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Design of an Optimized Rigid Fixation System for the Osteoporotic Sternum

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by

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1) Sternum
2) Rigid fixation
3) Bone screws

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Authorship

All group members participated equally in the writing and editing of this report.

Abstract

In 2006 nearly 700,000 open heart surgeries were performed, each of which required a sternotomy, or surgical bisection of the sternum. After the surgery is completed the sternum must be fixated back together, a process that usually utilizes cerclage wires. In a small subset of patients, these wires are ineffective at providing fixation which leads to malunion and infection of the sternum. Rigid fixation is proposed to be a better solution; however screw-plate systems are not currently optimized for the sternum. Different screw types and depths were assessed by cyclic loading (0 to 50N) in osteoporotic human sternum for 15,000 cycles. Cancellous and cortical screws, unicortical and bicortical purchase, and locking and non-locking screws were mechanically tested in osteoporotic human sternum. Using these results, an optimal rigid fixation system was proposed. A combination cortical-cancellous screw with novel locking head was designed that was shown to minimize displacement based on a proof of concept.

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Chapter 1. Introduction

The American Heart Association estimated, in 2005, over 80 million American adults had developed at least one type of cardiovascular disease. This led to over 700,000 open-heart surgeries being performed annually throughout the nation (American Stroke Association, 2007). In open-heart surgery, the sternum must be bisected to access to the heart in a procedure known as a sternotomy. Following the completion of the primary open-heart procedure, the sternum is realigned and secured back together with a sternal fixation device.

The standard sternal reapproximation procedure is generally successful. However, post-operative complications occur in approximately 2% of procedures generally in those over the age of 65 (Stahle E, 2007). High instances of osteoporosis are common in this age group and can cause the sternum to wear away at fixation points, resulting in loosening within the system. When loosening occurs, other complications can often occur due to this poor fixation. One such complication medianstinitis, or infection of the sternum, has been shown to have a mortality rate as great as 15% (Song, 2004). Due to the common instances of failure in osteoporotic bone, the sternal fixation device ought to account for a sternum of lower bone density.

Currently the most common practice of sternal fixation utilizes stainless steel surgical wires, but studies suggest that a rigid fixation lowers the lateral displacement improving the biomechanical stability of the sterna (Ozaki, 1998). By lowering sternal displacement, the incidence of medianstinitis was shown to decrease in osteoporotic patients (Song, 2004). Rigid plate fixation has shown to be beneficial to osteoporotic patients, yet the screws and plates within the system have not been adapted to the sternum. Designing a screw-plate system specifically for the sternum would lower sternal dehiscence, allowing for complete bone healing and decreasing the risk of infection. We sought to design a screw-plate system for rigid sternal fixation that is optimized for the physiology of an osteoporotic sternum, thereby lowering sternal displacement.

The screw parameters of current screw-plate systems were analyzed before designing a new system. Due to the limited published data on screw performance in osteoporotic sternum, current screws with various parameters were cyclically tested in osteoporotic human sternum. Cyclic loads simulating forces similar to normal respiration were used to determine screw displacement in the sternum samples. Parameters included screw type (variation in thread depth, pitch, and length), screw head design, number of cortical layers purchased, and locking mechanisms. The best of these parameters are to be combined to create an optimized screw-plate design.

The final design should include the best characteristics of the tested screw-plate systems thus reducing sterna displacement. This design will be validated through a proof of concept develop to perform the same mechanisms as the final design. This proof of concept should demonstrate an ability to effectively resist displacement when compared to the other current screw-plate systems. Ideally this proof of concept will have a final mean displacement which is significantly lower than the initial mean displacement of all other screws tested. A screw-plate system that enhances the rigid fixation system's ability to minimize sternal displacement lowers the incidences of wound infection within osteoporotic patients.

Chapter 2. Background

In order to create the best possible product, it is necessary to understand the importance of this research, as well as the current existing technologies, and the mechanisms by which they function.

2.1 Clinical Statistics

In 1985 less than 300,000 open-heart operations were completed. In 2005 the American Heart Association estimated 700,000 total open-heart operations, more than doubling the number in 20 years. Every year the majority of patients undergoing open-heart surgery are over the age of 65 and predominately males (American Stroke Association, 2007).

As the (American) life expectancy continues to increase, more thoracic related health predicaments are likely to occur. The U.S. National Institute of Health calculated 12% of the 2006 U.S. population are over the age of 65, and projects an increase to 20% by 2030. This infers that the number of surgeries will continue along the same increasing trend (National Institute on Aging, 2008).

Some of the reasons for the increase in open-heart procedures include valvularstenosis and regurgitation, which results in valve replacement surgery; lung and heart failure which results in transplants; clots, which often require bypass operations to reroute the blood; as well as various trauma related ordeals. Generally during an open-heart surgery the patient undergoes a sternotomy, the vertical bisection of the sternum (American Stroke Association, 2007).

Cardiothoracic surgeons begin performing an open-heart procedure with separating the tissue superficial to the sternum. A high frequency saw is used to bisect the sternum longitudinally along the center. With the sternum bisected a sternal retractor is situated between the bisected halves. Surgeons are able to adjust the size of the opening into the thoracic cavity. Once the primary operation is complete, surgeons follow with sternal fixation (Shields, LoCicero, Ponn, & Rusch, 2004).

The sternal reapproximation procedure is generally successful. However, post-operative complications occur in approximately 2% of procedures generally in those over the age of 65 (Stahle E, 2007). High instances of osteoporosis are common in this age group and can cause the sternum to wear away at fixation points, resulting in loosening within the system. When loosening occurs, other complications can often occur due to this poor fixation. One such complication medianstinitis, or infection of the sternum, has been shown to have a mortality rate as great as 15% (Song, 2004). Due to the common instances of failure in osteoporotic bone, the sternal fixation device ought to account for a sternum of lower bone density.

2.2 Sternum Anatomy and Physiology

The sternum, also known as the breastbone, occupies the central anterior thorax and in conjunction with pairs of ribs that encapsulate the heart and lungs. The ribs are connected to the sternum by costal cartilage that possesses the elastic property allowing the thoracic cage to be dynamic during respiration cycles (Sandring, 2004).

The respiration cycle is a dynamic process with the lung volume changing during inspiration and expiration. The inhalation process utilizes the following muscles: scalenes, sternocleidomastoid, external intercostals, parasternal intercostals, and diaphragm. During expiration, the lung gas pressure is greater than atmospheric and is capable of exiting the body without additional muscles contraction. However for forced expiration the following muscles are involved: internal intercostals, internal and external abdominal oblique, transverses abdominis and rectus abdominis. Since each of the muscles provide push and pull forces in different directions and amounts, the sternum experiences multiple forces in three-dimensions (Fox, 2008).

The sternum is comprised of three different bone regions fused together during the body's development. A depiction of a human sternum can be seen in Fig. 2.1. The most superior region is the manubrium which is the densest of the three. Fused below the manubrium is the corpus, where rib pairs two through seven attach. Below the corpus and not attached to any ribs is the xiphoid process. The average length of an adult sternum is approximately 17 centimeters, and typically shorter in females and longer in males (Gray, 2009).

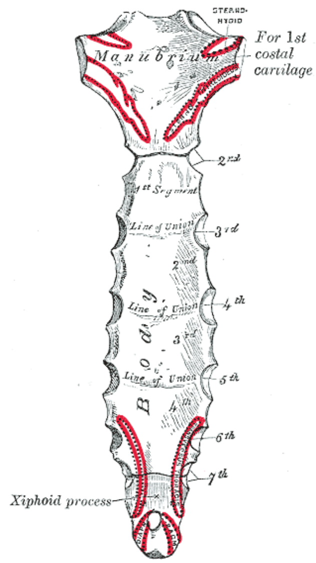


Figure 2.1 Anatomy of an Adult Human Sternum (Gray, 2009)

There are two forms of bone, the dense compact cortical bone and spongy cancellous bone, also called trabecular bone. The cancellous portion is also made of bone marrow responsible for generating new blood cells (Ozkaya & Nordin, 1998). Bones throughout the body vary in the percentage of cancellous and cortical bone based upon the bone's physiological function. Because the sternum encloses the lungs, it must be capable of flexing during inhalation and expiration. Thus the sternum contains a higher percentage of spongy trabecular cancellous bone, and a thin cover shell of cortical bone (Ozkaya & Nordin, 1998). Figure 2.2 shows the cross-section of a human sternum with the type of bone labeled.

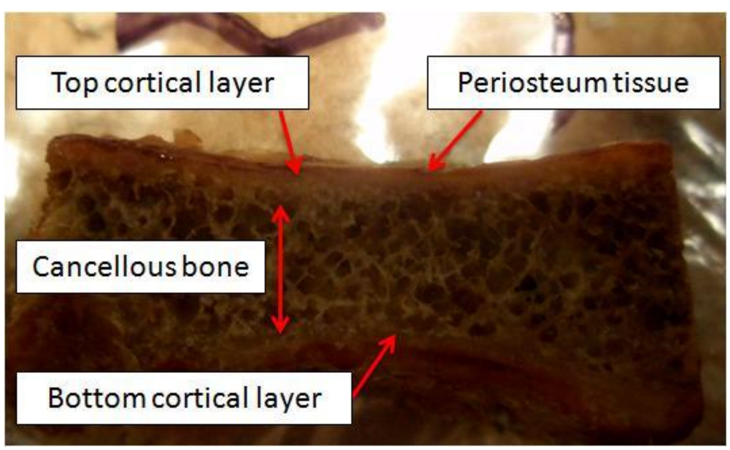


Figure 2.2 Cross-section of Human Sternum

2.3 Sternal Fixation Methods

There are a number of parameters that need to be considered for sternal fixation, including fatigue strength, sternal separation, speed of procedure, speed of re-entry, and cost. The most common method of closure is metal cerclage sutures. Rigid fixation methods vary widely and include screw-plate systems as well as some novel devices.

2.3.1 Wire Fixation

Since the mainstream birth of the sternotomy in 1957 the use of stainless-steel wire to circle the sternum has been used as the standard method of closing the sternum (Julian, 1957). A vast majority of inter-thoracic surgeries are closed using this technique. During the procedure four to seven parasternal sutures of stainless steel wires are wrapped around the sternum, with two wires placed through the manubrium, then the ends are twisted together securely to prevent loosening. The twisted ends are then buried in the sternal tissue. The pectoral fascia and lineaalba are then secured using a PGA (Poly-glycolic Acid) suture (Shields, LoCicero, Ponn, & Rusch, 2004). The wire placements can be seen in Fig.2.3.

Figure 2.3 Sternum Closed by Wire Fixation (Shields et al, 2004)

This technique has become the benchmark for closing the median sternotomy due to its relative simplicity, speed (including re-entry speed), rigidity and strength. When performed on a healthy sternum this technique provides minimum motion under the load of respiration which leads to faster healing times (Cohen & Griffin, 2002).

2.3.2 Rapid Sternal Closure “Talon” System

The newest device to be introduced for sternal fixation is produced by Rapid Sternal Closure®, and has been termed the “Talon” system. This system utilizes a titanium double hook design ("talons"), where the hooks are placed between the ribs on either side of the sternum (Fig. 2.4). The system then uses a complex ratchet mechanism to pull the halves of the sternum together. Although good in theory, the company has had trouble marketing the product to surgeons due to its high cost, complicated application, and high profile (rapidsternalclosure.com).

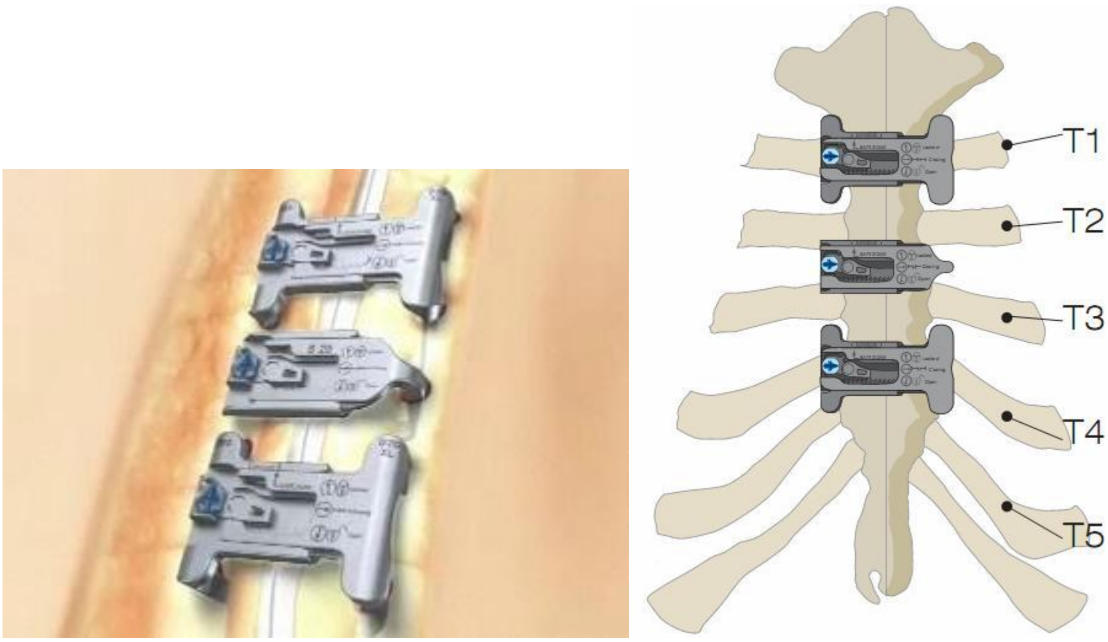


Figure 2.4 Talon system and Placement (rapidsternalclosure.com)

2.3.3 Rigid Fixation via Plate and Screw System

Plating offers advantages over other techniques because it physically holds bone fragments together during the healing process, limiting their movement and not disrupting the blood supply in the region (An Y. , 2002). There are many different varieties of these plates, with many bones having their own unique plate configurations.

The sternum is the only bone in the body where rigid fixation is not the commonly used fixation method. Rigid fixation techniques use plates and screws to hold the halves of the sternum in place while it heals. Initially published by Dr. David Song of the University of Chicago in 2004, this technique is often used in high risk patients where the wire ties may fail or cut through the bone (Song, Lohman, Renucci, Jeevandandam, & Raman, 2004). During the procedure, four small "X" shaped plates are screwed into the sternum horizontal to the manubrium using Titanium screws that are sized according to the size of the sternum. The final product of this can be seen in Fig. 2.5 below.

Figure 2.5 Sternum Closed by Rigid Plate Fixation (Song et al, 2004)

This technique is mainly performed in situations where wire closure is not recommended (only about 2% of cases). This is most common in osteoporotic patients where the wires may cut through the brittle bone of the sternum (Stahle E, 2007). Rigid plate fixation takes slightly longer to perform than wire closure because the plates have to be positioned and screwed into place properly. Although the cost of using a screw-plate system is higher than wire sutures, rigid fixation may be more cost effective for patients with certain risk factors such as osteoporosis who may develop complications and require a revision surgery (Dr. Dunn M.D. personal communication).

2.4 Rigid Fixation Design Overview

Due to the large variety of bone shapes and sizes within the body, there are several different types of rigid fixation screws and plates that can be used.

2.4.1 Plate Design

Plates are usually manufactured and designed specifically for a clinical application. Figure 2.6 gives an example of straight and X-shaped plates and friction plates.

Straight plates were first designed as an alternative to wire circling due to their geometric similarities. These devices are particularly useful in portions of bone that are entirely cortical, and have been shown to be less effective than X shaped plates for sternal fixation. This is due to the fact that straight plates only have one screw passing through the center of the bone, where X shaped plates have multiple (Ozaki, 1999).

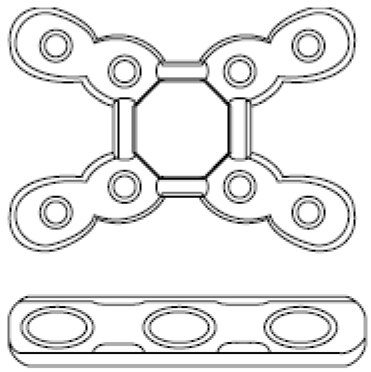


Figure 2.6 X shaped plate and Straight plate (Based on Ozaki 1998)

X plates have shown to be advantageous in long, flat bones, such as the bones in the face. This design capitalizes on the idea that screws placed in the central bone (which is stronger) will be less likely to fail than screws placed in the weaker edges of the bone (Ozaki, 1999). Because the sternum is similar in geometry to facial bones, this plate design is currently the most widely used fixation plate for the sternum.

2.4.2 Screw Design Overview

Rigid fracture fixation is possible mainly due to a large variety of bone screws. Over the past 20-30 years, the bone screw has become the most commonly used orthopedic implant device (Kissel, 2003). Without these screws, many types of rigid fixation would be much less effective or even impossible. Each type of screw is uniquely designed for its specific clinical purpose. Several parameters are taken into consideration when choosing a screw, including the health of the bone at the wound site (osteoporotic or healthy), the location of the fracture (long bone, short bone, flat bone, etc), the density of the bone (cortical or cancellous) and the type of fracture. A majority of orthopedic bone screws are categorized as cortical or cancellous, partially or fully threaded, solid or cannulated, self-tapping or non-self-tapping.

The cortical or cancellous properties of the screw are decided based on the density of the bone that the screw is being applied to. Cortical screws are very similar to metal screws found in your local hardware store; they have a very high thread count, with a very low thread depth and pitch. Because they are used in the hardest, highest density type of bone, thread penetration is not very important, but it is vital that the threads stay in constant contact with the bone surrounding it. Conversely cancellous screws are very similar to wood screws, with deeper thread penetration to maximize stabilization in the low-density cancellous bone (Shields, LoCicero, Ponn, & Rusch, 2004).

Cannulated screws are designed to have a hollow core with an exterior similar to that of a normal screw. These screws are usually used when a high degree of precision is required to properly fixate bone fragments of a fracture. A guide wire can be run through the cannulated center of the screw allowing for extremely precise screw placement. However, these screws often have decreased mechanical performance in pull out strength due to changes in thread dimensions and cross sectional area. Despite the change in pull out strength, cannulated often have similar properties to solid screws when comparing compressive strength, stripping torque and bending strength (Brown, 2005).

Partially threaded bone screws only have threads running a portion of the way down the shaft of the screw, instead of all the way to the head. These screws often have a smooth non-threaded tip that is useful for guiding the screw into hard to reach places, or areas where the surface of the bone is curved, such as the vertebrae of the spine (An Y. , 2002).

Self-tapping bone screws have sharper threads that will essentially make their own groves in the bone as they are inserted, where non-self-tapping screws must have groves put into the bone before they can be inserted. Self-tapping screws also have a specially designed tip that forces debris upwards and out of the hole, rather than forcing it into the groves. Essentially, self-tapping screws remove the step of tapping from the fixation procedure, making the operation faster and more efficient (An & Draughn, 2000).

2.5 Screw Parameter Description

Stabilization of an implant or plate is greatly dependant on the screw-bone/plate interface. The screws in a rigid fixation system function as stabilizers by exerting a compressive force on the plate and onto the bone. The screws also provide resistance to shear forces when the plate is loaded axially. The different parts of the screw serve to achieve the functions of providing compressive force and maintaining purchase in the bone material (An & Draughn, 2000).

The three main screw components are the head, core, and thread. The head of the screw functions to transmit the insertion torque onto the core and threads as well as provide a point of contact between the screw and plate. Once the screw head has contacted the plate, the torque exerted on the threads through the head generates a compressive force.

The core of a screw is the shaft that the threads wrap around. A screw is defined by a major diameter that is measured from the outside of the threads on one side to the outside of the threads on the other as well as a minor diameter that defines the smallest diameter of the shaft at the base of the threads that represents the core.

A screw's thread is defined by its depth (difference between the major and minor diameter) and its pitch. The thread depth is what responsible for thread purchase as it represents the area of the screw that is interacting with the bone. The thread is a helical ridge that is wrapped around the core. Its function is to convert rotation into translational movement. As can be seen in Fig. 2.7, the cross section is a series of ramps. Together with the helical shape, when rotated the triangular cross section functions as an inclined plane that provides a mechanical advantage in moving through the bone and to maintain a compressive force. The thread pitch is defined as the distance between threads on the screw (An & Draughn, 2000).

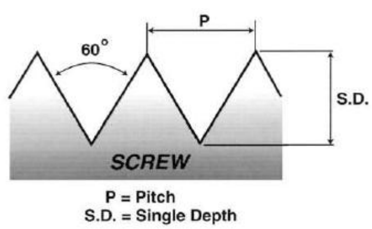


Figure 2.7 Screw Pitch Parameters (An &Draughn, 2000)

A sternal fixation system should be able to main the necessary compressive force between bone fragments to ensure proper bone healing. In rigid fixation utilizing plates and screws, significant and progressive loosening at the screw-bone interface would be the main mechanism of failure.

2.6 Problem Identification

Rigid fixation methods are used throughout the body; however, it is not commonly practiced on sternum. There are many screw-plate systems each designed to accommodate a specific bone’s attributes, for example pelvic plating systems allow screws to be installed at various angles to maximize rigidity. The sternum, however, cannot be treated similar to other bones due to the unusual applied loads from respiration. Additionally the sternum cannot be voluntarily immobilized during the recovery period.

Though there is a wide variation in the marketed sternal plating systems, rigid sternal fixation is still uncommon. The numerous options within the consumer market further imply the uncertainty regarding the best practice of sternal fixation. The published data regarding the performance of each variation is limited and the mechanisms of screw loosening in osteoporotic sternum are unclear. In order to identify the best option for rigid sternal fixation, the mechanisms of loosening and failure due to lateral cyclic loads must be determined.

Chapter 3. Project Strategy

The goal of our project was to determine the optimal screw-plate system for the sternum. To complete this goal, the MQP team followed the direction of our two clients, Stryker Medical and Dr. Raymond Dunn of University of Massachusetts Memorial Medical Center (to be referred to as UMass). From their lead, we were able to devise the objectives and constraints, and thus develop our project.

3.1 Client Statements and Design Goals

Before starting the design process, preliminary information regarding Stryker screw and plate systems had to be acquired. Stryker sought to gain data regarding their preexisting screw-plate systems within the sternum and to discern which preexisting systems preformed best. To accomplish this, the following client statement was generated:

> Determine the optimal parameters of the screw and plate system with the intention of minimizing the displacement, due to breathing, of a bisected osteoporotic sternum post sternotomy. Then, determine if a preexisting Stryker screw and plate system possessed these optimal characteristics.

After comparing the preexisting systems, the project team sought to design a new optimal system. This system would encompass the best traits of the previously tested. The chosen design should achieve all set objectives and functions and be within the proposed constraints. The following is a list of the overall project objectives, functions, and constraints.

PROJECT OBJECTIVES:

1. Market Potential
    a. Inexpensive
        i. Minimal components
        ii. Affordable materials
    b. Innovative
        i. Performs superior to current devices
2. Device aid healing process of patient
    a. Rigid proximal fixation of sternum halves
        i. Reduce post-operative complications leading to secondary surgery
        ii. Improve patient bone formation rate
        iii. Maintain proper sternum alignment
    b. Limit Osteonecrosis
        i. Minimal direct pressure on break site
3. Device should improve surgical course of action
    a. Ease of use
        i. Minimal number of components
        ii. Familiar procedures for implantation
    b. Time efficient
        i. Minimal time to implant and detach device
        ii. Option to cut device for rapid removal
    c. Minimal tissue damage around implant site
        i. Implantable and removable through small openings
        ii. Device capable of undergoing proper sterilization
    d. Minimize potential risks to patient and surgeon
4. Device should provide rigid mechanical stabilization of sternum
    a. Limited micro-motion
        i. Reduce distractions
            1. Traverse
            2. Lateral
            3. Longitudinal

PROJECT FUNCTIONS:

1. Mechanical
    a. Immobilized sternum halves
    b. Minimize system displacement and cutting
    c. Achieve high torsion
2. Biological advantages
    a. Enabling bone reformation
    b. Minimize osteonecrosis

PROJECT CONSTRAINTS:

1. Safety and FDA Standards
    a. Patient
        i. Biocompatible
        ii. Bioinert
        iii. Minimal thrombogenic response
    b. Surgeon (user)
2. Inexpensive
3. Low-profile device

A pair-wise comparison chart (PCC) was generated to rank the importance of the objectives compiled from the clients and stakeholders. The PCC can be seen in Table 3.1. A follow-up discussion with the clients revealed other than cost, each of the remaining goals needed to be high priorities throughout the entire design development. However, based on the PCC, the primary focus was on *safety* and *rigid fixation.*

Table 3.1 Pair-wise Comparison Chart for Sternal Fixation

GOALS	Rigid fixation	User-friendly	Safe	Low-profile	Inexpensive	SCORE
Rigid fixation	X	1	0	1	1	3
User-friendly	0	X	0	1	1	2
Safe	1	1	X	1	1	4
Low-profile	0	0	0	X	1	1
Inexpensive	0	0	0	0	X	0

A revised list of more specific goals, objectives, functions, and constrains were developed that addressed design requirements. This was used to revise the preliminary client statement.

Client statement brainstorm:

- To create a screw system for the fixation of an osteoporotic post sternotomy.
- To design an optimal plate and screw system that minimizes displacement of sternum halves of post sternotomy; repairing a bisected sternum

Goals:

- To determine which screw parameters are significant in axial plate loading via testing
- Examine failure modes of existing screws
- Use the identified parameters to design an optimized screw
- Compare the optimized screw to existing screw types
- To create a system for adapting the optimized screw for different locations along the sternum
- Design and propose an appropriate plate system to accompany the optimized screw

Function of the design:

- The design must maintain the sternum halves proximal to one another while providing rigid stability to help bone growth. The displacement must be limited to X-value (undefined) after so many numbers of cycles. The screws must maintain a tight seal, this torque must be gauged.

Additional Criteria:

- The design must be a screw and plate system, no wires, vices, or talons. The optimal plate and screws must be determined to accommodate for the various regions of the sternum: manubrium, corpus, and xiphoid process.

Current constraints:

- The selected maximum displacement of the sternum halves is 0.5mm of each; a total limit of 1.0mm as referenced by background literature.
- The material selection for testing, rapid prototyping, and suggested my all differ due to cost and level of difficulty in fabricating.
- Must be a plate and screw system
- Final system must be equally easy to use as existing system
- Displacement of sternal halves can be no greater than 1mm (0.5mm per half)
- Number of tests is limited (4 human sternums x 10 tests per sternum = 50 maximum tests)
- The ease of installation and doctors/surgeons preference need to be clarified
- The ideal length and depth of the screws has not been determined

Identified Objectives:

- Determine the ideal screw parameters e.g. lock/non-lock, pitch, thread count
- Identify and understand mechanism of screw loosening
- Determine the available resources of materials, cost, and non-IP hindering people resources.

With these additional needs and recommendations, a final client statement was proposed:

> Determine the optimal parameters of the screw and plate system with the intention of minimizing the displacement, due to breathing, of a bisected osteoporotic sternum post sternotomy. Design a screw and plate system that encompasses the best optimal parameters that cooperate in a single system. The proposed design must reduce sternal displacement in comparison to preexisting systems, not endanger the patient, not impede the fusion of the sternal halves, be time efficient for surgeons, be affordable when compared to the cost of a second surgery.

3.2 Experimental Design

The goal of the project was to design a screw-plate system designed around the specific physiology of an osteoporotic sternum that provides lower displacement within the sternum than preexisting screw-plate systems. By combining the beneficial components of preexisting systems, a rigid fixation device can be optimized for the sternum.

The project team assessed the performance of a number of screw-plate systems in human sternum once under a cyclic axial load. A screw-plate system was individually tested on a single section of sternum and provided an evaluation on the combination of two parameters. A series of different screw-plate systems were tested on a single sternum. This provided a perspective of how each parameter ranked opposed to one another. Screws were compared through analyzing the effect of mechanically loading a single screw. In this way, parameters including screw type, head design, and cortical purchase were evaluated. A number of tests were taken on a single sternum to provide a larger sample with greater statistical significance. Upon testing an entire sternum with the series of four, the project team discussed the possible modes of failure of each system. The parameters that performed poorly were then removed from the series of four and replaced by another set of parameters. Through this, the MQP team was able to determine the best parameters a sternal screw should have. Additional qualitative observations were made on the screw-plate systems mechanism of loosening.

With the knowledge of the optimal screw parameters, the design process began. Design alternatives were proposed that would optimize the bone-screw, screw-plate, and plate-bone interface. These design alternatives were then compared against the previously stated design objectives and constraints to determine which design to be chosen.

3.3 Methodology

The following methods were created to gauge the strengths and limitations of marketed medical plate-screw systems through cyclic loading tests. A uniaxial device (Instron® Electroplus E-1000) was used to perform cyclic tests on samples to emulate respiration (see Appendix A for instruction manual). Instron command programs, Console and Wavematrix, were used to design the cyclic testing parameters controlling force amplitude, cyclic rate, wave phase and number of cycles. In addition the program recorded the values of the previously mentioned variables as well as displacement and time.

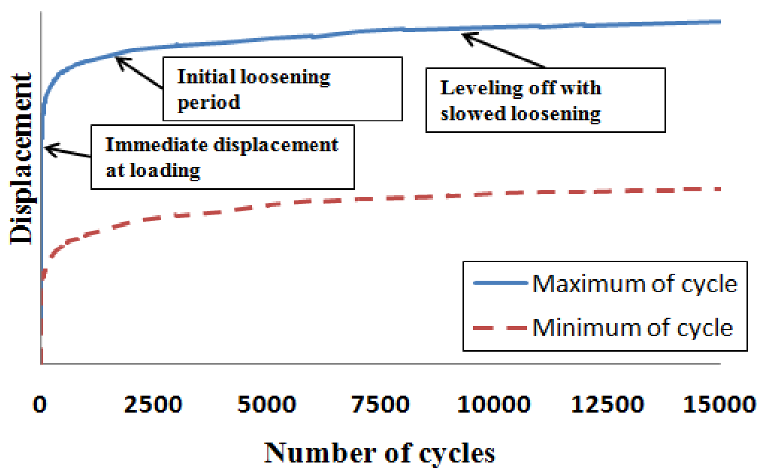


Figure 3.1 Typical displacement curve generated from cyclic loading

Displacement was the primary focus of each plate-screw system undergoing cyclic loading (Fig. 3.1). Displacement can be compared between each plate-screw system if tested in identical sample conditions and with matching testing parameters. Further parameters were emplaced based upon surgical preferences.

UMass Medical School provided porcine sternums and four complete human sternums (see Appendix B). Porcine sternums, considered non-osteoporotic, were used to determine required alterations in the test parameters/protocol as well as obtain preliminary data of each system. The low bone density of the human sternums served as an osteoporotic model, and was verified through observation and μCT analysis.

3.3.1 Sternum Preparations

The University of Massachusetts School of Medicine supplied four unmodified male human sternums with varying degrees of osteoporosis. The information for each patient is provided below in Table 3.2.

Table 3.2 Patient Information

Number	Age	Sex	Cause of death
#2252	66	Male	Respiratory arrest
#2253	88	Male	Aschemic cardiomyopathy
#2254	51	Male	Cancer
#2255	82	Male	Congestive heart failure

The sterna were received pre-bisected and maintained at -40°C. The sternum halves were cut into sections using a scroll saw (Task Force®) and labeled by their anatomical side with location starting from manubrium (M) then 1 through 5. Sections 1 – 3 were generally the corpus and 4 – 5 were the xiphoid process as shown in Fig. 3.2.

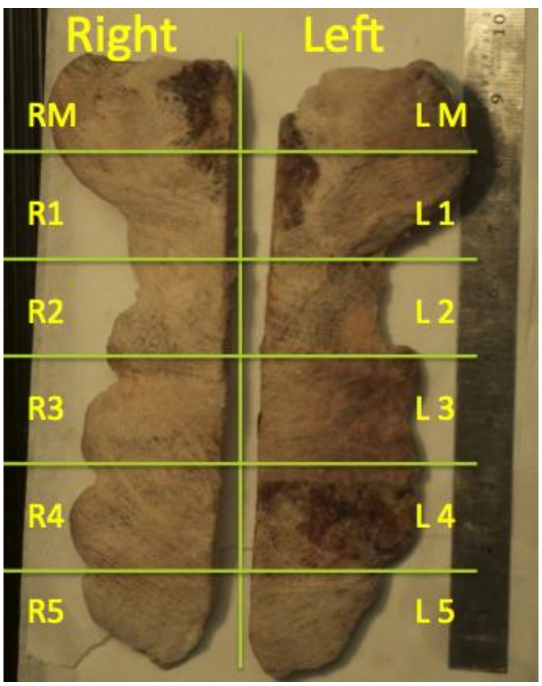


Figure 3.2 Bisected human sternum mapped with section location

Before cyclic testing the sternum sections were defrosted overnight in a refrigerator for a minimum of 12 hours yet no longer than 72 hours. After defrosting, the samples were cleaned of any loose periosteum, cartilage, and rib bone. All screws were installed with predrilled pilot holes through the first cortical layer using the corresponding drill bit provided by the manufacturer. Since non-locking screws will draw the plate proximal to the sternum as it continues to be tightened, non-locking screws were installed without applying direct pressed of the plate against the sternum. Locking screws, however, required the plate to be pressed against the sternum to ensure the screw does not prematurely lock into the plate, creating a gap between the plate and sternum. Additional hardware screws were installed on the opposing side of the plate-screw system, to aid in anchoring the sample within fixation cement (see Appendix C for complete methodology).

3.3.2 Preparing the Load Train

To allow clearance for the extensometer, polyvinylchloride threaded caps of 1.5-inch diameter (Lowell® Hardware) were machined to reduce their height to approximately 1 inch. The cap ends were also drilled with a No.7 drill and threaded with a ¼-20 tap to fit the base of the uniaxial device. A ¼-20 bolt was screwed into the cap and the complementing nut was secured to the other side of the cap.

The prepared sample was inserted into the cap with the additional hardware screws within the cup. Epoxy cement (Oatey®Fix-it) was used to secure the sternum sample into the cap. Epoxy once applied produced an exothermic reaction and was not disturbed until cooled to room temperature for 20 minutes. The plating system was retightened if any pre-test loosening occurring during the cementing process.

An extensometer was used to measure the local displacement between the plate and the bone. The moving arm of the extensometer was pinned into the bone as close to the screw as possible, while still providing enough clearance for moving components. The base of the extensometer was fastened to the clamp functioning as part of the load train. The mechanical testing apparatus of the load train is shown in Fig. 3.3 (see Appendix C).

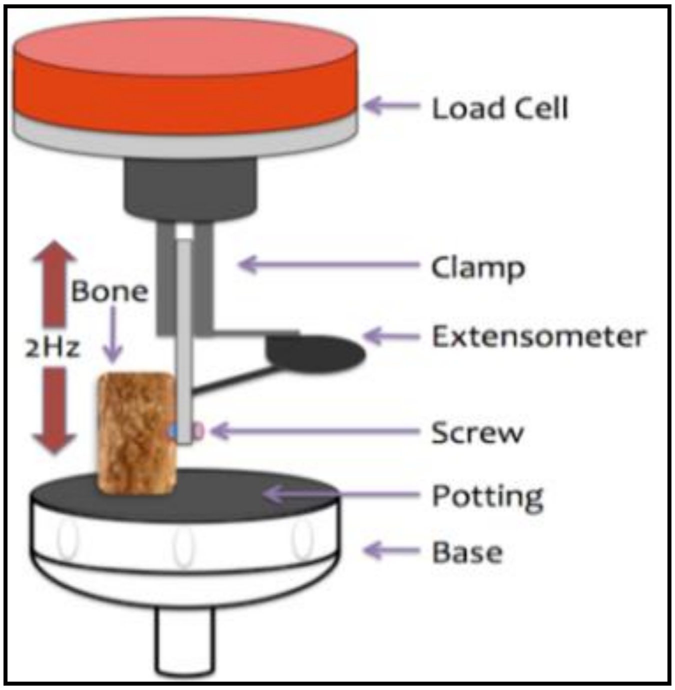


Figure 3.3: Mechanical testing apparatus

3.3.3 Programming

Instron Console and Wavematrix were used to program the test parameters of the uniaxial device. Testing commenced after the bone was fully potted. The test was programmed to initiate to a ramping phase lasting 5 seconds that reduced the load on the sample to zero before cycling. With a starting envelope of one second, a cyclic load was applied from 0-50 Newton at a rate of 2 Hz for a total of 15,000 cycles (Pai, 2008). After the cyclic phase was complete the program returned the sample to zero load (see Appendix C).

3.3.4 Screw Torque Measurements

In order to ensure consistency between tests, the screw tightness was measured and tracked using a torque-measuring screwdriver. Proper torque levels were measured by UMass orthopedic surgeons. They were requested to install a plate-screw fixation on an osteoporotic human sternum and bone analogs using the torque screwdriver. This single-blind test provided torque values that the surgeons instinctively felt were adequate for rigid fixation.

A screwdriver with built-in digital torque-meter (Cedar®) was set to “PP” settings indicating the maximum torque would only be recorded until reset. The digital screen was covered to ensure the surgeons could only determine a secure screw purchase by personal touch.

Sawbone was used for preliminary torque tests as a means to gain initial insight on the surgeons' tightness preference in non-osteoporotic bone (see Appendix D for instruction manual).

The torque screwdriver was also used to measure strip torques in which the screw was tightened until failure in the bone. This measured the ability of the screw to purchase and resist load once inserted. The torque values were also compared to the pullout strengths to see if any correlation existed.

3.3.5 Micro Computed Tomography

UMass Medical School department of histology provided their micro computed tomography (μCT) service to determine mineral content and bone density of the human sternums. In addition digital images of the screw damage in post-test samples were received. Sternum samples were cut to be no more than 2 cm in all dimensions due to the size limitation of the μCT device. The sectioned pieces were fixed with 70% ethanol for 96 hours in a vacuum chamber to achieve complete permeation and saturation (see Appendix E). μCT scans were done at 15 micron resolution. Preliminary μCT images and results are found in Appendix K.

3.3.6 Pullout Experiment

To determine the extent in which the cancellous portion of the sternum aids in fixating the screw, axial pullout tests were conducted within the cancellous portion of the sternum. The pullout tests were performed on the Instron E 1000 (see Appendix C). The section of sternum was fixated to a PVC cap as previously mention. The cancellous sternum was then predrilled with the drill bit provided by Stryker. Either a 4.0 mm cancellous or a 3.5 mm cortical pedicle screw was placed through a custom crosshead and fixated into the sternum. The pullout testing apparatus is shown in Fig. 3.4. A total of 10 mm of the screw was purchased the cancellous bone. The crosshead and custom plate was set to a speed of 5mm/min, in accordance with ASTM F 543 – 07 standards. During the test the forces required to remove the screw was recorded using a data acquisition system. The test ran till the screw was completely removed from the bone.

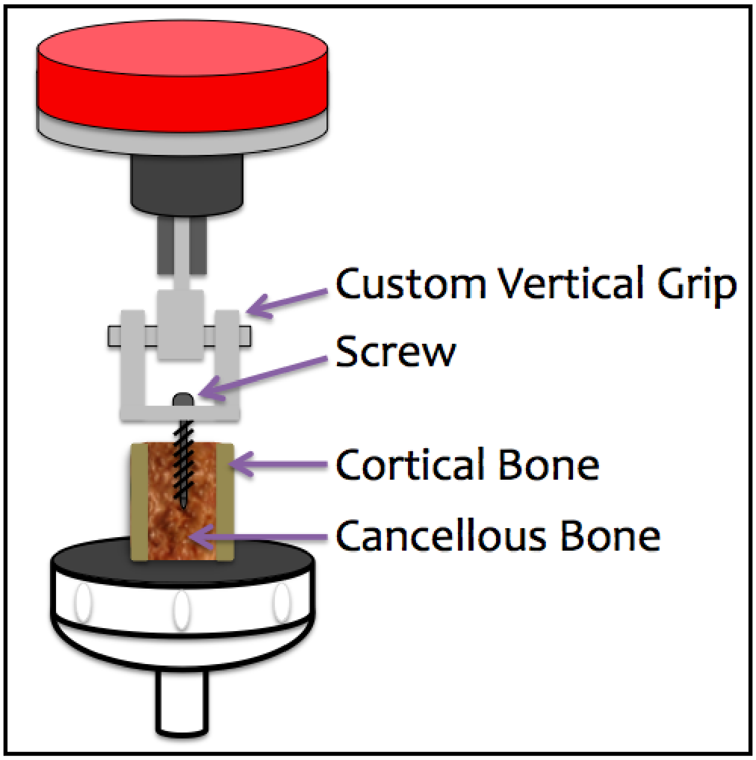


Figure 3.4 Pullout testing apparatus

Chapter 4. Current Designs

Currently marketed screw-plate systems were obtained from Stryker Medical. The two major screw types were from the Matta Pelvic System set and the VariAx Foot System (see Appendix F). The following section describes the specific parameters of the screws and plates acquired. The screw and plate characteristics from these rigid fixation systems were mechanically tested on human sternum and compared. The tested parameters represented the design space and the options to be considered in a design for an optimized rigid fixation system.

