Design of a Screw Plate System to Minimize Screw Loosening in Sternal Fixation

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3) Bone Screws

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

Abstract

The use of screw-plate fixation devices after sternotomy procedures is becoming more prevalent with studies showing the mechanical superiority of such devices. However, there is no current device that is capable of supplying both the compressive and locking forces needed to optimally fixate the plate to the bone. The goal of this project is to create an anti-wobble screw-plate fixation device capable of reducing sternal displacement after fixation using clinically relevant materials. The design achieves this anti-wobble effect through the use of a modified one piece, two-part screw that allows for full compression between the bone-plate interface before locking into the plate. The device was designed and manufactured to clinical specifications in the final prototype, and the anti-wobble concept was tested in a bone analog and human cadaveric sternum using an earlier prototype. Using a uniaxial mechanical testing machine, cyclic loading from 0 to 25N was applied for 15,000 cycles to mimic breathing forces. The anti-wobble concept, having both compression and locking, reduced displacement of the bone plate on a sternal segment. In a bone analog, the displacements for standard nonlocking and anti-wobble systems were 0.57mm and 0.20mm, respectively. The experimental results indicate that the anti-wobble system may significantly minimize screw-displacement, and a clinically relevant product was developed.

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1 Introduction

In 2006 there were an estimated 81.1 million cases of cardiovascular disease reported in the United State, which includes people suffering from coronary heart disease, stroke, high blood pressure, heart failure and high cholesterol (Heart Disease and Stroke Statistics, 2010). Of these reported cases, there were approximately 700,000 open-heart surgeries performed for that year.

During the open-heart procedure, a sternotomy is performed on the patient, where the sternum is laterally bisected to give doctors access to the internal organs. After the surgical procedure, the sternum needs to be closed up using a fixation device to restore mechanical stability to the sternum during the healing process. Of all these sternotomy procedures, there is a 0.5%-8% rate of sternal dehiscence, the process sternal separation in the lateral direction. This can lead to mediastinitis where inflammation and infection occur at the wound site. The mortality rate for patients in whom sternal dehiscence occurs is between 10%-40%. Factors such as AIDS, weight, and osteoporosis can affect the rate of sternal dehiscence, which in turn affects the mortality rate (Bek & Yun, 2010).

The current preferred surgical method for sternal fixation is using 5-7 stainless steel wires to hold the two sternal halves together. This method is preferred because of its proven success, low cost and ease of installation. The drawback is that older patients, whom the surgeries are done on, have more osteoporotic bone, which lowers its mechanical properties. This can lead to pain and inflammation due to the wires digging into the sternum which can ultimately lead to failure of the device, because it breaks the bone. The use of sternal wire fixation has also led to complications such as wound dehiscence, infection, mediastinitis and sternal nonunion (Grossi, Culliford, & Krieger, 1985). If the device does fail, doctors have to go back into the patient and perform a secondary surgery. Studies have suggested that a rigid sternal fixation system can reduce the sternal dehiscence and failure rates.

Due to this disadvantage, a better method of sternal fixation is required for those patients who are not suitable for the wire fixation method. Screw plate systems have been applied to other areas of the body such as the leg or the clavicle. Recently, screw plate systems have been designed for the sternum to account for the high percentage of cancellous bone and lowered mechanical properties of the sternum. Current sternal screw systems use bicortical screws to get purchase on both layers of the cortical bone in the sternum but this can pose a problem for the patient as the screw must not come in contact with the vital organs below the sternum.

The goal of our project is to design a rigid sternal fixation system to minimize screw loosening and help sternal bone healing. Our project will focus on designing a locking screw and plate system to have lower lateral displacement and improve biomechanical stability of the sternum compared to the currently available devices. It will be testable on cadaverous human hemi-sternum and a prototype will be created out of aluminum to save on initial supply costs.

2.0 Background

2.1 Clinical Statistics

In 1980, less than 300,000 open-heart operations were performed. In 2004, nearly 700,000 were done. In this short time span, the number of open-heart surgeries more than doubled (Heart Disease and Stroke Statistics, 2007).

