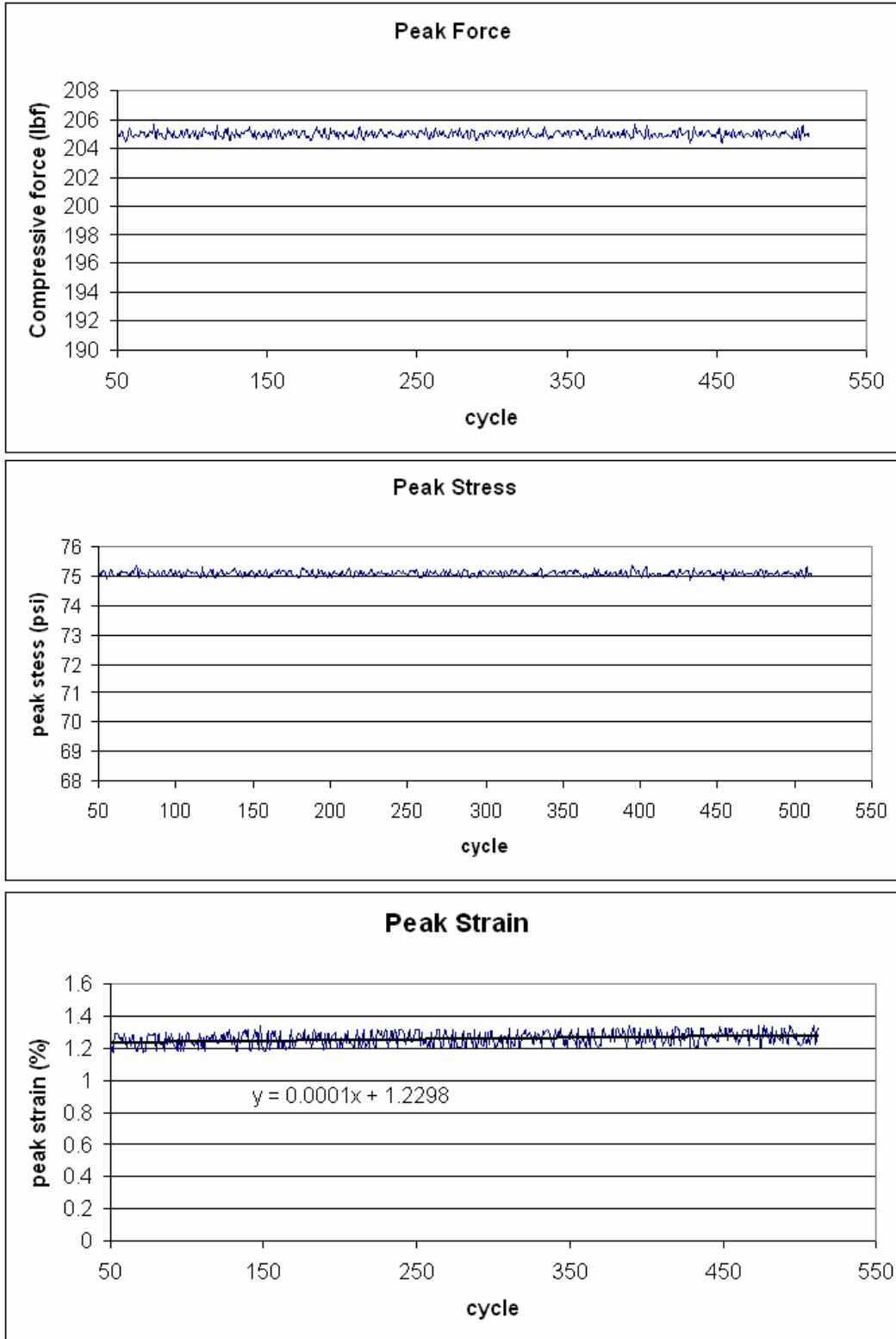


Figure AC.2: Graphs displaying peak force, stress, and strain versus cycles for foam-cortical shell sample #2.

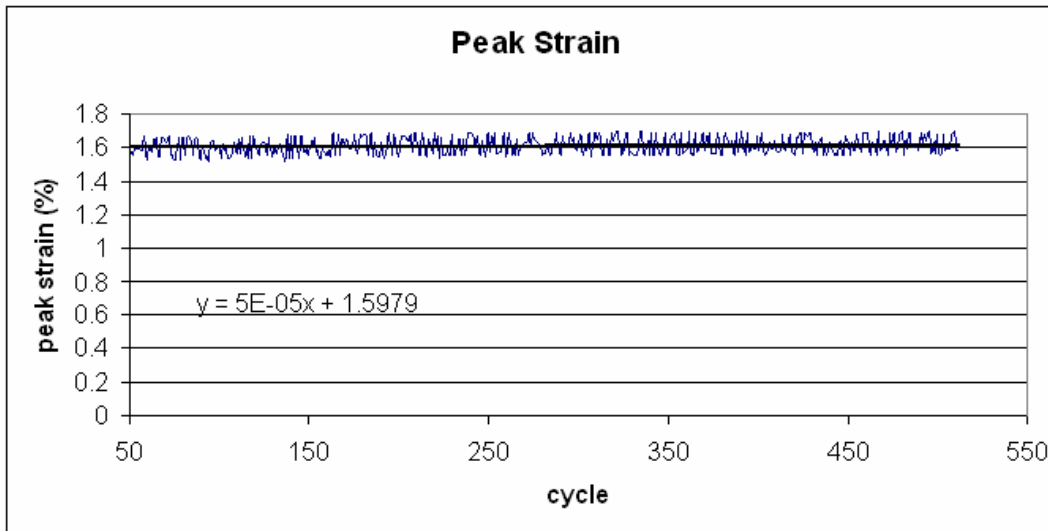
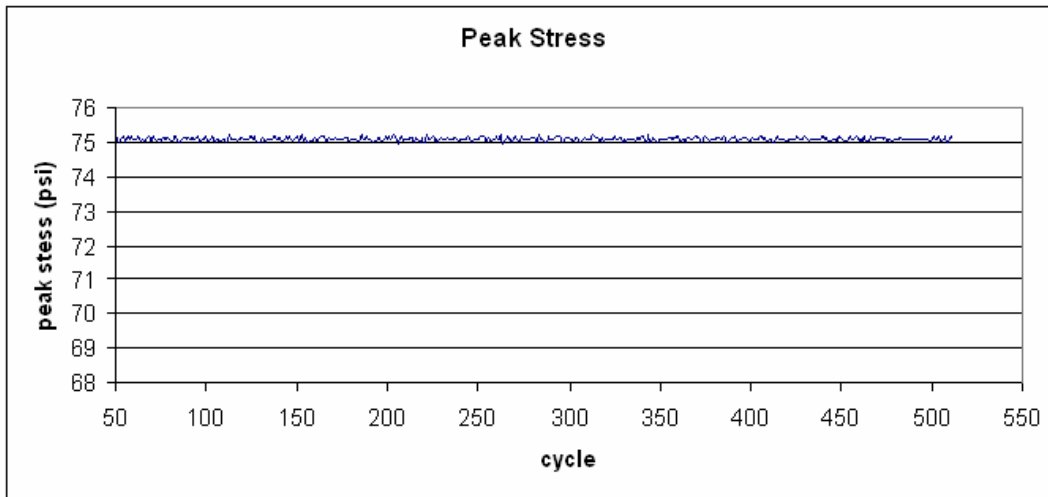
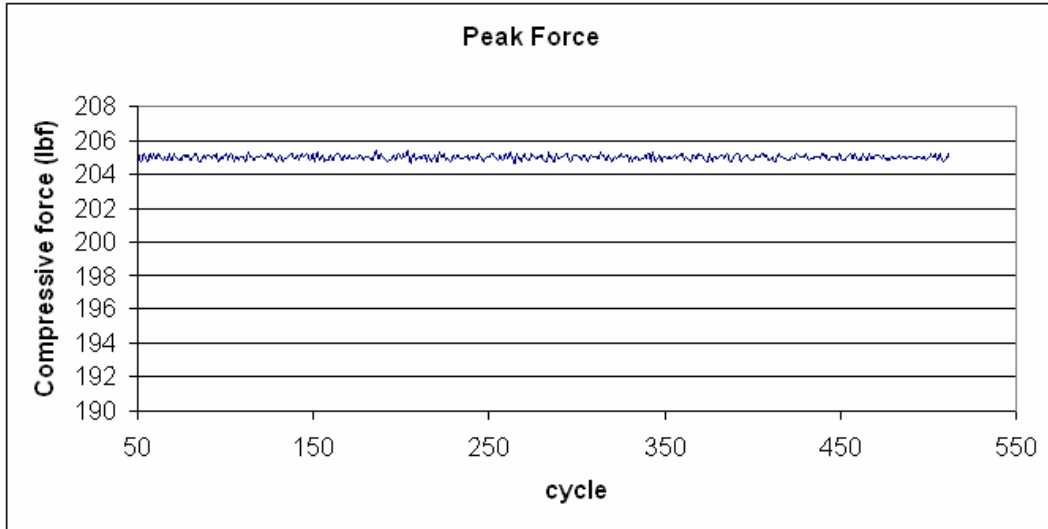


Figure AC.3: Graphs displaying peak force, stress, and strain versus cycles for foam-cortical shell sample #3.