As mentioned in our project approach, various screw parameters were tested in order to determine the optimal factors in screw-plate design. Stryker donated a number of screw-plate systems that were tested according to the described methodology. Each screw-plate system was designed to accommodate the physiological and surgical requirements necessary for a particular location of the body. By treating these designs as possible alternatives for sternal closure and analyzing each design as a combination of various parameters, the design team can determine the optimal parameters for sternal rigid fixation. Through matched paring, the MQP team was able to break down these various designs into comparable parameters. Thread and head design as well as the significance of the locking mechanism and cortical purchase was accessed.

4.1 Thread Design

One of the most distinguishing aspects of bone screws and their application within the body is the difference in threads. The screw threads have been modified to work more effectively within the different types of bone, cortical and cancellous (trabecular). Cortical screws are designed for purchase in dense bone with shallow threads cut at about 60º and decreased pitch. Cancellous screws typically follow a wood screws design that includes a tapered outside diameter for easier insertion and wider threads to increase purchase in less dense and compressive bone (An & Draughn, 2000). In this way, both cortical and cancellous screws attempt to contact the same amount of bone in order to achieve similar pullout strengths. The cortical and cancellous screws used in testing can be seen in Fig. 4.1.

Figure 4.1 Cancellous (Left) and cortical (Right) screws from the Matta Pelvic System

To demine which thread parameter, cancellous or cortical threads, would be beneficial in a sternal fixation system, pelvic screws were cyclically loaded in the sternum. Stryker® provided the pelvic screws (seen in Fig. 4.1) from their trauma department. The pelvic screw came from the Matta Pelvic System that is used to address fractures of the acetbulum and pelvis. All implants in this system are made from stainless steel (316 LVM). It also should be noted that the screws comply with the requirements set by ASTM F138 and F139, and ISO 5832 standards.

4.2 Head Design

Another aspect to be assessed in a screw-plate system is the screw head design and its interaction in the plate. The plate holes and screw head can be modified to interact at different angles permitting the screws to be inserted at numerous angles. The increased screw angulation allows for a larger range of plate positioning and the avoidance of predicament potentially associated with screw placement.

Two types of screws were assessed due to their variance in head design. These screws can be seen in Fig. 4.2. The first was the Stryker pelvic screws mentioned in the thread design section. The screws from the Matta Pelvic system were designed to be inserted at angles up to 35 degrees in all directions. This allows the surgeon to avoid positioning a screw into the hip joint or into a previously inserted screw if multiple rigid fixation systems are in place. The second type of screw was from Stryker's VariAx Foot Locking System. This system contains grade V titanium alloy screws designed to fixate and reconstruct injuries in the foot bones. The screw head and plate interact for a range of motion of ±15 degrees. This allows the surgeon to deal with the geometries associated with fracture or osteotomy of the foot. Figure 4.3 gives a clearer representation of different head designs. The rounded head of the Matta Pelvic System provides the greater angulation over the tapered head of the VariAx Foot System. However, this extent of angulation may not be beneficial in the sternum.

Figure 4.2 Stryker Matta Pelvic (right) and VariAx Foot (left) System screws

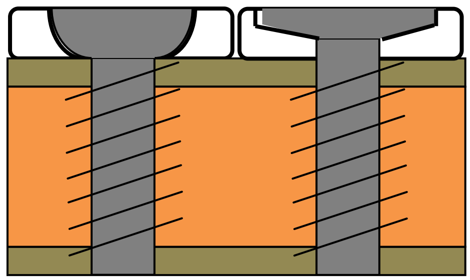


Figure 4.3 Schematic of tested head designs

4.3 Locking Mechanism

A third potential characteristic of a screw plate system is a locking mechanism. In locking plate systems, the screw head is also threaded such that it locks into respective threads on the plate. A locking screw is limited in the torque to which it can be tightened; however, it prevents the wobbling of the screw (An & Draughn, 2000). These screws move in a cutting motion, where the screw and plate move together in direction of loading. Non-locking screws are able to achieve a torque only limited by the purchase into the bone. Because of this, non-locking screws are able to press the plate against the bone creating a friction-fit. When loaded, however, the screws wobble within the plate and bone. Another screw-plate system with a locking mechanism was design by the MQP team to obtain a friction-fit and move as though were a locking screw.

The screws from the VariAx Foot System are either locking or non-locking, and so were utilized in testing the locking mechanism. The locking foot screws use the patented

“SmartLockPolyaxial” Locking Technology where threads on the head of the screw reshape the plate creating a form fitting geometry. This reshaping occurs since the screw is made of a harder material than the plate, grade V titanium alloy versus grade II titanium. Figure 4.4 shows the locking and non-locking screws of the VariAx Foot System. As can be seen in the figure, the locking screw has two threads on the head which are able to rotate into the plate.

Figure 4.4 VariAx Foot System screws non-locking (left) and locking (right)

Along with the VariAx screws, a screw-plate system was designed and custom machined to test another possible locking mechanism. This designed screw-plate system was referred to as “anti-wobble” and can be seen in Fig. 4.5. The anti-wobble system allows for a friction fit of the plate as well as the motion of a locking screw. To get these characteristics, a non-locking screw would press the plate into the bone and then a second machine screw would be pressed on top of the non-locking screw. The second screw prevents wobbling through locking the head of the first screw into place.

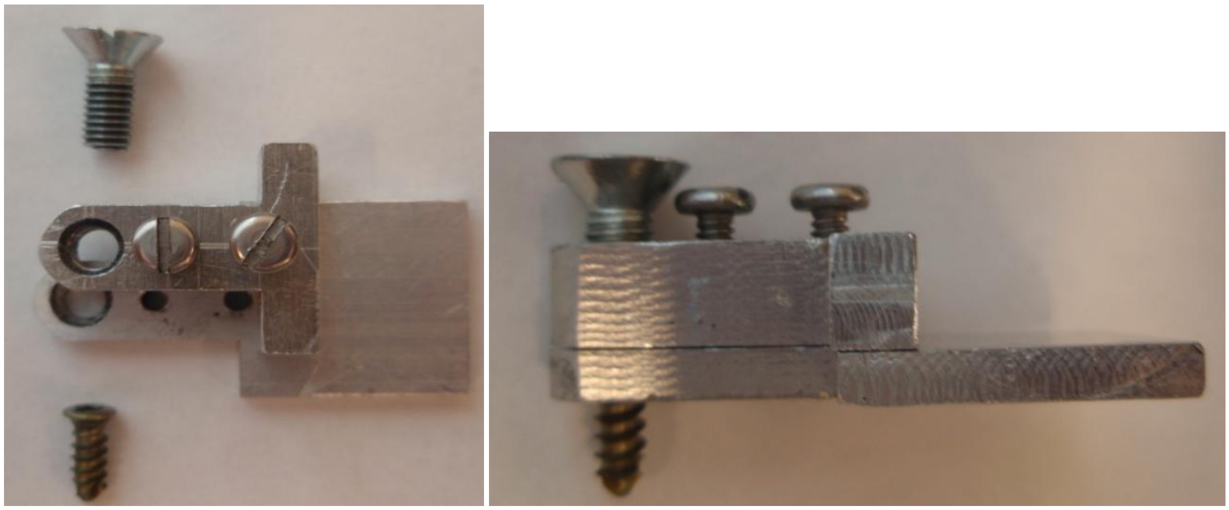


Figure 4.5 Anti-wobble screw-plate system

4.4 Cortical Purchase

Another characteristic of rigid fixation taken into account is number of cortices purchased. Each trait listed above was assessed in combination with a unicortical or bicortical arrangement. As seen in Fig. 4.6, unicortical purchase results when the screw only passes through one cortical layer of the bone and the tip of the screw is within the cancellous layer of bone; bicortical purchase occurs when the screw passes through the first cortex and into or through the second cortical layer. Bicortical arrangement provides greater stability with respect to both wobble and pullout due to the greater purchase into denser bone. However there is an inherent risk associated with bicortical purchase in a sternal screw-plate system due possibility of scraping the heart.

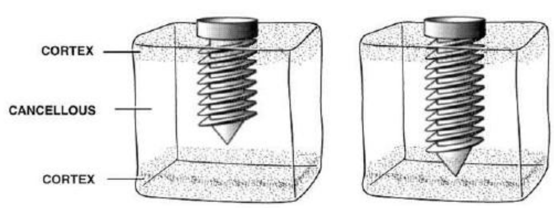
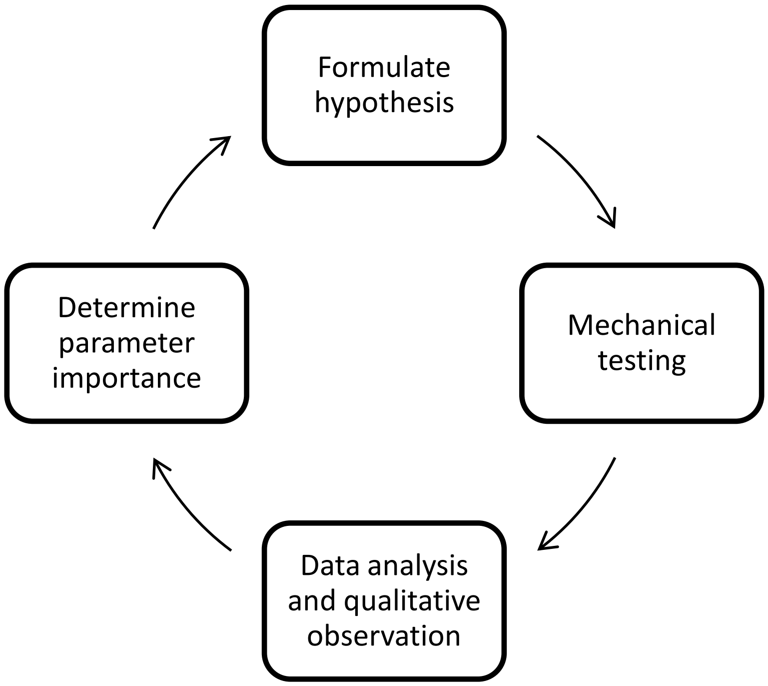


Figure 4.6 Unicortical vs. Bicortical (An &Draughn, 2000)

Chapter 5: Design Verification

The various screw-plate systems obtained were then tested. The defined methodology was followed, with four parameter options compared per sternum. A series of hypotheses were proposed based on the predicted the behavior of the obtained screw-plate systems. The results of both displacement data and mechanical observations were reviewed to determine the optimal parameter from the hypothesis. The results from the previous test were then used to formulate the next experiment set and group of parameters to test.



5.1 Hypothesis 1: Screw-Bone Interface

Based on client input, it was hypothesized that the type of screw thread (cortical or cancellous) would have the most significant effect on screw loosening. Hypothesis 1 involves the testing of cortical and cancellous screw in both the unicortical and bicortical configurations according to the stated methodology. This hypothesis tested screw thread type under cyclic loading as well as pullout. Cyclic tests were paired down the sternum to minimize differences between the tests. A total of 15 tests were run in 4 groups: Cortical screw/bicortical (n=4), Cancellous Screw/bicortical (n=4), Cortical screw/unicortical (n=3) and cancellous screw/unicortical (n=4). Graphs and individual data points for these tests can be seen in Appendix G and H, but their results are summarized in Table 5.1.

Table 5.1: Peak displacement (mm, mean SD) at 50N during uniaxial cyclic loading

	Unicortical		Bicortical	
Cycles	Cortical	Cancellous	Cortical	Cancellous
10	1.01 ± 0.55	1.09 ± 0.75	0.27 ± 0.07	0.44 ± 0.09
100	1.06 ± 0.59	1.49 ± 0.94	0.37 ± 0.17	0.63 ± 0.22
1000	1.09 ± 0.63	1.74 ± 1.05	0.67 ± 0.62	1.11 ± 0.74
15000	1.15 ± 0.72	2.06 ± 1.27	1.20 ± 1.07	3.13 ± 1.40

The initial (10 cycle) and final (15,000 cycle) displacement data was then analyzed using SigmaStat software, utilizing a two-way ANOVA test. This test used screw type (cancellous vs. cortical) and purchase (unicortical vs. bicortical) as factors, and $p<0.05$ was considered significant.

In the first 10 cycles of loading screw type was found to be not statistically significant. However it was determined that unicortical tests had significantly more displacement than the bicortical tests (1.05mm vs. 0.36mm, $p=0.015$). Despite its lack of effectiveness in the initial phases of loading, screw type appeared to be significant in the final stages (2.6mm vs. 1.17mm, $p=0.039$), with cortical screws having substantially less displacement despite the large percentage of cancellous bone in this region.

The conclusion that cortical screws provided increased purchase and resistance to axial loading brought into question the ability of cancellous screws to find purchase in cancellous bone. The purchase provided by the screws in the cancellous region was compared through pullout testing. The pullout results of cortical and cancellous screws were not significantly different. The original hypothesis was cancellous screws would be more beneficial in the sternum since a large percentage of the sternum is cancellous bone. However, cancellous screws in osteoporotic cancellous sternal bone did not have significantly higher biting strength than cortical. Though the mean of cancellous pullout force is slightly greater than cortical as shown in Fig. 5.1, the margin of error superimpose on one another.

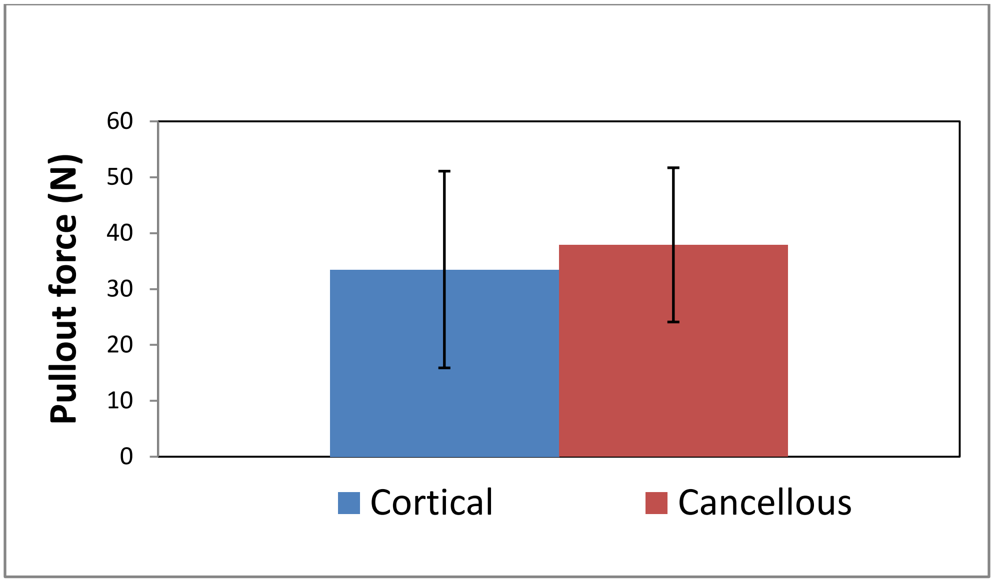


Figure 5.1 Average Pullout Force

The paired torque measurements from the pullout tests were also not statistically different between the two screws in the osteoporotic cancellous bone. As seen in Fig. 5.2,the cancellous bone was far too weak for the either of the screw type to achieve a mean torque near 27 oz-in, the desired torque of the UMass surgeons. The desired torque was determined by having UMass surgeons perform single-blond tests tightening a screw and plate into a human sternum with the torque screwdriver.

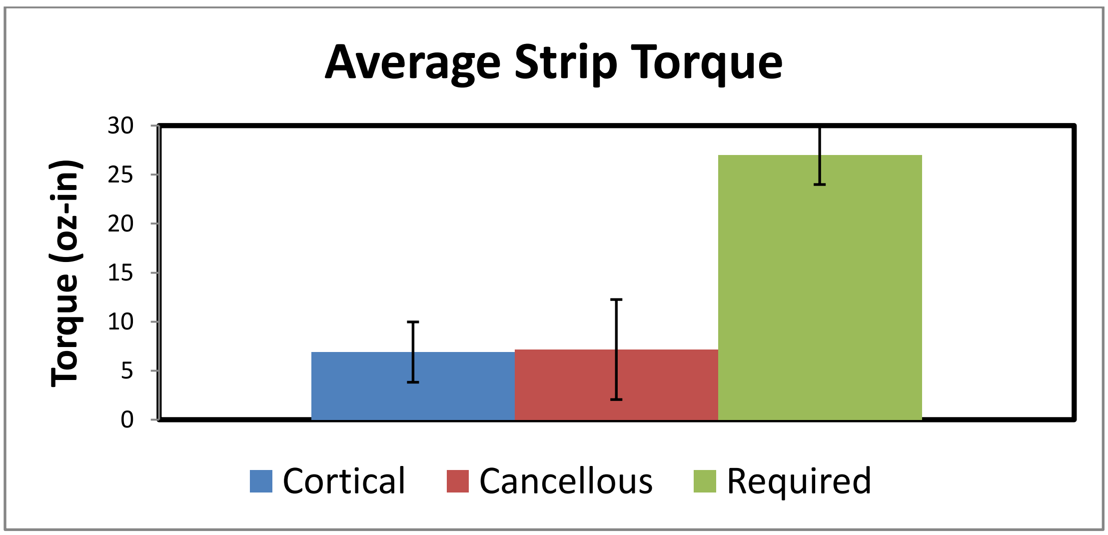


Figure 5.2 Average Strip Torque

The pullout tests showed that cancellous screws, designed for purchase in cancellous bone, did not perform significantly better than cortical screws in osteoporotic sternum. The torque strip test also demonstrated that the cortical layers provide the greater amount of screw purchase. It was therefore concluded that cancellous screws provide no advantage, despite the greater proportion of cancellous bone in the sternum. It was decided to eliminate cancellous screws from further tests.

5.2 Hypothesis 2: Screw-Plate Interface

For the second series of tests, the screw types were adjusted based on the data from the previous hypothesis outcomes. Cancellous screws were eliminated, and cortical pedicle screws were used. These screws have a triangular shaped head as opposed to the rounded head characteristic of the pelvic screws, creating a more rigid plate-screw interface.

A problem with the non-locking pelvic plates was that they allowed the screw to pivot freely within the plate. The previous test demonstrated a need to reduce the ability of the screw to wobble. Locking systems exist that ensure that the screw remains perpendicular to the plate. However, standard locking systems are limited by their inability to provide a full friction-fit. In order to fix the screw from wobbling within the plate after achieving full press-fit, a proof of concept plate was designed and machined. After the screw is fastened into the bone, a cap is threaded into the plate's outer threads over the top of the screw to prevent the screw from loosening out of the plate or pivoting (Fig. 5.3).

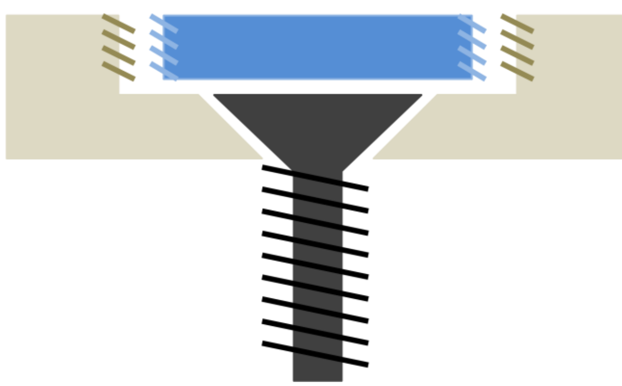


Figure 5.3 Proof of concept anti-wobble diagram

A total of 16 tests were performed in 4 groups: Pedicle Unicortical (n=4), Pedicle Bicortical (n=3), Pelvic Bicortical (n=3) and our antiwobble screw (n=3). Although more tests were performed, some tests had to be removed due to mechanical problems during the test (poor fixation to putty and bad bone bisection were the most common reasons). Individual graphs and data points for these tests can be seen in Appendix G and H, but their results are summarized in Table 5.2.

Table 5.2: Peak displacement (mm, mean) at 50N during uniaxial cyclic loading

	Unicortical		**Bicortical**	
Cycles	**Pedicle**	**Anti-wobble**	**Pedicle**	**Pelvic**
10	**0.308 ± 0.18**	**0.129 ± 0.04**	**0.226 ± 0.16**	**0.227 ± 0.20**
15000	**0.950 ± 0.37**	**0.204 ± 0.09**	**0.386 ± 0.38**	**0.723 ± 0.69**

As can be seen in Table 5.2, the assumption that the screw-plate interface would have a great impact on the outcome of the test was correct. The custom anti-wobble plate had an average final displacement of 0.204 mm, which is less than any of the other group's final values. In fact, this value is less than any of the other group's initial values as well. When compared statistically using a 2-way ANOVA for screw type it was found that there was no statistical difference between the screw types at either the 10^{th} or 15000^{th} cycle (p=0.279 for the 10^{th} cycle and p=263 for the 15000^{th} cycle). This lack of statistical evidence occurs because of a high number of variables and a relatively low number of tests, which results in a very low statistical power (Power = 0.103 at 10^{th} cycle and 0.113 for the 15000^{th} cycle).

5.3 Hypothesis 3: Locking Mechanism

The final series of tests was done to compare the anti-wobble screw to a standard locking screw, which has a similar mechanism of motion when loaded. A total of 11 tests were performed on sternum I with 4 groups: anti-wobble (n=4), locking unicortical foot screw (n=3), non-locking unicortical foot screw (n= 2), and non-locking bicortical foot screw (n=2). There were substantially fewer tests on this particular sternum because it was especially osteoporotic and had an improper bisection that left very little usable bone to perform tests on.

The results of the tests on this sternum show a substantial increase in displacement for all tests due to the lack of structural integrity of the bone. A majority of the tests in this group tore out of the bone before the full 15000 cycles could be completed, although it was more prominent in certain test groups. All of the unicortical locking, and unicortical non-locking tests pulled out (between 36 and 12225 cycles), while none of the anti-wobble or bicortical non-locking tests pulled out. A statistical analysis of the data when compared using a 2-way ANOVA with screw type and unicortical/bicortical as factors it is shown that both anti-wobble and locking screws are statistically better than nonlocking screws (p=0.001 at the 10^{th} cycle and p=0.047 at the final cycle). Despite this, there was no statistical difference between the anti-wobble screw and locking screw at either the 10^{th} or final cycle. Even though there was no statistical difference, several mechanical observations were made that were found to be extremely useful in comparing the screw types.

It appears that in osteoporotic bone normal locking mechanisms may increase the chance of the screw tearing through the bone, while piercing both cortexes with a bicortical screw or utilizing our anti-wobble screw system may decrease this chance. Also, if tests are looked at without comparing to other sternum sections, the results still follow our predictions. For example in one particular piece of bone (R4 on Sternum I) 3 tests were performed, non-locking unicortical, non-locking bicortical and anti-wobble. When these results are compared, the unicortical non-locking test pulled out at a high displacement and low cycles (5009 cycles), the non-locking bicortical test completed the test with a low initial displacement and a final displacement similar to the unicortical test on the same piece, and the anti-wobble test completed with the lowest displacement. These tests follow our predictions that a bicortical interface decreases initial displacement, unicortical tests are more likely to pull out and that the anti-wobble screw system generates the best results on all levels.

5.4 Design Verification Summary

Through a sequential series of tests, it was determined that a cortical screw with a locking mechanism that allowed a full friction fit was effective at minimizing screw loosening (see Appendix G for all data, Appendix H for graphs and Appendix I for MATLAB code used for analysis). The following figure summarizes the hypotheses proposed, tests accomplished, and resulting conclusions that lead to the next hypotheses. A flowchart of the methodology can be seen in Fig. 5.4.

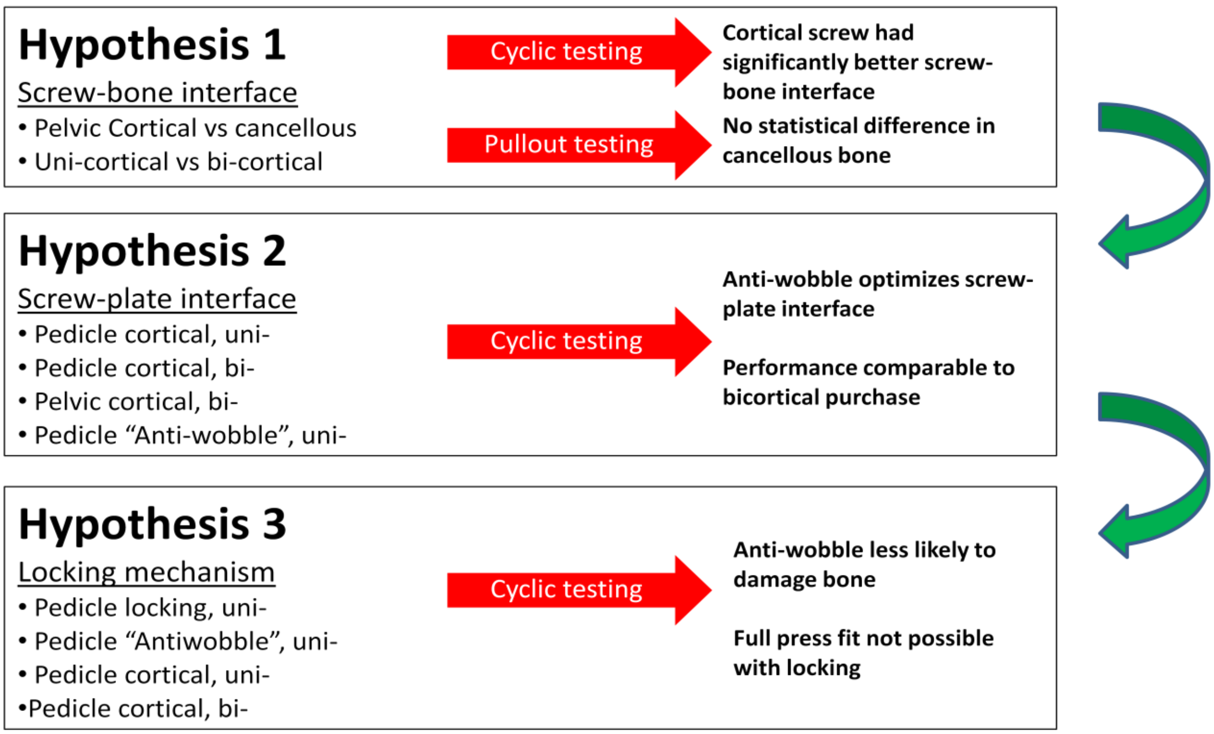


Figure 5.4 Flowchart of Design Verification Steps

Chapter 6. Discussion

The mechanical tests quantitatively measured the loosening of each screw under cyclic loading. The rigid sternal fixation design is comprised of a plate and screw interface. Observations of screw loading behavior were divided into three interfaces for analysis: screw to bone, screw to plate, and plate to bone (see Fig. 6.1). If these three interfaces can be optimized for the sternum than the resulting system will generate the least possible displacement. The design alternatives are based off the design criteria and the mechanisms of loosening identified from the tests.

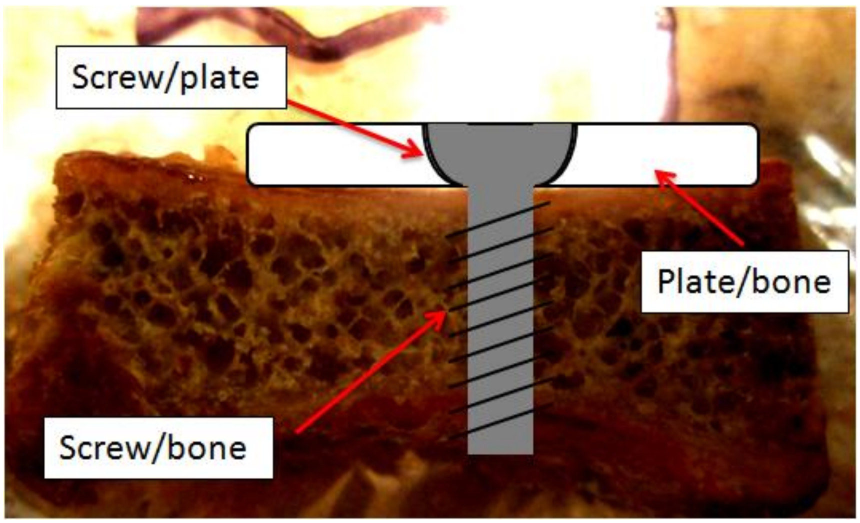


Figure 6.1 Rigid fixation interfaces

6.1 Screw-Bone Interface

The results indicate cortical threads minimize displacement better than cancellous threads. Even though the sternum is composed more of cancellous than cortical bone, the cancellous region being osteoporotic does not exhibit significant structural integrity. The screw design is primarily focused on achieving the greatest fixation in the cortical bone layer. The cancellous screws had an insufficient number of threads in the cortical bone; a high thread density screw permits greater thread surface to cortical bone. The screw threads are the primary fixation source of the entire plate system and must securely bite into the cortical bone.

Cortical screws have more threads due to a lower pitch and higher thread count. These extra threads provide for increase purchase in the cortical bone layers. It was hypothesized that cancellous screws would perform better in the sternum due to a greater percentage of the bone being composed of cancellous bone. Although most of the sternal physiology is composed of cancellous bone, due to osteoporosis this bone is soft and not suitable for fixation. Therefore, most of the fixation and screw purchase will have to come from the cortex layers indicating that cortical screws may be more effective.

Also, the pullout results indicate there is no statistical difference of biting strength between cancellous and cortical screws in osteoporotic cancellous sternum. This indication supports the use of cortical screws in osteoporotic sternum. The cancellous bone is too weak for any plate stability and the plating system must be designed to fully utilize the rigidity of the scarce cortical bone. Cortical screws have been designed to have greater biting strength in cortical bone than cancellous. The strip torque of cancellous bone was very low for both screws therefore the screw must depend on the cortical bone shell to achieve a higher torque. The surgeon clients expressed their need to achieve a high torque with the screws or the plating system would not be installed to that location of the sternum. Based on the torques recorded for each cyclic test, cortical screws achieved a higher torque than cancellous.

The second screw to bone variable is the number of cortical layers a screw purchases: whether it pierces both cortical layers (bicortical) or just one (unicortical). Bicortical purchase transforms a unicortical single shear into a double shear model increasing the rigidity (Fig. 6.2). The number of threads in contact with the cortical bone doubles as well, which increases the torque on the screw. Despite the advantages of bicortical purchase, bicortical becomes impractical because of the location of the heart directly beneath the sternum, creating a safety hazard.

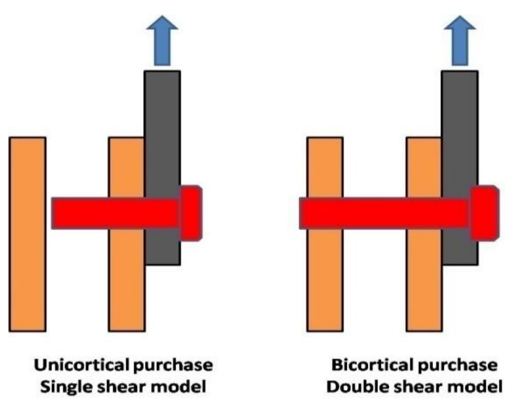


Figure 6.2 Single and double shear models

Aside from injuring vital organs, there are additional concerns of applying bicortical purchase. During the process of screwing into the second cortical bone layer if the screw tip is unable to bite into the second cortex the user may push the second cortex apart and create a void, damaging the cancellous bone. If on the other hand, the second cortex is successfully purchased there is a possibility of drawing in the second cortex and compressing the cancellous bone. The modes of bicortical purchase damage are shown in Fig 6.3.

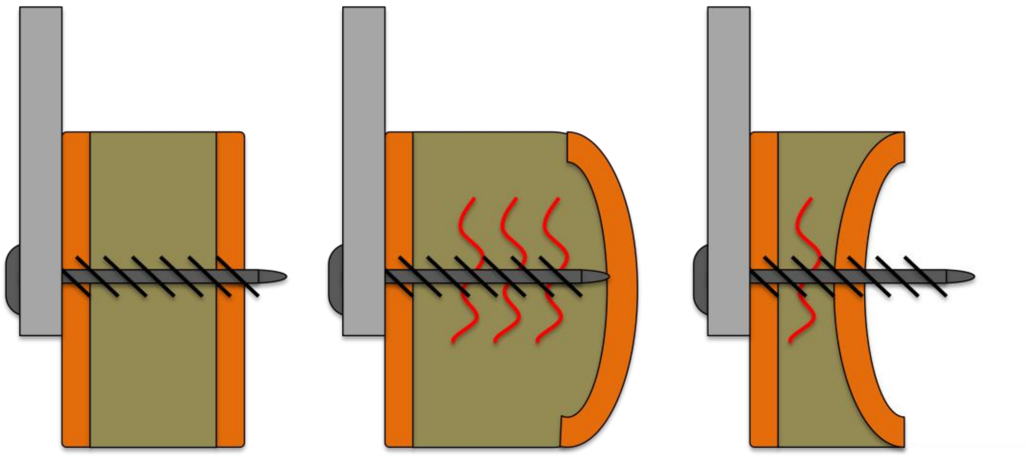


Figure 6.3 Failure modes of bicortical purchase in osteoporotic bone.

The thread design must maximize cortical surface contact with unicortical purchase and still distribute forces effectively within the cancellous region. The first screw design is a high thread density with a smaller outer diameter at the tip. The smaller diameter is intended to lightly anchor into the second cortical layer, while the remaining screw is wider and fixates to the remaining bone. A second design maintains a constant outer diameter size with a decreasing inner diameter; screw core tapers in the distal direction of the screw cap. The third design has a lower thread density to offer enough distance for the threads to curve slightly backwards, acting as barbs clinching against the bone.

6.2 Screw-Plate Interface

The screw head design determines the interaction between the screw and the plate. Two types of screw-plate systems were tested: pedicle and pelvic. Pelvic plates have a rounded bottom, where as the pedicle plates have a wedged bottom. Diagrams of these can be seen in Fig. 6.4.

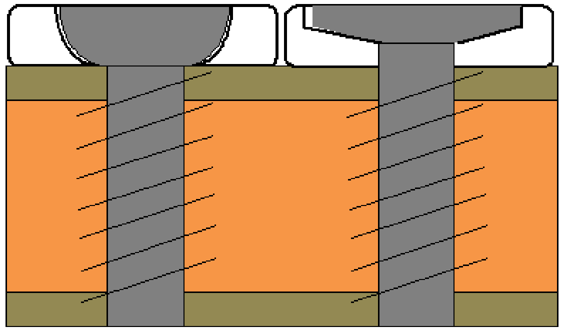


Figure 6.4 Diagram of two head designs: left – orthopedic, right – maxillary-facial

Due to the rounded countersink used on the pelvic plate, the pelvic screw is able to rotate freely, as seen in **Error! Reference source not found.** 6.5. Instead of moving the plate and screw together, only the screw is loaded.

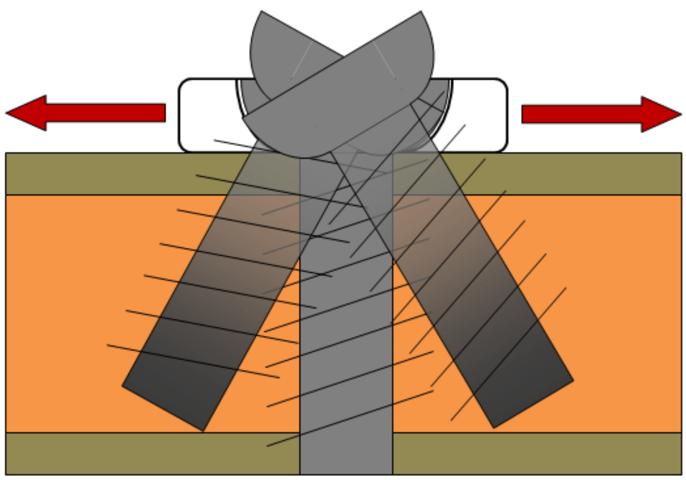


Figure 6.5 Rotation within sternum of pelvic screws

Due to a wedge-type action between the screw and the plate, the screw is forced away from the bone. Axial loading then causes vertical loading on the screw rather than shear, resulting in a pull-out mechanism instead of lateral loading. The smaller the wedge angle, the less wedge leverage is available to pull the screw out, as seen in **Error! Reference source not found.** 6.6. For the orthopedic screws, the wedge angle is large.

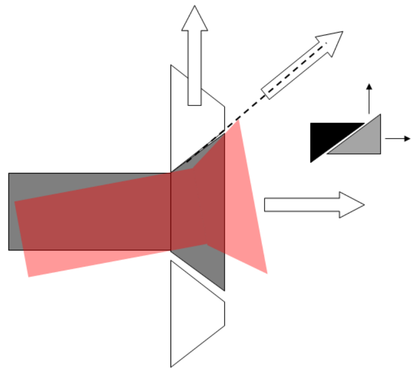


Figure 6.6 Screw motion due to wedge action

Another design parameter observed to have an effect on loosening, particularly loosening due to initial loading, is the difference between the inner diameter of the screw and the inner diameter of the plate. Typically, the minimum inner diameter of the plate hole is the outer diameter of the screw so that the screw can pass through. The screw is centered by the contour of the screw head to the plate. If the threads are deep, the inner diameter of the screw is much smaller than the diameter of the plate hole. During axial loading, the screw will be pulled axially with immediate displacement occurring to the gap between the core of the screw and the edge of the plate, as can be seen in Fig. 6.7.

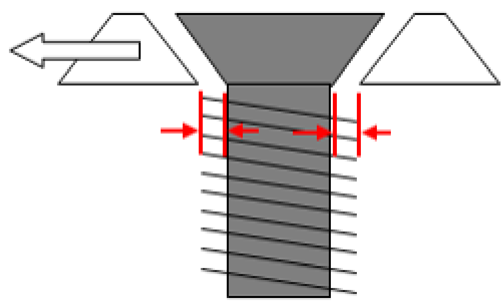


Figure 6.7 Screw movement due to plate inner diameter

An additional parameter important to the screw-plate interface is the ability to limit screw wobble through a locking mechanism. The screw to plate interface is concerned with the degree of freedom the screw is permitted after installation. Based on the Stryker pedicle plates, a locking screw and plate limits the pressure of the plate to the bone due to premature locking.

This decrease in friction-fit decreases the effectiveness of the plate-bone interface by effectively getting rid of it (Fig.6.8).

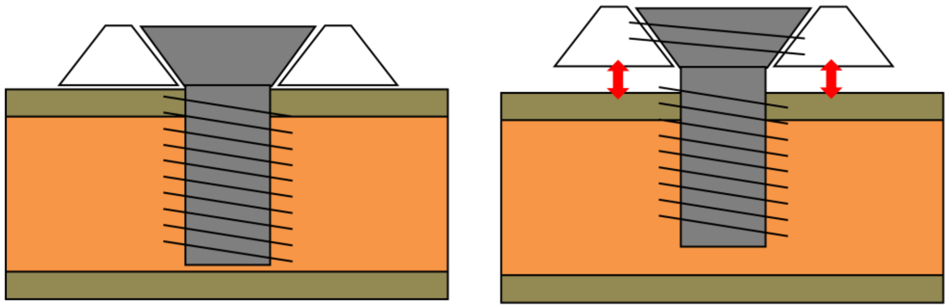


Figure 6.8 Decrease in friction-fit for locking screws

If the plate is floating atop and not securely pressed against the bone, the cyclic forces apply additional leverage against the bone and increase the stress on the screws. By using a non-locking mechanism the plate can be pressed against the bone as much as the screw can be tightened.

The Stryker pelvic plate systems were designed to allow the screw to freely pivot approximately 30^{o} within the plate. Observations of the tests showed that this much pivoting was detrimental to the fixation of the screw. The screw is designed to be loaded traverse, however if the screw is pivoted to a certain extent the screw is loaded similar to a pullout (**Error! Reference source not found.** 6.9). As the screw pivots, the softer cancellous bone becomes damaged. Screws that maintain a permanent angle with the plate distribute the cyclic forces evenly throughout both the cortical and cancellous bone, minimizing stress on the screw-bone interface and bone damage.