During any open-heart operation, a median sternotomy is performed, where the sternum is bisected in order to access the chest cavity. Roughly 750,000 median sternotomies are done every year in the United States. After this procedure is done, sternal closure is performed. Of all these closure procedures, there is a 0.5% to 8% rate of sternal dehiscence, the process of separation of the sternum, occurring. The mortality rate of patients in whom sternal dehiscence occurs is between 10% and 40%. Patients over the age of 75, who are morbidly obese, or with a history of osteoporosis have a higher rate of sternal dehiscence, and subsequently high mortality rates (Bek & Yun, 2010).

2.2 Sternum Anatomy and Physiology

The sternum, or the breastbone, is located in the anterior midline of the thorax. It is about 15 cm long and formed from the fusion of three bones: the manubrium, the body, and the xiphoid process. The manubrium is the upper portion of the sternum where the bone is thick and dense. The body, also known as the midportion, is the bulk of the sternum. The xiphoid is the lower section of the sternum. The manubrium and midportion have sufficient mechanical properties for use in fixation, while the xiphoid does not. The sternum is a small, variably shaped process composed of ossified cartilage (in adults).

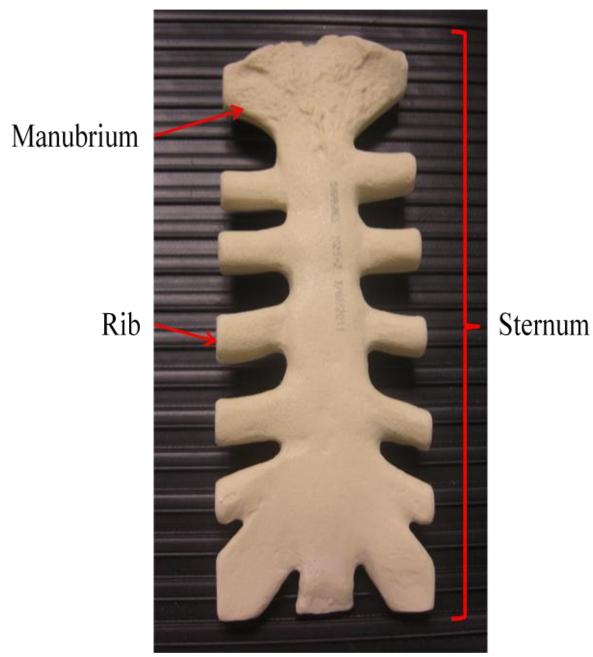

Figure 1: Sawbone sternum model.

The sternum is composed of both cortical and cancellous bone. Cortical bone is a dense bone while cancellous, or spongy bone, is made of thin plates in a loose, porous structure. The sternum is comprised of a large amount of cancellous bone with a thin cortical shell. Most of the mechanical properties of the sternum come from the cortical bone layer. Above the sternum is the periosteum, a dense fibrous membrane. In many elderly patients in whom the sternotomy is performed, the bone is osteoporotic. Osteoporotic bone has a lower apparent density, largely reducing the stiffness and strength of the bone. Consequently, osteoporotic bone deforms easier and will fracture under lower loads. This can make the sternal closure procedure difficult, as the compromised mechanical properties make the bone more susceptible to failure and sternal separation can occur. (Fundamentals of Biomechanics, 206-210)

During respiration, the ribcage, sternum and diaphragm all move together to pump air out of the body. The diaphragm is a thin, flat muscle that separates the thoracic cavity from the abdomen wall (Koeppen & Stanton, 2010). During inspiration, the diaphragm contracts into the abdominal cavity, creating a negative pressure inside the chest. The external intercostals muscles help create more negative pressure during inspiration by moving the ribs upward and forward (Koeppen & Stanton, 2010). During expiration, the abdominal wall and internal intercostals muscles work together to shrink the thoracic cavity. The rectus abdominis and oblique muscles help push the diaphragm up while the internal intercostals muscles pull the ribs closer together (Koeppen & Stanton, 2010). This cyclic loading that occurs during respiration exerts significant force on the sternum, which must hold the rib cage together during this process. A sternal closure method needs to provide sufficient mechanical stability to the sternum to accommodate these forces.