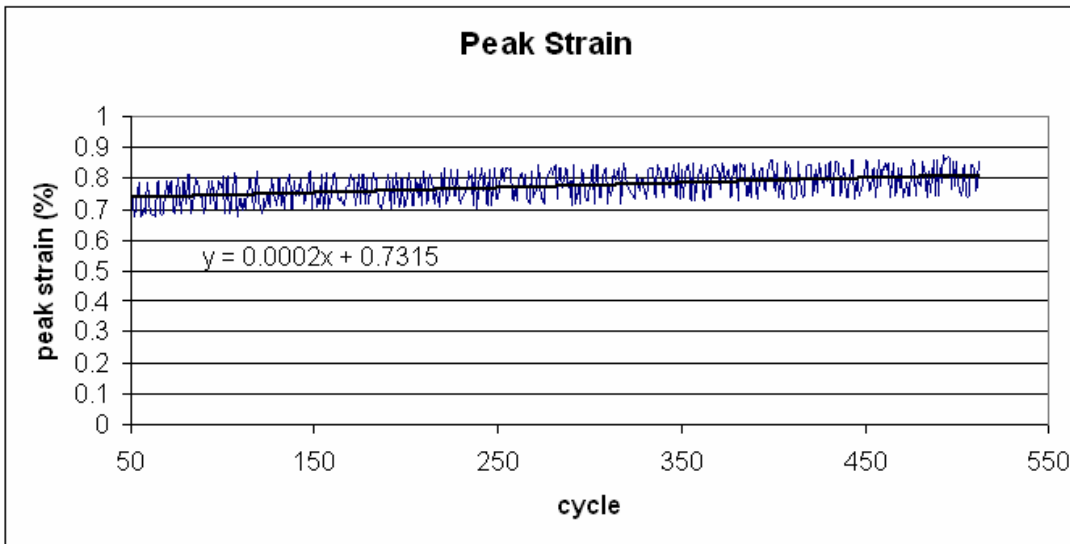
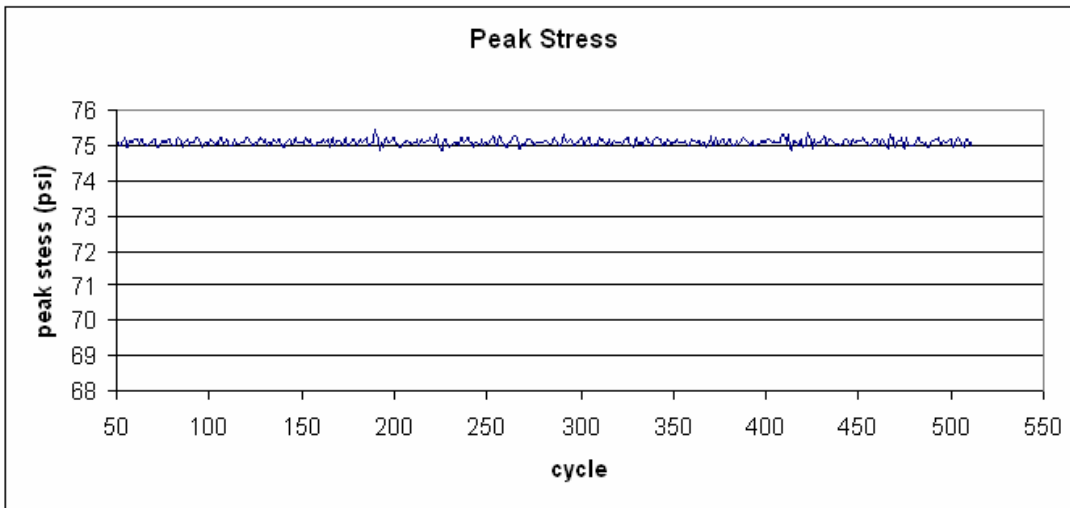
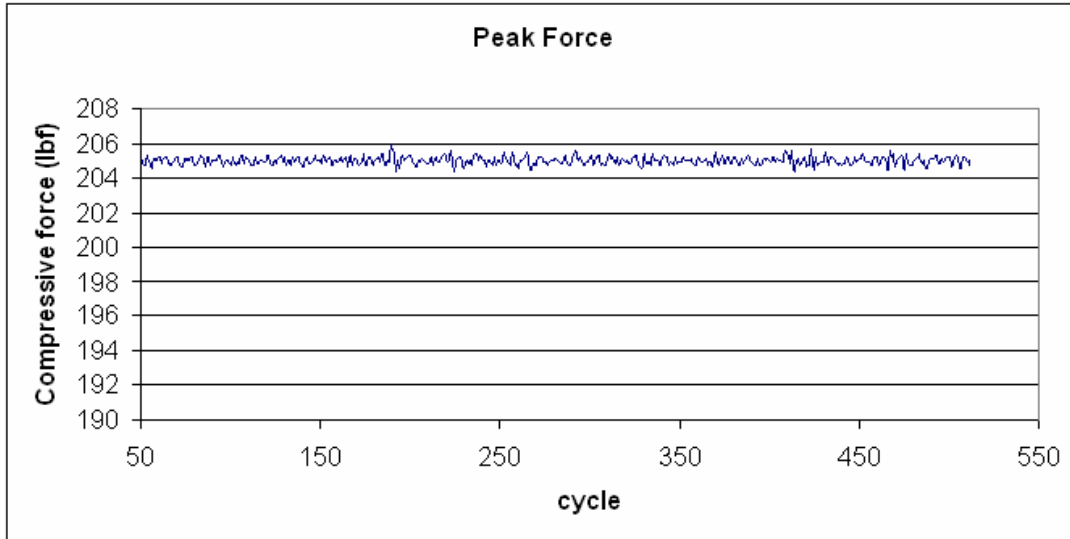


Figure AC.4: Graphs displaying peak force, stress, and strain versus cycles for plastic-cortical shell sample #1.