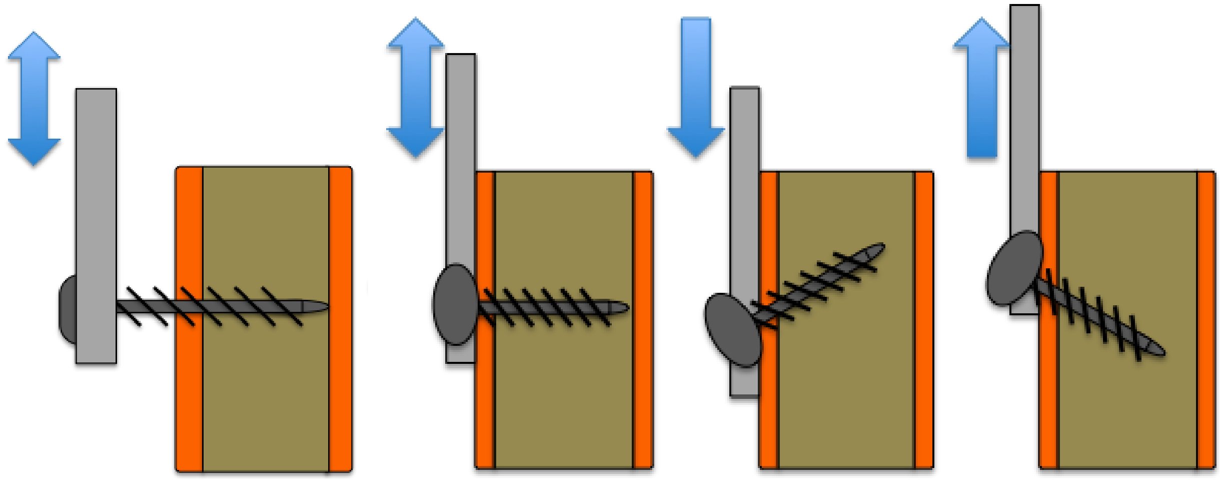


Figure 6.9 Screw pivoting as the mechanism of loosening

6.3 Plate-Bone Interface

The interface between the plate and the bone consists of the surface area contact when the plate is compressed against the bone. In the effort to minimize local distraction between the bone halves, a plate that resists shear loading against the bone is desirable. This could possibly be achieved through increasing the coefficient of friction on the plate surface. In the specific case of a sternotomy, the periosteum covering the sternum is not usually removed, introducing a soft tissue layer between the plate and bone. The plate to bone tightness generally depends on the fixation of the screw, however a higher friction-fit reduces the plate sliding on the periosteum of the sternum option proposed having a plate.

6.4 Resulting Screw Parameters

The following table summarizes the qualitative mechanical observations and the effect they have on screw loosening.

Table 6.1 Summary of Screw Parameters

Parameter	Effect
Tightening torque	Ability to reach higher torque will decrease loosening
Screw head/plate interface	Should be a shallow angle to minimize wedge angle effect
Number of threads	Better for purchase in cortical bone
Depth of threads	Better for purchase in cancellous bone
Locking mechanism	Inhibits sawing effect
OD of screw vs ID of plate	When Screw OD = Plate hole ID, there is minimal initial loosening

6.5 Project Considerations

The following discussion addresses the economic, ethical, and societal implications of the project. The design for manufacturability according to ASTM and ISO is also discussed.

6.5.1 Economic

The U.S. spends the greatest sum of money on medical care, however the healthcare system performs the poorest compared to all other advanced counties (Keehan, 2008). Nearly $2.4 trillion are spent annually, with many people receiving unnecessary medical interventions and other not enough (Pear, 2004). By treating patients with evidence-based best practices this will counter the poor distribution of healthcare costs.

Rigid fixation systems may be the best option for patients with osteoporosis however there has been a large uncertainty regarding the best practice. There is a wide variation of screw-plate systems being marketed however there has not been published data regarding the best system. The purpose of this project was to determine the best screw-plate parameters and the mechanisms responsible for maintaining minimal dehiscence. With this knowledge the best sternal closure system can be selected for this subset of patients with weak bone.

By selecting the best system for the first operation the likelihood of the patient undergoing a revision surgery to address sternal complications is minimized. Though the cost of screw-plate systems are more than standard cerclage wires, the cost of a revision surgery is much greater. More importantly by using the best fixation system, the patient will experience less discomfort.

6.5.2 Environmental Impact

This research project does not pose any environmental impacts even if extended beyond the context of a qualifying project. The purposes of this project were to identify the best screw-plate parameters in current fixation systems then to develop a new fixation system with the obtained experimental data. The most environmental influence this project would pose may pertain setting up and powering the necessary manufacturing machines. Metal resource consumption is not a concern since these systems are comprised of relatively small components and the percent of patients in need of this device is small. The use of gamma sterilization may be more of a health concern however this is essential for all endosseous implants to minimize patient complications.

6.5.3 Societal influences and Political Ramifications

The motive behind this study was to identify the best option for osteoporotic patients to minimize future complications and improve patient care. The published evidence from this project will help the medical community make more appropriate decisions. In doing so physicians will have more knowledge and select the best practice, maximizing patient recovery and indirectly decreasing the need for clinical revisions. Also, patients can be reassured they are receiving the best treatment for their condition.

The findings and final device design do not have any substantially influence the global market. However, this project may influence the current sales and future development of sternal fixation systems. This project directly compared the performance of various current screw-plate systems and discussed the reasons for poor fixation. Statements such as these may deter surgeons from using one company's product over another's. Because the findings are the first of its kind, they may also influence the direction of development for other companies producing sternal rigid fixation systems.

6.5.4 Ethics

The major ethical concern involving our device is when to use it in practice. Our screw design addressed the clinical problem of sternal dehiscence which occurs in only a small proportion of patients who undergo open heart surgery. The standard method of sternal fixation, cerclage wires, is relatively inexpensive. An analysis of the balance between the risk factors of wire failure with the cost of rigid fixation should be performed. Rigid fixation should be applied to higher risk patients in order to avoid a costly and possibly dangerous revision surgery.

6.5.5 Health and Safety Issues

Our design is intended to increase the success of inter thoracic surgery through reducing the incidences of sternal dehiscence post sternotomy. Our design upon implementation will have been tested and manufactured according to ASTM and ISO standards as well as acquired FDA approval. The device in similar in design and materials to currently marketed products and thus would be expected to operate under FDA regulations. The proof of concept has shown that the design will reduce sternal displacement compared to current rigid fixation systems. This reduction will enhance the rate of bone growth and minimize the chance of malunion and infection of the sternum. The design also is safe for the user. It can be implemented safely with a custom screwdriver and has no additional risk to the user.

6.5.6 Manufacturability

The screw-plate system involves several different thread types. The screw head outer threads were designed to be made using standard metric threads and tap drill sizes. The outside of the screw head and corresponding hole in the plate is threaded M8 x 1.25. The threaded core on corresponding hole in the screw top is threaded M3 x 0.5. The bone threads were designed using ISO standard bone screw dimensions (ISO 5835-1991).

The current plate design presents some difficulty from a manufacturing perspective as an extruded hole is located in between a threaded region of small diameter and a through-hole of smaller diameter. Rapid prototyping could be used to build the plate with a 3-D printer in plastic. The actual product could be made using custom tooling.

6.5.7 Sustainability

The screw and plate system can be manufactured following pre-existing standards such as ISO and ASTM and are made of materials such as titanium alloy that are used commonly in the medical field.

Chapter 7. Final Design

Based on the results and observations from mechanical testing a new screw-plate system was designed that incorporated the optimal features. Additional requirements from the user's point of view include the need to "feel" how tight the screw is in the bone while they are hand-tightening the screw down, which are not possible using typical locking screws. It is also desirable to be able to be able to fully tighten the screw against the plate to obtain the friction fit.

The anti-wobble proof of concept screw-plate system that was tested provided a starting point for design as accomplished the basic goals of allowing a full friction fit as well as locking. However, the addition of a threaded plate on top of a screw is not practical as it doubles the number of parts, requires more time to install, and relies on pressure to achieve the locking effect. Alternative designs focused on allowing nonlocking insertion with locking capability in a single screw system.

The screw final design has two parts which allow it to be installed as a non-locking screw and subsequently locked. The screw is designed with dense wide blade threads; similar to a cortical screw with the thread depth of a cancellous screw. The screw is threaded into the plate beyond the upper thread portion of the hole and into a non-threaded region. With no thread interactions between the screw and plate, the screw may be fastened without plate restriction to increase the pressure of the plate to the sternum; thus the system is non-locking.

The exact screw dimensions as designed according to ASTM and ISO standards for ease of manufacture is shown in Appendix J.

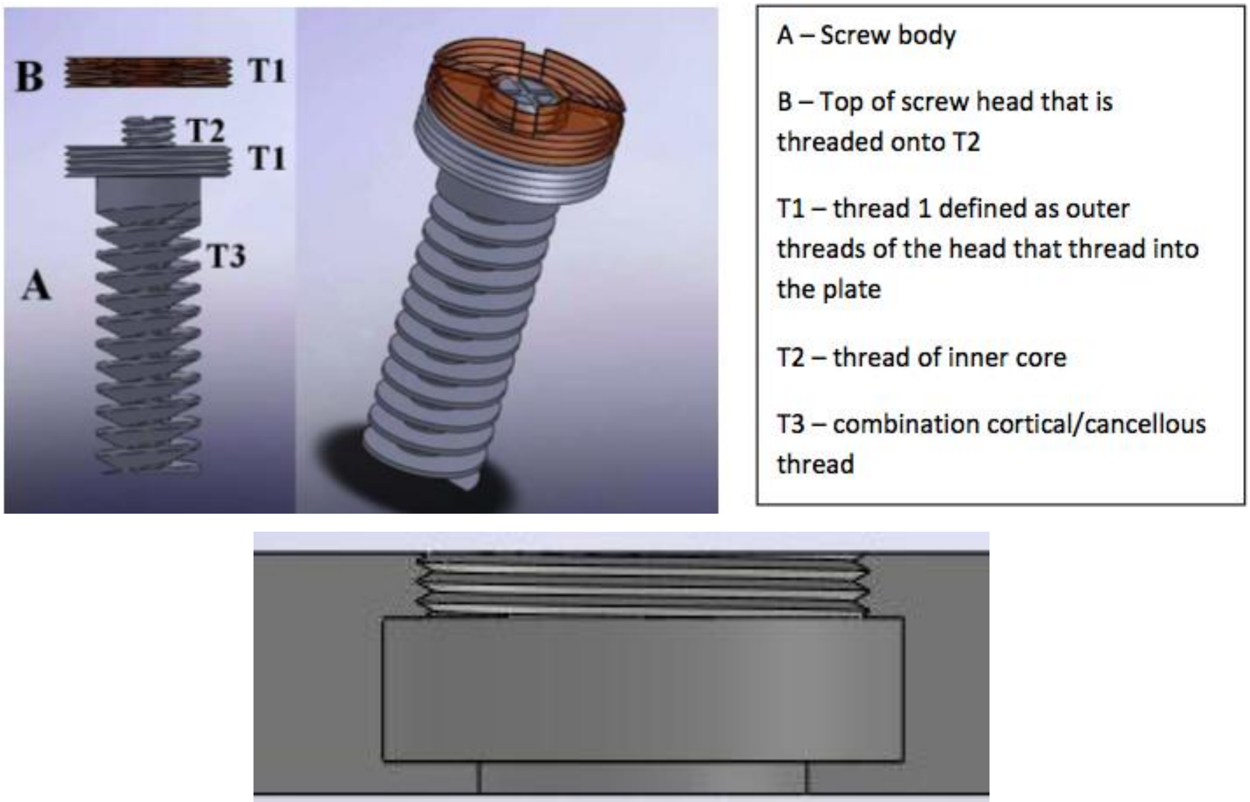


Figure 7.1 Screw component layout and plate design

The screw consists of two components: a screw base (A) and screw top (B). Both components pass through the initial plate threads and arrive in the non-threaded region in the plate as a single unit. The screw can rotate limitlessly as long as B and A remains as a single unit. The torque feedback of the screw is generated only from the sternum and not influenced by the plate threads, allowing the user to hand tighten the plate.

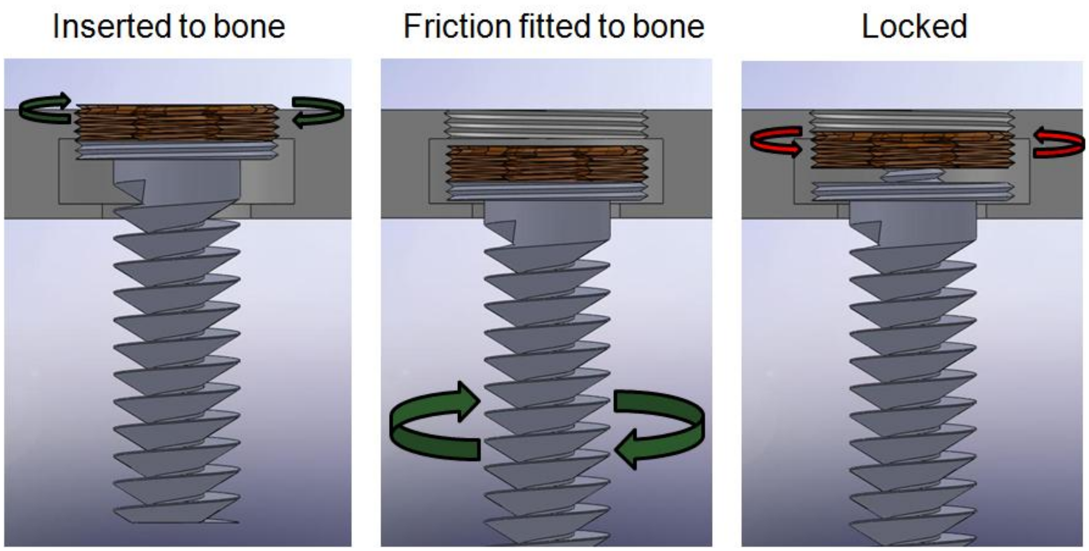


Figure 7.2 Final design method of toggling between non-locking and locking

Once the screw has reached the desired torque the screw top is rotated back up the threaded core and threads into the plate. The screw top is prevented from completely backing out of the plate by a difference in thread pitch between the inner core and the outside of the screw head. This causes a binding effect that effectively locks the screw. This mechanism also causes backpressure upon locking that maintains the torque applied to the screw. To remove the screw, the screw top must be rotated inward and returned to screw body. The screw can be rotated outward once restored to initial single unit form.

Chapter 8. Conclusions

Cortical screws proved to be more resistant to against cyclic lateral loading than cancellous even though the sternum is largely structured from trabecular bone. Though bicortical is not an acceptable practice and may cause profound damage to the cancellous region, limiting screw pivoting appears to benefit rigid fixation.

There is still concern of poor press-fit from locking screw due to early unwanted locking. However the non-locking screw results suggest the need for a screw to remain fixed in its complementing plate to limit the screw from pivoting in the plate and loosening. Non-locking screws are able to achieve full press-fit however are susceptible to screw pivoting leading to loss of fixation.

There were two concerns of wobbling, non-locking screws pivot within the plate whereas locking screws do not pivot in the plate however levers the entire plate. The anti-wobble concept combined the needed press-fit to securely fasten the plate against the bone and a locking mechanism to prevent the screw to pivoting in the plate. The concept proved achieving a full press-fit and locking of the screw to plate significantly reduced the dehiscence produced by lateral cyclic loads, more than these each of these mechanisms could do independently.

The final design combines the thread density of a cortical screw with cancellous thread blades to maximize contact with the cortical bone layer. The screw head incorporates the anti-wobble concept, designed to toggle between a non-locking and locking mode within the plate compartment. This allows for the user to fasten the screw without any plate restriction to achieve full friction-fit and to follow up with locking the head into the plate to prevent pivoting. The overall findings and observations indicate the best option of rigid plate fixation for osteoporotic sternum is the anti-wobble screw-plate system.

Chapter 9. Recommendations

Due to time constraints and limited resources, there are several areas that should be addressed as a follow-up to this project. First, the final design was never tested in comparison to other screws, and therefore it should be prototyped and tested. Currently, a prototype has been submitted to SECUROS for manufacture. Second, this prototype should be proposed to surgeons to be sure that it meets their specifications for purchase and torque parameters. Finally additional μCT analysis should be done on existing samples to help identify more loosening mechanisms.

Furthermore, another area of the rigid fixation system could be considered. In this project, the bone to plate interface was not effectively investigated. However the following design recommendations have been recorded in hopes of further improving the rigidity of the plating design. From what is known based on previous literature excessive pressure against the bone from another surface may decrease vascularity causing osteonecrosis (Sumner-Smith & Fackelman, 2002). This interface has clashing constraints with the need for friction-fit to prevent screw-plate leveraging while simultaneously ensuring the bone properly heals. In the event, if this study were to be continued we recommend studying the effects of different plate surfaces.

One recommendation would be to create a friction wave plate, with directional barbs that distribute the lateral loads over the entirety of the plate to bone surface. By including these small anchors the friction-fit may be slightly relaxed to improve bone vascularity. The concern of a locking system leveraging is dismissed since the plate does not solely rely on one point of purchase however many distributed points. The center break where the sternum halves reunite should also include a slight wave to guarantee no pressure is compromising the healing factors. The friction wave plate schematic is shown in Fig. 9.1.

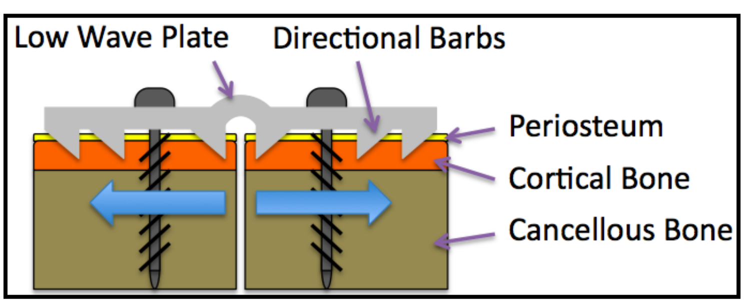


Figure 9.1 Friction wave plate design schematic

GLOSSARY

Cancellous: The porous inner section of bone characterized by low density, low strength, and high surface area. Also known as trabecular bone.

Cortical: The dense surface layer of bone

Displacement: the distance moved from the initial location; movement between the plate and the bone

Friction-fit: a downward pressure resulting from a screw pushing down on a plate a plate

Locking: a characteristic of a screw and plate to link so that the screw and plate always remain perpendicular

Manubrium: the broad upper portion of the sternum

Osteoporosis: a disease of the bone characterized by low bone mineral density

Purchase: degree of fixation of a screw, amount of torque achieved

Rigid fixation: a screw and plate system

Sternotomy: surgical procedure where the sternum is vertically bisected

Sternum: a flat bone that lies in the median part of the chest and connects the ribs. Also known as the breastbone.

Torque: application of a force about a perpendicular distance to rotate an object

Xyphoid: small cartilaginous extension of the lower part of the sternum

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Appendix A – Instron E-1000 Information

INSTRON®

E1000 Electrodynamic Test Instrument

System Overview

The ElectroPuls™ E1000 is a state-of-the-art electrodynamic test instrument designed for dynamic and static testing on a wide range of materials and components. It includes Instron®'s advanced digital control electronics, Dynacell™ load cell, Console software and the very latest in testing technology – hassle-free tuning based on specimen stiffness, electrically operated crosshead lifts, a T-slot table for flexible test setups and a host of other user-orientated features. It is an all-electric system, powered from a single-phase supply and requires no additional utilities (for example, pneumatic air, hydraulics or water).

Technical Highlights

- Patent-pending, oil-free linear motor technology for clean conditions.
- Designed for both dynamic and static testing on a variety of materials and components.
- High dynamic performance.
- ± 1000 N dynamic load capacity and ±710 N static load capacity.
- Electrically powered from single phase main supply, no need for hydraulic or pneumatic air supplies.
- Temperature-controlled air-cooling system.
- High stiffness, precision-aligned twin column load frame with actuator in upper crosshead.
- Versatile T-slot table for regular and irregular grips and specimens.
- Compact instrument - frame requires less than 0.15 m^2 (1.6 ft^2) of desk space.

Hardware and Software Interfaces Designed to Put You In Control

- Console software control interface - engineered with Instron's knowledge of machine usability.
- Rigidly mounted control pod with critical controls and emergency stop at your fingertips.
- Optional hardware panel for use when full computer functionality is not required.
- Electrically powered crosshead lift system with manual lever clamps for ease of test space adjustment.
- Crosshead status indicator to show system conditions (off, on, emergency stop and fault).

Hidden Technology Designed to Improve Your Test

- Hassle-free stiffness-based loop tuning system.
- Unique actuator bearing system that maintains load string alignment when offset or lateral loads are induced by specimens or fixtures.
- In-line optical encoder for noise-free digital extension control and LVDT for coarse position control.
- Digital controller based on the industry's most advanced controller.
- Dynacell patented load cell technology for faster testing and reduction of inertial errors.

A High Level of Versatility

- Readily adjustable test space to suit a wide variety of specimens, grips, fixtures and accessories.
- 60 mm (2.36 in) stroke for a wide range of tests, as well as ease of specimen setup.
- Offset diagonal column configuration provides optimum access to the test area.
- Compatible with FastTrack™ suite and Bluehill® 2 software.
- Compatible with a large range of grips, fixtures, chambers, saline baths, video extensometers and other accessories.
- Optional accessory kit to allow frame to be mounted in horizontal orientation for ease of testing with imaging systems and microscopes.

E1000 test instrument in vertical configuration ▶

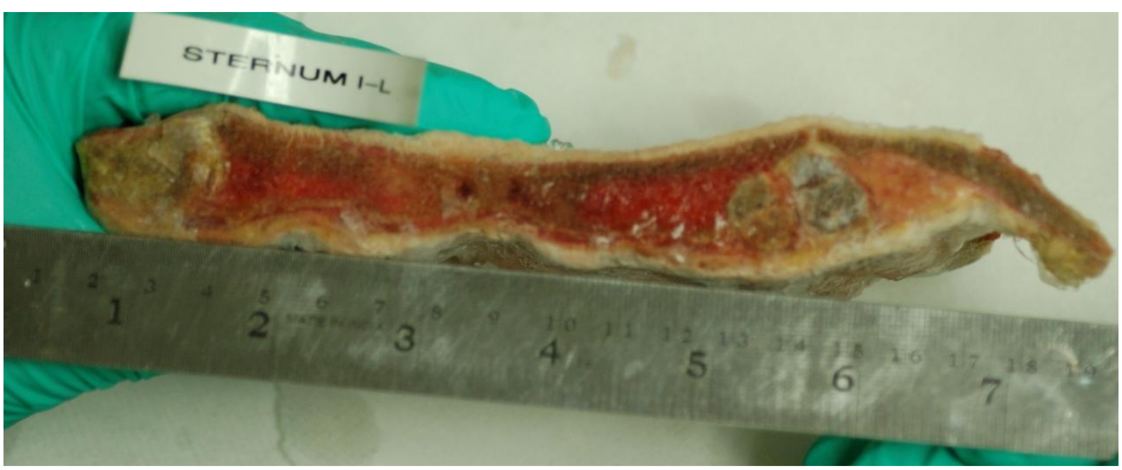
A New Wave In Testing

Appendix B - Documentation of Sternum Samples

Four unfixed human sternum were acquired from UMass Medical School. The sex, age, and cause of death of the patients were recorded as shown below. The osteoporotic nature of the sternum was determined through by Dr. Dunn, observation during testing, and microCT measurements.

Number	**Age**	**Sex**	**Cause of death**
#2252	66	Male	Respiratory arrest
#2253	88	Male	Aschemic cardiomyopathy
#2254	51	Male	Cancer
#2255	82	Male	Congestive heart failure

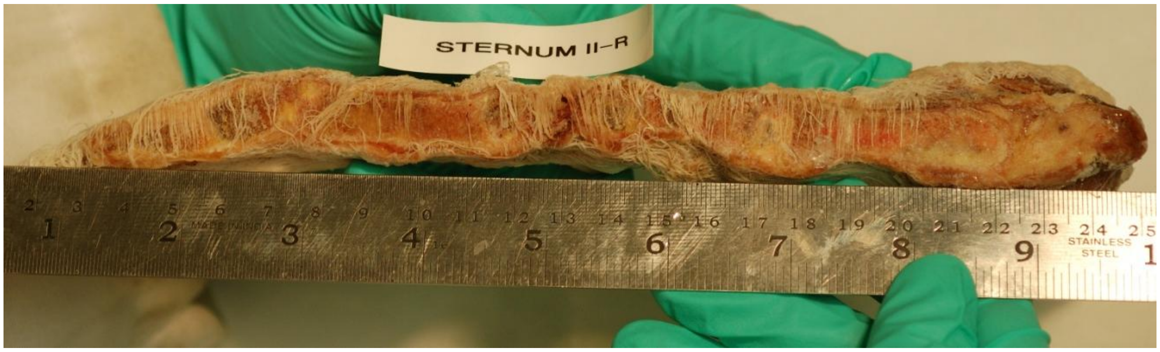
Sternum I



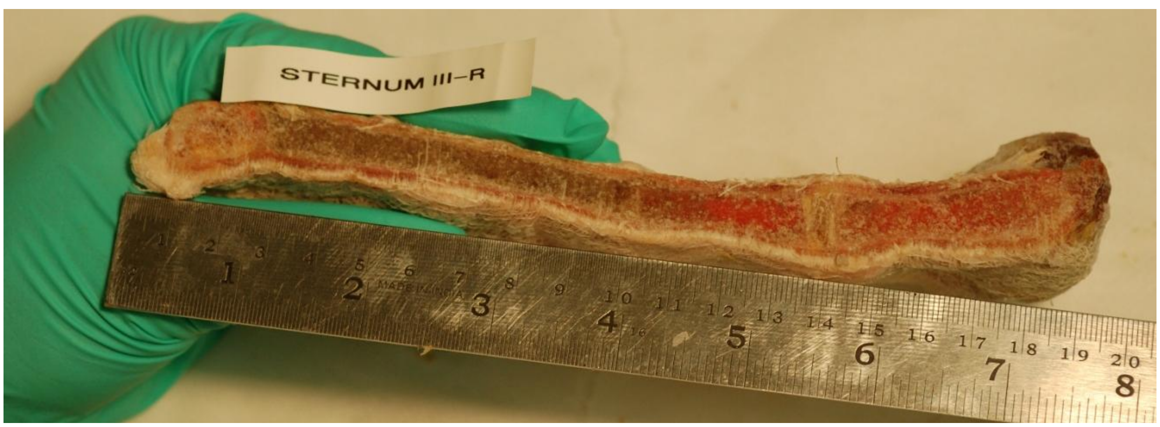
Sternum II

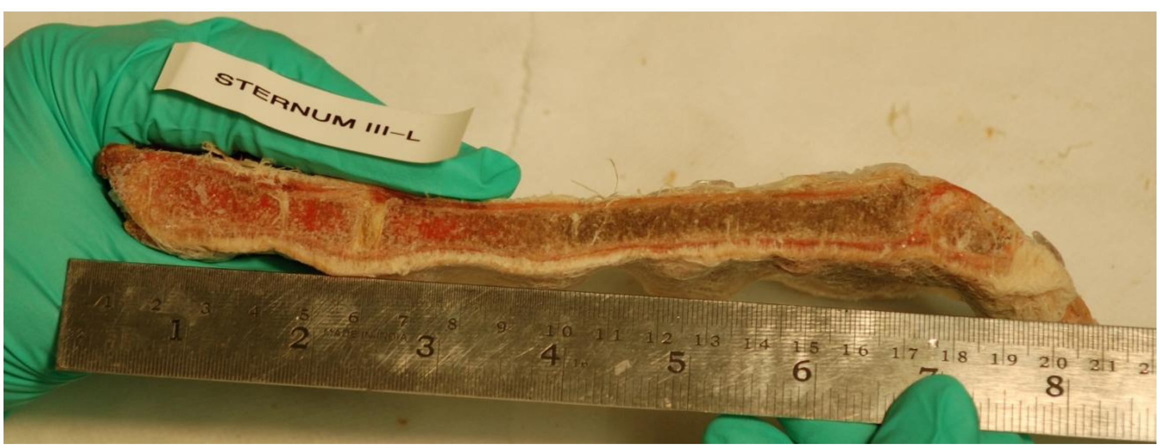

STERNUM II


STERNUM II–L
STAINLESS
STEEL

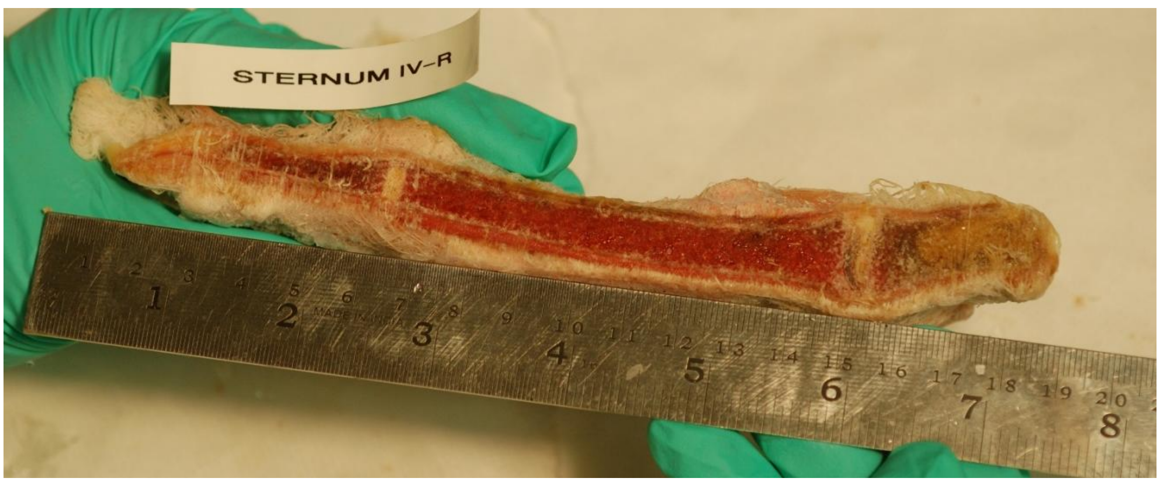

STERNUM II–R
STAINLESS
STEEL

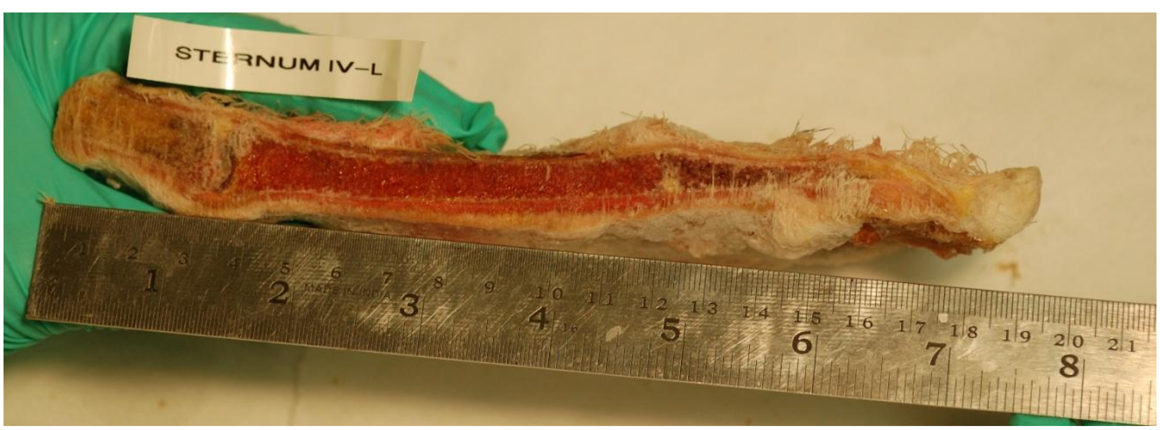
Sternum III





Sternum IV





Appendix C - Methodology

Methodology of Experimental Design
MQP-SSD 2008-2009

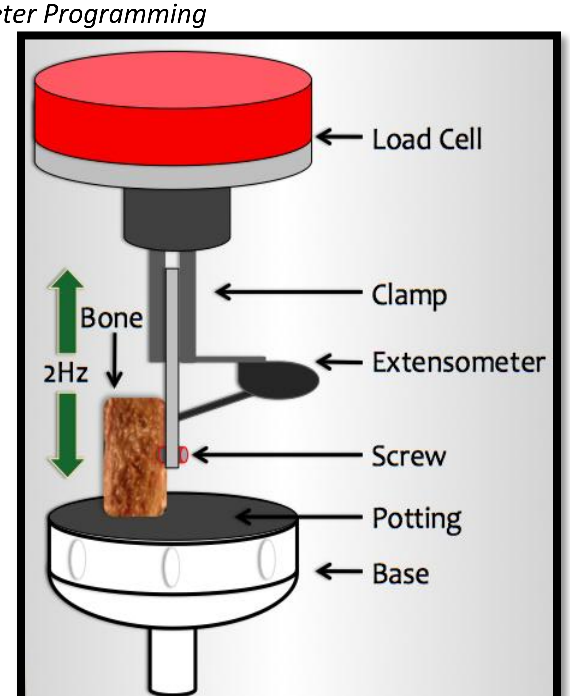
Motive
Theobjective is to identify the optimal screw parameters for rigid fixation of osteoporotic post-sternotomy patients. The displacement trends of different screws combined with unicortical or bicortical purchase are to be compared.

Materials List
- **Instron**
    - Electroplus E-1000
    - 2000 N Load Cell
    - Extensometer
    - Crosshead Vice Plate System (WPI custom manufactured)
    - PulloutCrosshead System (WPI custom manufactured)
    - Program
        - Console
        - Wavematrix
- **Biological Specimen**
    - Human Sternum
- **Screw and Plate Systems**
    - Stryker Matta PelvicFixation System
    - Stryker VariAx Pedicle Plating System
    - Anti-wobble proof of concept system(WPI custom manufactured)
- **Additions**
- Torque Screw Driver
- Humidifier (Tracker Miniature Air)
- Custom Acrylic Humidifier Case
- Epoxy Cement (Oatey Fix-it Stick)
- PVC Threaded Cap (1.5 inch Diameter)
- Bolt and Nut Screw (0.25 inch Diameter, 20 threads/inch)
- Various Cement Fixation Screws
- Instruments/Tools
    - Razor/Scalp
    - Forceps
    - Power Drill
    - Ink pen
- Personal Protection Equipment (PPE)
    - Latex/Nitrile Gloves
    - Lab Coat (Long Sleeve, Knee-length)
    - Safety Goggles (ANSI Z87.1)
- 70% Ethanol Solution
- 1X PBS (saline)
- Surgical Towel Drapes
- Biohazard Bag

Methodology of Experimental Design
MQP-SSD 2008-2009

Cyclic Load Test: Sternum and Load train preparations

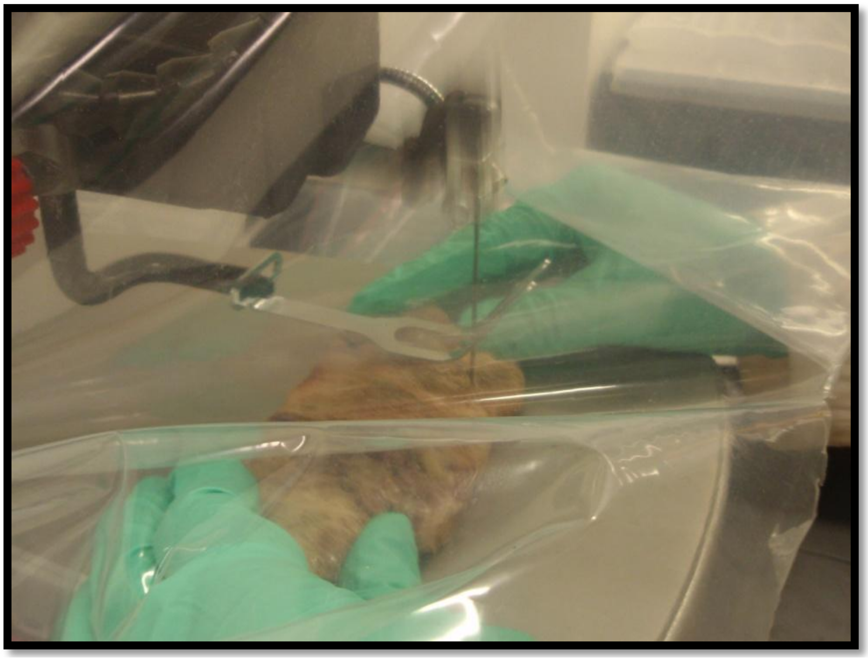
1. Cut the frozen sternum into strips using the scroll saw with a containment field
2. Defrost frozen human sternum piece overnight in a refrigerator
3. Wear all required personal protection equipment
4. Remove gauze and other foreign non-biological coverings from the sternum
5. Carefully scrape away loose periosteum using forceps and sharps.
6. Identify an ideal locations on the anterior region of sternum to properly install the plate
7. Mark locations with ink pen and drill sternum with OEM drill bit using the power drill
8. Install the plate to the predrilled sites using torque screw driver with proper head fitments
9. Record the final torque
10. Drill and install additional appropriate hardware screws distal to the plate
11. Secure the plate-sternum complex to the crosshead
12. Deposit epoxy into the PVC cap and lower plate-sternum complex using the crosshead controls
13. Apply any additional epoxy to the sternum while preventing any influence to the test sites
14. Ensure epoxy has cooled and formed a rigid fixation
15. Install the extensometer to the crosshead and proximal to the sternum plate
16. Place surgical towel drapes around the base of the testing device
17. Spray saline on the sample and position the humidifier (full with water) and case into position, ensure the case does not come into contact with the crosshead or any other components in motion.
18. Ensure the pillar handles are tightened and no stationary materials interfere with moving parts
19. If, a second test is to be performed repeat steps 5 – 18 of *Sternum and Load train preparations* and all of *Test Parameter Programming*



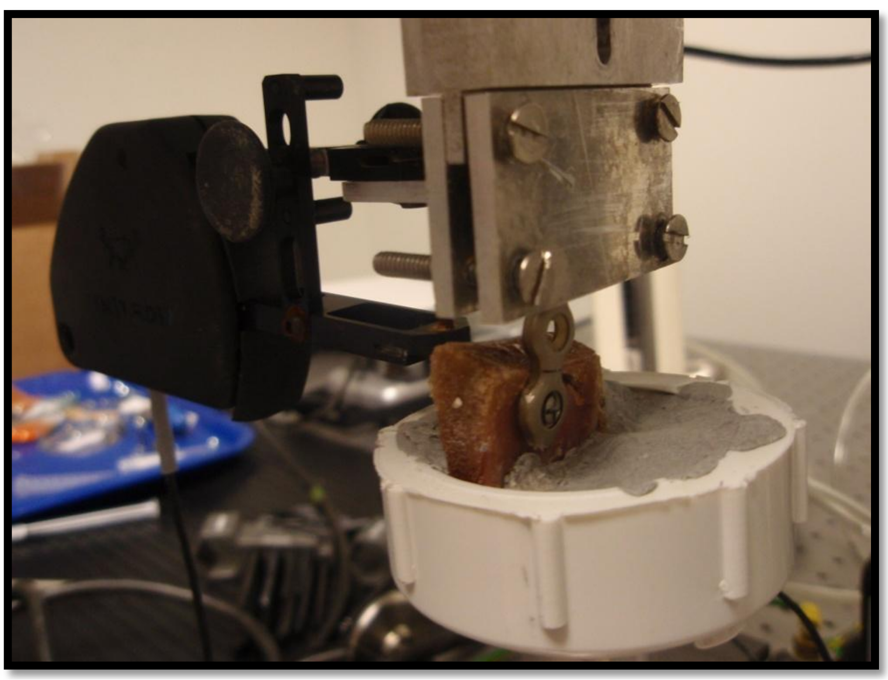
Methodology of Experimental Design
MQP-SSD 2008-2009

Cyclic Load Test: Visual Notes

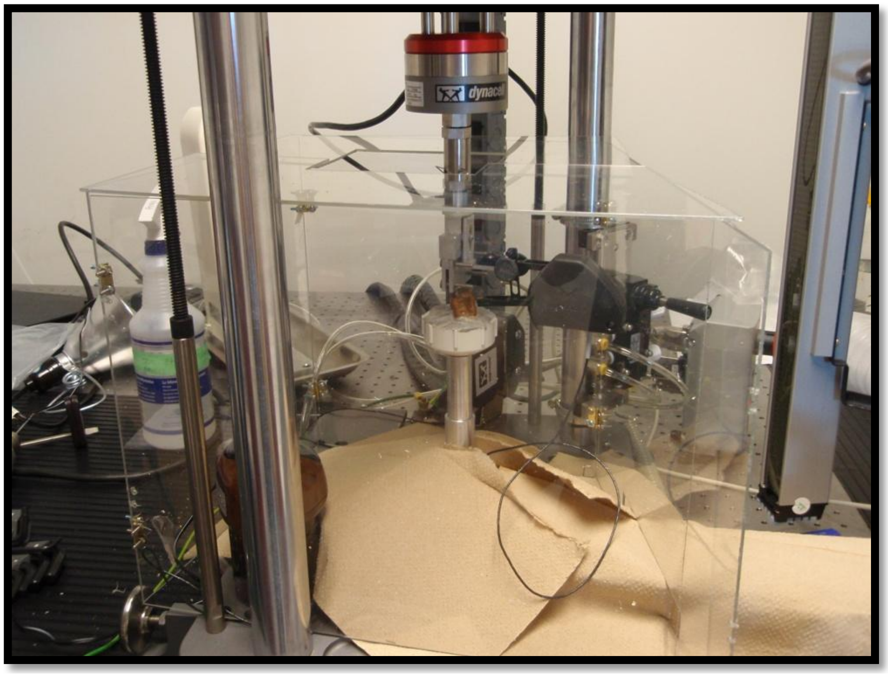
- Referring to Step 1. Cut the frozen sternum into strips using the scroll saw with a containment field



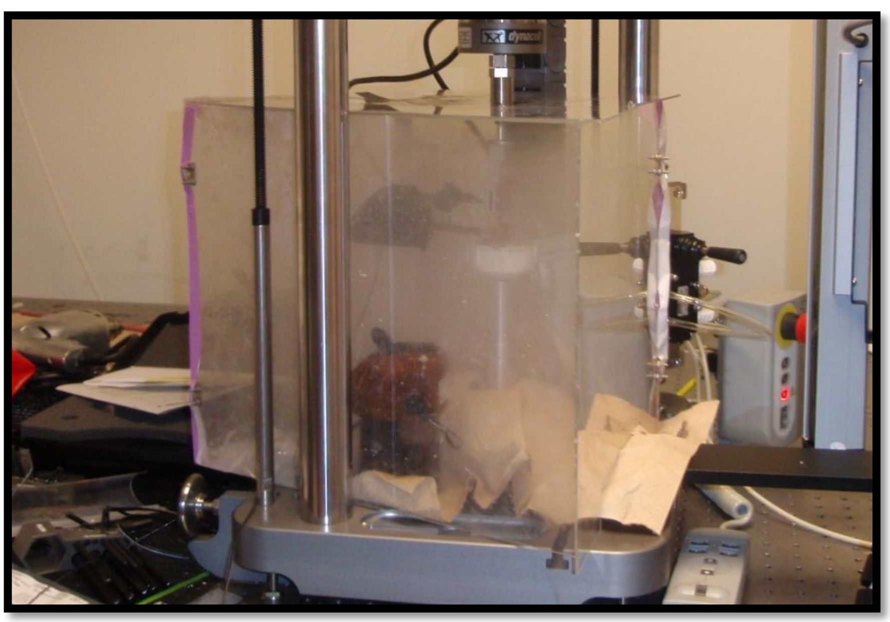
- Referring to Step 10. Secure the plate-sternum complex to the crosshead



- Referring to Step 17. Position the humidifier (full with water) and case into position, ensure the case does not come into contact with the crosshead or any other components in motion.