2.3 Sternotomy procedure

In the majority of cardiac operations, a median sternotomy is performed. The median sternotomy is a quick procedure for the opening and closing of the chest cavity, and is familiar to many surgeons. In this procedure, the sternum is bisected longitudinally down the center using a power saw. After the sternum is bisected, the two halves are retracted so that operation can be performed. During sternal closure, five to seven stainless steel wires are used for sternal fixation. Complications, such as sternal dehiscence, leading to infection, can arise from sternal instability resulting from the non-rigid fixation method currently used (Shields, 2009).

2.4 Current Methods

There are a variety of non-rigid and rigid sternal closure methods currently being used. There are advantages and disadvantages to each method, which need to be considered by the surgeon when choosing the proper fixation method for the patient.

2.4.1 Non-rigid Fixation

Non-rigid fixation methods allow for movement of the sternal halves and there are a variety of wire configurations used by surgeons. These methods allow for movement during everyday activities but it can pose problems such as sternal dehiscence and sternal nonunion in osteoporotic patients. Sternal osteosynthesis cannot occur with sternal gaps greater than 2mm and Ozaki et al. showed that wire ties can result in lateral displacements of 2.46±2.7mm (Ozaki, 1998). Wire fixation methods have a failure rate of 0.5-4% and failure of individual ties can result in more motion of the sternum causing increase sternal dehiscence. The advantage of wire ties is its low cost, six sternal wires cost approximately 40$ whereas three titanium plates with twelve screws cost approximately 500$ (Ozaki, 1998).

2.4.2 Rigid fixation

Rigid sternal fixation can hold the sternum tightly and prevent lateral movement and sternal nonunion. Titanium plates can help minimizes sternum mobility and holds the sternal halves together. The solid metal plates allow for screws to be inserted away from the sternotomy cut, thus hold the bone more rigidly. Surgeons have also stated that rigid fixation with plates can be quicker than tying carcelage wires. The complications include screw loosening due to repeated movement of the sternum and the thoracic cavity (Ahn & Christakis, 2009).

2.4.3 Cerclage Wire

The current method of using stainless steel wire for sternal fixation has been used since 1957, and is still the standard fixation method (Ozaki, 1998).In this method, stainless steel wires are used to close the sternum after surgery. In this procedure, five to seven stainless steel wires are twisted around and buried in the sternal tissue. The pectoral fascia is closed using a PGA (polyglycolic acid) suture.

This method is preferred because of its proven success, low cost and ease of installation (Shields, 2009) (Cohen, 2002). The drawback is that older patients tend to have more osteoporotic bone, causing the stainless steel wires to cut and wear into the less dense bone of the sternum. This leads to complications such as wound dehiscence, infection, mediastinitis and sternal nonunion (Grossi, Culliford, & Krieger, 1985). If the device does fail, doctors are forced to go back into the patient and perform a secondary surgery. Studies have suggested that a rigid sternal fixation system can reduce the sternal dehiscence and failure rates (Song, 2004) (Cicilioni, 2005) (Syzdlowski, 2007). Overall, the need for a more biomechanically friendly device is critical in helping more patients survive through these very tough and challenging surgeries. Patients with mediastinitis have much higher mortality rates, increased length of stay and increased healthcare costs (Moerenhout, 2009).

Figure 2: Wire cerclage around a sternum model.

2.4.4 Rapid Sternal Closure Talon System

The Talon system is a rigid fixation device created by KLS Martin that offers great mechanical properties for rigid sternal fixation without the need for screws. The Talon has a titanium double-foot hook that pulls the two sternal halves together using a ratchet mechanism, as shown in Figure 3. A screw on the anterior surface can lock-in the device so that the two halves are always pulled together. This system is made for any cardiothoracic patient including morbid obesity, diabetes, chronic obstructive pulmonary disease and transverse sternal fractures. The ideal attachment of the Talon system can be seen in Figure 4. The Talon is a novel idea to rigid fixation but the high cost and non-functionality in osteoporotic bone make it less appealing to surgeons (Martin, 2011).