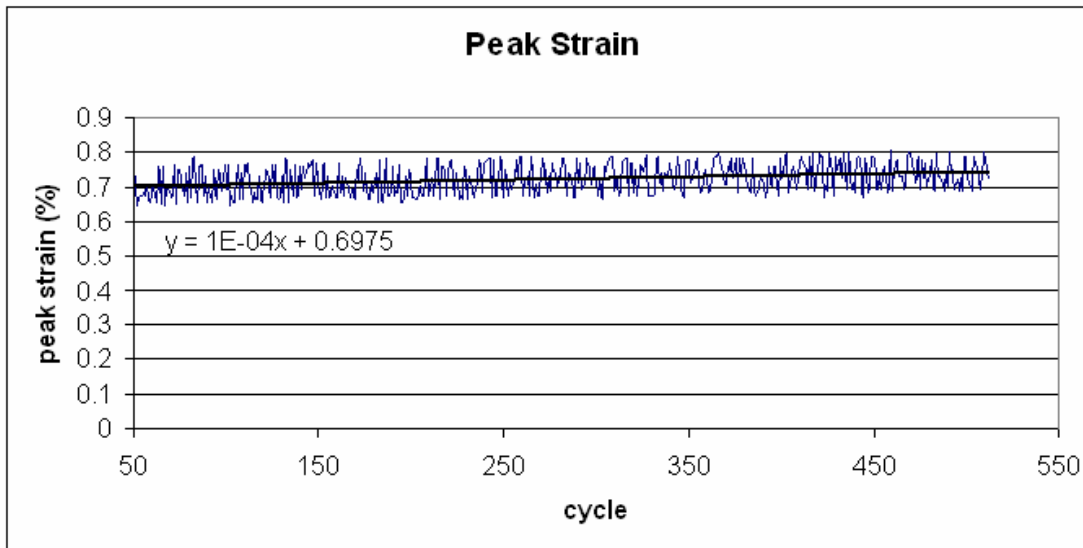
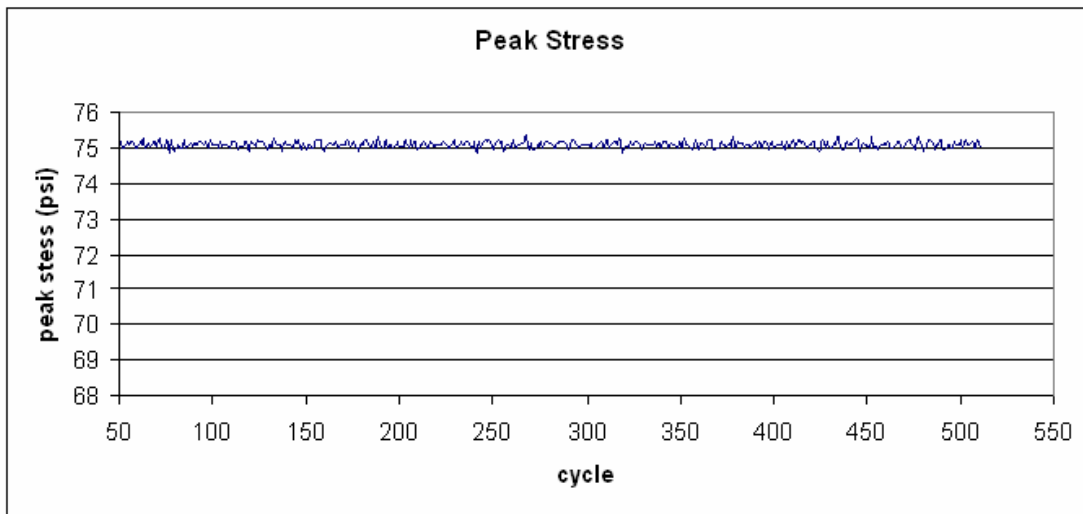
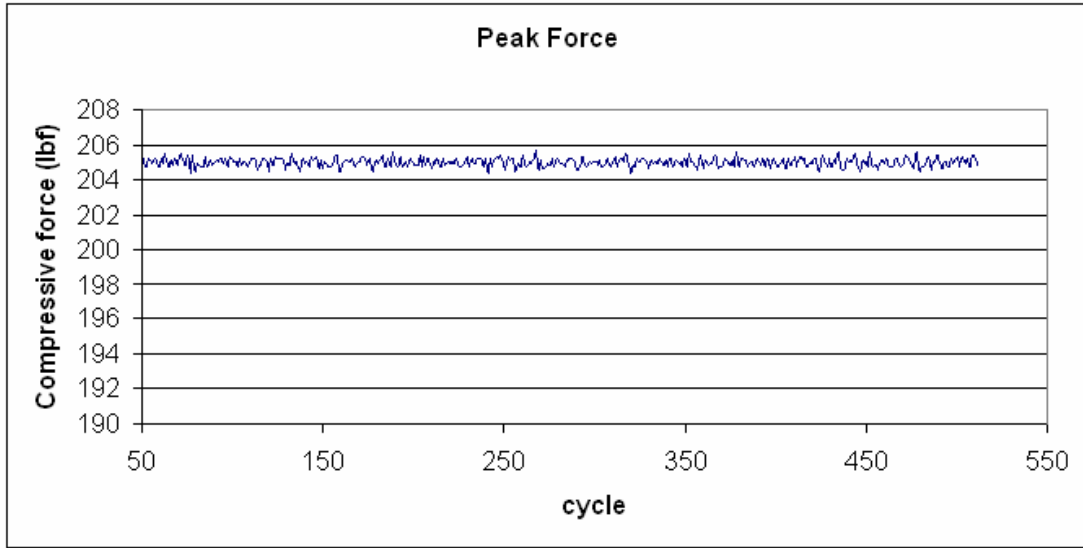


Figure AC.5: Graphs displaying peak force, stress, and strain versus cycles for plastic-cortical shell sample #2.

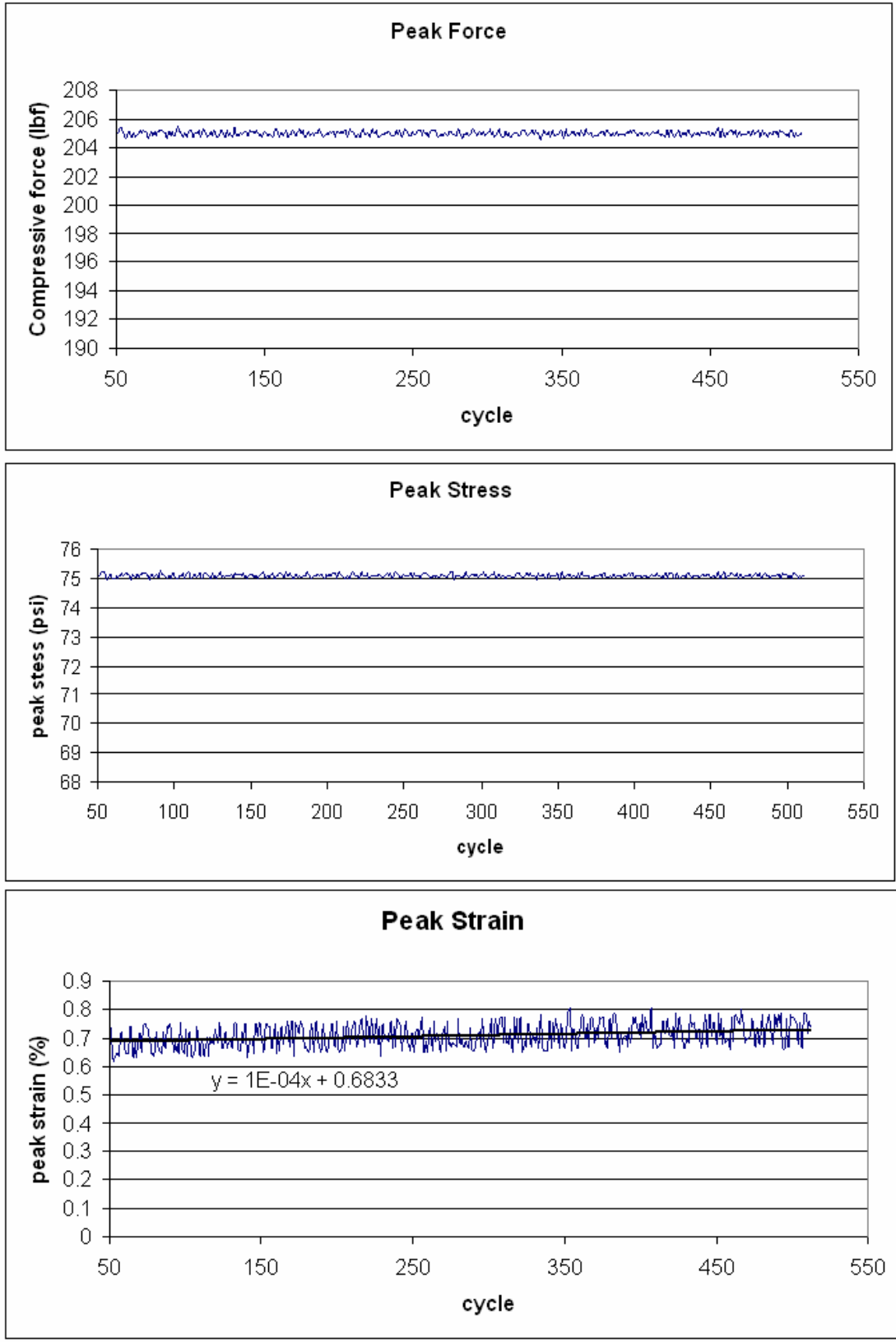


Figure AC.6: Graphs displaying peak force, stress, and strain versus cycles for plastic-cortical shell sample #3.