- Referring to Step 17. Cont. Sample is completely humidified.



Methodology of Experimental Design
MQP-SSD 2008-2009

Cyclic Load Test Parameter Programming

1. Input correct title of the sternum test
2. Select methods 'Human Stryker Testing'
3. Test parameters should be set to:
   a. Amplitude: 25 N
   b. Frequency/Rate: 2 Hz
   c. Wave Phase: *Sin*
   d. Cycles: 15,000
   e. Degree: 270^{O}
4. Calibrate Digital Position and Extensometer
5. Apply displacement limits to be ±8 mmof the current position reading
6. Post-test, before touching anything select *Transfer>Immediate*

Data Analysis

1. MATLAB R2008a is used to formulate the exported testing device data plots onto a graph
2. Graphical displays of digital position and extensometer:
   a. The maximum and minimum displacement over cycles
   b. The maximum and minimum displacement over cycles in logarithmic scale
   c. The difference between the maximum and minimum displacement over cycles
   d. The maximum change every 1,000 cycles

Laboratory Safety and Disposal

1. A biohazard bag is prepared before preparing the sternum
2. All biological tissue and disposables coming into contact with biological tissues are deposited into the biohazard bag
3. All tools and instruments in contact or proximal to biological tissue is cleaned using 70% ethanol
4. Biohazard bags containing biological tissue are sealed and stored in the designated freezer for proper disposal later

Methodology of Experimental Design

MQP-SSD 2008-2009

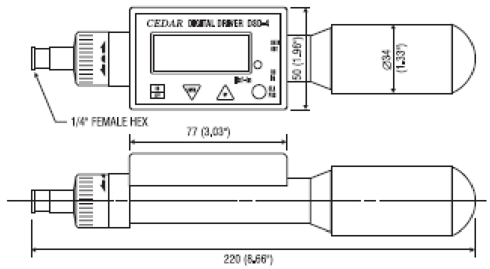
Pullout Mechanical Test: Sternum and Load train preparations

1. Defrost frozen human sternum piece overnight in a refrigerator
2. Wear all required personal protection equipment
3. Remove gauze and other foreign non-biological coverings from the sternum
4. Carefully scrape away loose periosteum using forceps and sharps.
5. Drill and install additional appropriate hardware screws
6. Deposit epoxy into the PVC cap
7. Ensure epoxy has cooled and formed a rigid fixation
8. Install screw into trabecular region with the pullout crosshead
9. Clamp pullout cross head into the crosshead
10. Place surgical towel drapes around the base of the testing device
11. Ensure the pillar handles are tightened and no stationary materials interfere with moving parts

Appendix D – Digital Torque Tester/Screwdriver Instruction Manual

TORQUE MEASUREMENT

DIMENSIONS



2 YEAR WARRANTY (RESTRICTIONS APPLY)

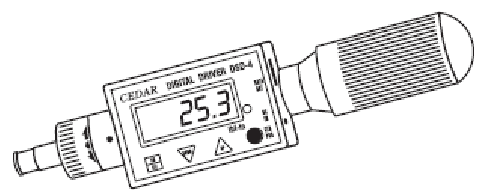
Imada, Inc. warrants its products to the original purchaser to be free from defects in workmanship and material under normal use and proper maintenance for two years (one year for adapters, attachments and cables) from original purchase. This warranty shall not be effective if the product has been subject to overload, shock load, misuse, negligence, accident or repairs attempted by others than Imada, Inc.

During the warranty period, we will, at our option, either repair or replace defective products. Please call our customer service department for a return authorization number and return the defective product to us with freight prepaid.

The foregoing warranty constitutes the SOLE AND EXCLUSIVE WARRANTY, and we hereby disclaim all other warranties, express, statutory or implied, applicable to the products and/or software, including but not limited to all implied warranties of merchantability, fitness, non-infringement, results, accuracy, security and freedom from computer virus. In no event shall Imada, Inc. and/or its affiliated companies be liable for any incidental, consequential or punitive damages in connection with the use of its products and/or software.

01/07 *Specifications subject to change without notice.*

Digital Torque Tester/Screwdriver



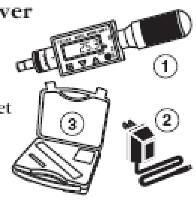
Model DSD-4

with ratchet and continuous RS-232 output

INSTRUCTION MANUAL

Digital Torque Tester/Screwdriver Model DSD-4

List of Equipment



1. Torque Tester with CW and CCW ratchet (¼" female hex)
2. AC adapter/charger
3. Carrying case

DSD-4 Digital Torque Tester Ranges

Accuracy ± 0.5% F.S., ±1 LSD

Model	Capacity
DSD-4	0.30 – 35.00 lbf-in (Factory standard)
DSD-4oz	3.0 – 560.0 ofz-in
DSD-4kg	0.30 – 40.00 kgf-cm
DSD-4cN	3.0 – 400.0 N-cm
DSD-4N	0.030 – 4.000 N-m

Read First: Safety Information

For safety, and for damage avoidance, be sure to read this manual thoroughly. The warranty is only valid when the product is used following the instructions provided within this manual.

- Do not use tester in high temperature, high humidity, or in damp or wet areas.
- Recommended operating temperature is between 0-42ºC (32-100ºF).
- Do not apply torque exceeding the rated capacity (35 lbf-in), regardless of whether the unit is On or Off. Avoid shock load. Do not use with impact wrenches.
- When charging the battery, be sure to use the provided AC adapter/charger exclusively.
- Do not use lacquer thinner or any solvent to clean the unit.
- Do not disassemble or modify the unit.
- Recommended re-calibration cycle is one (1) year.

IMPORTANT! Use the provided CEDAR AC adapter/charger exclusively and plug into the correct AC output. It takes 8 hours to fully recharge. Do not recharge for more than 12 hours. When fully charged, disconnect the AC adapter/charger to avoid overcharging.

In order to avoid high heat, explosion or toxic fumes, please note the following precautions:

1. Be sure to use only the provided AC charger exclusively.
2. Do not plug the charger into unspecified higher voltage.
3. Do not recharge until LOBAT icon appears.

System Reset

When battery power is completely depleted, the tester may not work even though it has been recharged. In this case, press the System Reset Button.

RS-232C Serial Output

Output is available in PD, PP and C modes. In PD and PP modes peak data is output when ZERO is pressed or activated by the AUTO ZERO function. In C mode, the gauge outputs data continuously.
RS-232C Signal: 8 data, 2 stop, no parity. Baud Rate: 9600 bps.

Peak Data Output Format

[CAN] _ _ _ [SO] [value] _ [SI] [unit] [CR]

[CAN]:	ASCII control code 24
_:	Space (code 32)
[SO]:	ASCII control code 14
[value]:	Output data with sign and decimal point. Plus sign represents for CW torque and minus sign for CCW. [Value] always occupy six locations and empty locations will be filled with spaces.
[SI]:	ASCII control code 15
[unit]:	N*m _ _ _=N·m kgf*cm = kg·cm lb*in _ = lb·in
[CR]:	ASCII control code 13 (Carriage Return)

Continuous Output Data Format

[CAN] [value] [CR]

Storing and Recalling Data from Memory

Memory functions work in PP, PD and C modes. Store up to 300 values in memory. Values are simultaneously output as RS-232 even after memory is full.

1. Measure in PP or PD mode, press CLR/PRG to store peak values. In C mode, the tester outputs data continuously (80 data/sec).
2. To recall a value, press UP or DOWN to select a memory location, the display cycles between location and torque value (i.e. .0.0.1 for first location).

Note: Selecting an invalid location, defaults to measurement mode.

Clearing Data from Memory

1. **Single Clear:** When a memory value is displayed, press CLR/PRG, then "CLR" displays and blinks 3 times. Press CLR/PRG switch again before "CLR" stops blinking and the memory value is erased.
2. **All Clear:** Press CLR/PRG and DOWN simultaneously until "ALL" is displayed. While "ALL" is blinking, press CLR/PRG again. Display changes to "CLR" and blinks 3 times. Press CLR/PRG again before "CLR" stops blinking and all memory data is erased.

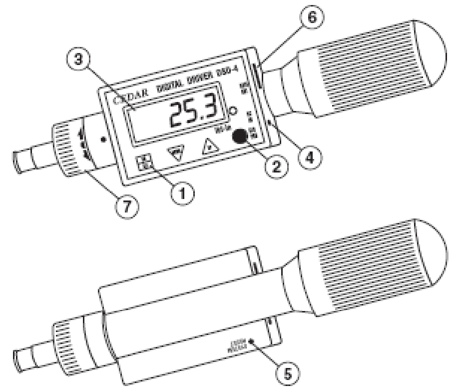
Downloading Memory Data

1. Press ON/OFF to turn on.
2. Press UP and DOWN switches simultaneously. The display blinks "FA" twice and then displays numbers with decimal points in between (.0.0.1 for first memory location).
3. Press UP or DOWN switch to select the desired beginning memory location and press CLR/PRG to enter. The displays blinks "LA" for the ending memory location.
4. Press UP switch or DOWN switch to select the desired ending memory location and press CLR/PRG to enter.
5. Press CLR/PRG switch to download the data. While downloading the data, the display shows "-P-".

Note: By pressing DOWN switch for more than 1 sec, the download function can be terminated.

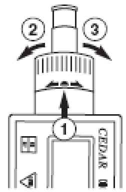
Auto Power Off

To maximize the life of the battery, power automatically shuts off after 10 minutes of non-use.



1. **ON/OFF Switch** Press to turn on, press again to turn off (click once, do not hold). After 10 minutes of non-use the unit shuts off.
2. **CLR/PRG Switch** To reset display to zero and to store data.
3. **LCD Display** Displays torque value as well as low battery icon (LOBAT).
4. **AC charger/adapter receptacle** If LOBAT icon appears, 8-hour battery recharge required.
5. **System reset button** When the battery has been depleted completely and a recharge has been executed, the system may not yet operate. In this case, press the System Reset Button.
6. **RS-232 output**
7. **CW and CCW Ratchet**

SELECTING RATCHET OPERATION



1. To disable ratcheting, turn the ratchet so the semi circle is in the center position.
2. Enable CW ratcheting operation by turning the ratchet one click counter-clockwise from the center position.
3. Enable CCW ratcheting operation by turning the ratchet one click clockwise from the center position.

SELECTING MEASURING MODES

Press ON/OFF to turn on. Hold CLR/PRG for more than 4 seconds. Display cycles GO, PP, PD or C. Select desired measuring mode, which becomes the default mode. Press CLR/PRG to display the measuring mode.

GO *(Real Time) Display torque transient (no output).*
PP *(Peak) Capture peak torque (peak data output).*
PD *(Peak Down) Capture peak down value (peak data output).*
C *(continuous RS-232 output, 80 data/sec) Display torque transients.*

PROGRAMMING (to exit programming at any time press OFF)

Press ON/OFF to turn on. Press CLR/PRG and UP switches simultaneously and hold for more than 4 seconds. The Green LED lights and one beep sounds, "HI" is displayed, then the High setpoint value. The tester is now ready for the following programming steps.

1. **High Setpoint (HI)**
   After "HI" is displayed and then the High setpoint value. Press UP or DOWN switch to select the High setpoint value i.e. 25.0 for 25.0 lbf-in (for lbf-in gauge), then press CLR/PRG to enter.
2. **Low Setpoint (LO)**
   After High value is entered, "LO" is displayed and then the Low setpoint value. Press UP or DOWN switch to select the Low setpoint value, then press CLR/PRG to enter.
3. **Peak Down Minimum and Trigger Point (PdLO)**
   After Low value is entered, "PdLO" is displayed and then the PdLO value. Press UP or DOWN switch to select, then press SET to enter.
   PdLO sets a minimum torque value for Peak Down mode. For example, if "PdLO" value is set at 5.0 lbf-in, only a reading over 5.0 lbf-in will be measured in Peak Down mode.
   PdLO also sets the start and stop trigger points for Continuous data output. When torque reaches the PdLO value, the gauge starts to output data and stops if torque falls below the value.

4. **Batch Counter (CO)**
   After "PdLO" value is entered, "CO" is displayed and then the batch count number. Press UP or DOWN switch to select (0 to 99), then press CLR/PRG to enter.
   Batch counter retains the number of properly torqued fasteners counted in memory even if the tester is turned OFF. Press and hold ON/OFF for more than 1 second to reset.
5. **Beeper (bp)**
   After the batch count number is entered, "bp" is displayed and the display shows "On" for beeper set ON, "Off" for beeper set OFF or "FF" for no beep unless over high setpoint. Press UP or DOWN switch to select, then press CLR/PRG to enter.
6. **Auto Zero Reset (AC)**
   After Beeper selection is entered, "AC" is displayed and then Auto Zero Reset duration value. Press UP or DOWN to select 0.0C - 0.5C - 1.0C - 1.5C - 2.0C - 2.5C - 3.0C, and press CLR/PRG to enter (0.5C for 0.5 second and 0.0C for MANUAL RESET).
   After measuring, Auto Zero automatically resets the tester to "0.0".
7. **Time (In)**
   After Auto Zero Reset is entered "In" is displayed and then the Time duration. Press UP or DOWN switch to select (0 to 24 seconds), then press CLR/PRG to enter.

After "In" is entered, "S-" is displayed to confirm programming completion and 0.0 is shown.

After setpoints and batch counter are set, the tester counts the number of properly torqued fasteners (between High and Low setpoint) and beeps three times when completed. If time ("In" value) elapses before reaching the batch count number, a beep sounds to alert to possible mis-tightening or stripped thread.

Appendix E – MicroCT Protocol

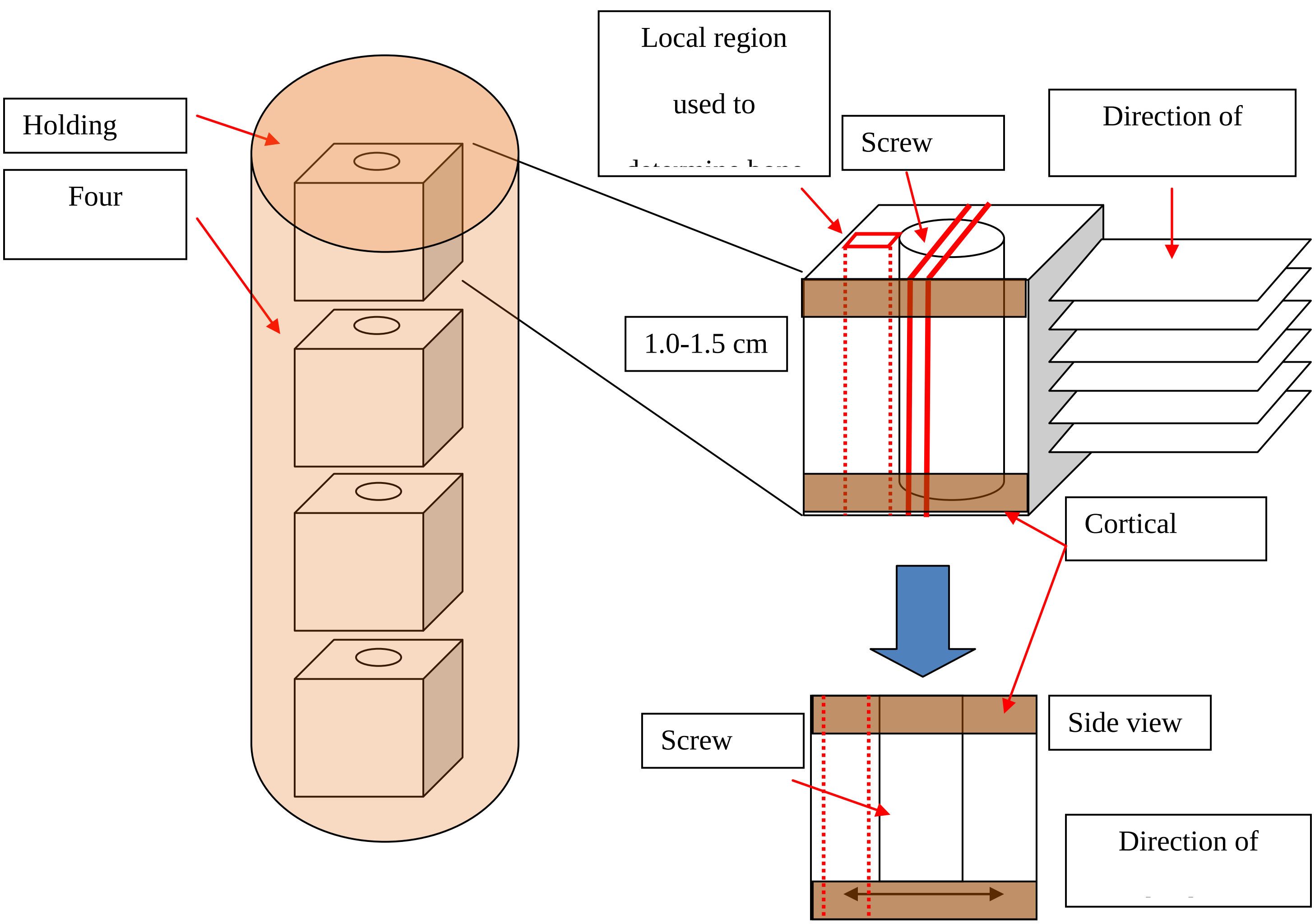
MicroCT – Sternum samples Alexander Christakis

(3/18/09)

Protocol and proposed analysis

Determine:

- Bone volume density of region around screw hole
- Shape of screw hole to determine mechanism of loosening



Appendix F – Screw Inventory

Stryker Matta Pelvic Fixation System

- Screw type: **Cortical**
    - Dimensions:
        - Length: 10 mm, 14 mm
        - Outer diameter: 3.5 mm
        - Inner diameter: 2.68 mm
        - Distance between threads: 1.31 mm

- Screw type: **Cancellous**
    - Dimensions:
        - Length: 10 mm, 14 mm
        - Outer diameter: 4.0 mm
        - Inner diameter: 2.35 mm
        - Distance between threads: 1.91 mm

- Plate: **Pelvic**

Stryker VariAxPedicle Plating System

- Screw type: **Locking cortical**
  - Dimensions:
    - Length: 10 mm, 14 mm, 20 mm
    - Outer diameter: 3.5 mm
    - Inner diameter: 3.56 mm
    - Distance between threads: 1.35 mm

- Screw type: **Non-locking cortical**
  - Dimensions:
    - Length: 10 mm, 14 mm, 20 mm
    - Outer diameter: 3.5 mm
    - Inner diameter: 3.56 mm
    - Distance between threads: 1.35 mm

- Plate: **Pedicle**

Appendix G - Complete Data Set for All Sternum Tests

Sternum I

25-Feb	Foot Locking	I	L 2	Unicortical	0.277101	0.412885	0.619548	2.032932	Test stopped at 12225 cycles
25-Feb	Foot Nonlocking Uni	I	L 2	Unicortical	0.448189	0.561466	0.726482	0.891895	Limit tripped at 4717 cycles, limit set incorrectly
28-Feb	Antiwobble	I	R 2	Unicortical	0.282356	0.338354	0.406731	0.56413	
28-Feb	Foot Locking	I	R 2	Unicortical	0.244804	0.555795	0.775528	1.057418	Test pulled out at 13862 cycles
28-Feb	Foot Nonlocking Bi	I	R 2	Bicortical	0.186406	0.222991	0.250857	0.264493	
1-Mar	Antiwobble	I	L 3	Unicortical	0.162607	0.202727	0.246763	0.382002	
2-Mar	Foot Nonlocking Bi	I	R 4	Bicortical	1.316735	1.62932	2.371193	4.528872	It appears that this piece of bone was terrible. Obvious based on subsequent data
2-Mar	Foot Nonlocking Uni	I	R 4	Unicortical	1.524856	1.924303	3.000607	3.546052	Test pulled out at 5009 cycles
2-Mar	Antiwobble	I	R 4	Unicortical	0.284868	0.371006	0.480657	1.244041	Did something happen here?
3-Mar	Foot Locking	I	L 4	Unicortical	0.24228			3.052438	Pulled out at 36 cycles
4-Mar	Antiwobble	I	L M	Unicortical	0.576011	0.7209	1.010973	2.050655	Used angled plate probably caused displacement

Sternum III

Date	Screw Type	Sternum	Location	Depth	10 Cycles	100 Cycles	1000 Cycles	Final	Keep?
10-Feb	Antiwobble	III	R2	Unicortical	0.585599	0.820007	1.148246	1.799227	No, poor bisection, limited bone putty fixation
10-Feb	Foot	III	R2	Unicortical	0.510426	0.648991	0.794389	1.003049	
11-Feb	Foot	III	R3	Bicortical	0.402181	0.536348	0.687965	0.818862	
11-Feb	Pelvic	III	L2	Bicortical	0.016773	0.237046	0.35823	0.485594	No, Bone did not fixate to putty, only one fixation screw, no change in extensometer signal
12-Feb	Antiwobble	III	L3	Unicortical	0.170612	0.196883	0.224278	0.292937	
12-Feb	Foot	III	L3	Unicortical	0.188757	0.235249	0.289078	0.3667	
13-Feb	Foot	III	L1	Bicortical	0.103732	0.116211	0.129085	0.143208	
13-Feb	Pelvic	III	L1	Bicortical	0.157988	0.21791	0.249512	0.269495	
14-Feb	Antiwobble	III	R1	Unicortical	0.088137	0.108325	0.114102	0.11532	
14-Feb	Foot	III	R1	Unicortical	0.228035	0.360016	0.36419	0.37292	
16-Feb	Foot	III	L4	Bicortical	0.17118	0.182211	0.183687	0.194859	
16-Feb	Pelvic	III	L4	Bicortical	0.506396	0.660881	0.792934	1.414856	
17-Feb	Antiwobble	III	R4	Unicortical	0.184636	0.163167	0.192533	1.021504	No, previous test damaged bone integrity.
17-Feb	Foot	III	R4	Unicortical	0.304248	0.397765	0.673583	2.055598	This test ended at 14328 cycles, pulled out
19-Feb	Antiwobble	III	L5	Unicortical	0.10904	0.124403	0.135613	0.152672	
19-Feb	Pelvic	III	L5	Bicortical	0.170821	0.186264	0.130055	0.191119	

Sternum IV

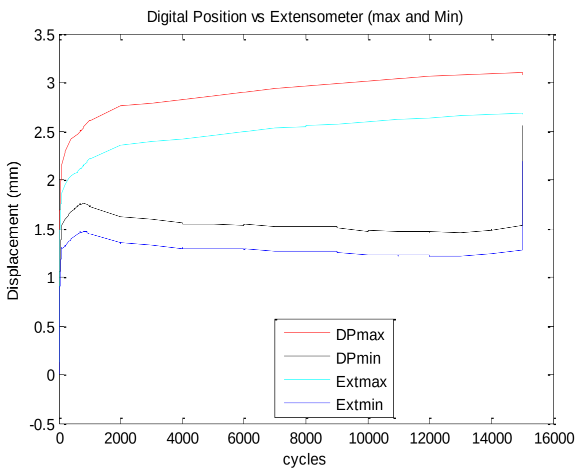
11-Dec	Cortical	IV	2	Bicortical	0.252039	0.290825	0.336037	0.389859
12-Dec	Cancellous	IV	3	Bicortical	0.304779	0.391167	0.635909	4.690206
12-Dec	Cortical	IV	3	Bicortical	0.23756	0.284094	0.314772	0.351368
13-Dec	Cancellous	IV	4	Bicortical	0.460255	0.939323	2.216366	3.747588
14-Dec	Cancellous	IV	5	Bicortical	0.496778	0.603559	0.755206	1.485222
14-Dec	Cortical	IV	5	Bicortical	0.213514	0.2807	0.425634	1.430574
10-Dec	Cancellous	IV	2	Unicortical	1.179469	1.852076	2.213006	2.677978
10-Dec	Cortical	IV	2	Unicortical	1.641476	1.737405	1.809578	1.975313
11-Dec	Cancellous	IV	3	Unicortical	1.203141	1.860965	2.287633	2.59721
11-Dec	Cortical	IV	3	Unicortical	0.603476	0.651585	0.666694	0.673743
14-Dec	Cancellous	IV	4	Unicortical	1.902544	2.163095	2.308568	2.804685
14-Dec	Cortical	IV	4	Unicortical	0.782871	0.78729	0.783575	0.788316