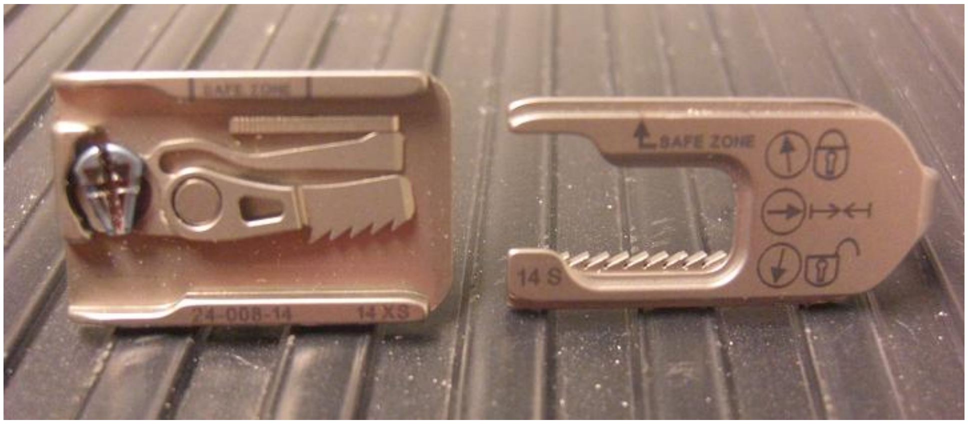

Figure 3: Picture of the Talon system. The double titanium hooks can be seen in the picture and the surface screw locks are also visible.

Figure 4: Picture of an ideal Talon system set up on a sternum.

2.4.5 Rigid Sternal Fixation with Plate Systems

Another alternative to standard wire fixation is rigid fixation with screw and bone plate systems. Bone plates have been shown to decrease motion and accelerate bone healing (Song, Lohman, Renucci, Jeevanandam, & Raman, 2004). Titanium alloy {Ti-6Al-4V} plates have been recognized as the plate of choice when choosing a material for internal fixation of fractures for over a quarter of a century due to its increased strength and overall bioactivity (Uhthoff, 1981). The titanium alloy is bioinert, and does not degrade in the body. Titanium plates have also been shown to increase bone growth and decrease soft tissue reaction.

Current screw plate systems, such as the Synthes Titanium Sternal System (Synthes, Oberdorf, Switzerland, 2007) involve both titanium plates and titanium screws within its system. Synthes also creates a wide variety of shaped plates; H plates, X plates, T plates and straight plates that can be bent and altered to fit sterna of all sizes. An image of the implanted Synthes plate can be seen in Figure 5. The Synthes system also uses self-tapping locking screws that can be secured tightly onto the titanium frame. This fixation method extends the plating system into the ribs, which can limit the compliance of the thoracic cavity during respiration.

Figure 6: Custom H plate created by KLS-Martin. It has 4-2.3mm holes and the plate is made out of titanium. (Ozaki, 1998)

Figure 5: SternaLock titanium locking plates that can be contoured with pliers to better fit different sized sterna. (Song, 2004)

2.5 Screw Design Parameters

In the screw-plate system for sternal fixation, the screw serves to provide sufficient force to press the plate against the bone. In locking systems, the screw also has separate threads on or near the head, which serve to firmly lock the screw in place, to prevent screw loosening from occurring. Self-locking and self-tapping screws are generally used for this system, as the self-tapping screw drills its own hole so pre-drilling of the site is not required. The self locking component serves to fix the screw in place to limit backing out or loosening of the screws. Usually a combination of these different screw types are used in order to obtain the necessary press fit of the plate against the bone, and to provide a locking component to limit distraction of the system.

The main components of the screw are the head, core, and threads. The head transmits the initial torque to the core and threads, and can act as a stop when it comes in contact with the bone. The core is the minor diameter, or the diameter of the core of the screw. The threads have a pitch and depth. The pitch is the spacing between threads, while the depth is the distance from the core to the outer diameter of the screw (An & Draughn, 2000). These screw parameters are altered in various screw types to help the different screw types function better in certain situations.

2.5.1 Current types of screws used

There are several types of screws being used for fixation methods. Each one has different parameters that allow it to function better in certain situations.