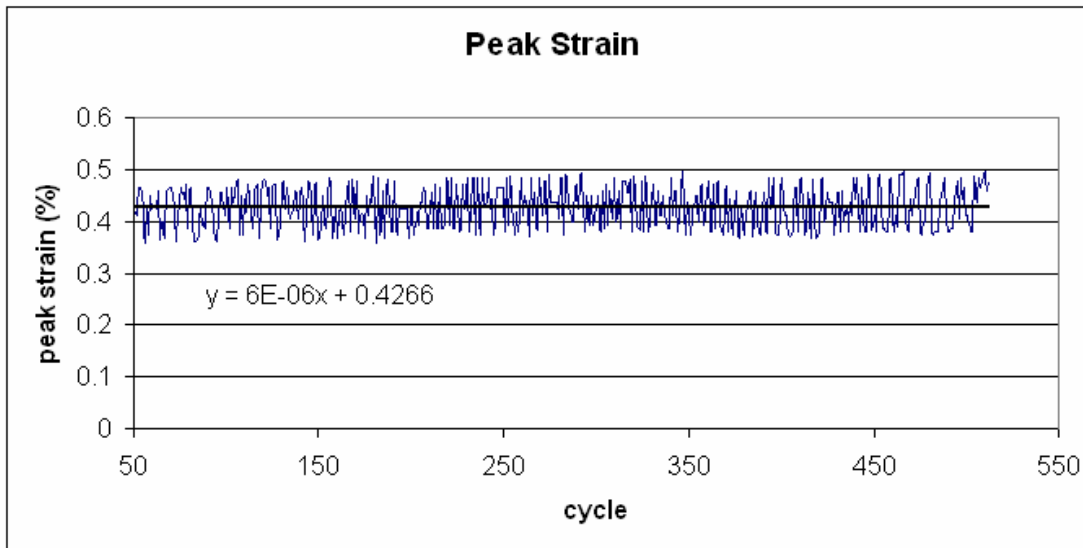
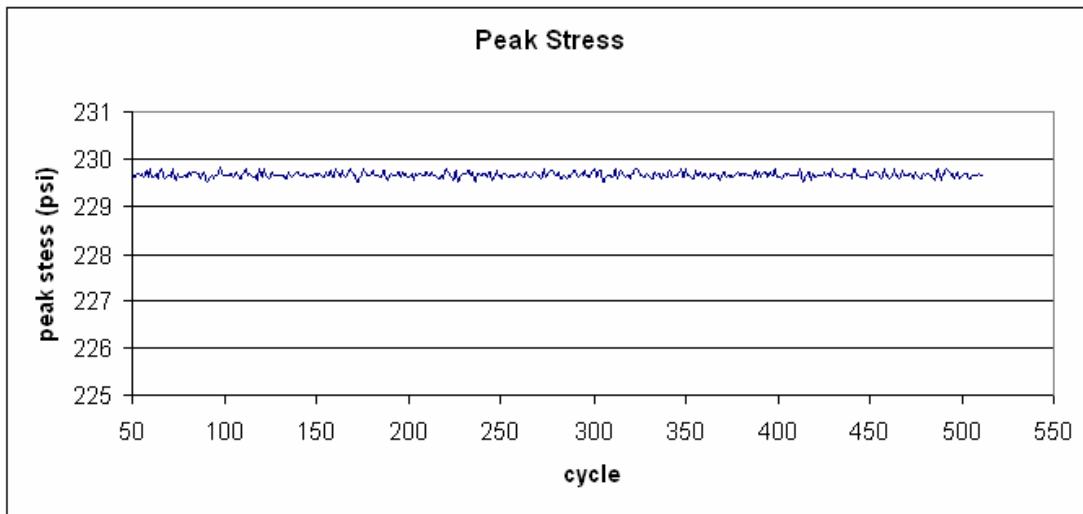
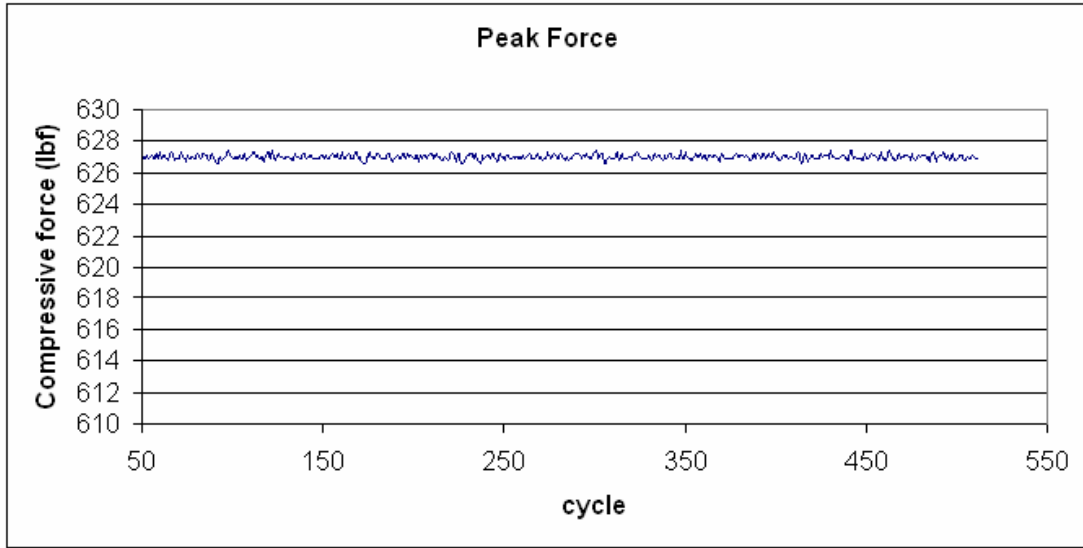


Figure AC.7: Graphs displaying peak force, stress, and strain versus cycles for bovine bone sample #1.

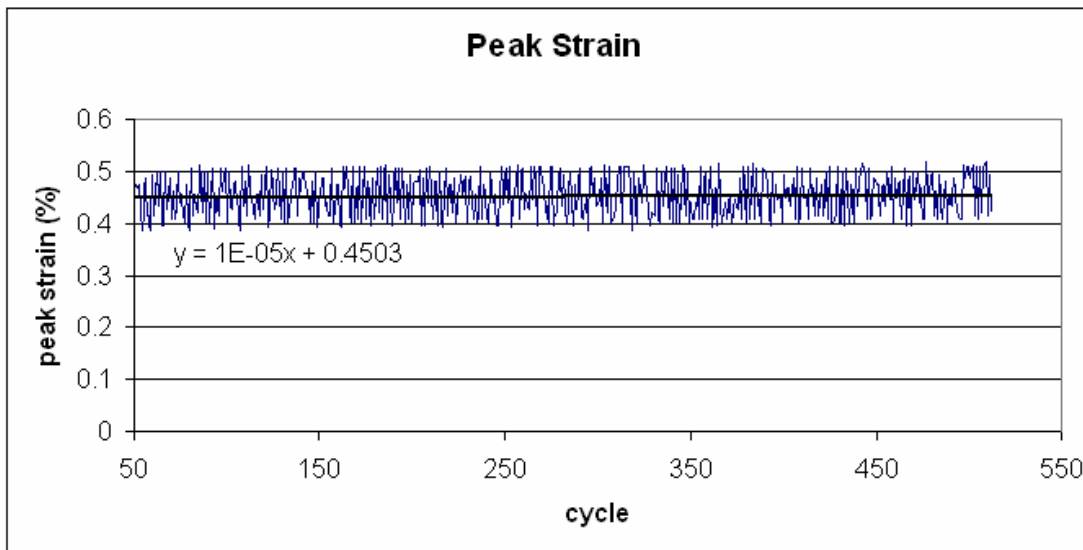
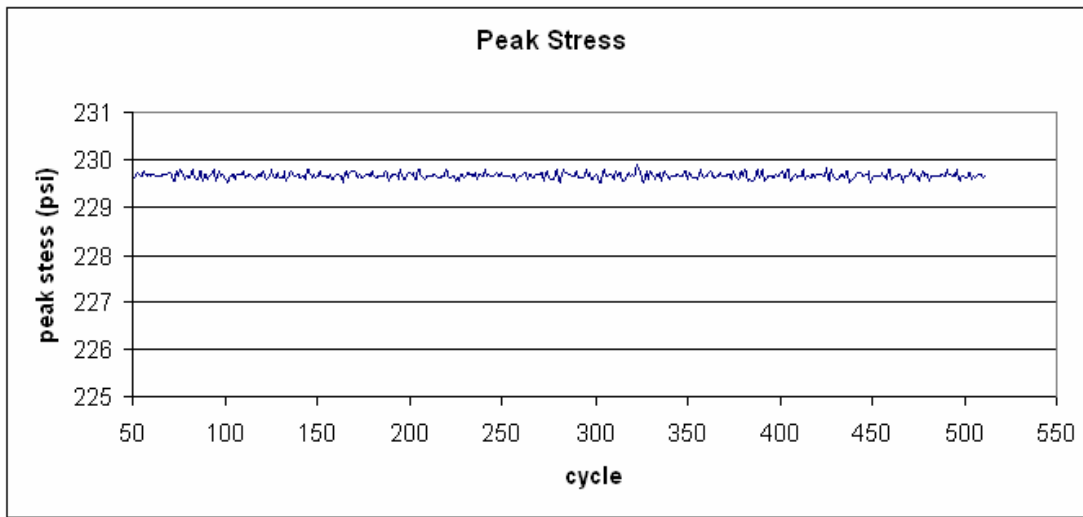
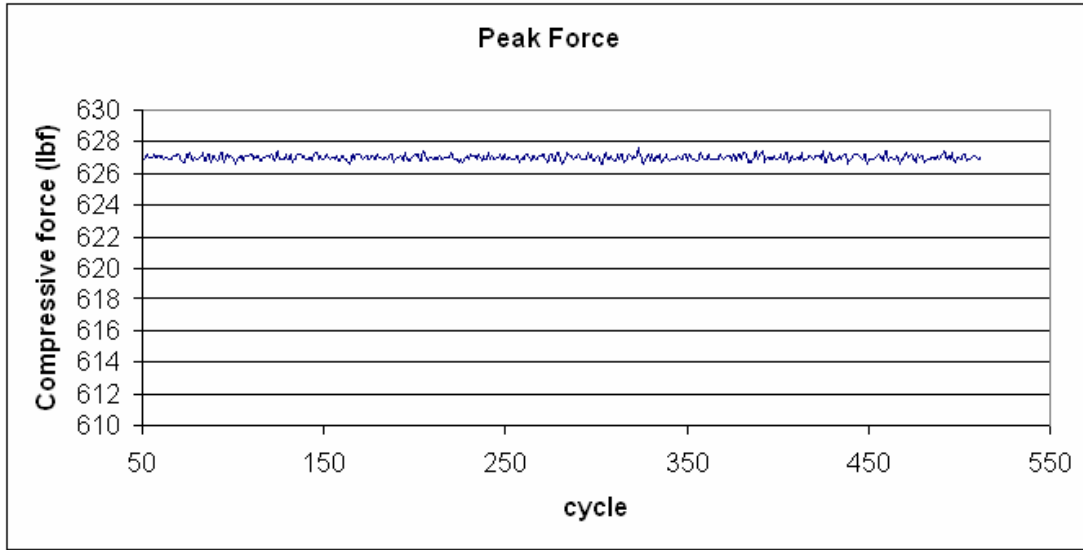