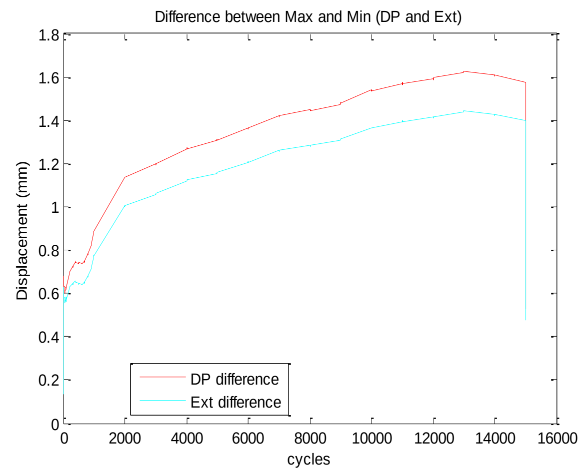
Appendix H – Matlab Plot Results

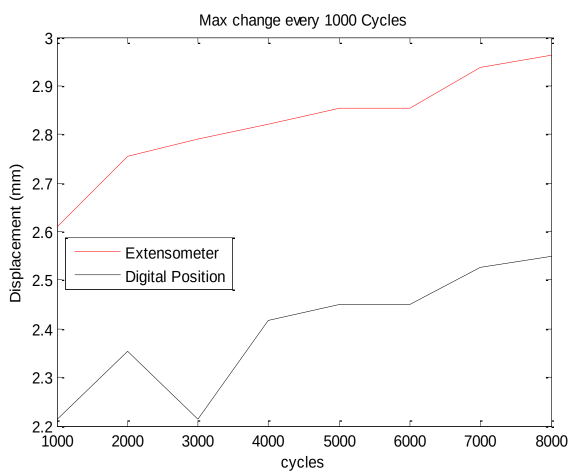
Sample: sternum IV R2

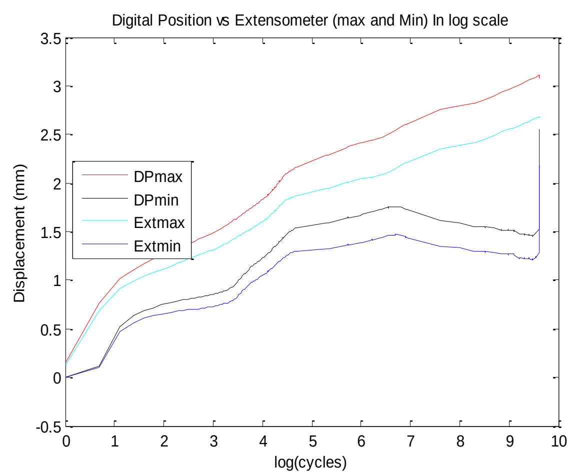
Screw: pelvic cancellous

Purchase: uni-cortical





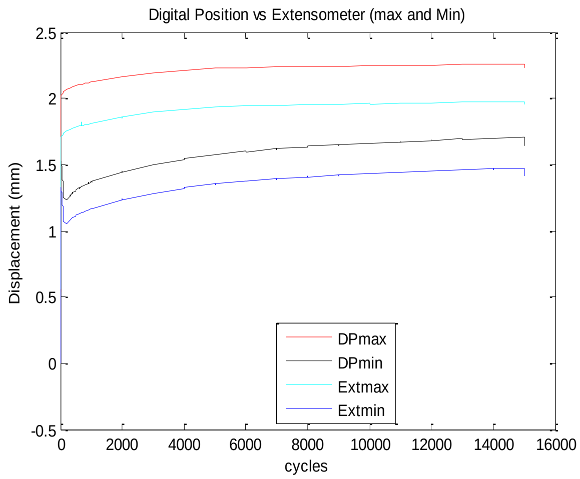


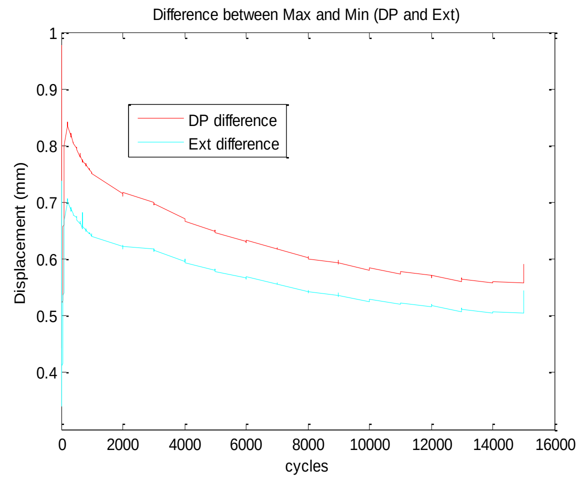


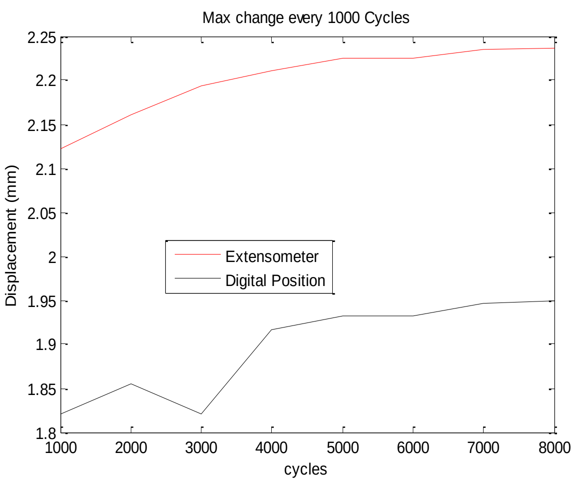
Sample: sternum IV R2

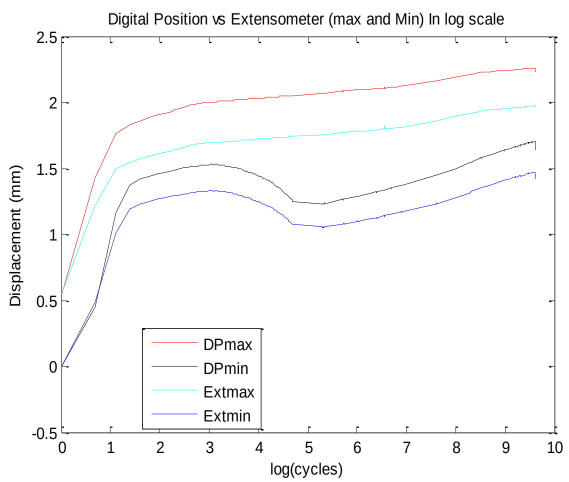
Screw: pelvic cortical

Purchase: uni-cortical





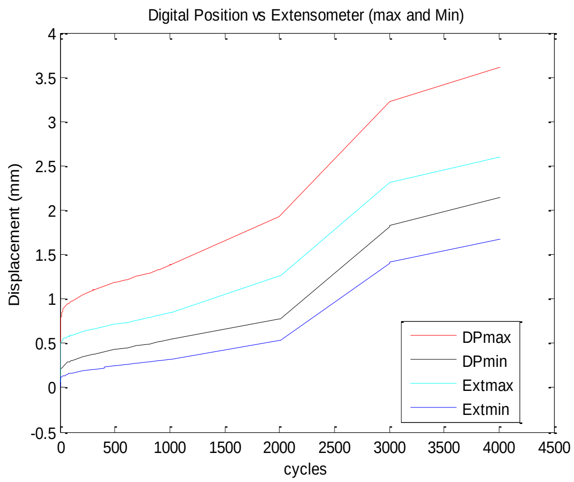


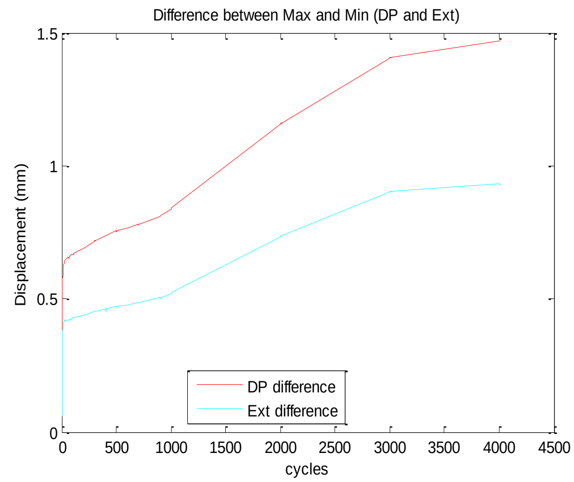


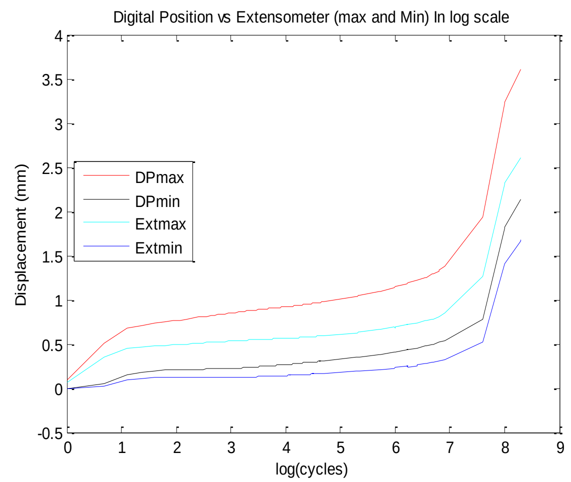
Sample: sternum IV L2

Screw: pelvic cancellous

Purchase: bi-cortical



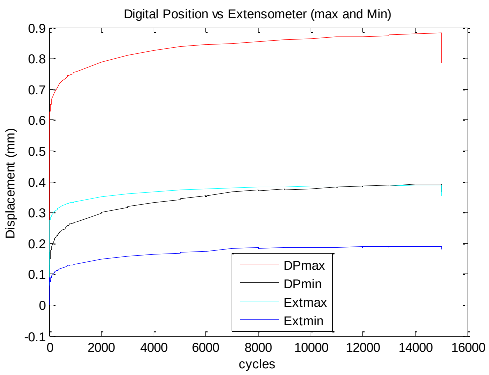


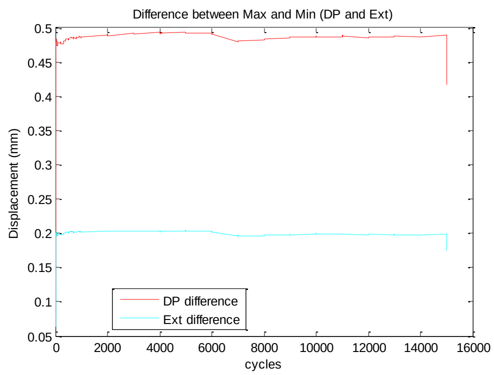


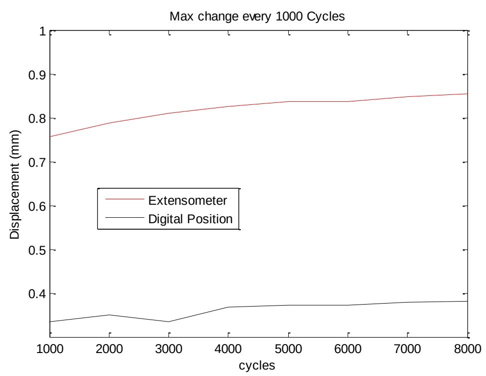
Sample: sternum IV L2

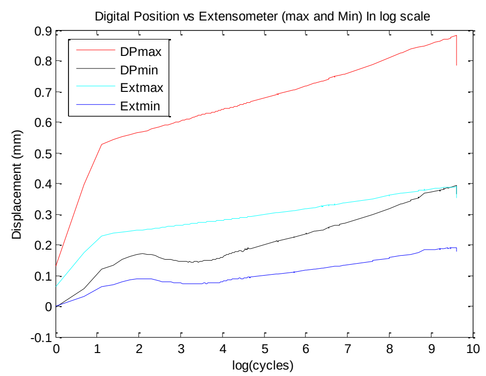
Screw: pelvic cortical

Purchase: bi-cortical





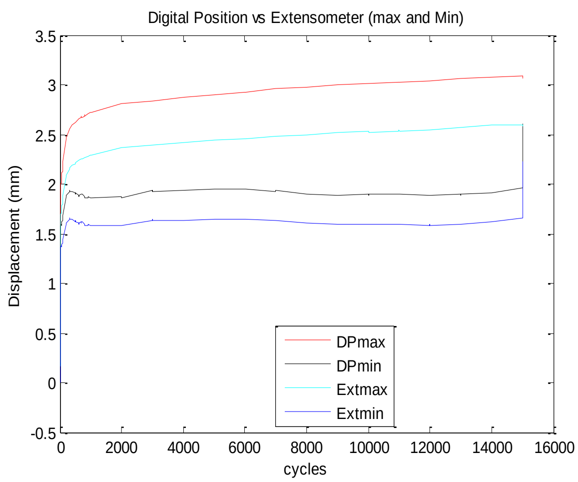


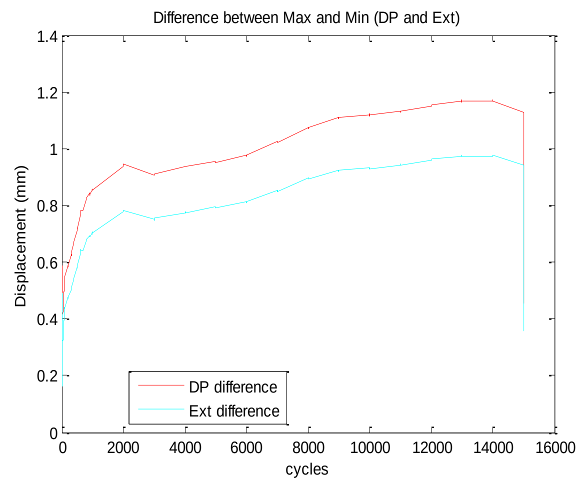


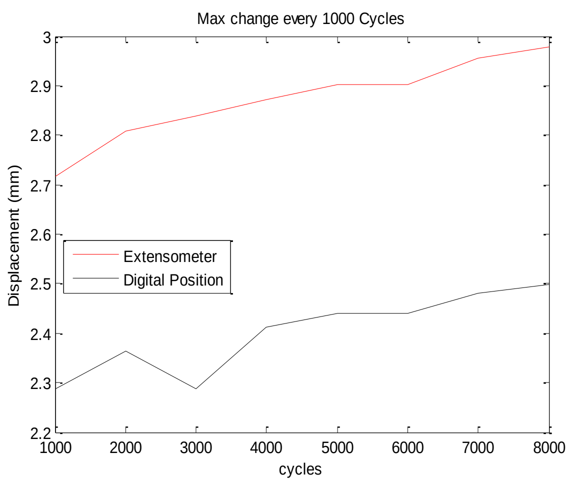
Sample: sternum IV R3

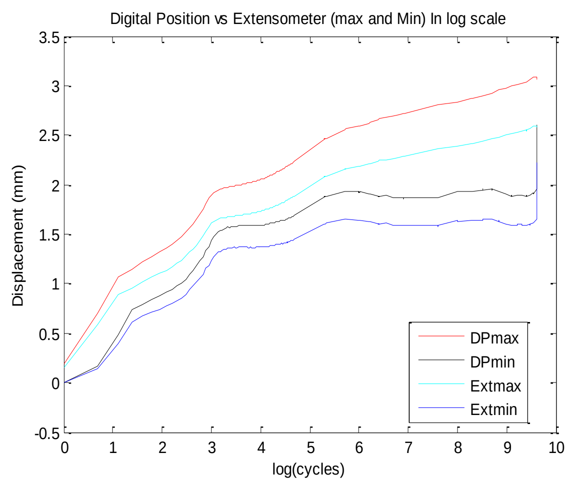
Screw: pelvic cancellous

Purchase: uni-cortical





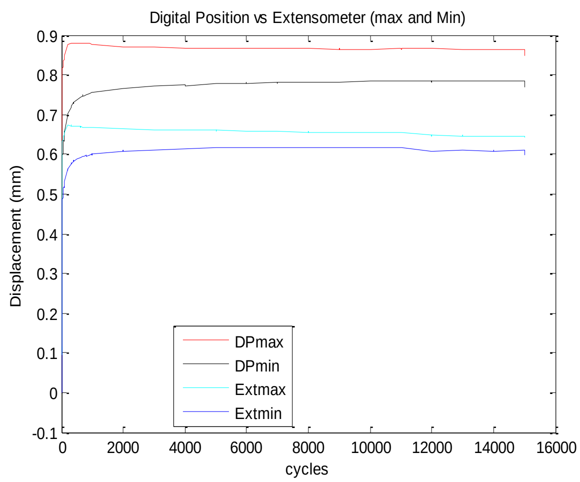


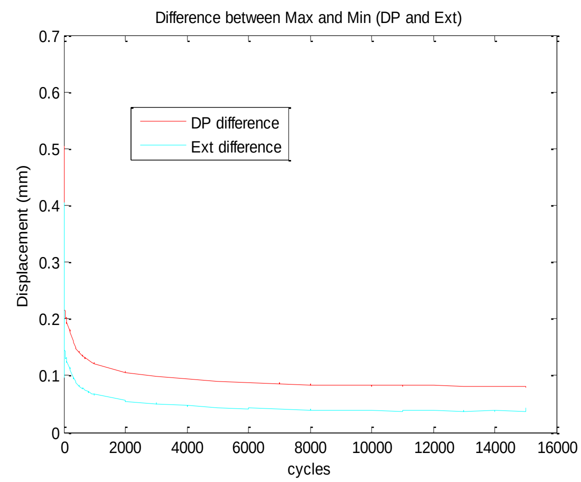


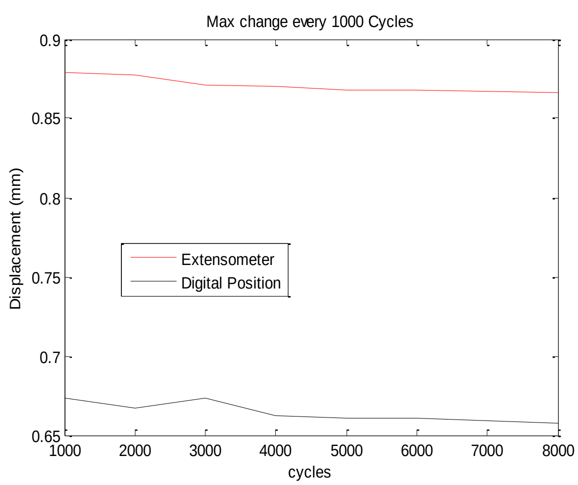
Sample: sternum IV R3

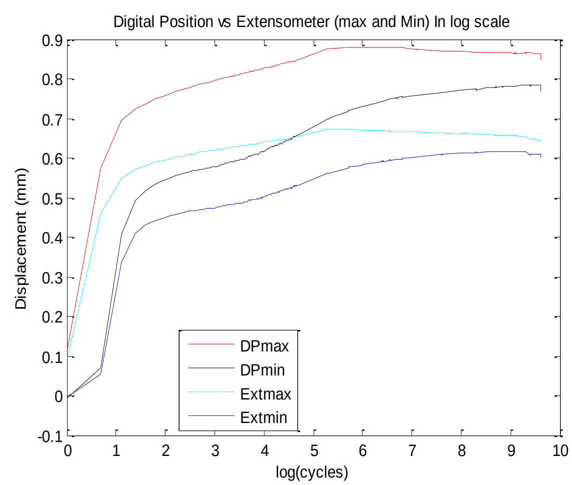
Screw: pelvic cortical

Purchase: uni-cortical





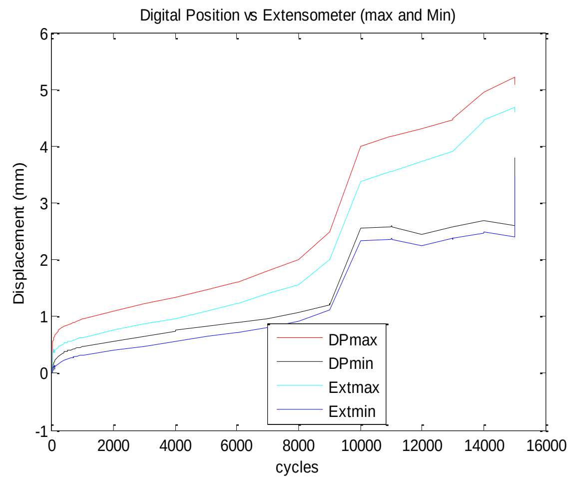


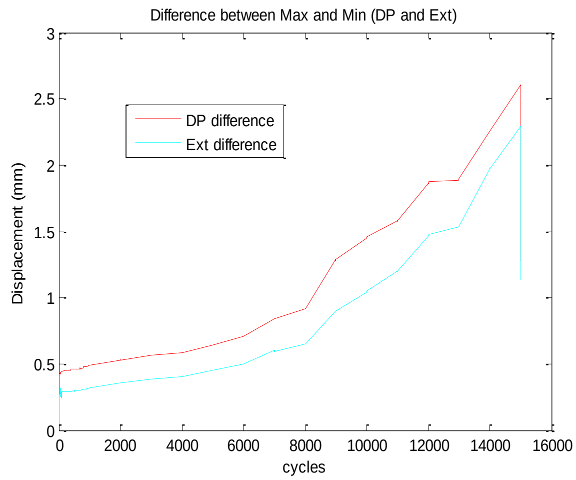


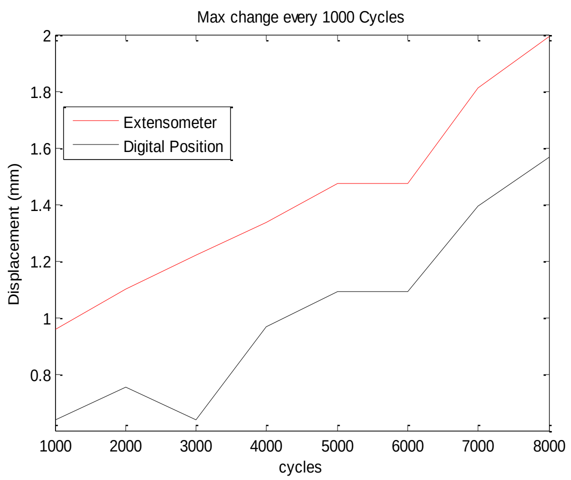
Sample: sternum IV L3

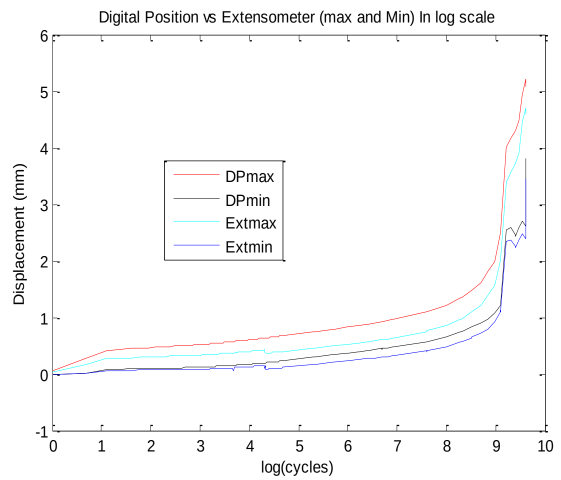
Screw: pelvic cancellous

Purchase: bi-cortical





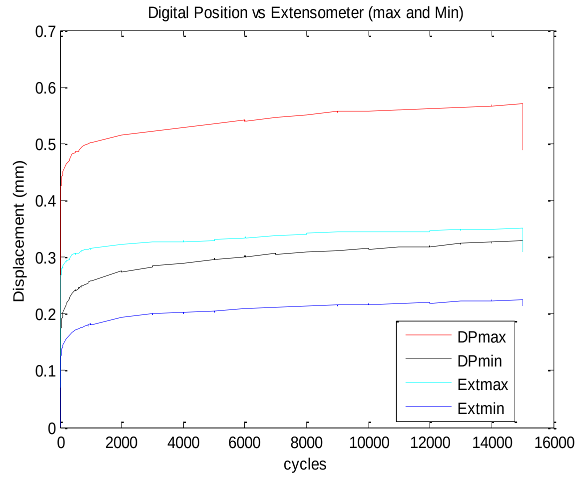


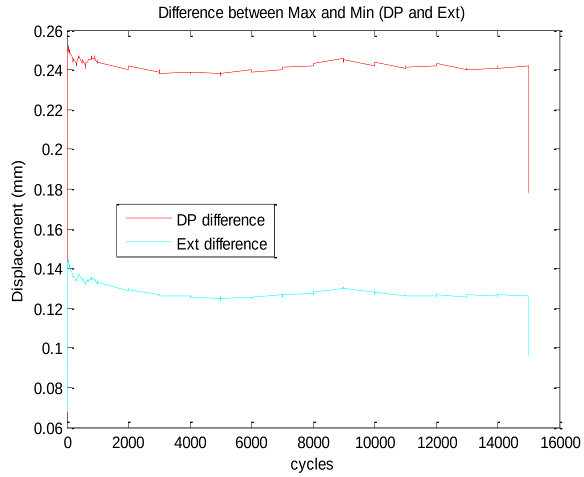


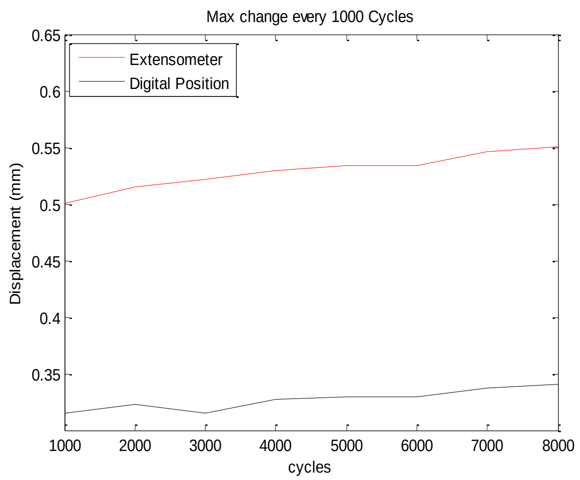
Sample: sternum IV L3

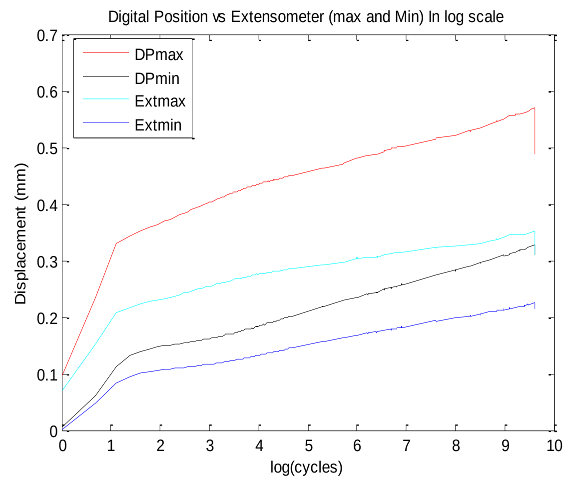
Screw: pelvic cortical

Purchase: bi-cortical





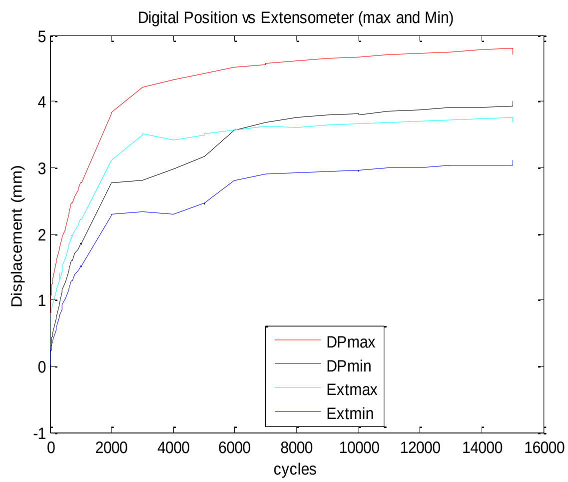


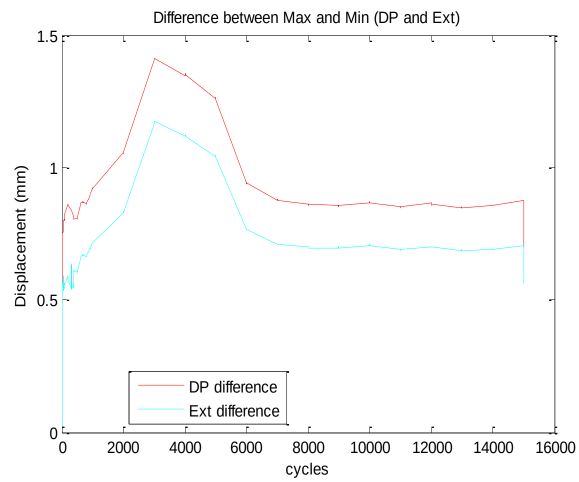


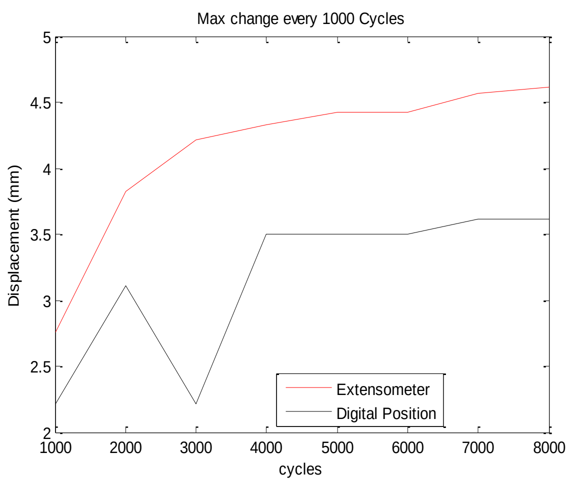
Sample: sternum IV L4

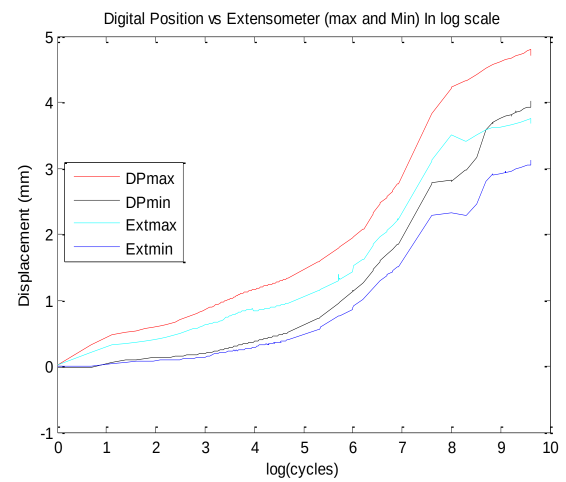
Screw: pelvic cancellous

Purchase: bi-cortical





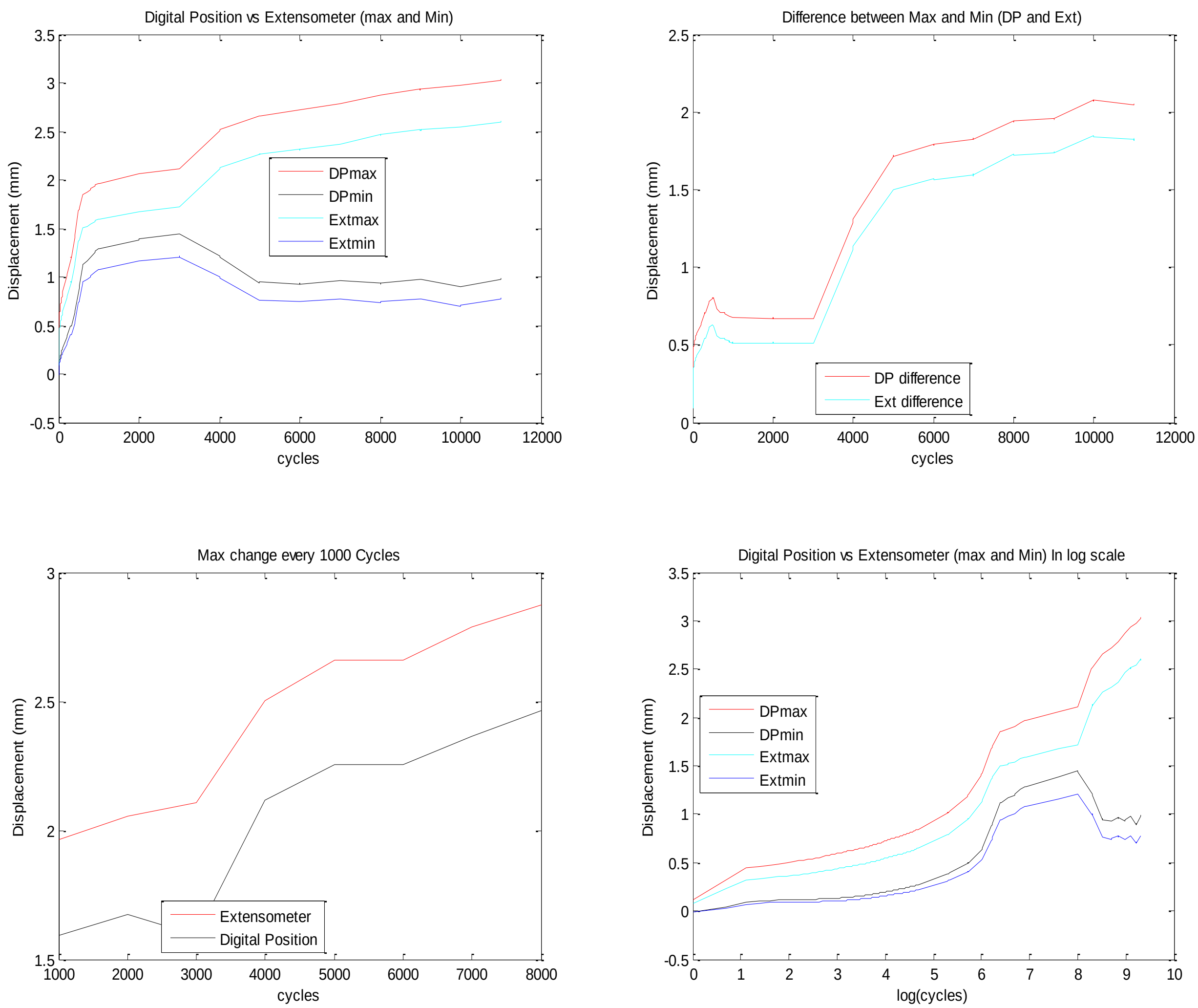




Sample: sternum IV L4

Screw: pelvic cortical

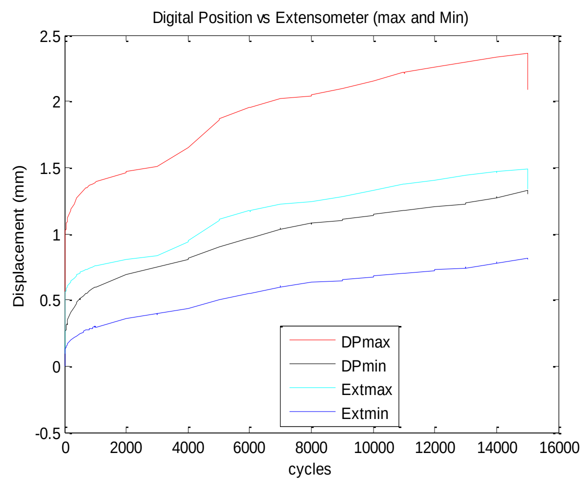
Purchase: bi-cortical

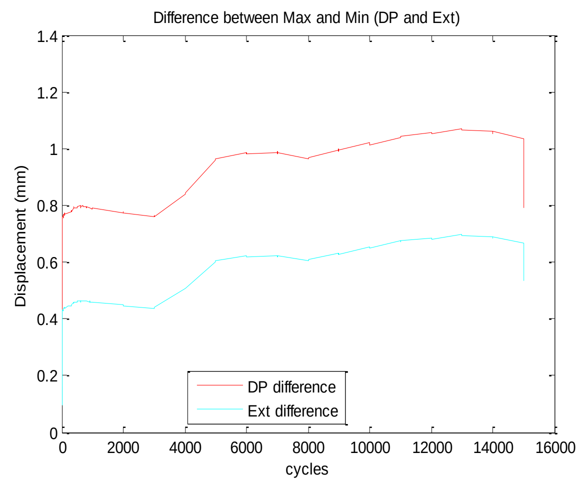


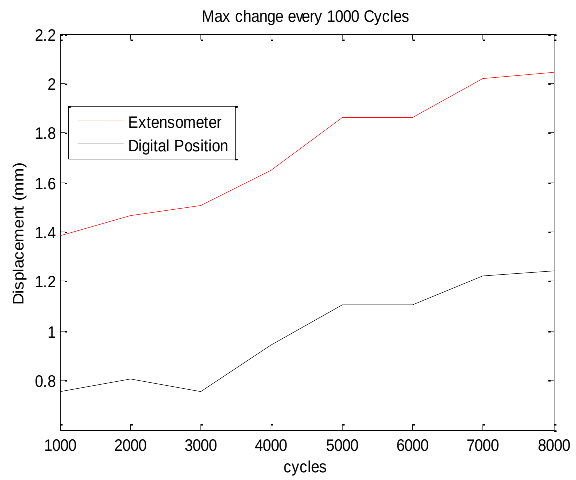
Sample: sternum IV L5

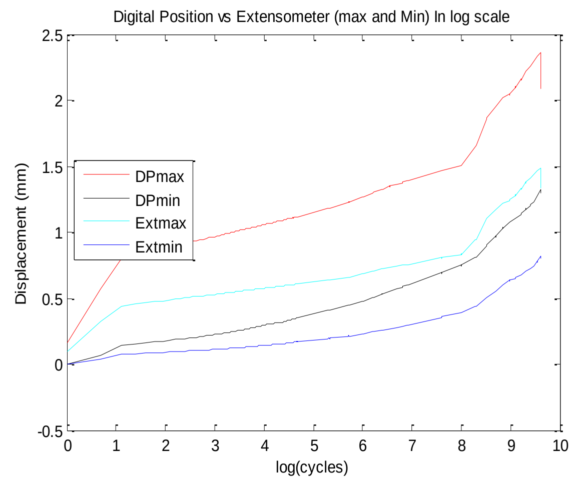
Screw: pelvic cancellous

Purchase: bi-cortical





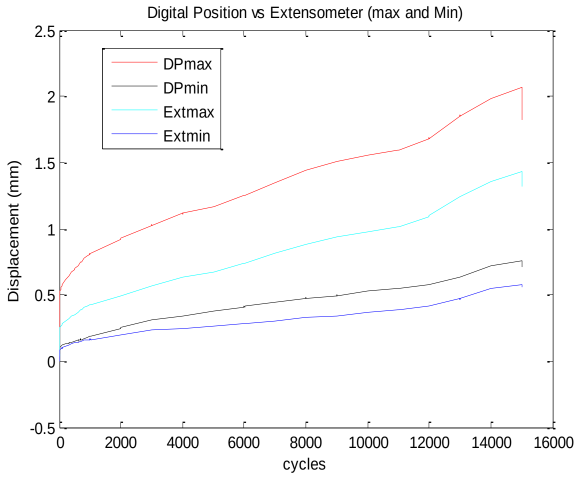


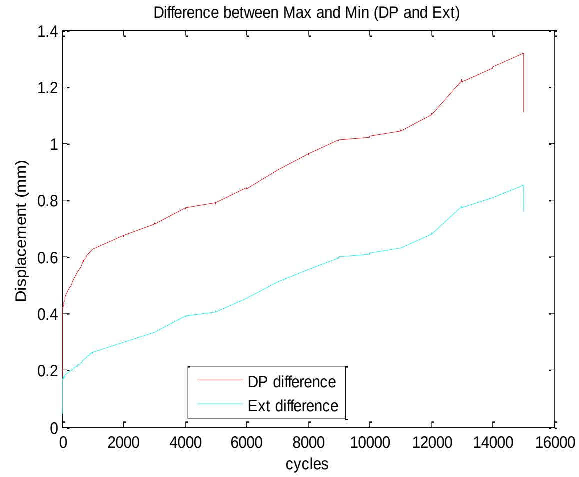


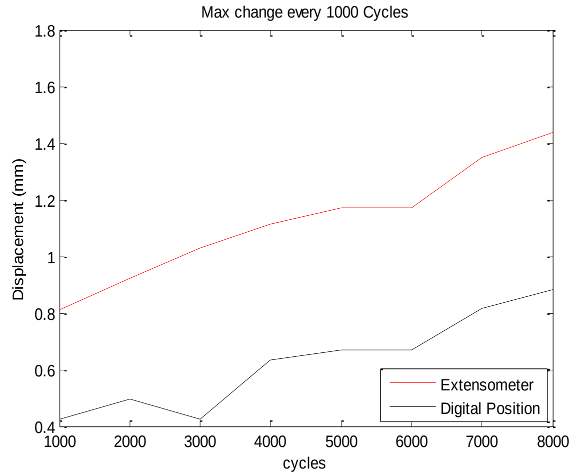
Sample: sternum IV L5

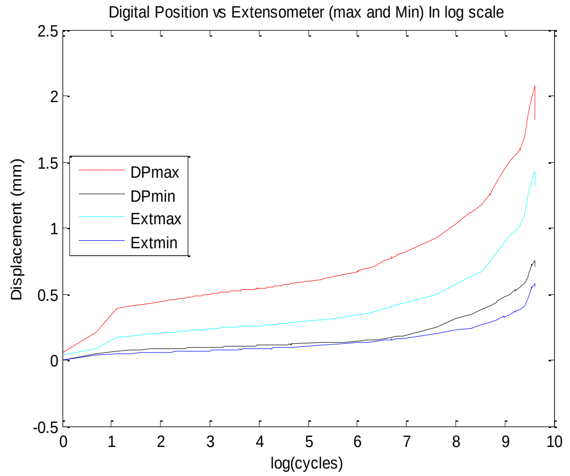
Screw: pelvic cortical

Purchase: bi-cortical





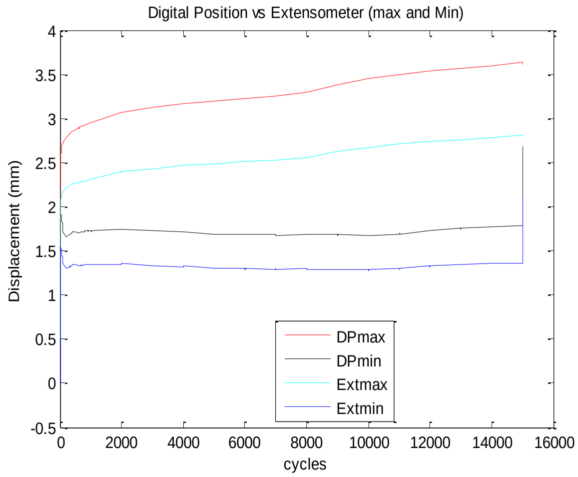


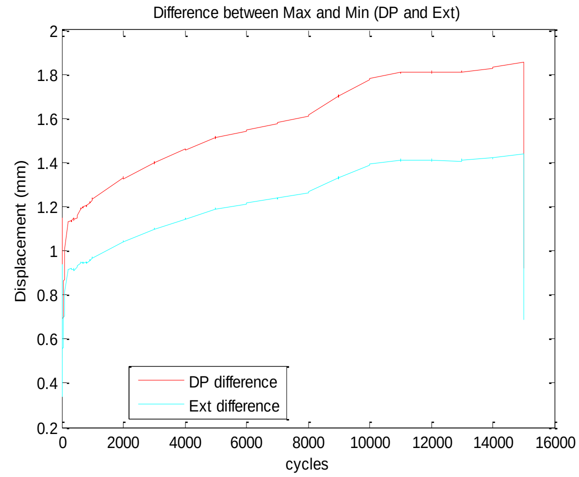


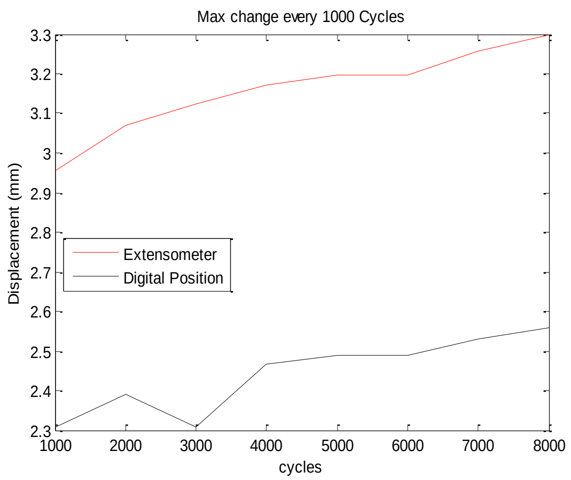
Sample: sternum IV R4

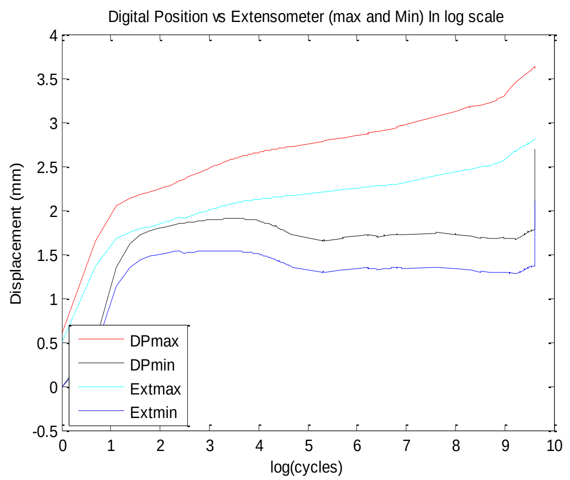
Screw: pelvic cancellous

Purchase: uni-cortical





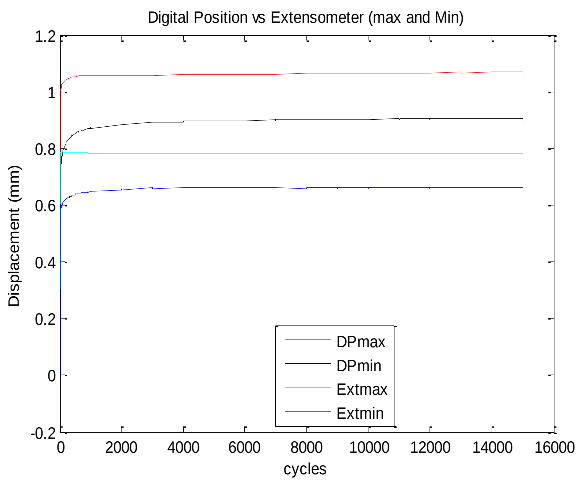


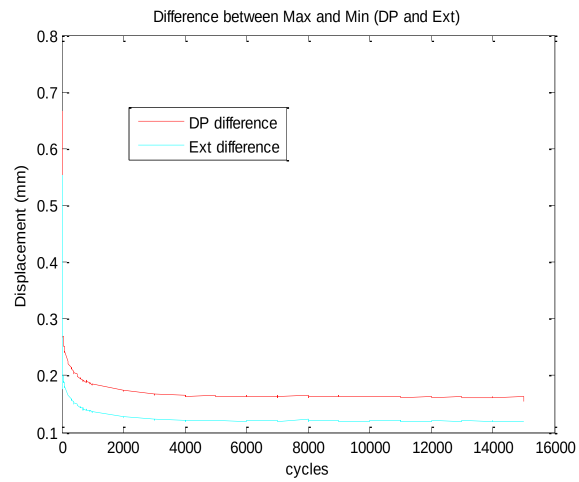


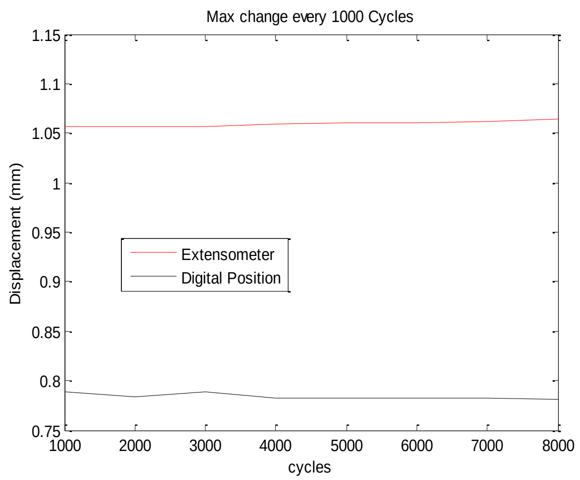
Sample: sternum IV R4

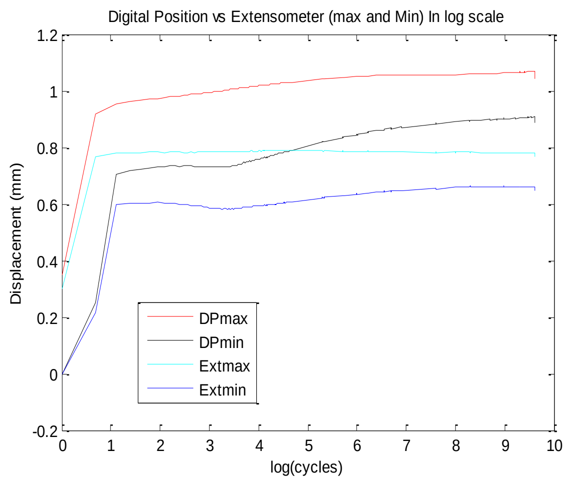
Screw: pelvic cortical

Purchase: uni-cortical





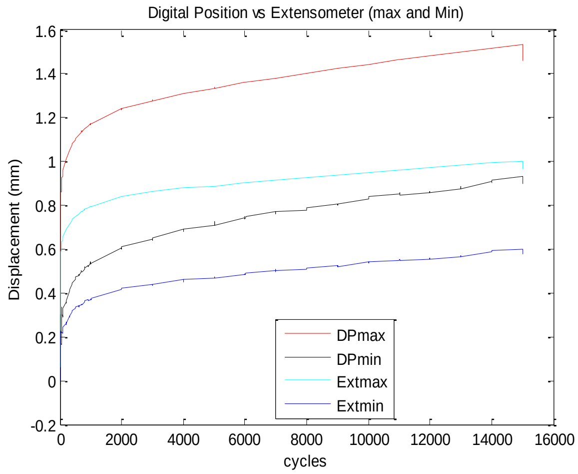


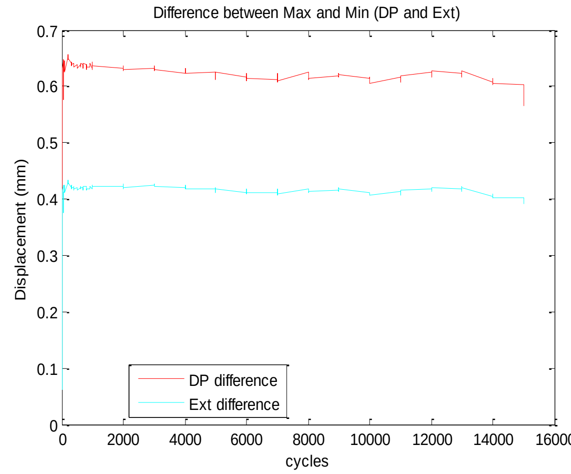


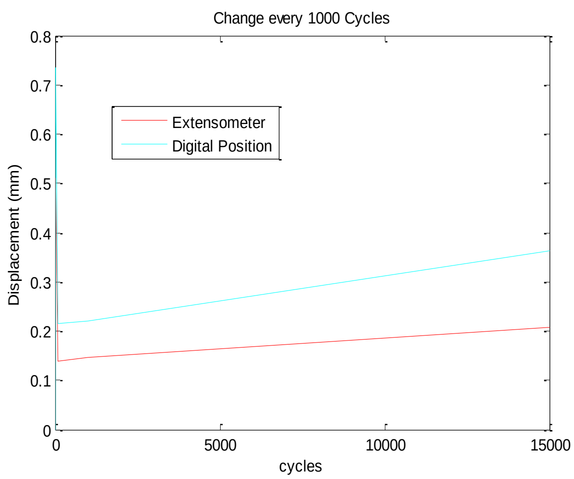
Sample: sternum III R2

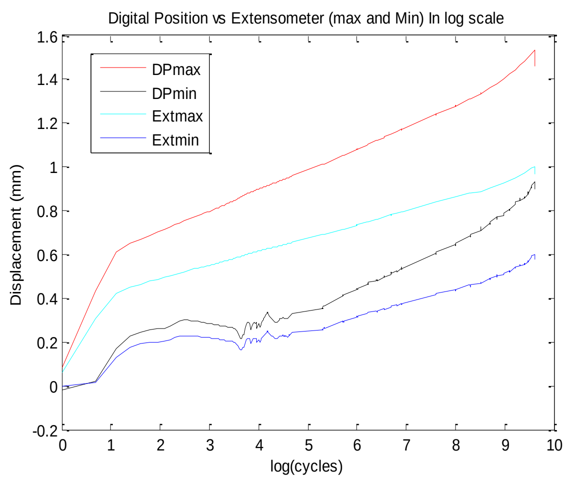
Screw: pedicle cortical

Purchase: uni-cortical





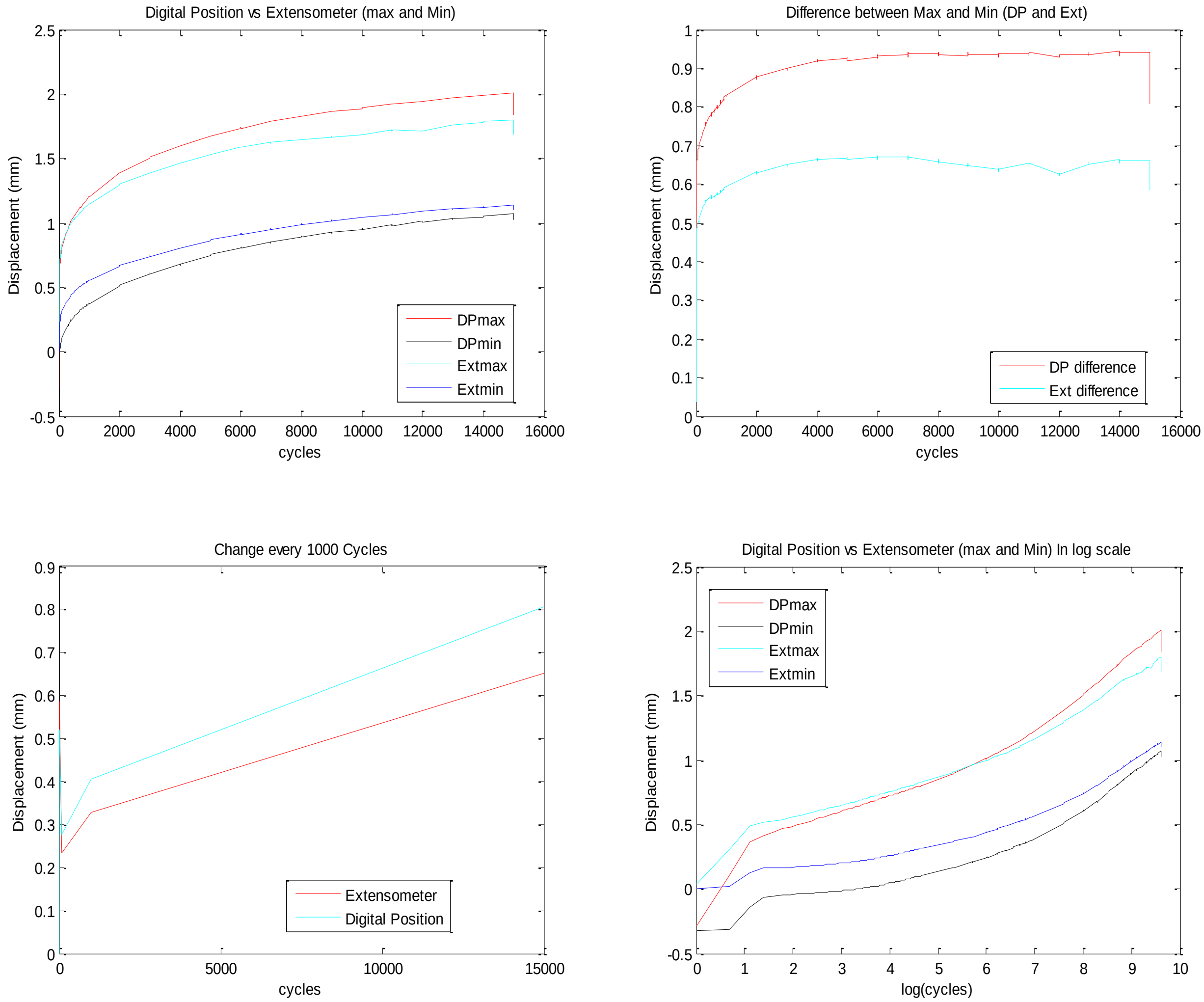




Sample: sternum III R2

Screw: anti-wobble pedicle cortical

Purchase: uni-cortical

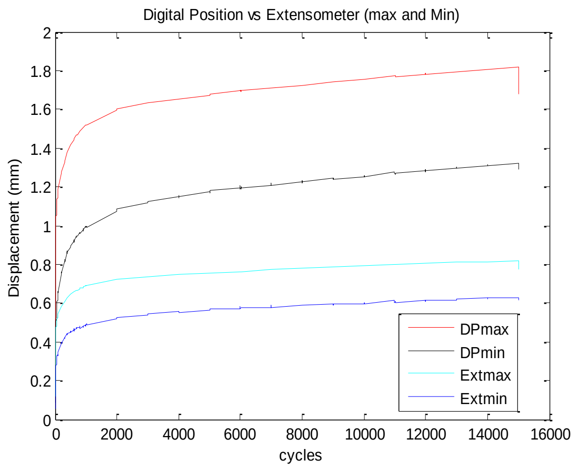


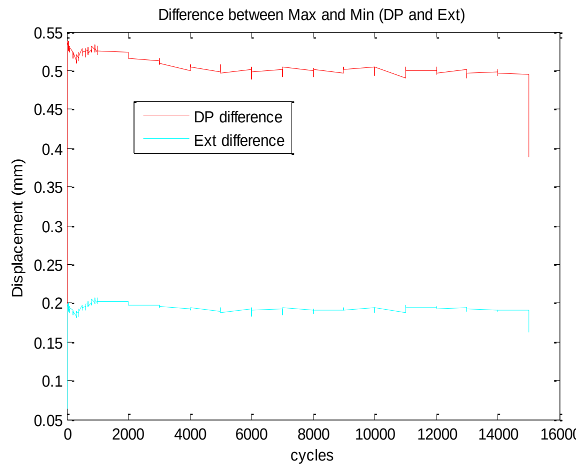
Error: bone sample damaged prior to testing