Figure AC.8: Graphs displaying peak force, stress, and strain versus cycles for bovine bone sample #2.

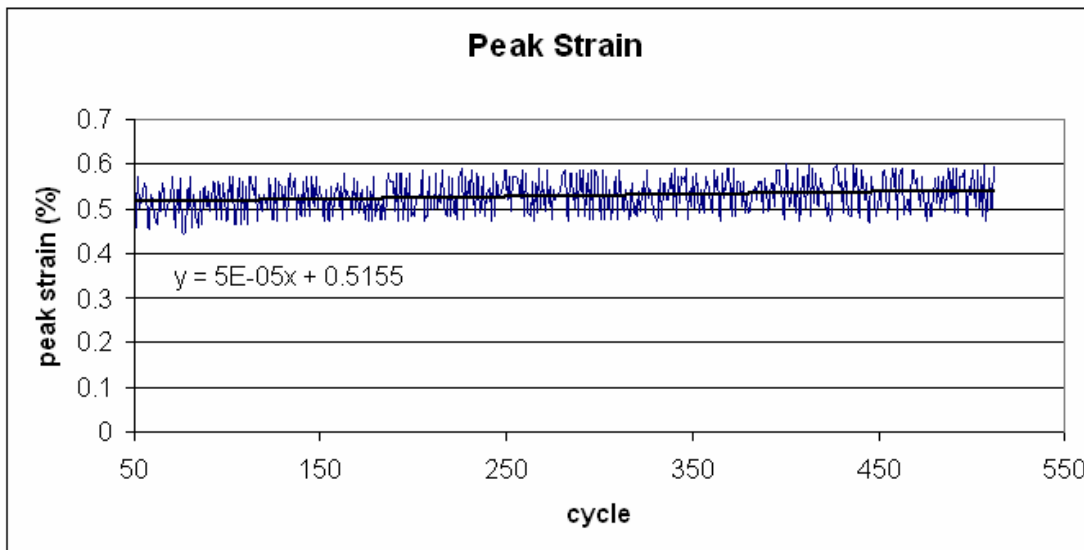
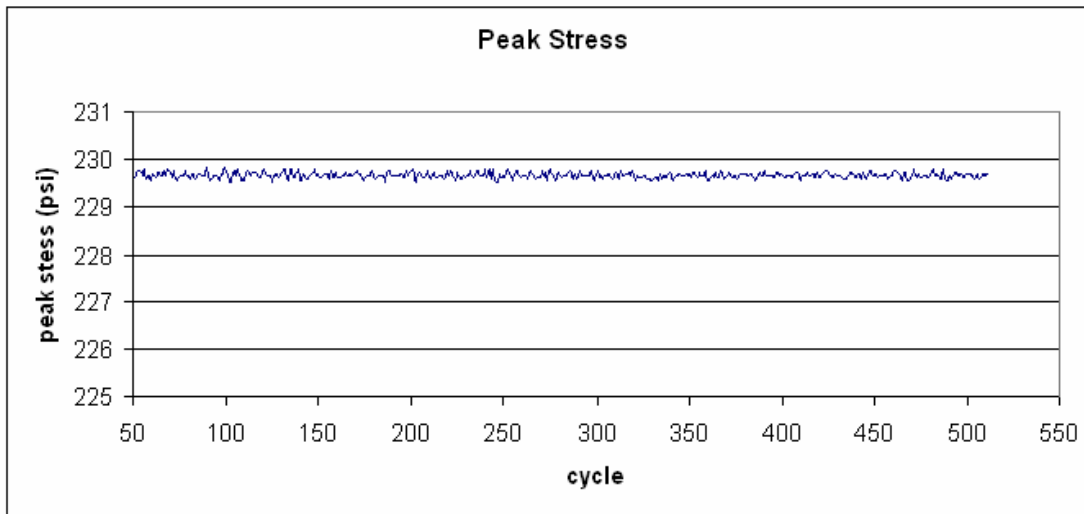
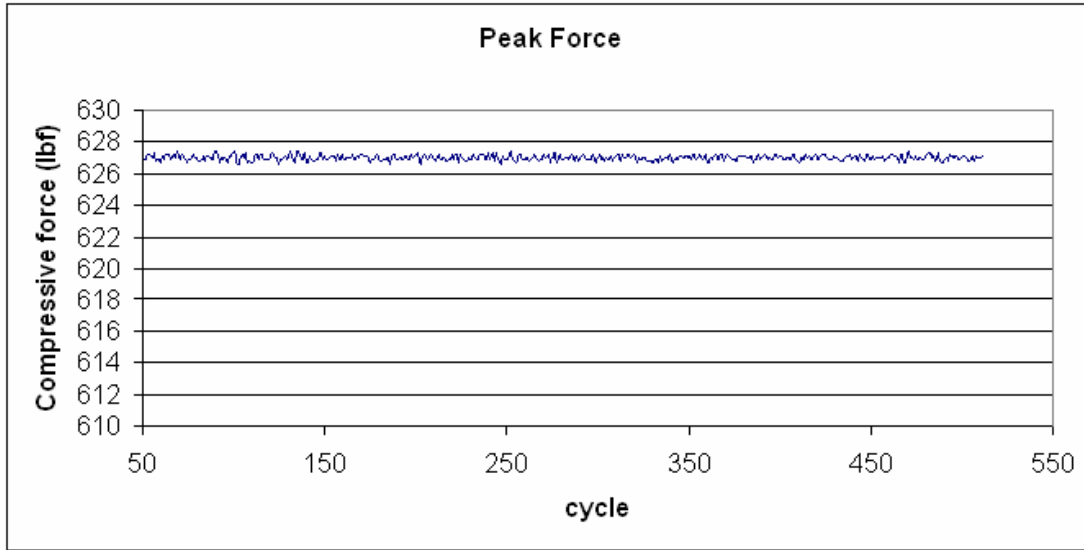


Figure AC.9: Graphs displaying peak force, stress, and strain versus cycles for bovine bone sample #3.

Table AC.1: Comparison of slopes for strain versus cycles curves.