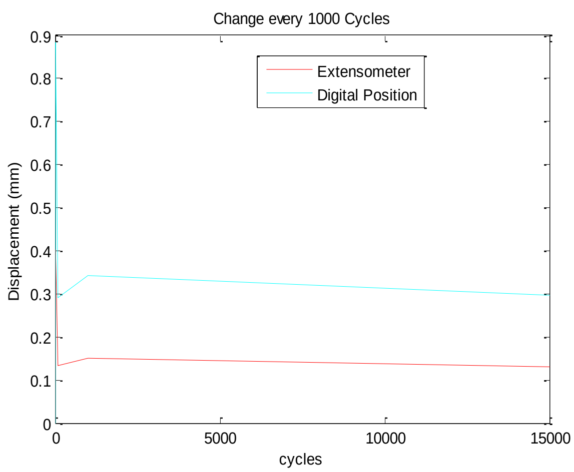
Sample: sternum III L2

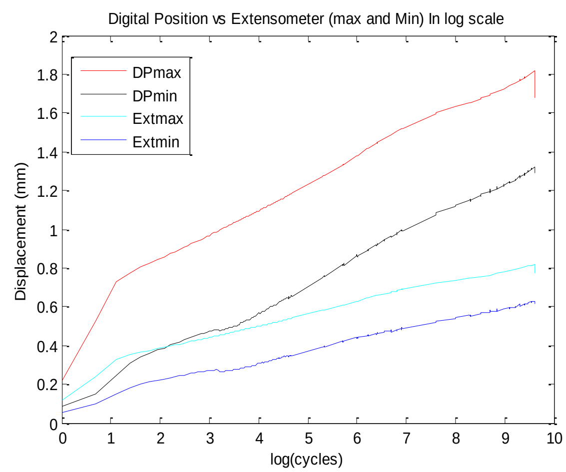
Screw: pedicle cortical

Purchase: bi-cortical





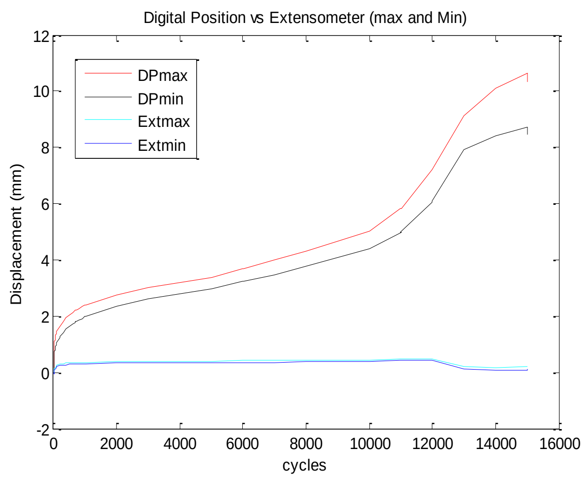


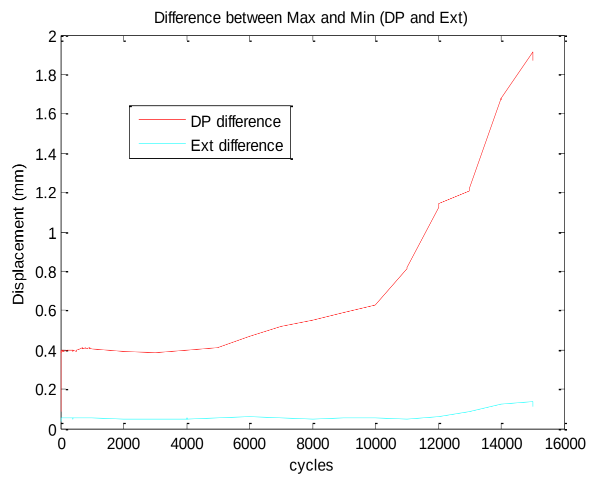


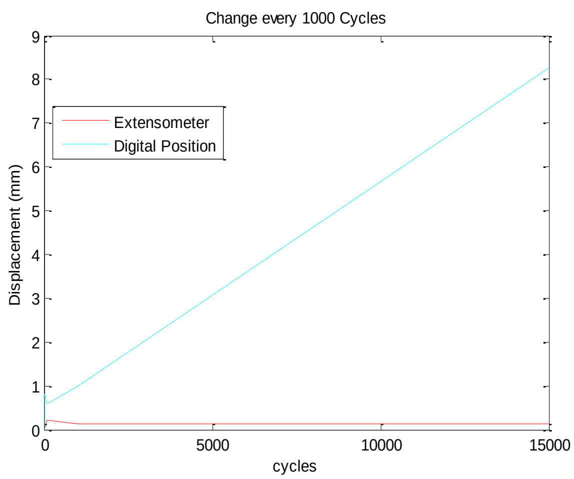
Sample: sternum III L2

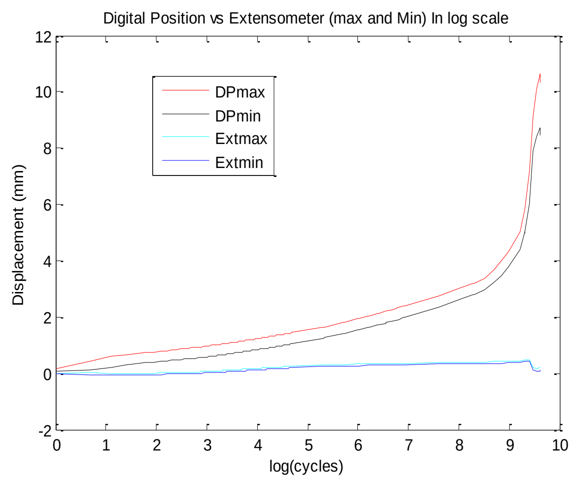
Screw: pelvic cortical

Purchase: bi-cortical







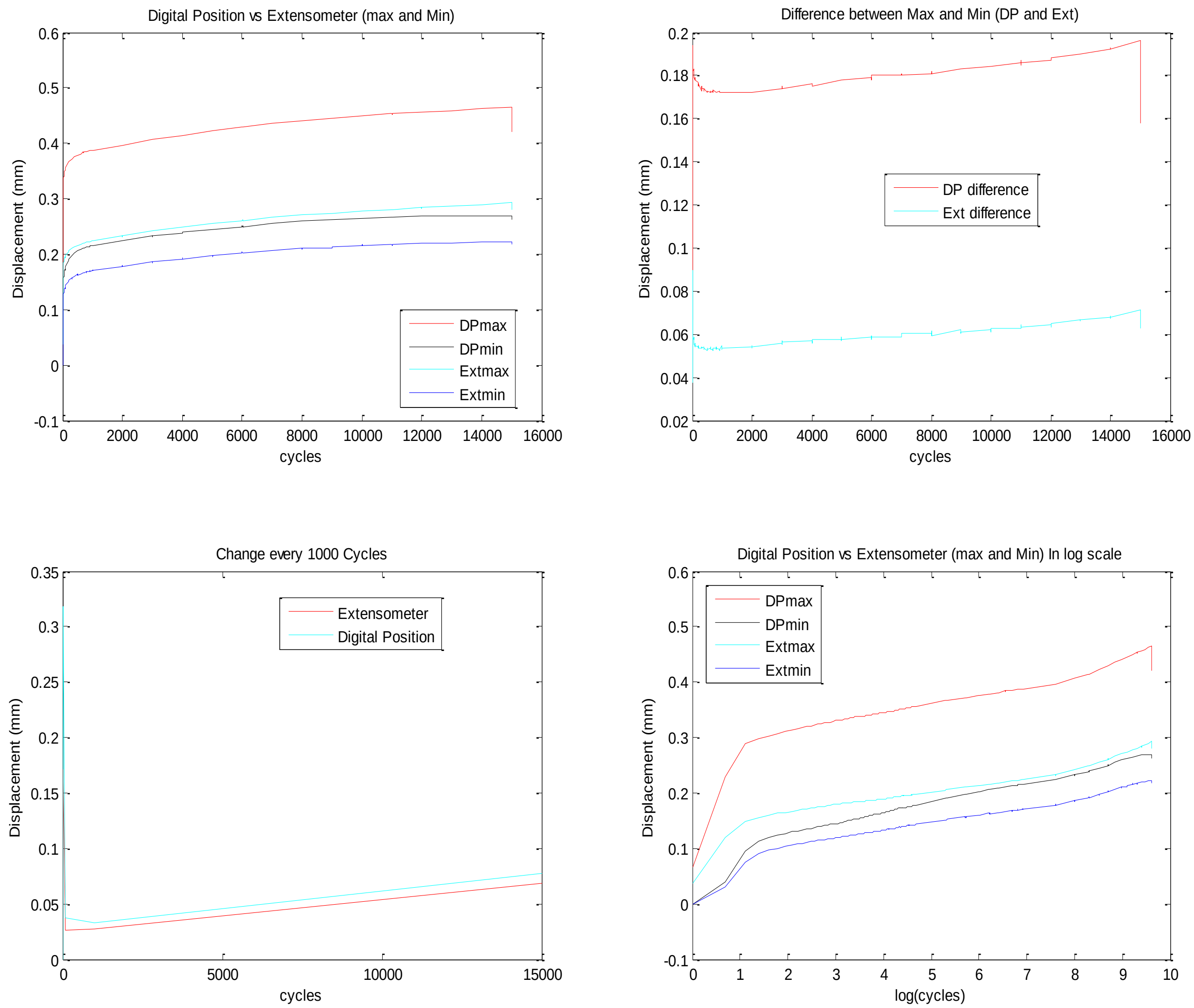


Error: bone sample small and in poor condition

Sample: sternum III L3

Screw: anti-wobble pedicle cortical

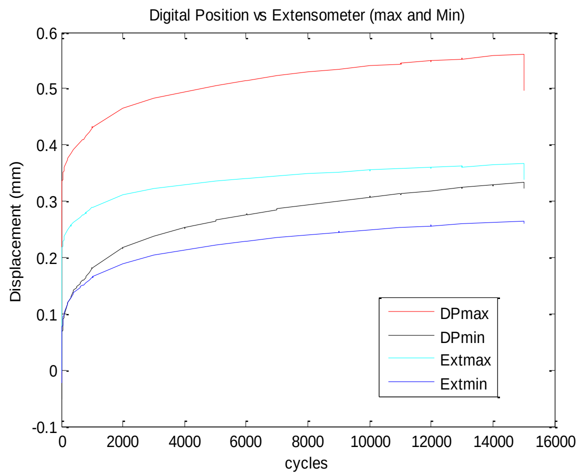
Purchase: uni-cortical

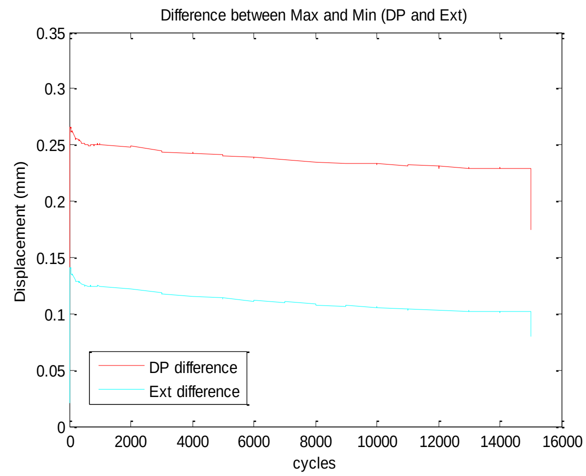


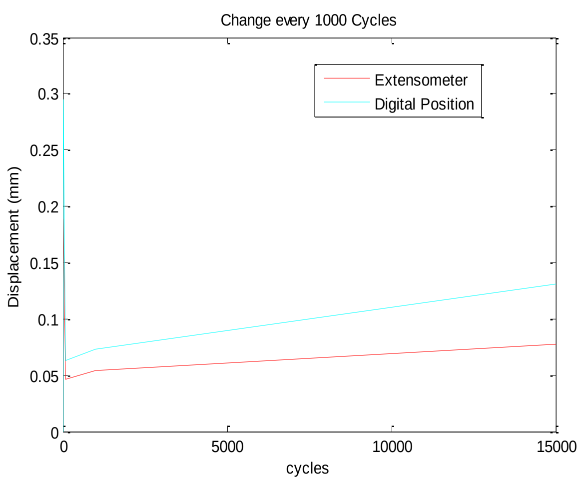
Sample: sternum III L3

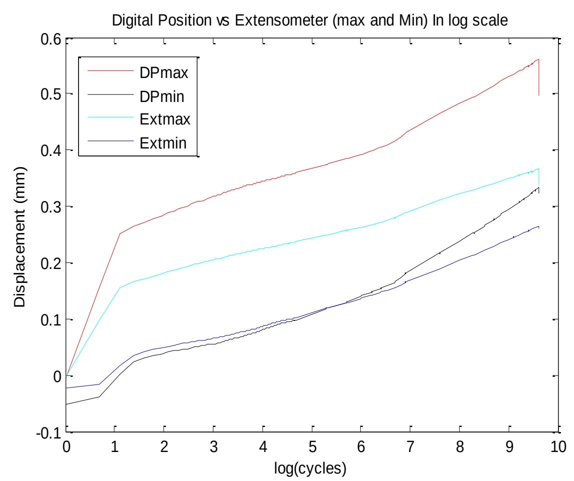
Screw: pedicle cortical

Purchase: uni-cortical





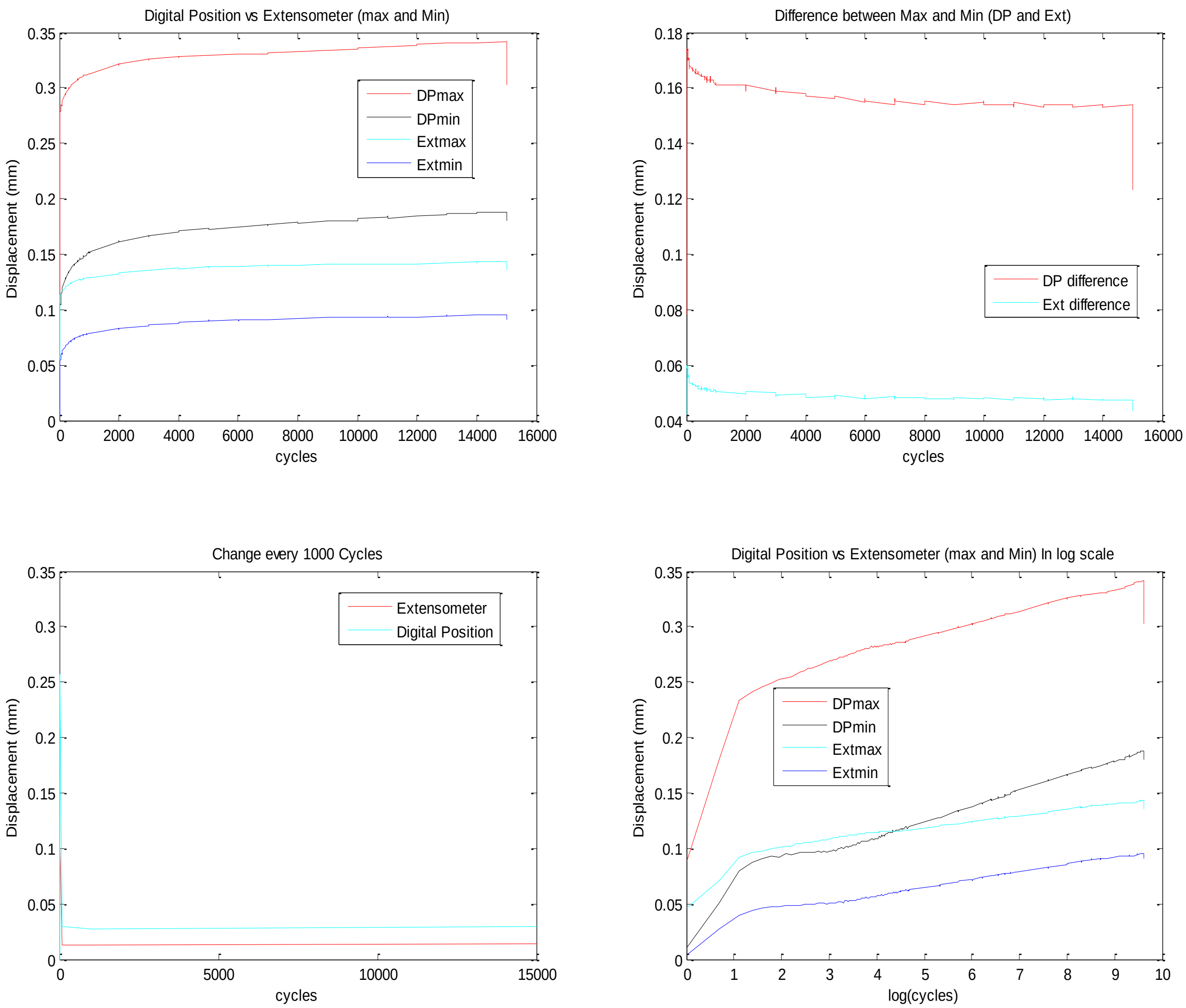




Sample:sternum III L1

Screw: pedicle cortical

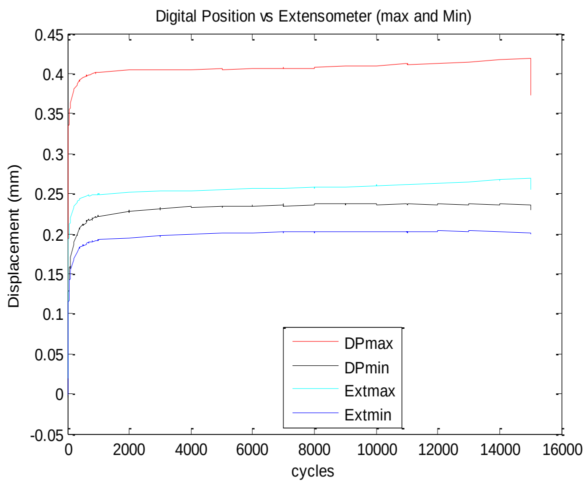
Purchase: bi-cortical

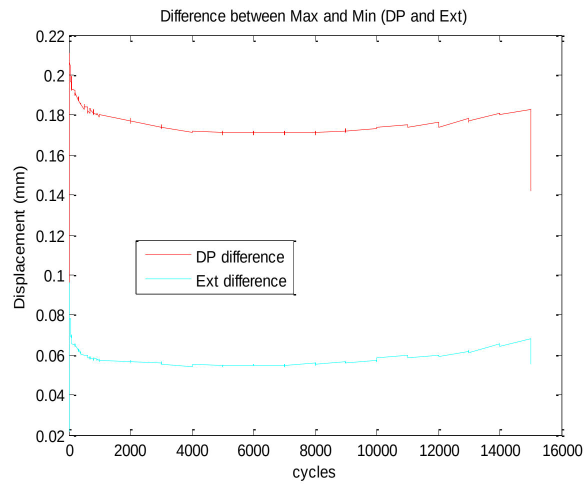


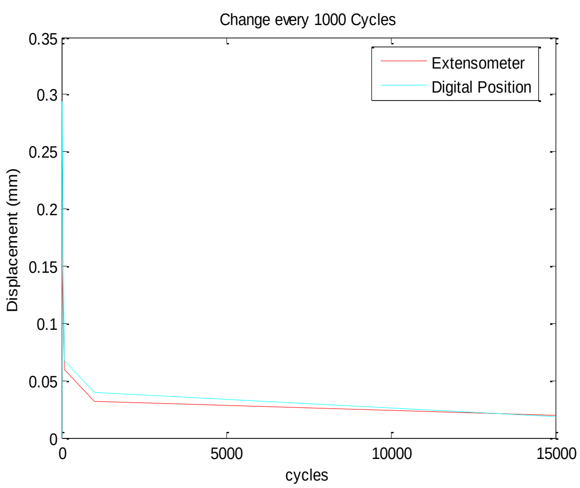
Sample: sternum III L1

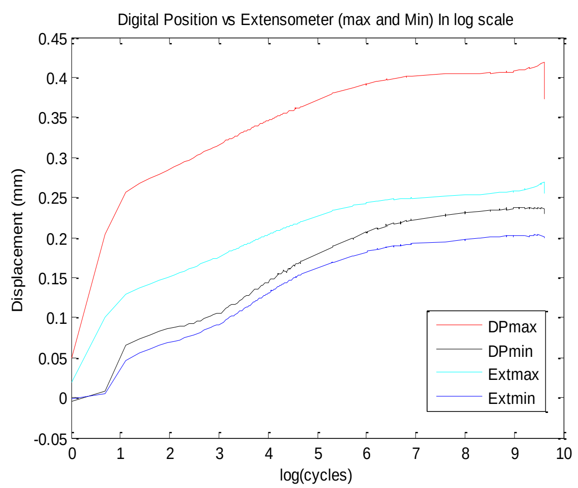
Screw: pelvic cortical

Purchase: bi-cortical





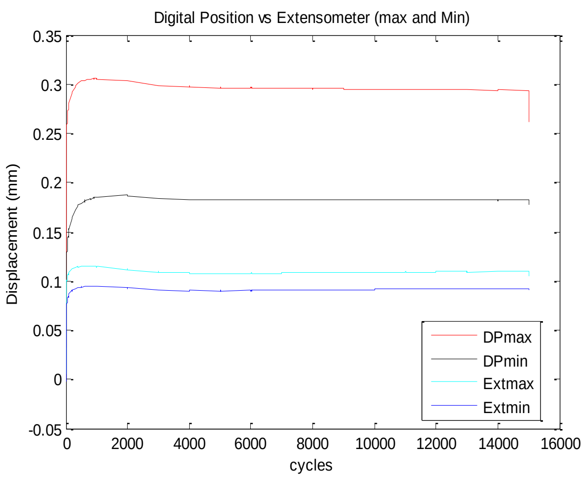


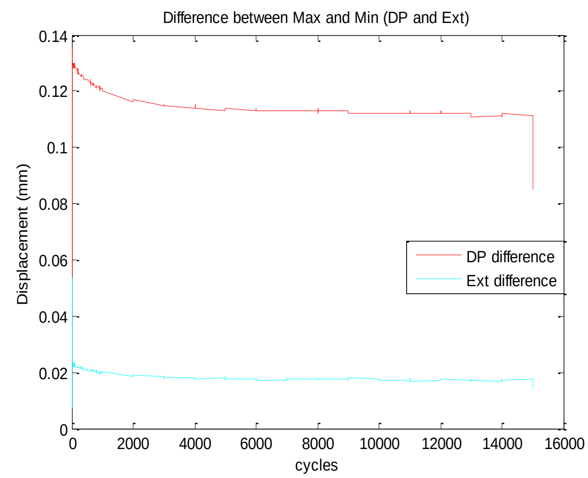


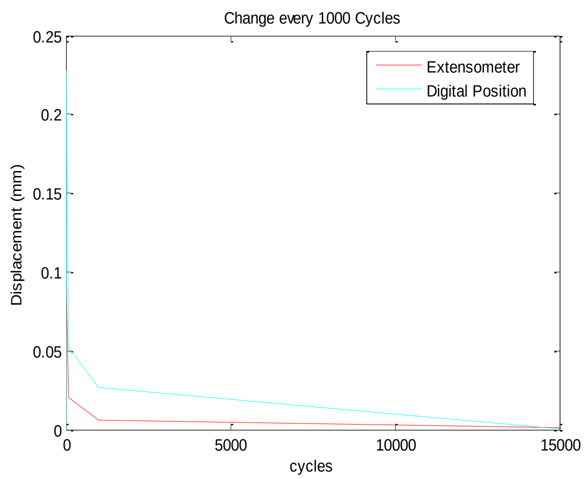
Sample: sternum III R1

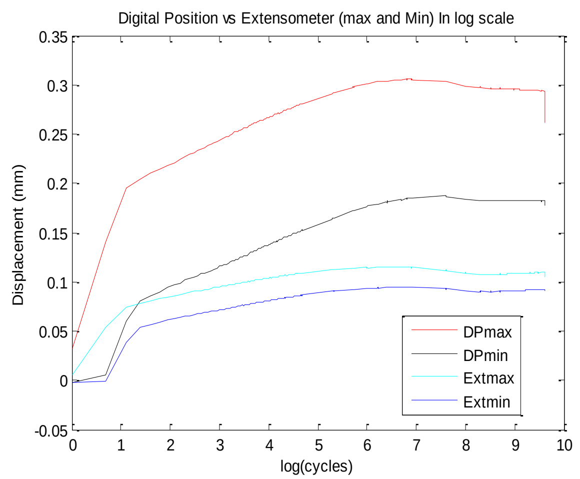
Screw: anti-wobble pedicle cortical

Purchase: uni-cortical





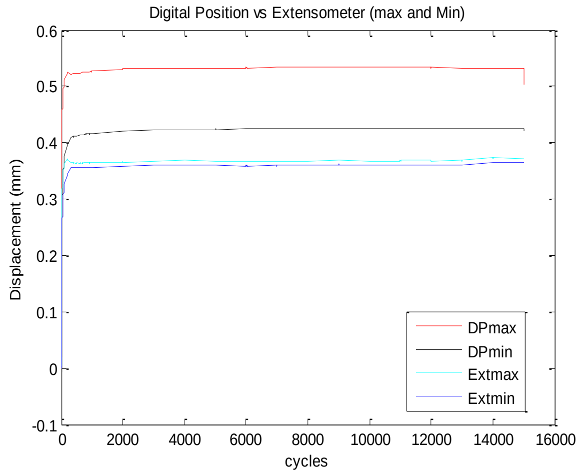


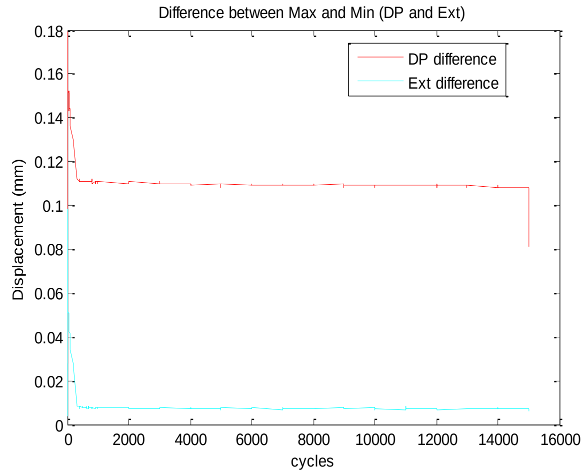


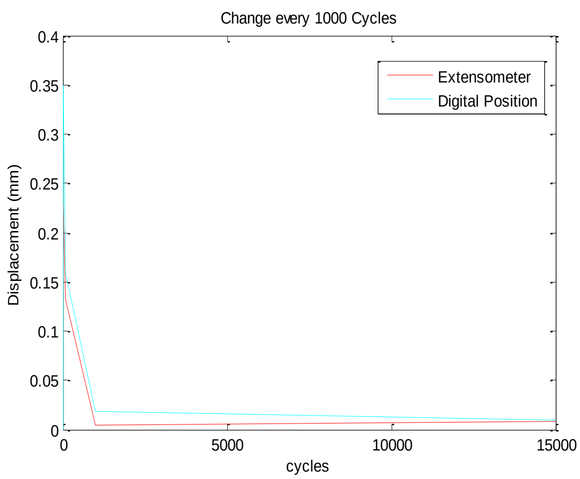
Sample: sternum III R1

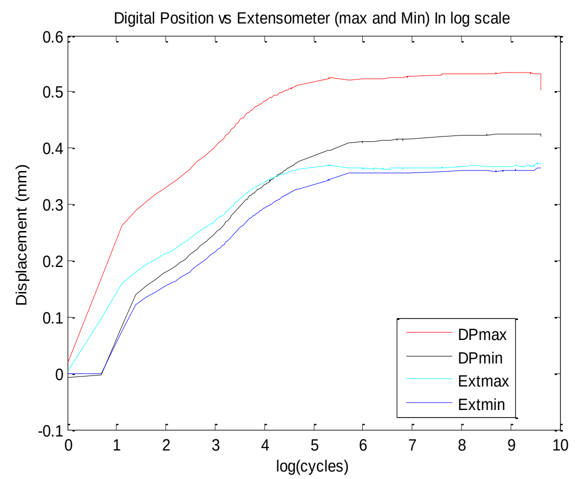
Screw: pedicle cortical

Purchase: uni-cortical





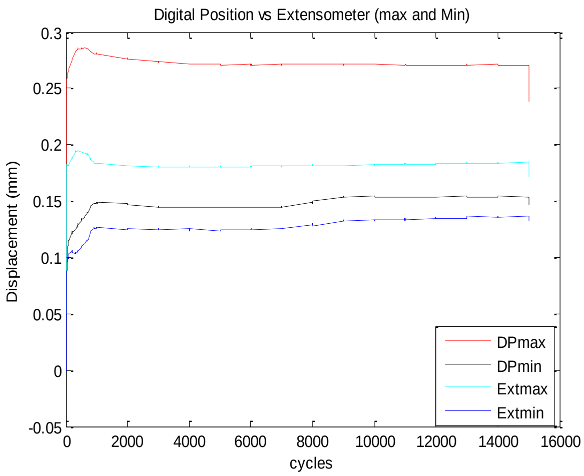


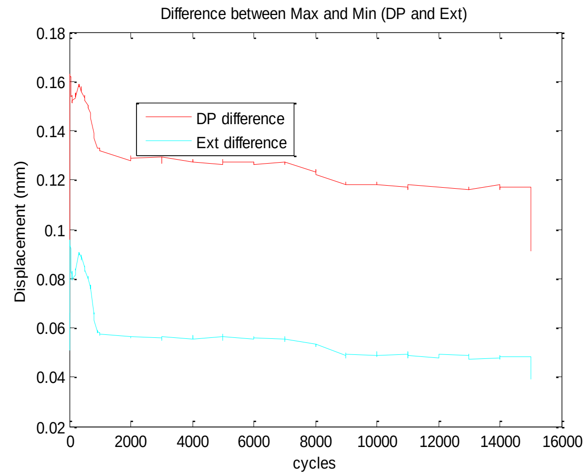


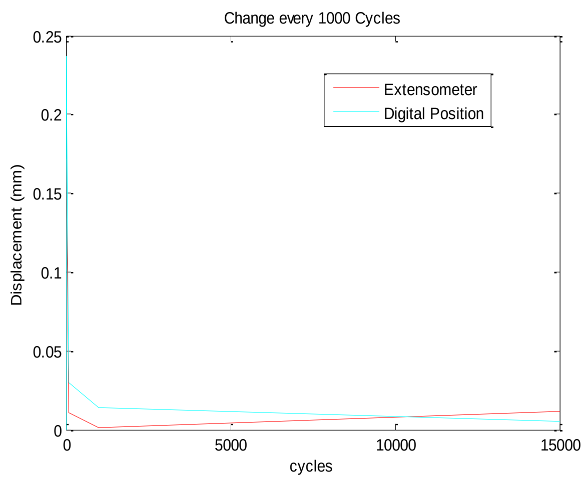
Sample: sternum III L4

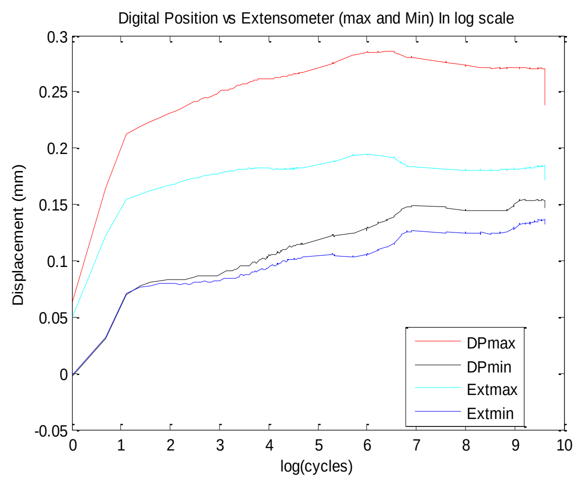
Screw: pedicle cortical

Purchase: bi-cortical





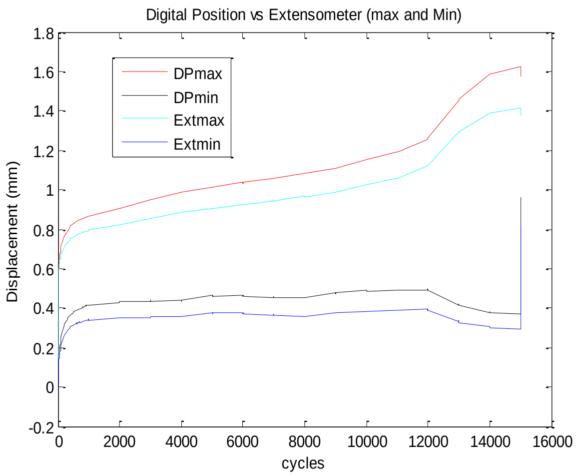


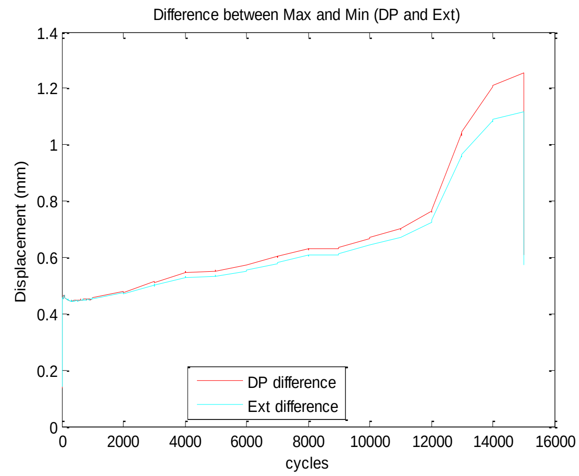


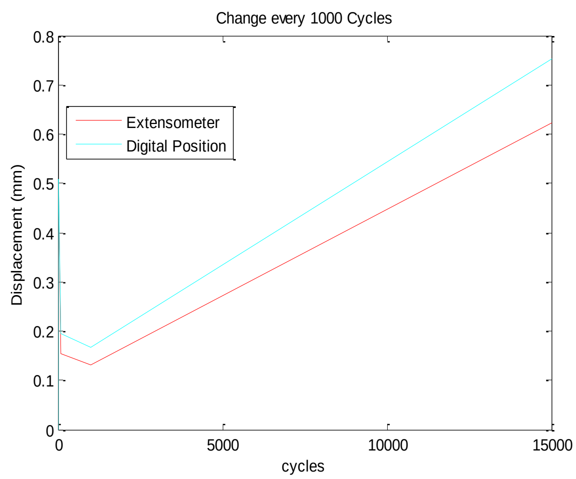
Sample: sternum III L4

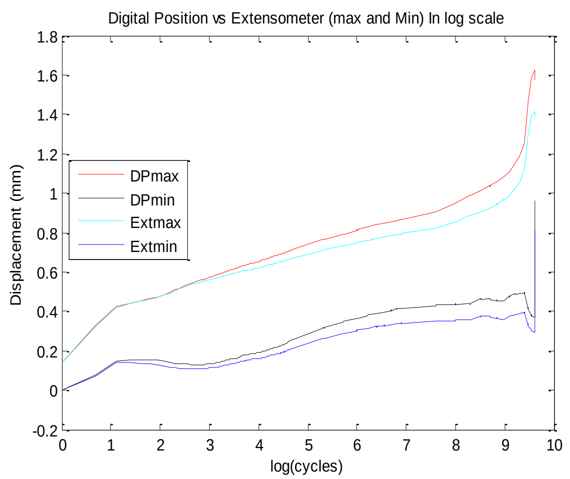
Screw: pelvic cortical

Purchase: bi-cortical





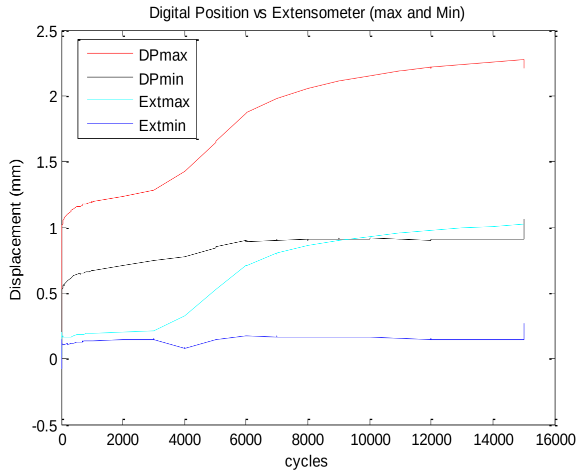


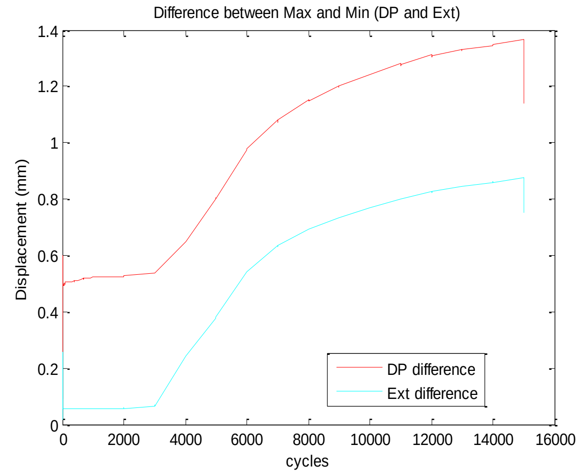


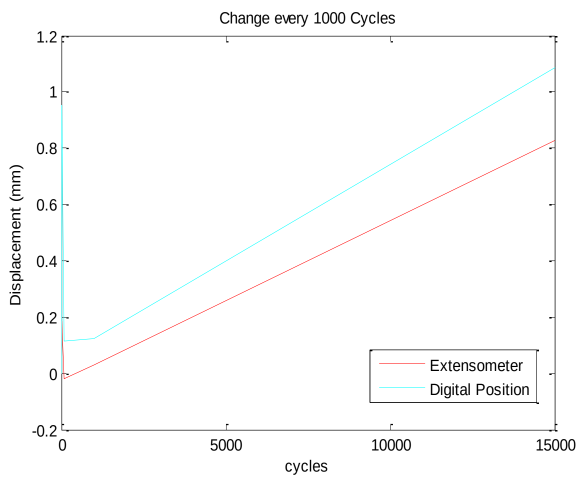
Sample: sternum III R4

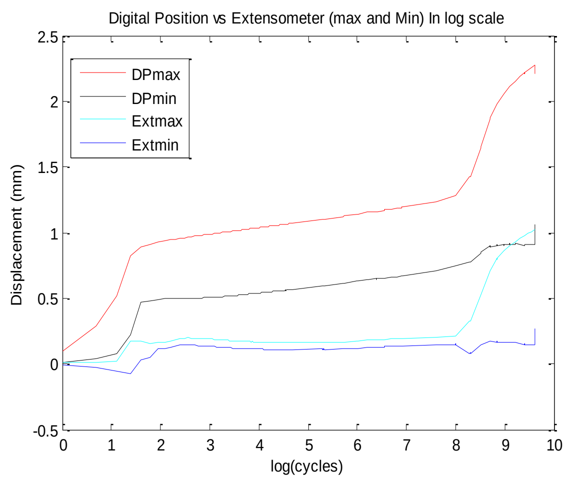
Screw: anti-wobble pedicle cortical

Purchase: uni-cortical







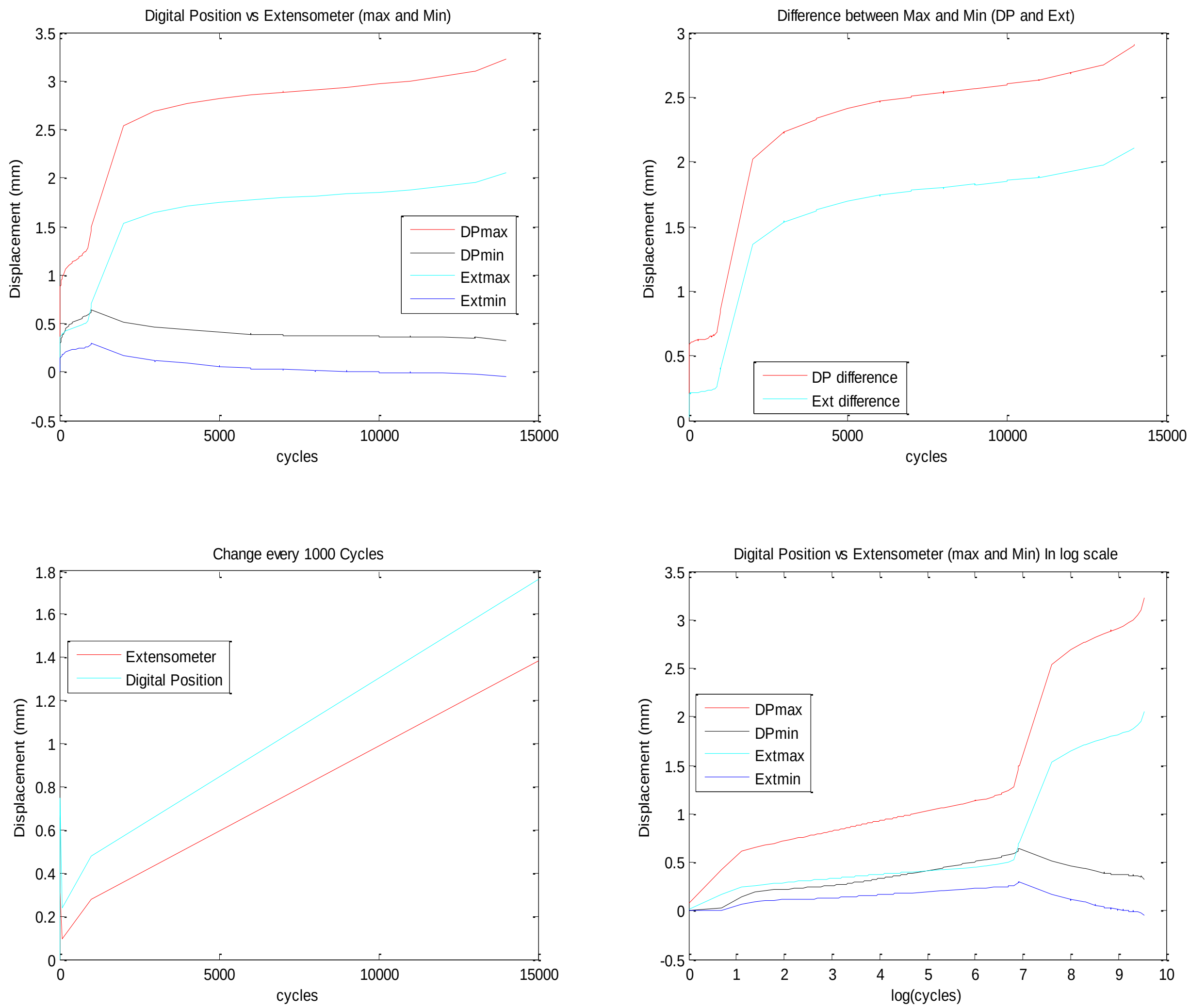


Error: bone sample failed from fixation screws and cement site

Sample: sternum III R4

Screw: pedicle cortical

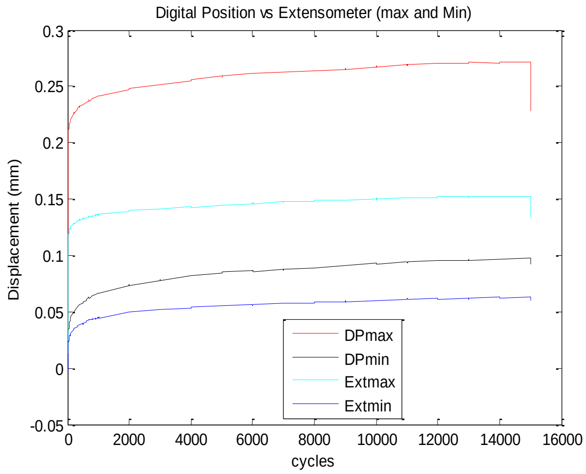
Purchase: uni-cortical

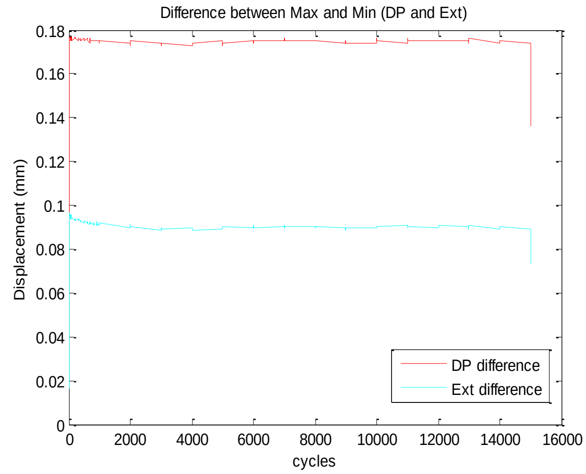