Strain Coefficients			
	Foam	Plastic	Bovine
Sample 1	1.0 E-04	2.0 E-04	6.0 E-06
Sample 2	1.0 E-04	1.0 E-04	1.0 E-05
Sample 3	5.0 E-05	1.0 E-04	5.0 E-05
Average	8.3 E-05	1.3 E-04	2.2 E-05
Standard Deviation	2.9 E-05	5.8 E-05	2.4 E-05
Predicted Strain Value at 10,000 cycles	2.08	1.98	0.683

Appendix D: Professional Drawings of Specially Designed Grips

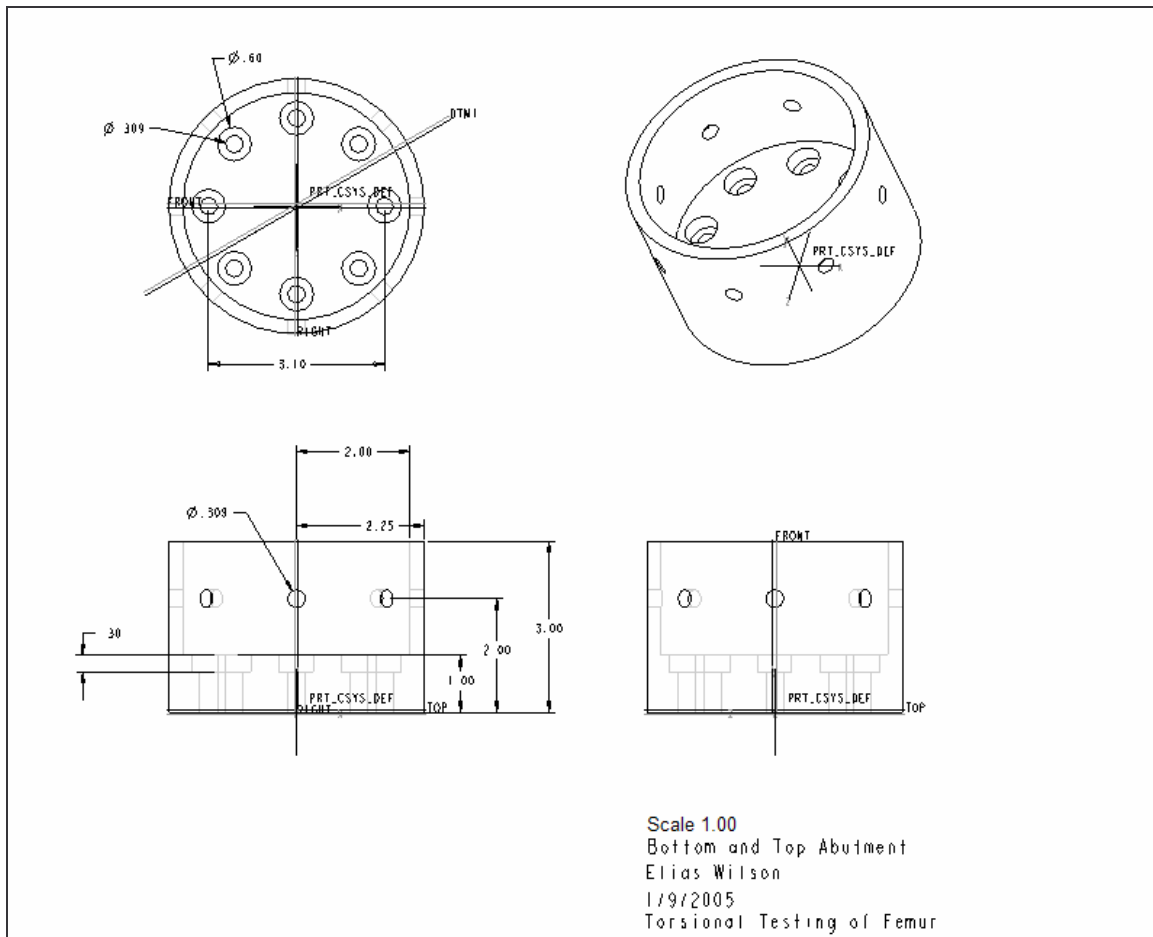
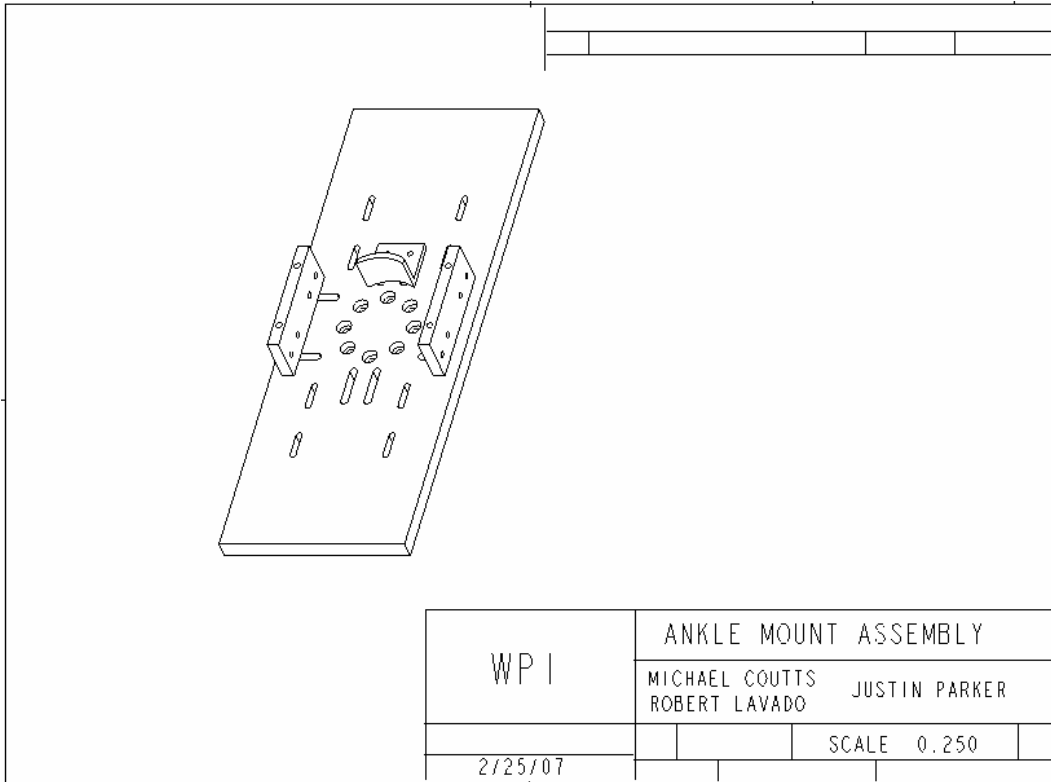
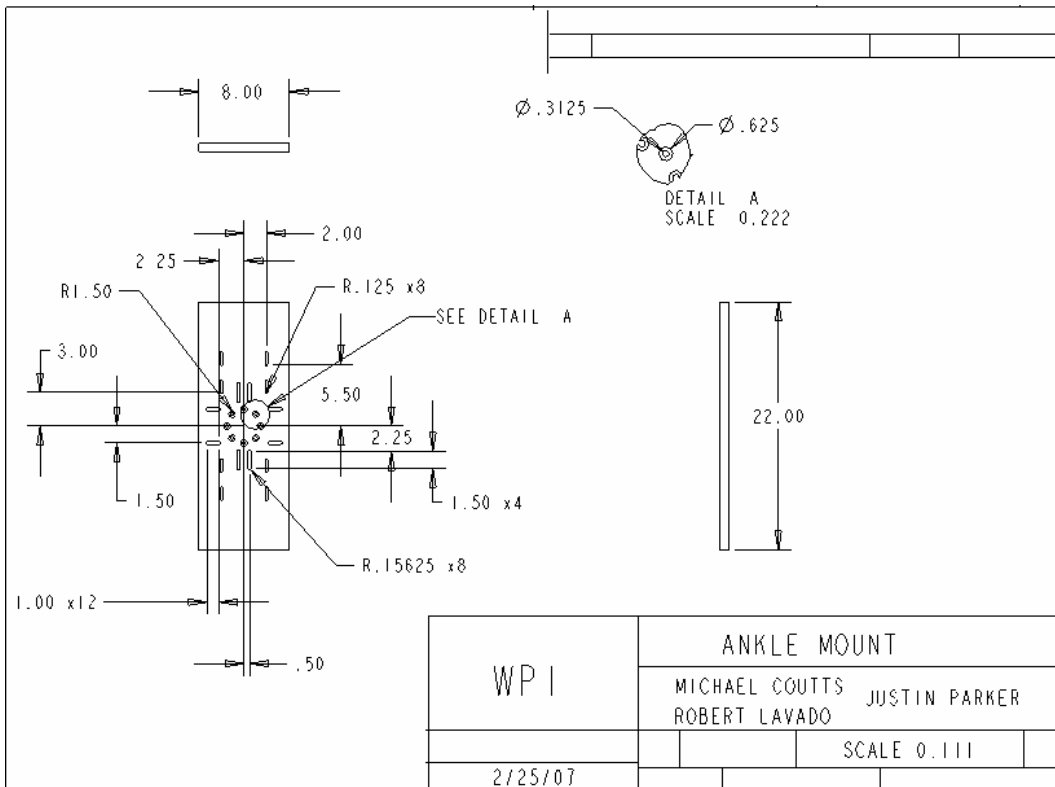


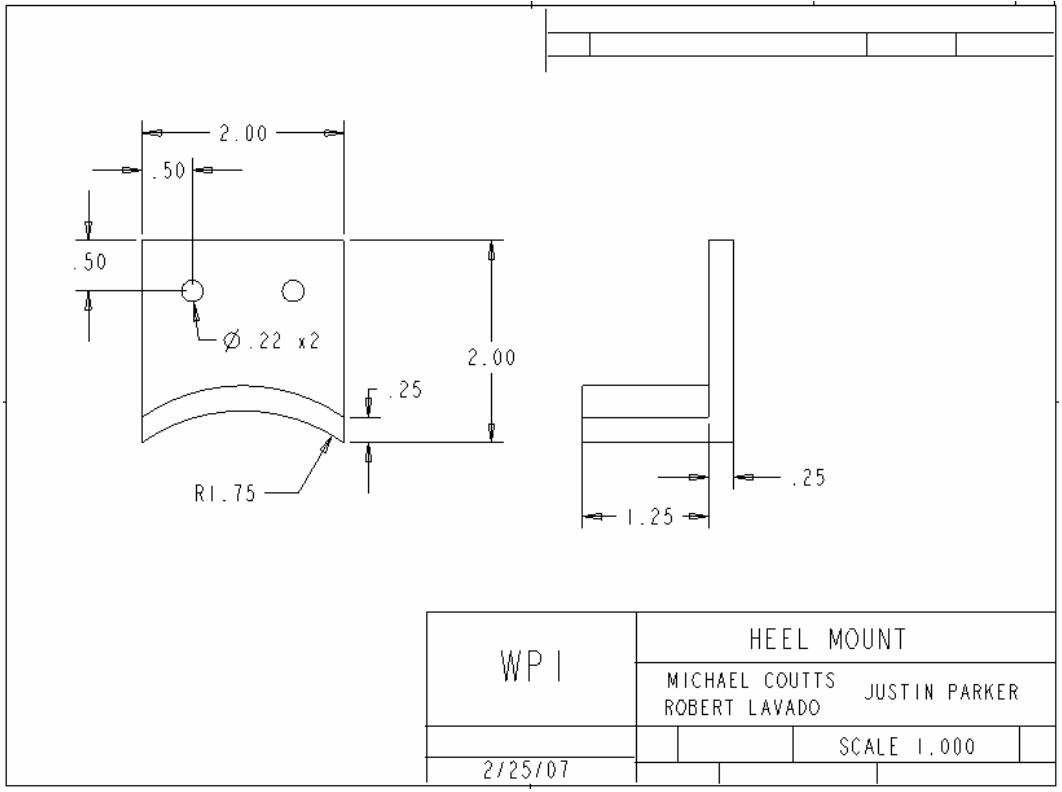
Figure AD.1: Grips for holding potted femurs and tibias designed by Eli Wilson.



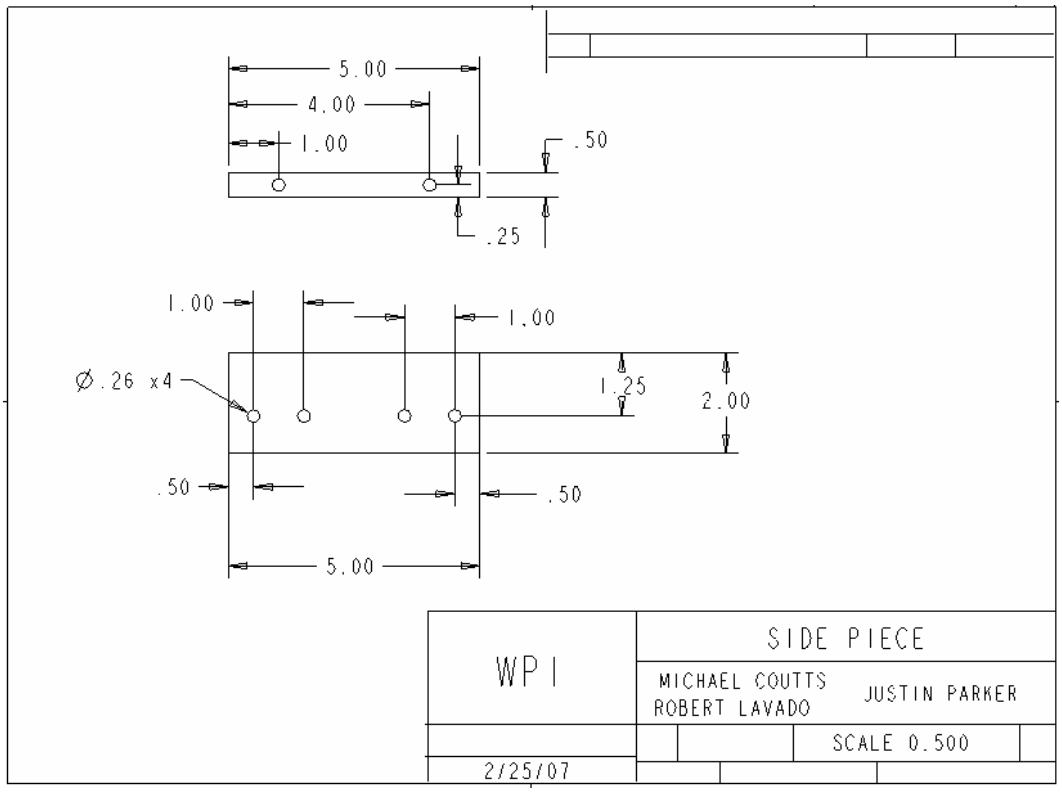
AD.2: Professional Drawing for Ankle Mount Assembly



AD.3: Professional Drawing for Ankle Mount



AD.3: Professional Drawing for Heel Mount



AD.4: Professional Drawing for Side Piece

Appendix E: Testing Protocol

Sawbone Preparation

For knee joint, use Sawbones' *Large Left Knee*: Item number 1107-2.

For ankle joint, use Sawbones' *Large Left Foot/Ankle*: Item number 1132-3.

1. Separate Tibia and Femur by cutting elastic ligaments.
2. Using a 5/8" drill bit and a power drill, drill a hole in the Posterior Intercondyloid Fossa of tibia.
3. Using a table saw, flatten the proximal end of the tibia, keeping the Medial Malleolus pressed against the push arm.
4. Make the Distal Femoral Osteotomy Cut by setting the blade to 5° posterior slope and the push arm to 6°, keeping the Femoral Head pressed against the push arm.
5. Using a band saw, cut the tibias and femurs to 7 ⁷/₁₆" long.