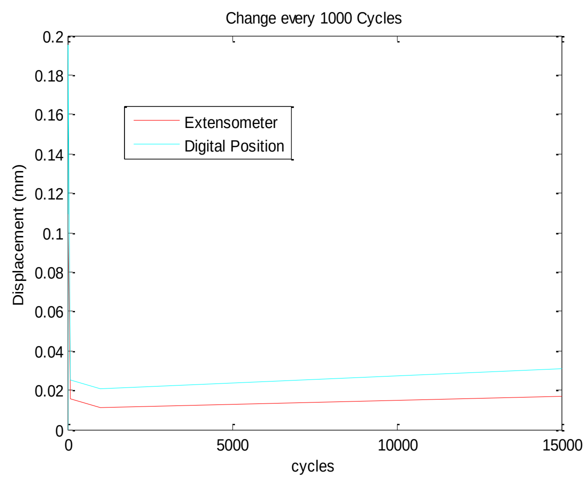
Sample: sternum III R5

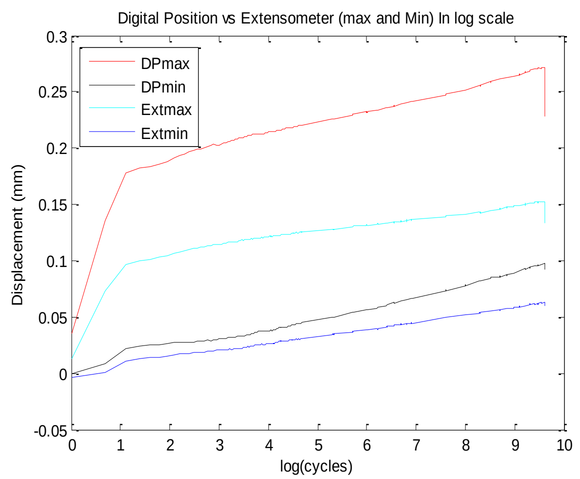
Screw: anti-wobble pedicle cortical

Purchase: uni-cortical





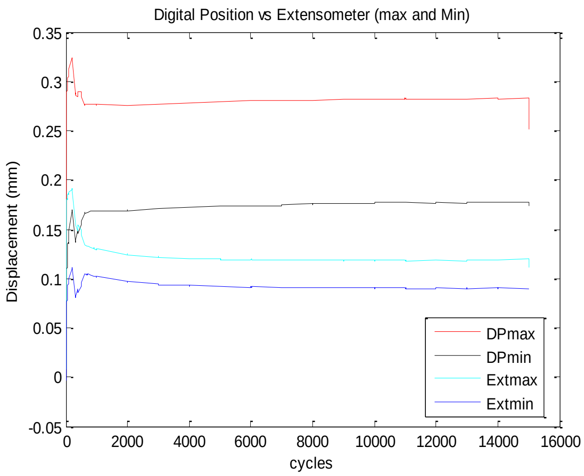


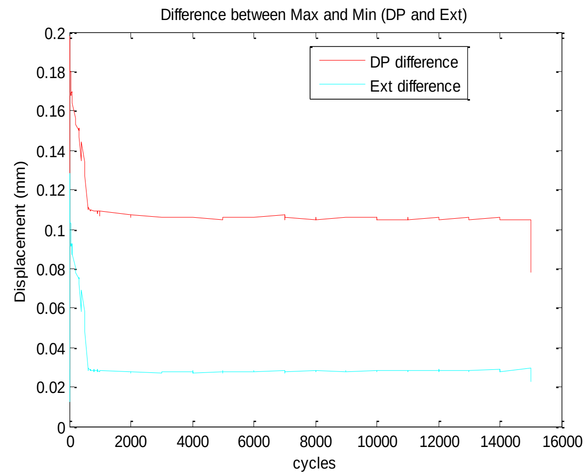


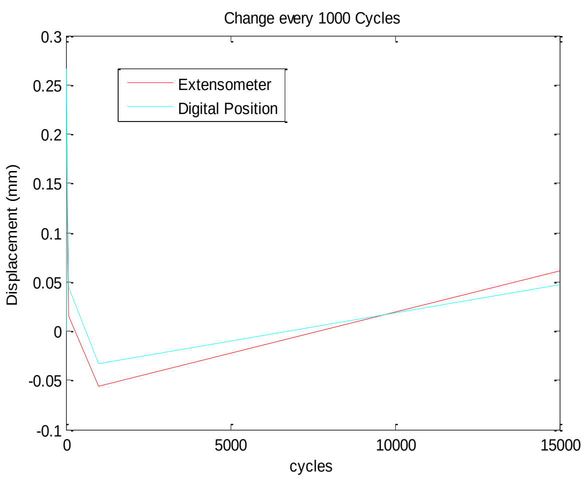
Sample: sternum III L5

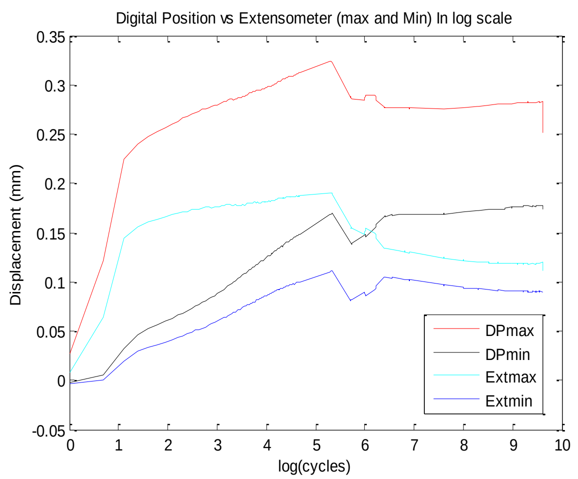
Screw: pelvic cortical

Purchase: bi-cortical





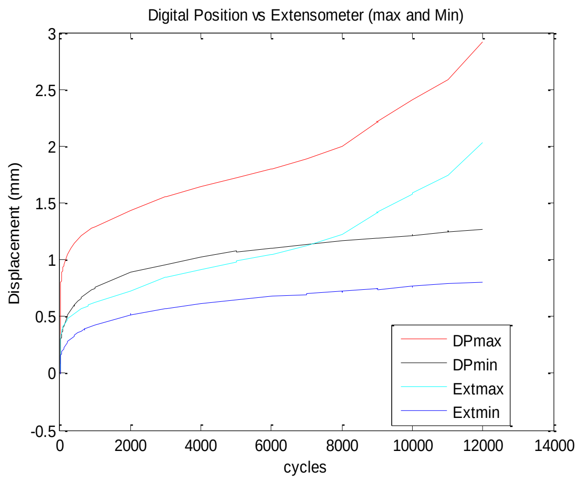


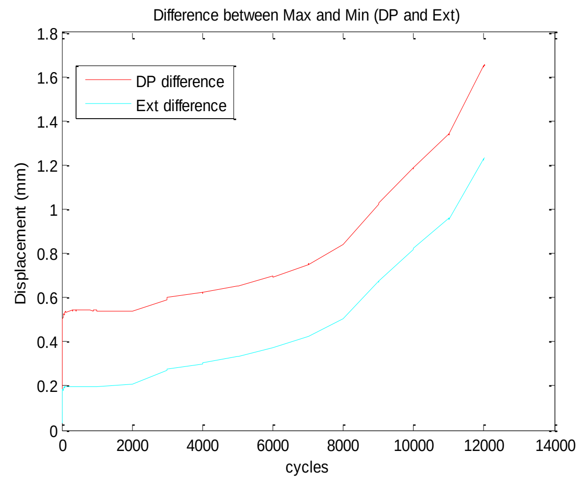


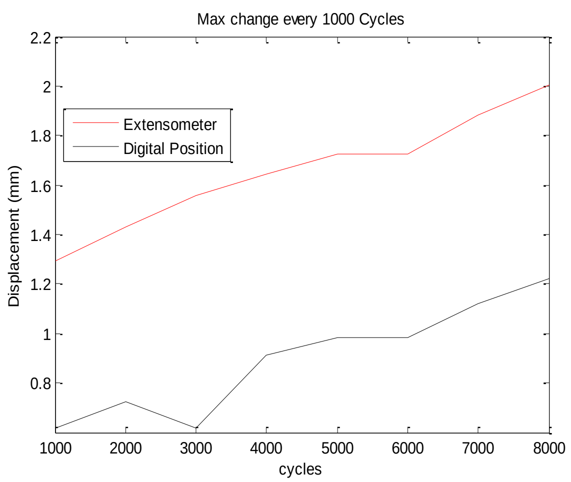
Sample: sternum I L2

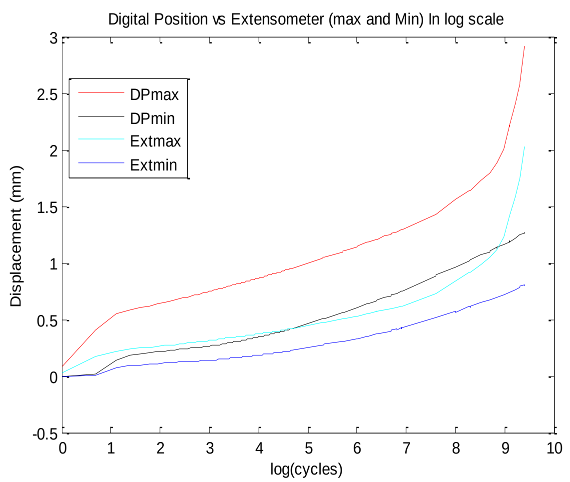
Screw: locking pedicle cortical

Purchase: uni-cortical





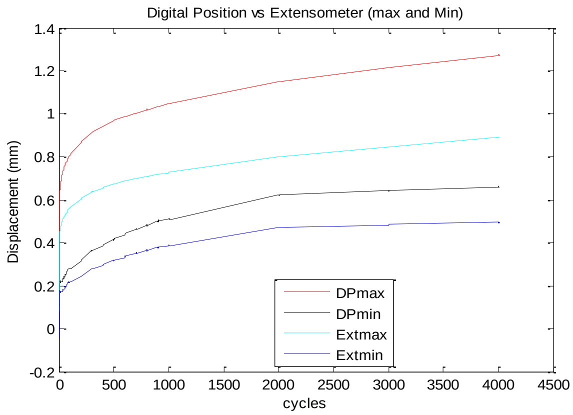


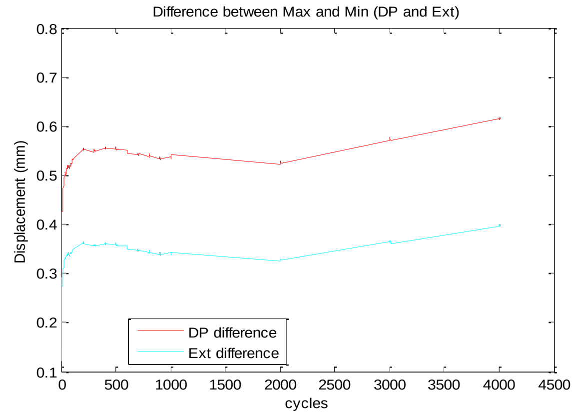


Sample: sternum I L2

Screw: pedicle cortical

Purchase: uni-cortical



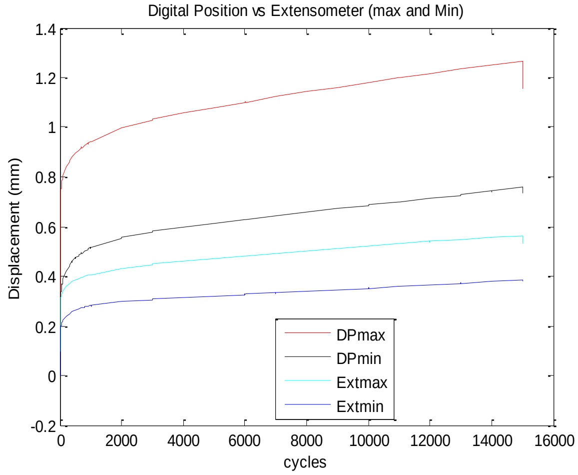


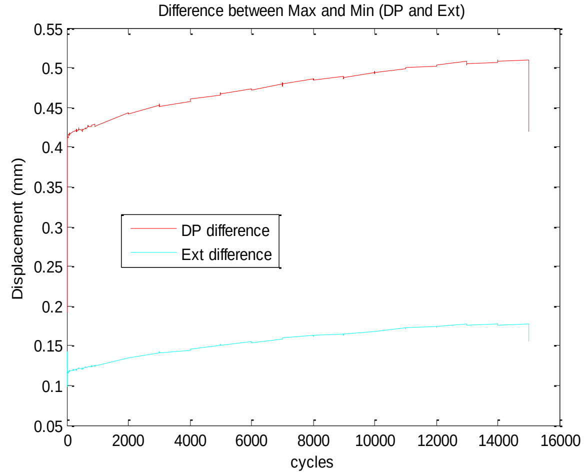
Error: screw striped from bone; failed

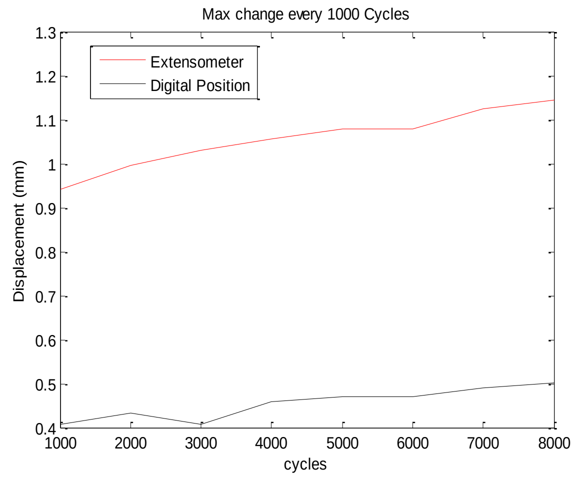
Sample: sternum I R2

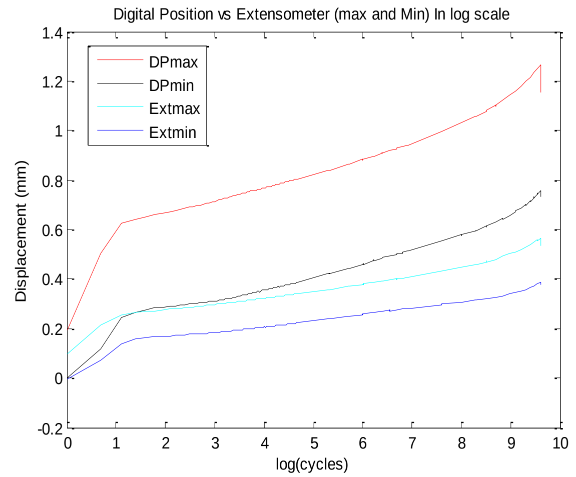
Screw: anti-wobble pedicle cortical

Purchase: uni-cortical





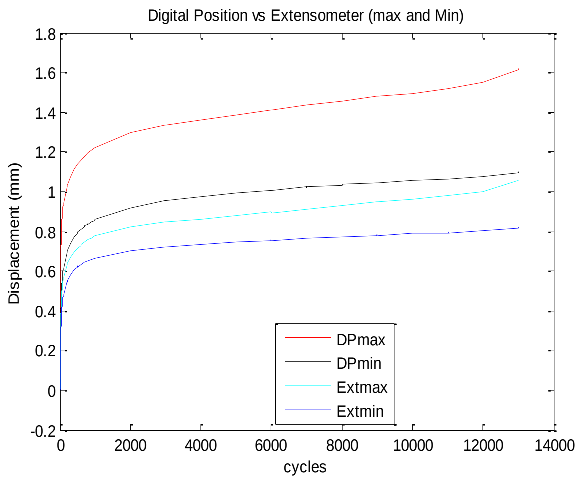


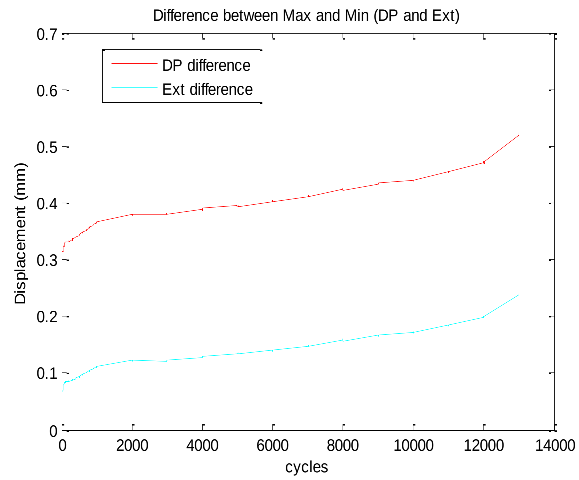


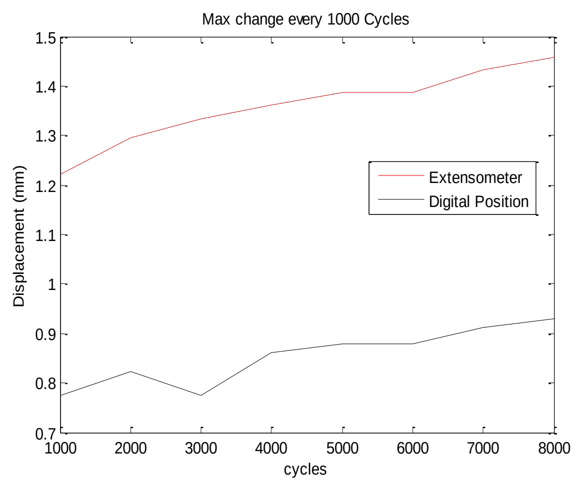
Sample: sternum I R2

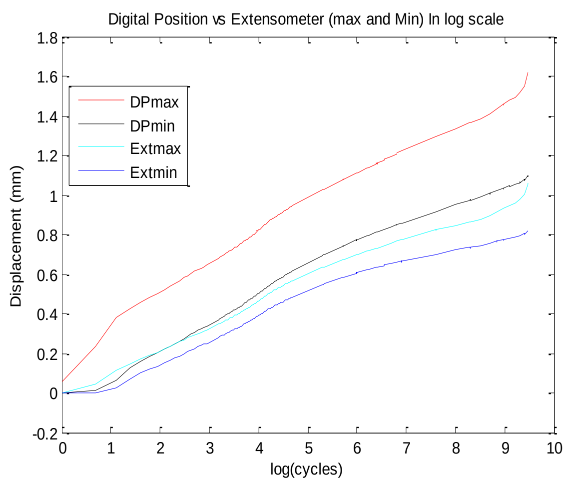
Screw: locking pedicle cortical

Purchase: uni-cortical





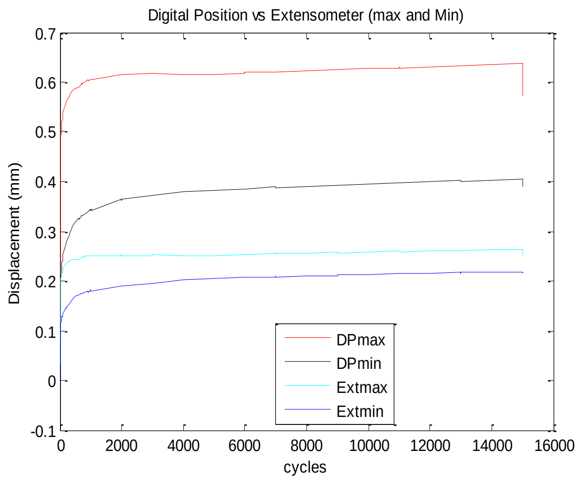


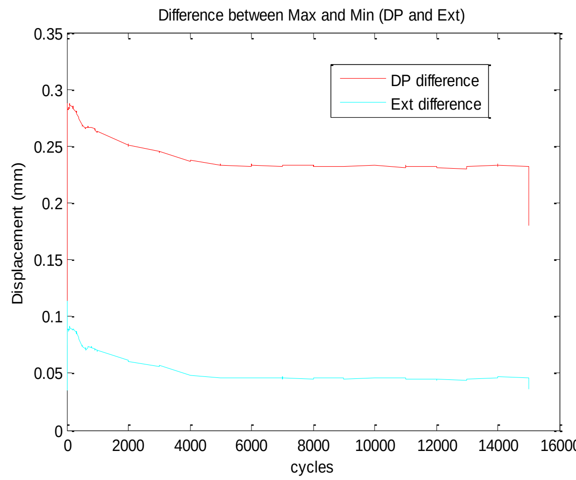


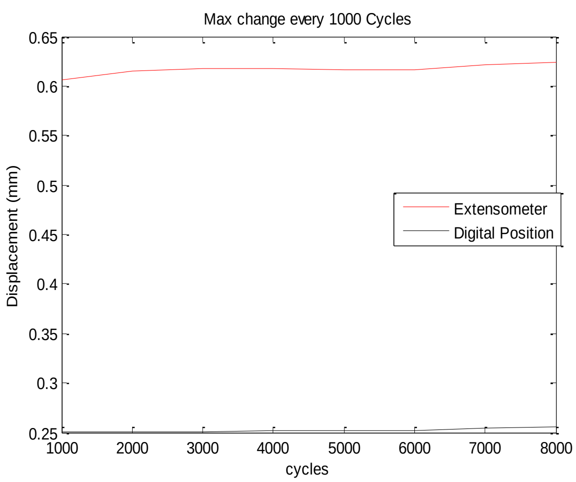
Sample: sternum I R2

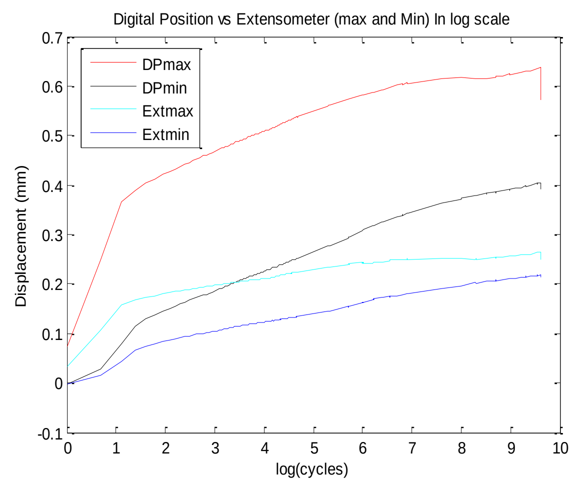
Screw: pedicle cortical

Purchase: bi-cortical





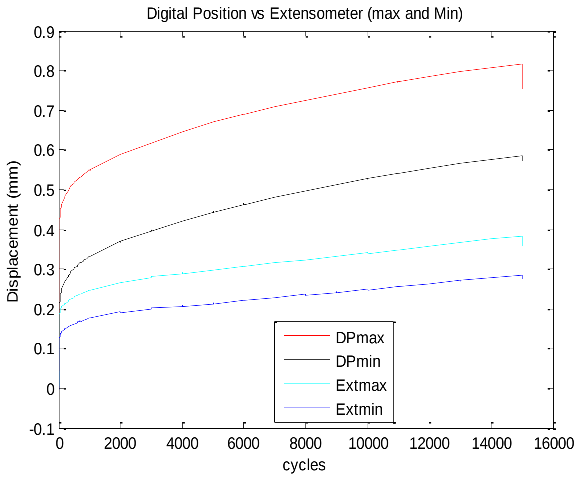


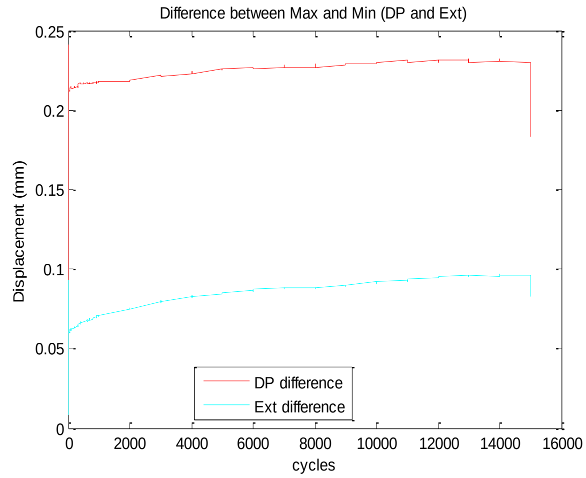


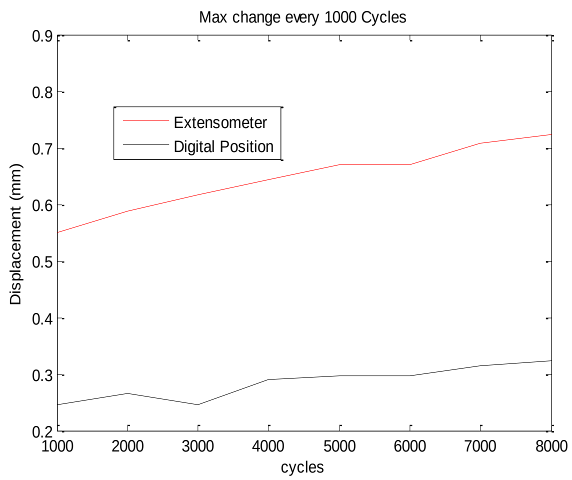
Sample: sternum I L3

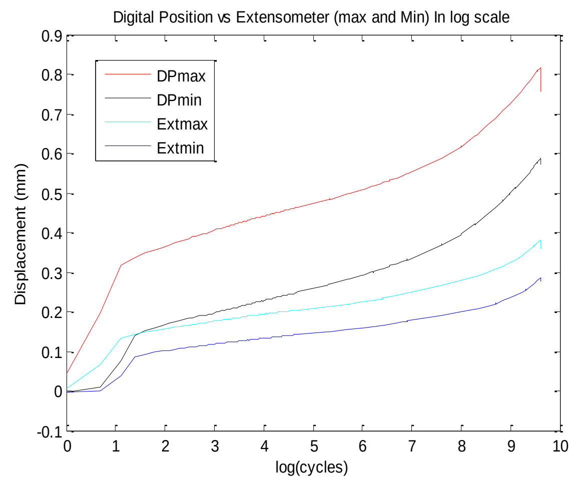
Screw: anti-wobble pedicle cortical

Purchase: uni-cortical





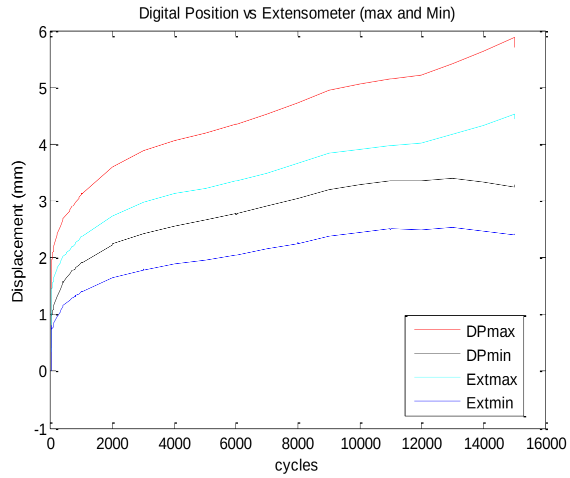


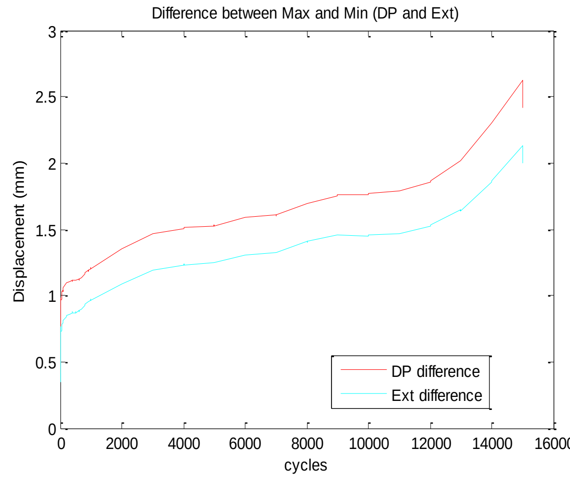


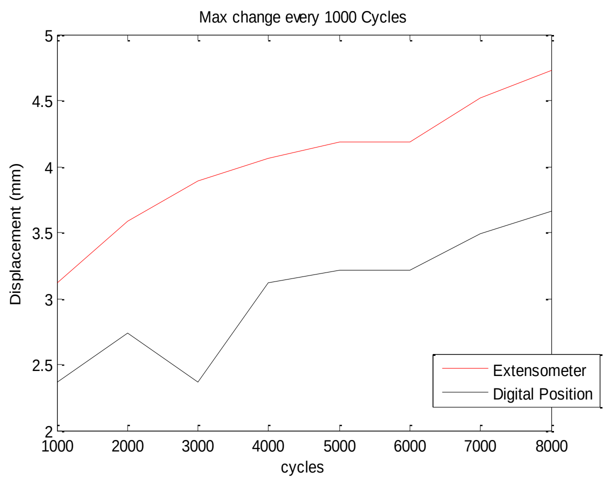
Sample: sternum I R4

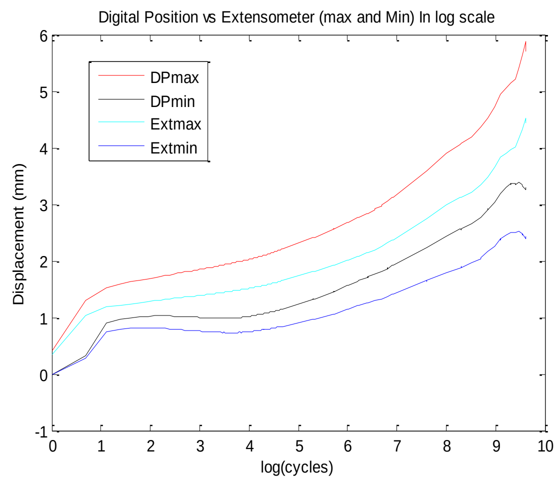
Screw: pedicle cortical

Purchase: bi-cortical





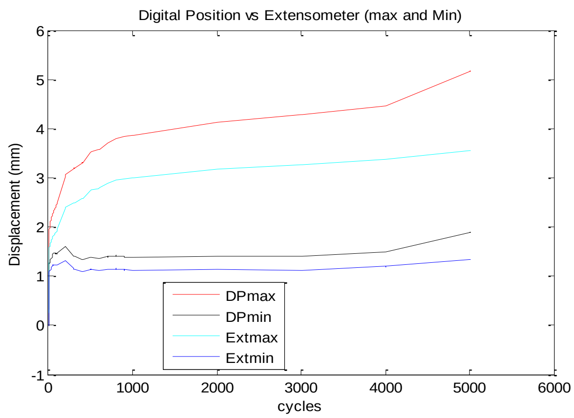


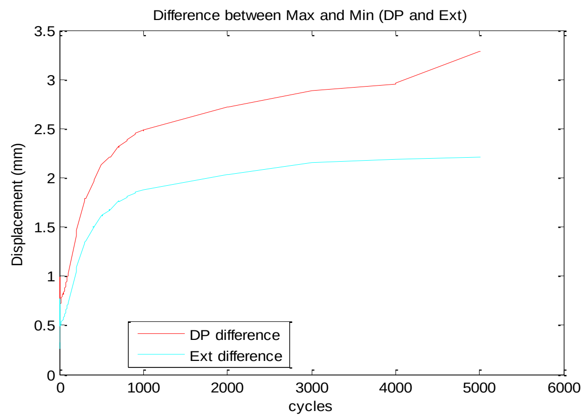


Sample: sternum I R4

Screw: pedicle cortical

Purchase: uni-cortical

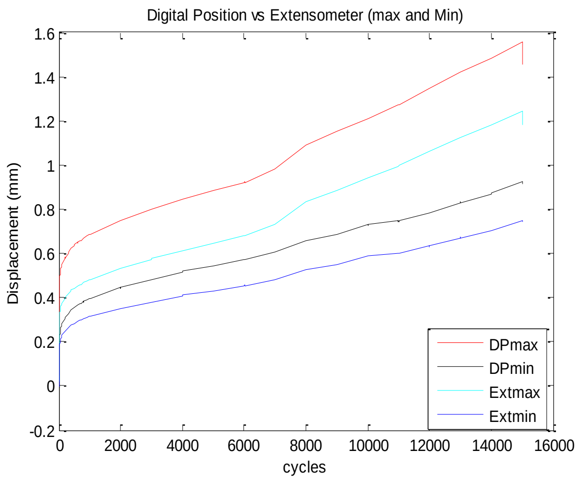


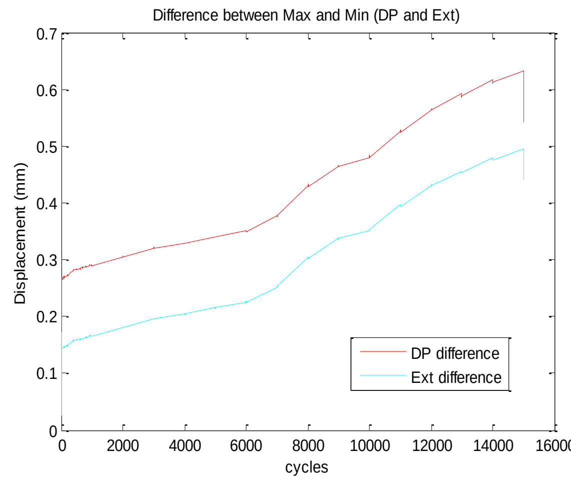


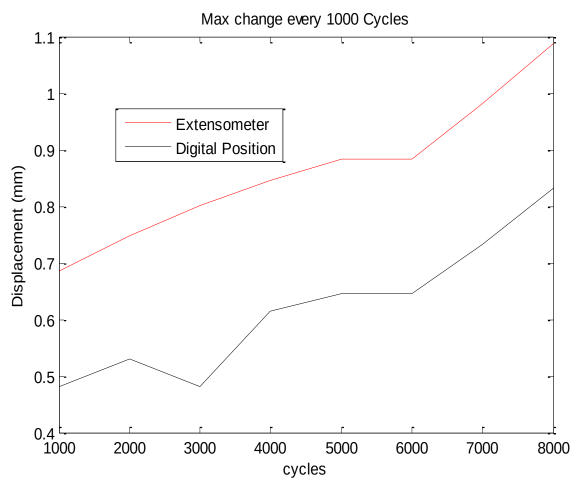
Sample: sternum I R4

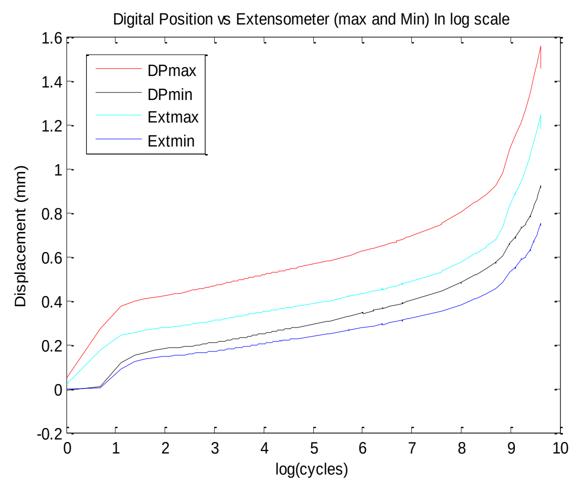
Screw: anti-wobble pedicle cortical

Purchase: uni-cortical





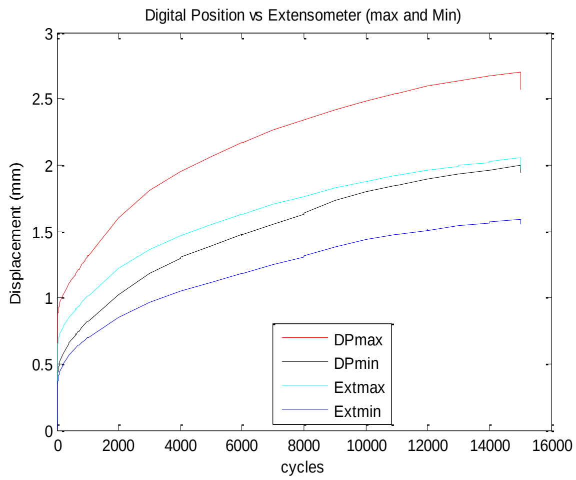


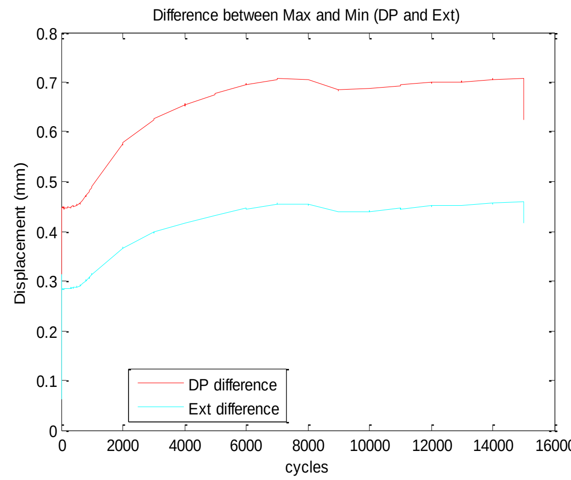


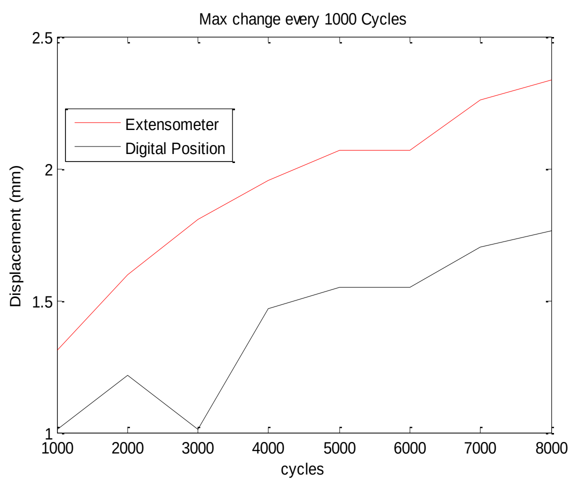
Sample: sternum I LM(manubrium)