Potting the Sawbones

1. Place 3" PVC endcaps into the holes in potting device.
 2. In the proximal end of the femur and distal end of the tibia, plug the intramedullary canal with Play-Doh®.
 3. Insert a 5/8" rod into the intramedullary canal on the distal end of the femur.
 4. Place proximal end of the femur into the PVC endcap and clamp it in place.
 5. Using a level, adjust the clamp screws until the bone is centered in the PVC cap and the rod is perfectly vertical.
 6. Using Quikrete Anchoring Cement, mix the amount of concrete necessary to fill the endcaps to a putty-like consistency (when potting two samples at a time the amount of concrete and water needed is approximately 3 full endcaps of mix and about 300mL of water).
 7. Scoop the mixed concrete into the endcaps.
 8. Tap endcap and top of concrete mixture for 30 seconds to 1 minute to remove any air bubbles.
 9. Let the cement set for approximately 4 hours or until hardened.
 10. Place the tibia on top of femur and flip the system over.
 11. Put new endcaps in potting device.
 12. Using a straightedge and a level, align the top and bottom endcaps.
 13. Repeat steps 6-9
 14. Let all concrete cure for 24 hours before doing any testing
- *Note that when performing an ankle test, the only pot that needs to be done is to the proximal end of the tibia

Running the Test

1. Mount the appropriate specialized grips to MTS machine (2 collets for a knee test and a collet on the top and foot plate on the bottom for an ankle test).
2. Connect and screw load cell input and output wires into the amplifier.
3. Insert the nail according to manufactures instructions with load cell in between joint (be sure to make sure bottom and top washers are in place).
4. Connect the load cell BNC connector to slot in back of controller unit (J78 for 2K load cell used in the knee, J77 for 1K load cell used in the ankle)
5. Plug in load cell power source.
6. Log onto TestStar using the tibianail configuration (username: mts, password: mts).
7. Apply initial compression to joint (to insure compression in each joint is the same, be sure to monitor the load cell meters in the TestStar software).
8. Power on MTS machine components in the following order: Cooler, hydraulics turned to high, reset the interlocks on control arm, turn HPS control to high, turn HSM control to low then high, then turn Actuator Positioning Control on.
9. Unlock the cross head and raise it all the way up, and raise the actuator to midway.
10. Place the sample in bottom grip.
11. Zero the MTS load cell.
12. Lower the cross head into place so as to only put a small force on the sample (this can be anywhere between 1 and 100 lbf compression).
13. Lock cross head in place and tighten the top and bottom grips.
14. In TestStar, go to "Adjust-Tuning". Insert tuning parameters if you have them, or run tuning procedures. For plastic sawbones, P=22.056, I=5.175, D=.0085, F=0.
15. Open TestWare.
16. Open the appropriate testing template ("kneetest" for testing knee nails, "ankle test" for testing ankle nails).
17. Execute procedure (it will ask you to name the data file, give the data file a name and click ok). Before doing this step make sure Actuator Positioning Control is turned off.
18. When the test is complete, loosen the grips and raise the crosshead to remove the sample.
19. Re-lock the cross head.
20. Shut off the hydraulics by hitting the red "Stop" button on hydraulic unit.
21. Shut off the power to the cooling unit.
22. Close all of the test ware windows.
23. Open the TSCX folder on desktop.
24. Locate the data file and copy it to 3 ½" floppy or USB drive (Note: when using a USB drive to remove data, the drive must be safely removed using the safely remove hardware wizard in order for files to be saved on the drive).

Appendix F: Data from Validation of Testing Protocol

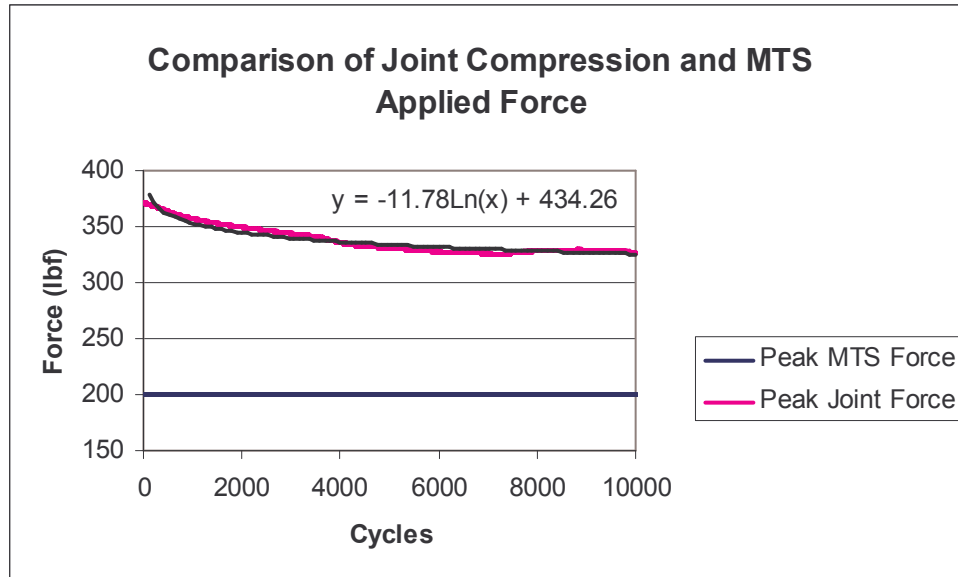


Figure AF.1: Graph demonstrating the both compressive force created by the MTS machine and the compressive force within the knee joint of Sample 1 over 10,000 cycles.

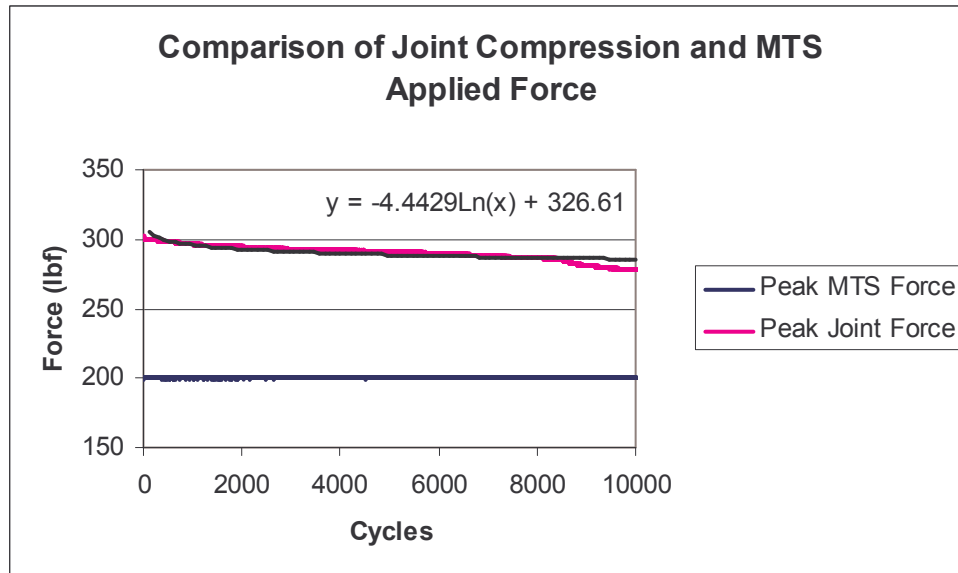


Figure AF.2: Graph demonstrating the both compressive force created by the MTS machine and the compressive force within the knee joint of Sample 2 over 10,000 cycles.

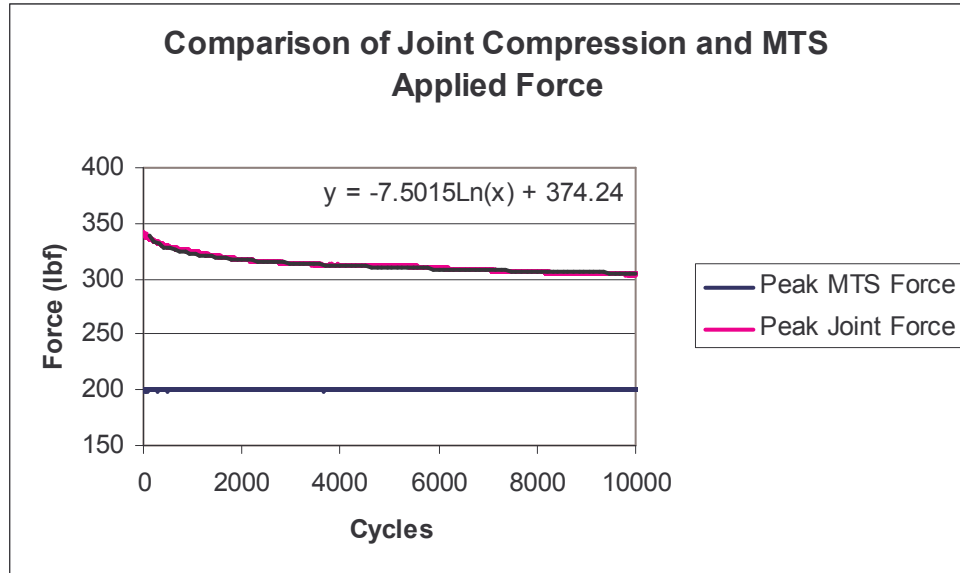


Figure AF.3: Graph demonstrating the both compressive force created by the MTS machine and the compressive force within the knee joint of Sample 3 over 10,000 cycles.

Appendix G: Video Tutorials

See disc sleeves at the end of the report.