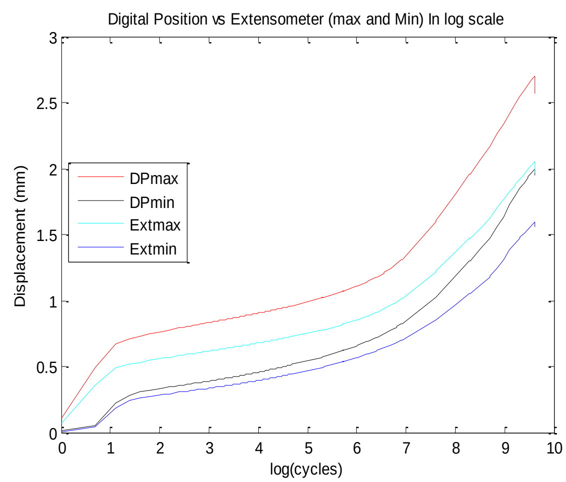
Screw: anti-wobble pedicle cortical

Purchase: uni-cortical









Appendix I – Matlab Code

Matlab Code – display of displacement plots - DataAnalysis2

```
%Graph 1: Comparison of Digital position and Extensometer Max and Mins
%Graph 2: Difference between the max and min for each
%Graph 3: Maximum change for each 1000 cycles.
%This will also output the change per cycle for the whole test. This will
%appear in the console.

close; clear; clc;
ldata=xlsread('Test1.steps.trends.csv');
lc=ldata(:,1);
ldpmax=ldata(:,8);
ldpmin=ldata(:,9);
lextmax=ldata(:,13);
lextmin=ldata(:,14);
ldifference=(ldpmax-ldpmin);
lextdif=(lextmax-lextmin);

max(ldpmax)./max(lc);

%taking the average displacement per cycle of the first 1000 cycles (for
%first test)
%EVENS ARE THE FIRST TEST
%a's are Digital Position, b's are EXTENSOMETER
adata=xlsread('Test1.steps.trends.csv',1,'A2:N191');
ac=adata(:,1);
adpmax=adata(:,8);
aextmax=adata(:,13);

a1=max(adpmax);
b1=max(aextmax);
%taking the average displacement per cycle of the first 1000 cycles (for
%SECOND test)
%ODD OUTPUTS ARE THE SECOND TEST

%and so on
cdata=xlsread('Test1.steps.trends.csv',1,'A192:N201');
cc=cdata(:,1);
cdpmax=cdata(:,8);
cextmax=cdata(:,13);
a3=max(cdpmax);
b3=max(cextmax);

edata=xlsread('Test1.steps.trends.csv',1,'A201:N211');
ec=edata(:,1);
edpmax=edata(:,8);
eextmax=adata(:,13);
a5=max(edpmax);
b5=max(eextmax);

gdata=xlsread('Test1.steps.trends.csv',1,'A211:N221');
```

```
gc=gdata(:,1);
gdpmax=gdata(:,8);
gextmax=gdata(:,13);
a7=max(gdpmax);
b7=max(gextmax);
idata=xlsread('Test1.steps.trends.csv',1,'A221:N231');
ic=idata(:,1);
idpmax=idata(:,8);
iextmax=idata(:,13);
a9=max(idpmax);
b9=max(iextmax);

kdata=xlsread('Test1.steps.trends.csv',1,'A231:N241');
kc=idata(:,1);
kdpmax=kdata(:,8);
kextmax=kdata(:,13);
a11=max(idpmax);
b11=max(iextmax);

mdata=xlsread('Test1.steps.trends.csv',1,'A241:N251');
mc=mdata(:,1);
mdpmax=mdata(:,8);
mextmax=mdata(:,13);
a13=max(mdpmax);
b13=max(mextmax);

odata=xlsread('Test1.steps.trends.csv',1,'A251:N261');
oc=odata(:,1);
odpmax=odata(:,8);
oextmax=odata(:,13);
a15=max(odpmax);
b15=max(oextmax);

% qdata=xlsread('Test1.steps.trends.csv',1,'A261:N271');
% qc=qdata(:,1);
% qdpmax=qdata(:,8);
% qextmax=qdata(:,13);
% a17=max(qdpmax);
% b17=max(qextmax);
%
%
% sdata=xlsread('Test1.steps.trends.csv',1,'A271:N281');
% sc=sdata(:,1);
% sdpmax=sdata(:,8);
% sextmax=sdata(:,13);
% a19=max(sdpmax);
% b19=max(sextmax);
%
%
%
%
% udata=xlsread('Test1.steps.trends.csv',1,'A281:N291');
% uc=udata(:,1);
% udpmax=udata(:,8);
% uextmax=udata(:,13);
% a21=max(udpmax);
```

```
% b21=max(uextmax);
%
%
% wdata=xlsread('Test1.steps.trends.csv',1,'A291:N301');
% wc=wdata(:,1);
% wdpmax=wdata(:,8);
% wextmax=wdata(:,13);
% a23=max(wdpmax);
% b23=max(wextmax);

%PLOTTING
figure
subplot(2,2,1)
axis manual
plot(lc,ldpmax, 'r-')
xlabel('cycles'); ylabel('Displacement (mm)');
title('Digital Position vs Extensometer (max and Min)');
hold on
plot(lc,ldpmin, 'k-')
hold on
plot(lc,lextmax, 'c-')
hold on
plot(lc,lextmin, 'b-')
legend('DPmax','DPmin','Extmax','Extmin',0);
hold on
subplot(2,2,2)
plot(lc,ldifference, '-r')
hold on
plot(lc,lextdif, '-c')
legend('DP difference','Ext difference',0)
xlabel('cycles'); ylabel('Displacement (mm)')
title('Difference between Max and Min (DP and Ext)')
hold on


adp=[a1 a3 a5 a7 a9 a11 a13 a15];
bdp=[b1 b3 b5 b7 b9 b11 b13 b15];
t=1000:1000:8000;
subplot(2,2,3)
plot(t,adp, '-r')
hold on
plot(t,bdp, '-k')
legend('Extensometer','Digital Position',0)
xlabel('cycles'); ylabel('Displacement (mm)')
title('Max change every 1000 Cycles')

subplot(2,2,4)
plot(log(lc),ldpmax, 'r-')
xlabel('log(cycles)'); ylabel('Displacement (mm)');
title('Digital Position vs Extensometer (max and Min) In log scale');
hold on
plot(log(lc),ldpmin, 'k-')
hold on
plot(log(lc),lextmax, 'c-')
hold on
plot(log(lc),lextmin, 'b-')
```

```
legend('DPmax','DPmin','Extmax','Extmin',0);
```

Matlab Code – display of displacement plots - Displacement2

```
%For Extensions
%code will export the max values at 10 cycles, 100 cycles and 1000 cycles.

data=xlsread('1.csv');
dpmax=data(:,13);
maxdisplace=0;

for i=1:10;
   maxdisplace10=max(maxdisplace,max(dpmax(i)));
end
maxdisplace10
for i=10:100;
   maxdisplace100=max(maxdisplace,max(dpmax(i)));
end
maxdisplace100
for i=100:191;
   maxdisplace1000=max(maxdisplace,max(dpmax(i)));
end
maxdisplace1000

finaldisplace=max(dpmax)
A=[maxdisplace10;maxdisplace100;maxdisplace1000;finaldisplace]
xlswrite('extensions',A,'B2:B5')


data=xlsread('2.csv');
dpmax=data(:,13);
maxdisplace=0;

for i=1:10;
   maxdisplace10=max(maxdisplace,max(dpmax(i)));
end
maxdisplace10
for i=10:100;
   maxdisplace100=max(maxdisplace,max(dpmax(i)));
end
maxdisplace100
for i=100:191;
   maxdisplace1000=max(maxdisplace,max(dpmax(i)));
end
maxdisplace1000

finaldisplace=max(dpmax)
A=[maxdisplace10;maxdisplace100;maxdisplace1000;finaldisplace]
xlswrite('extensions',A,'c2:c5')


data=xlsread('3.csv');
dpmax=data(:,13);
maxdisplace=0;

for i=1:10;
```

```
   maxdisplace10=max(maxdisplace,max(dpmax(i)));
end
maxdisplace10
for i=10:100;
   maxdisplace100=max(maxdisplace,max(dpmax(i)));
end
maxdisplace100
for i=100:191;
   maxdisplace1000=max(maxdisplace,max(dpmax(i)));
end
maxdisplace1000

finaldisplace=max(dpmax)
A=[maxdisplace10;maxdisplace100;maxdisplace1000;finaldisplace]
xlswrite('extensions',A,'d2:d5')


data=xlsread('4.csv');
dpmax=data(:,13);
maxdisplace=0;

for i=1:10;
   maxdisplace10=max(maxdisplace,max(dpmax(i)));
end
maxdisplace10
for i=10:100;
   maxdisplace100=max(maxdisplace,max(dpmax(i)));
end
maxdisplace100
for i=100:191;
   maxdisplace1000=max(maxdisplace,max(dpmax(i)));
end
maxdisplace1000

finaldisplace=max(dpmax)
A=[maxdisplace10;maxdisplace100;maxdisplace1000;finaldisplace]
xlswrite('extensions',A,'e2:e5')


data=xlsread('5.csv');
dpmax=data(:,13);
maxdisplace=0;

for i=1:10;
   maxdisplace10=max(maxdisplace,max(dpmax(i)));
end
maxdisplace10
for i=10:100;
   maxdisplace100=max(maxdisplace,max(dpmax(i)));
end
maxdisplace100
for i=100:191;
   maxdisplace1000=max(maxdisplace,max(dpmax(i)));
end
maxdisplace1000
```

```
finaldisplace=max(dpmax)
A=[maxdisplace10;maxdisplace100;maxdisplace1000;finaldisplace]
xlswrite('extensions',A,'f2:f5')


data=xlsread('6.csv');
dpmax=data(:,13);
maxdisplace=0;

for i=1:10;
   maxdisplace10=max(maxdisplace,max(dpmax(i)));
end
maxdisplace10
for i=10:100;
   maxdisplace100=max(maxdisplace,max(dpmax(i)));
end
maxdisplace100
for i=100:191;
   maxdisplace1000=max(maxdisplace,max(dpmax(i)));
end
maxdisplace1000

finaldisplace=max(dpmax)
A=[maxdisplace10;maxdisplace100;maxdisplace1000;finaldisplace]
xlswrite('extensions',A,'g2:g5')


data=xlsread('7.csv');
dpmax=data(:,13);
maxdisplace=0;

for i=1:10;
   maxdisplace10=max(maxdisplace,max(dpmax(i)));
end
maxdisplace10
for i=10:100;
   maxdisplace100=max(maxdisplace,max(dpmax(i)));
end
maxdisplace100
for i=100:191;
   maxdisplace1000=max(maxdisplace,max(dpmax(i)));
end
maxdisplace1000

finaldisplace=max(dpmax)
A=[maxdisplace10;maxdisplace100;maxdisplace1000;finaldisplace]
xlswrite('extensions',A,'h2:h5')


data=xlsread('8.csv');
dpmax=data(:,13);
maxdisplace=0;
```

```
for i=1:10;
   maxdisplace10=max(maxdisplace,max(dpmax(i)));
end
maxdisplace10
for i=10:100;
   maxdisplace100=max(maxdisplace,max(dpmax(i)));
end
maxdisplace100
for i=100:191;
   maxdisplace1000=max(maxdisplace,max(dpmax(i)));
end
maxdisplace1000

finaldisplace=max(dpmax)
A=[maxdisplace10;maxdisplace100;maxdisplace1000;finaldisplace]
xlswrite('extensions',A,'i2:i5')


data=xlsread('9.csv');
dpmax=data(:,13);
maxdisplace=0;

for i=1:10;
   maxdisplace10=max(maxdisplace,max(dpmax(i)));
end
maxdisplace10
for i=10:100;
   maxdisplace100=max(maxdisplace,max(dpmax(i)));
end
maxdisplace100
for i=100:191;
   maxdisplace1000=max(maxdisplace,max(dpmax(i)));
end
maxdisplace1000

finaldisplace=max(dpmax)
A=[maxdisplace10;maxdisplace100;maxdisplace1000;finaldisplace]
xlswrite('extensions',A,'j2:j5')


data=xlsread('10.csv');
dpmax=data(:,13);
maxdisplace=0;

for i=1:10;
   maxdisplace10=max(maxdisplace,max(dpmax(i)));
end
maxdisplace10
for i=10:100;
   maxdisplace100=max(maxdisplace,max(dpmax(i)));
end
maxdisplace100
for i=100:191;
   maxdisplace1000=max(maxdisplace,max(dpmax(i)));
end
```

```
maxdisplace1000

finaldisplace=max(dpmax)
A=[maxdisplace10;maxdisplace100;maxdisplace1000;finaldisplace]
xlswrite('extensions',A,'k2:k5')


data=xlsread('11.csv');
dpmax=data(:,13);
maxdisplace=0;

for i=1:10;
   maxdisplace10=max(maxdisplace,max(dpmax(i)));
end
maxdisplace10
for i=10:100;
   maxdisplace100=max(maxdisplace,max(dpmax(i)));
end
maxdisplace100
for i=100:191;
   maxdisplace1000=max(maxdisplace,max(dpmax(i)));
end
maxdisplace1000

finaldisplace=max(dpmax)
A=[maxdisplace10;maxdisplace100;maxdisplace1000;finaldisplace]
xlswrite('extensions',A,'l2:l5')


data=xlsread('12.csv');
dpmax=data(:,13);
maxdisplace=0;

for i=1:10;
   maxdisplace10=max(maxdisplace,max(dpmax(i)));
end
maxdisplace10
for i=10:100;
   maxdisplace100=max(maxdisplace,max(dpmax(i)));
end
maxdisplace100
for i=100:191;
   maxdisplace1000=max(maxdisplace,max(dpmax(i)));
end
maxdisplace1000

finaldisplace=max(dpmax)
A=[maxdisplace10;maxdisplace100;maxdisplace1000;finaldisplace]
xlswrite('extensions',A,'m2:m5')


data=xlsread('13.csv');
dpmax=data(:,13);
maxdisplace=0;
```

```matlab
for i=1:10;
   maxdisplace10=max(maxdisplace,max(dpmax(i)));
end
maxdisplace10
for i=10:100;
   maxdisplace100=max(maxdisplace,max(dpmax(i)));
end
maxdisplace100
for i=100:191;
   maxdisplace1000=max(maxdisplace,max(dpmax(i)));
end
maxdisplace1000

finaldisplace=max(dpmax)
A=[maxdisplace10;maxdisplace100;maxdisplace1000;finaldisplace]
xlswrite('extensions',A,'n2:n5')


data=xlsread('14.csv');
dpmax=data(:,13);
maxdisplace=0;

for i=1:10;
   maxdisplace10=max(maxdisplace,max(dpmax(i)));
end
maxdisplace10
for i=10:100;
   maxdisplace100=max(maxdisplace,max(dpmax(i)));
end
maxdisplace100
for i=100:191;
   maxdisplace1000=max(maxdisplace,max(dpmax(i)));
end
maxdisplace1000

finaldisplace=max(dpmax)
A=[maxdisplace10;maxdisplace100;maxdisplace1000;finaldisplace]
xlswrite('extensions',A,'o2:o5')

% data=xlsread('15.csv');
% dpmax=data(:,10);
% maxdisplace=0;
%
% for i=1:10;
%    maxdisplace10=max(maxdisplace,max(dpmax(i)));
% end
% maxdisplace10
% for i=10:100;
%    maxdisplace100=max(maxdisplace,max(dpmax(i)));
% end
% maxdisplace100
% for i=100:191;
%    maxdisplace1000=max(maxdisplace,max(dpmax(i)));
% end
```

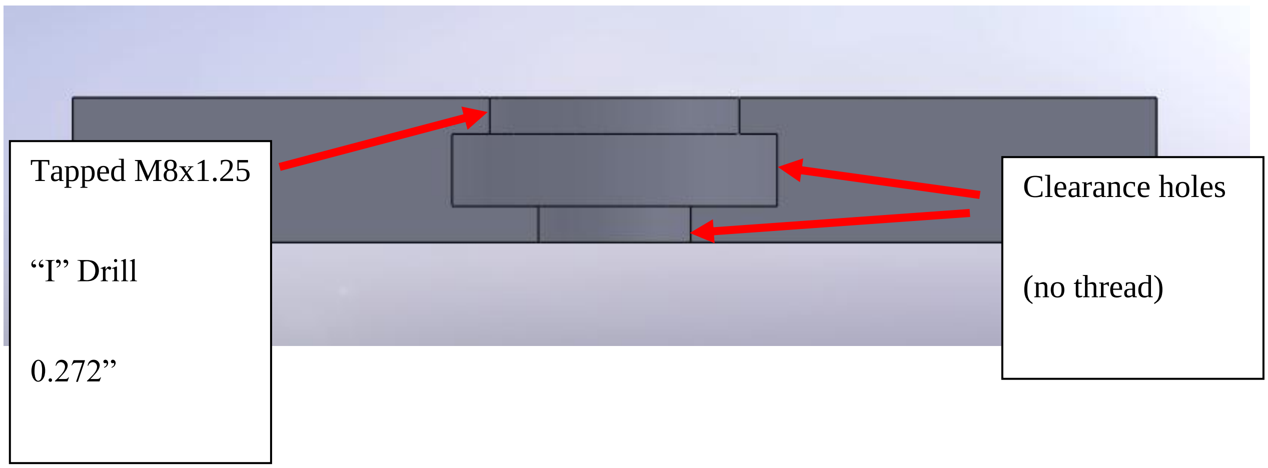
```
% maxdisplace1000
%
% finaldisplace=max(dpmax)
% A=[maxdisplace10;maxdisplace100;maxdisplace1000;finaldisplace]
% xlswrite('extensions',A,'p2:p5')
%
%
% data=xlsread('16.csv');
% dpmax=data(:,10);
% maxdisplace=0;
%
% for i=1:10;
%    maxdisplace10=max(maxdisplace,max(dpmax(i)));
% end
% maxdisplace10
% for i=10:100;
%    maxdisplace100=max(maxdisplace,max(dpmax(i)));
% end
% maxdisplace100
% for i=100:191;
%    maxdisplace1000=max(maxdisplace,max(dpmax(i)));
% end
% maxdisplace1000
%
% finaldisplace=max(dpmax)
% A=[maxdisplace10;maxdisplace100;maxdisplace1000;finaldisplace]
% xlswrite('extensions',A,'q2:q5')
%
%
% data=xlsread('17.csv');
% dpmax=data(:,10);
% maxdisplace=0;
%
% for i=1:10;
%    maxdisplace10=max(maxdisplace,max(dpmax(i)));
% end
% maxdisplace10
% for i=10:100;
%    maxdisplace100=max(maxdisplace,max(dpmax(i)));
% end
% maxdisplace100
% for i=100:191;
%    maxdisplace1000=max(maxdisplace,max(dpmax(i)));
% end
% maxdisplace1000
%
% finaldisplace=max(dpmax)
% A=[maxdisplace10;maxdisplace100;maxdisplace1000;finaldisplace]
% xlswrite('extensions',A,'r2:r5')
%
%
% data=xlsread('18.csv');
% dpmax=data(:,10);
% maxdisplace=0;
%
% for i=1:10;
%    maxdisplace10=max(maxdisplace,max(dpmax(i)));
```

```
% end
% maxdisplace10
% for i=10:100;
%    maxdisplace100=max(maxdisplace,max(dpmax(i)));
% end
% maxdisplace100
% for i=100:191;
%    maxdisplace1000=max(maxdisplace,max(dpmax(i)));
% end
% maxdisplace1000
%
% finaldisplace=max(dpmax)
% A=[maxdisplace10;maxdisplace100;maxdisplace1000;finaldisplace]
% xlswrite('extensions',A,'s2:s5')
%
%
% data=xlsread('19.csv');
% dpmax=data(:,10);
% maxdisplace=0;
%
% for i=1:10;
%    maxdisplace10=max(maxdisplace,max(dpmax(i)));
% end
% maxdisplace10
% for i=10:100;
%    maxdisplace100=max(maxdisplace,max(dpmax(i)));
% end
% maxdisplace100
% for i=100:191;
%    maxdisplace1000=max(maxdisplace,max(dpmax(i)));
% end
% maxdisplace1000
%
% finaldisplace=max(dpmax)
% A=[maxdisplace10;maxdisplace100;maxdisplace1000;finaldisplace]
% xlswrite('extensions',A,'t2:t5')
%
% data=xlsread('20.csv');
% dpmax=data(:,10);
% maxdisplace=0;
%
% for i=1:10;
%    maxdisplace10=max(maxdisplace,max(dpmax(i)));
% end
% maxdisplace10
% for i=10:100;
%    maxdisplace100=max(maxdisplace,max(dpmax(i)));
% end
% maxdisplace100
% for i=100:191;
%    maxdisplace1000=max(maxdisplace,max(dpmax(i)));
% end
% maxdisplace1000
%
% finaldisplace=max(dpmax)
% A=[maxdisplace10;maxdisplace100;maxdisplace1000;finaldisplace]
% xlswrite('extensions',A,'u2:u5')
```

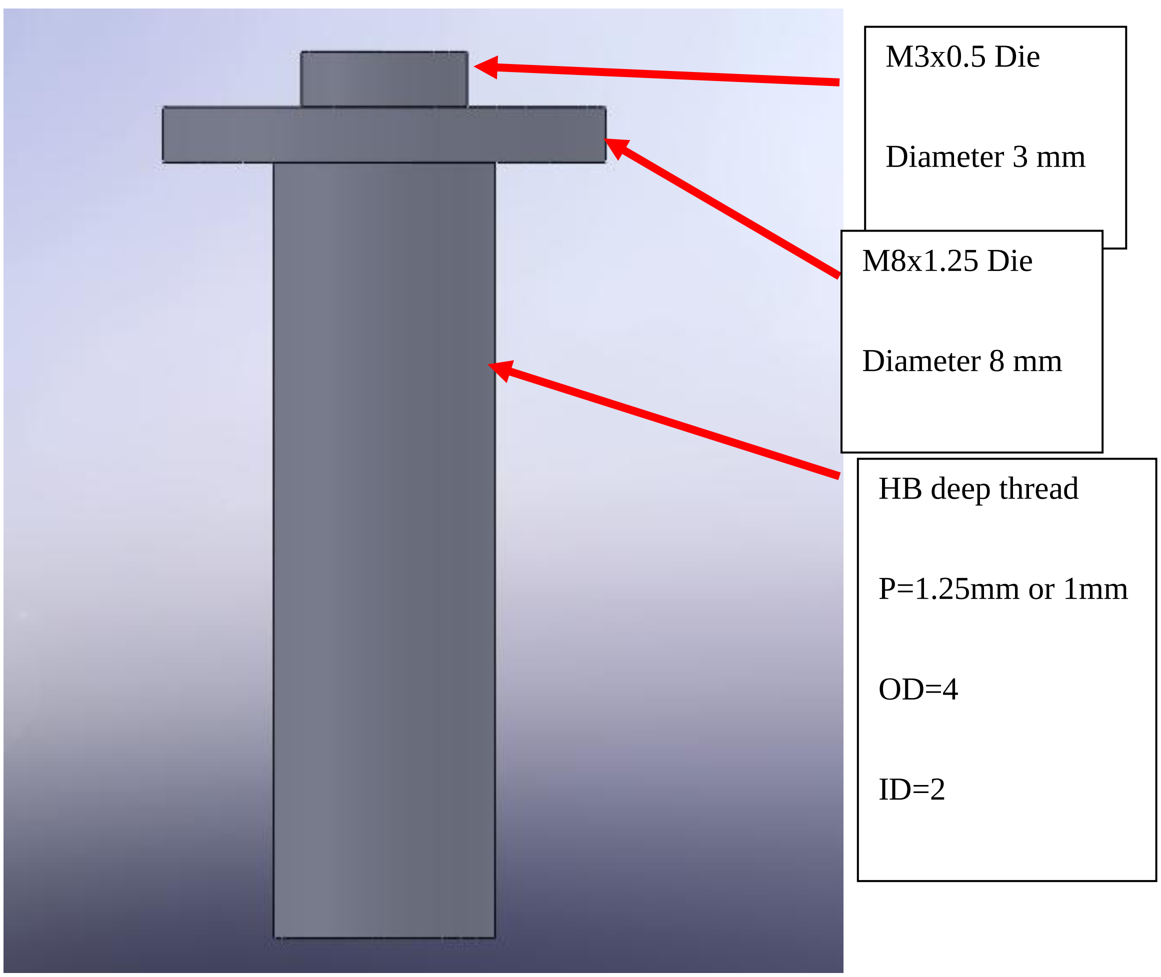
Appendix J – Dimensions of Screw Prototype

Sternal Screw

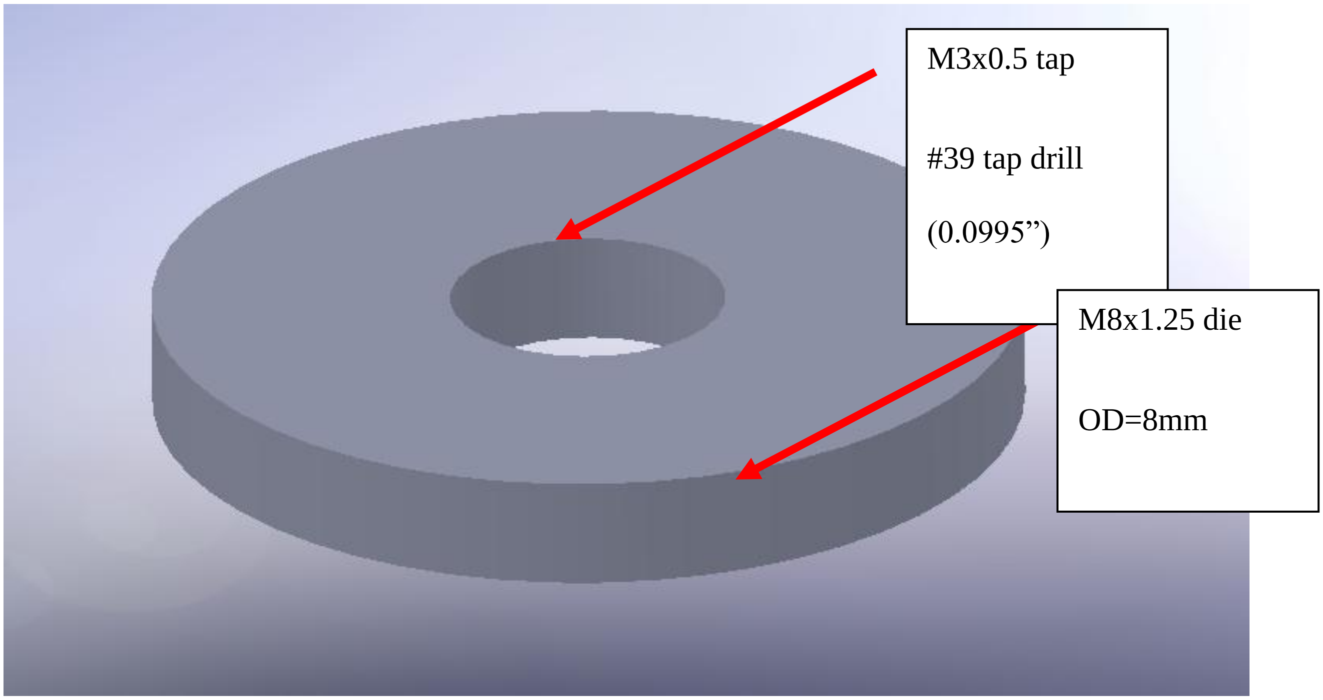
Plate



Screw Bottom



Screw Top

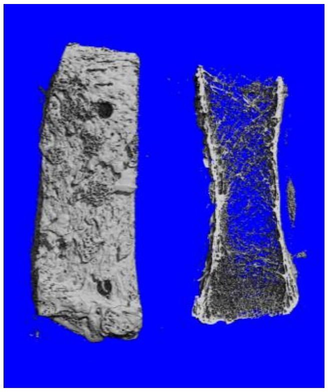


Appendix K – Preliminary MicroCT Data and Images

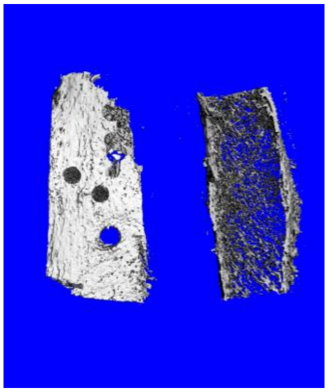
Group	Sample #	Bone Volume (mm^3)	Mean Density of BV (mg HA/cm^3)
II	L1	582.8889	847.6940
II	L3	249.3252	840.9200
II	R1	195.5781	865.7576
II	R3	253.7932	910.3521
	Mean	320.3964	866.1809
	Std Dev	176.983071	31.25781306
	COV	55.2%	3.6%

Group	Sample #	Bone Volume (mm^3)	Mean Density of BV (mg HA/cm^3)
IV	L2	318.6286	831.8883
IV	L3	374.6085	847.5999
IV	L4	355.3242	819.9399
IV	L5	231.9777	905.4598
IV	R2	589.4540	801.9705
IV	R3	356.6064	807.6153
IV	R4	356.9291	808.2739
IV	R5	254.9380	843.9307
	Mean	354.8083	833.3348
	Std Dev	108.119678	33.74813902
	COV	30.5%	4.0%

Christakis 08-01: Sternum



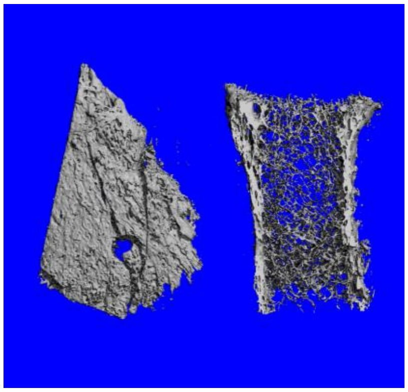
Sample L1



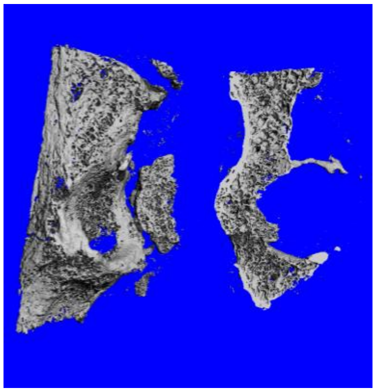
Sample L3

Group II

Christakis 08-01: Sternum



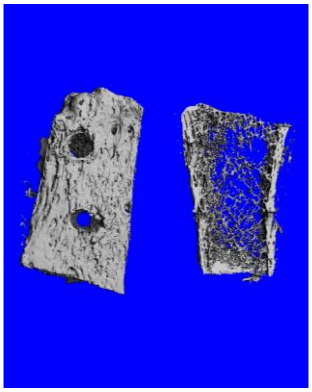
Sample R1

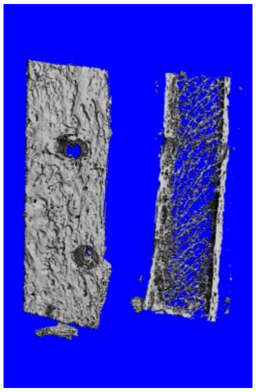


Sample R3

Group II

Christakis 08-01: Sternum



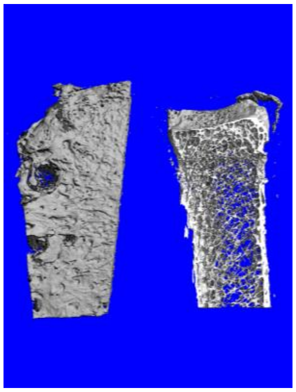


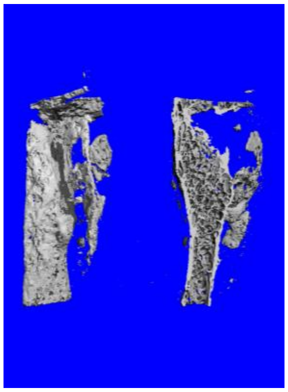
Sample L2

Sample L3

Group IV

Christakis 08-01: Sternum



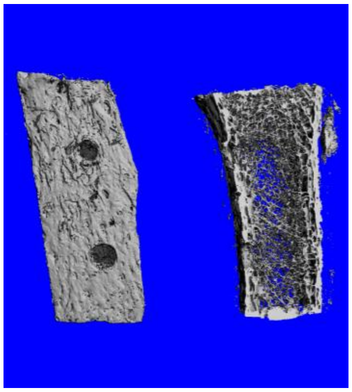


Sample L4

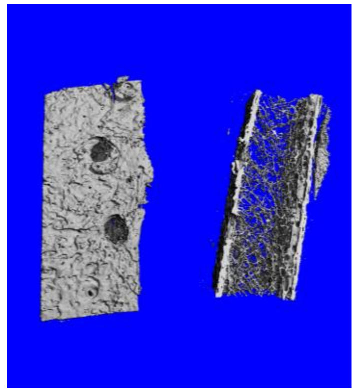
Sample L5

Group IV

Christakis 08-01: Sternum



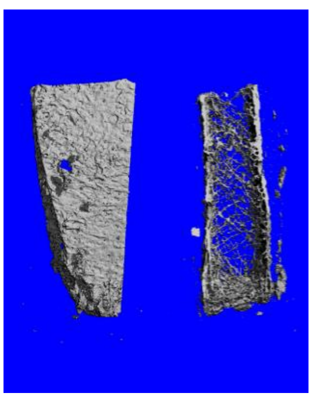
Sample R2



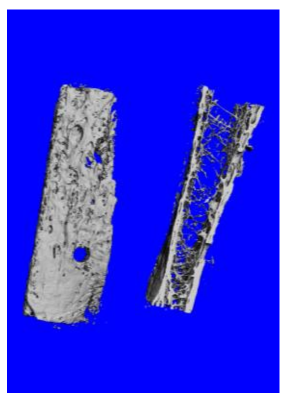
Sample R3

Group IV

Christakis 08-01: Sternum



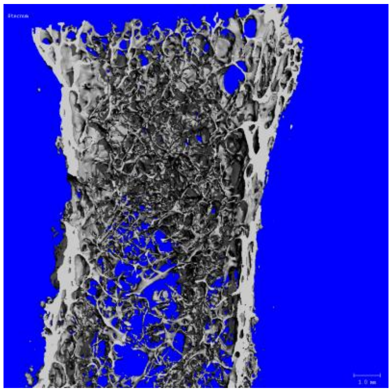
Sample R4



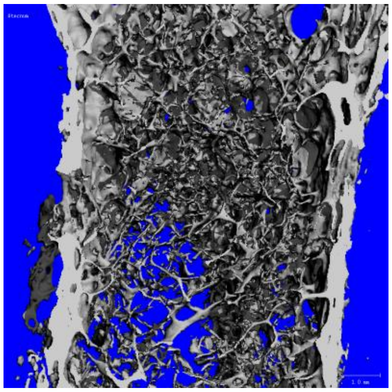
Sample R5

Group IV

Christakis/Billiar 08-01: Sternum

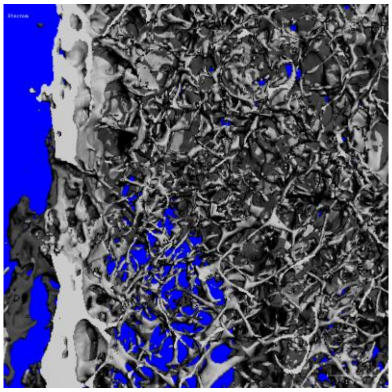


2X



3X

Christakis/Billiar 08-01: Sternum



4X