2.5.2 Cortical vs cancellous screws

The differing properties of cortical and cancellous bone lead to these different screw types. Cortical bone is much stronger and offers high mechanical properties. In cortical screws the threads are spaced closer together and the pitch is smaller. In cancellous screws, the threads are spaced farther apart and the pitch is larger so the threads can compress the cancellous bone and obtain better holding properties. It was hypothesized in previous studies that because of the high concentration of cancellous bone in the sternum, cancellous screws would provide better fixation. This was not the case in osteoporotic sternum though, since the thin cortical shell retains its mechanical properties but the cancellous bone is degrades/compromised to its properties are not useful or sufficient to assist in fixation. (Decoteau, Flannery, Hart, & Zec, 2005)

2.5.3 Standard vs Locking screws

Standard screws have an unthreaded section at the top of the screw so the screw is able to press the plate down against the bone. Locking screws have threads around the cap that mate with threads in the plate to lock the system in place. The press fit obtained from using standard screws is necessary to ensure there is no gap between the plate and bone interface. The locking effect obtained from the locking screw plate systems is also a necessary feature of the screw plate fixation system as to prevent screw wobble and loosening. Currently using both types of screws in the screw plate system is used, but this increases the number of screws the surgeon must install during the screw plate installation procedure. An ideal screw would be able to combine the properties of both these screws into a single piece screw.

2.5.4 Bicortical vs unicortical purchase

Bicortical screws are ones which go through both cortices of the bone. These are traditionally used in many screw plate systems that are currently used. By obtaining purchase on both cortices, more mechanical stability is obtained and better fixation is thought to occur from this. The main drawback of bicortical screws is since they pierce the second cortical layer, they risk puncturing organs and tissues located below the bone. This is a large concern for surgeons as when these bicortical screws are used for sternal fixation, using a screw that is not measured properly and is too long, may result in puncturing the heart or other tissues located below the sternum. Unicortical screws only purchase the top cortical layer. This is viewed as safer than the bicortical purchase as the screw will not have the chance of puncturing vital organs located below the site. The major drawback of using unicortical screws is they provide less stable fixation. Generally bicortical screws are the preferred screw type since having sufficient holding strength is the main concern of surgeons so the screws are measured carefully so the proper depth or length is used.

3.0 Project Strategy

The overall goal of the project is to design an anti-wobble screw –plate system that is more successful than preexisting sternal screw-plate fixation systems. In order to produce a better device, it is crucial to understand the gaps in knowledge and technology with the current devices. With the direction of our client, Dr. Raymond Dunn of the University of Massachusetts Medical Center in Worcester, MA, our project team was able to determine the following objectives, functions, and constraints to develop the project.

3.1 Client Statement and Project Goals

Before starting the design process, information on sternal screw-plate systems was gathered through recent literature and a series of interviews with our client. Based upon the needs and wants of Dr. Dunn, a client statement was developed.

> ***Initial Client Statement:*** *Design and build an ideal anti-wobble screw-plate sternal fixation device capable of reducing sternal displacement post sternotomy more effectively than existing systems. The device must supply "rigid sternal fixation" in the stabilization of two full hemi-sterna. A quick and easy installation and re-entry method should be determined. The device must not endanger the patient or surgeon. Validation testing on the device must be done using cadaverous sterna.*

After research on the preexisting systems, the project team sought to design a new anti-wobble system focusing on the interface between the device and the bone, as this is where the project group felt was the biggest gap of knowledge in the development of a sternal fixation device. The device would include the best characteristics of pre-existing models, while being able to add increased stability to the device with an anti-wobble system. An ideal anti-wobble system should be able to apply both a compressive and locking force to the plate to ensure maximum mechanical abilities. The device chosen should be able to accomplish the intended objectives and functions and while staying within the proposed constraint limits. The following is a list of the overall project objectives, functions, and constraints.

3.2 Objectives

The list of objectives below was created for the client to identify what the exact needs and wants that an ideal device would be able to provide. The design team was able to obtain four main objectives based upon the interviews and recent literature. Overall, the device should, safe, provide strong stabilization of the separated halves, allow for ease of use during surgery, and should be a simple design that allows for quick, reproducible manufacturability.

1. Device should provide rigid stabilization of sternum
    a. Strong bone purchase
        i. Maximize bone-plate interface
        ii. Anti-wobble
    b. Maintain proper alignment
    c. Limits distractions- multidirectional
    d. Adjustable sizes and curvature
2. Device should allow for ease of use
    a. Surgery
        i. Minimize installation time
        ii. Minimal device parts
        iii. Minimize need for specialized surgical tools
        iv. Small learning curve for adaptation of surgical procedures
        v. Minimal surrounding tissue damage
3. Device should be safe to use
    a. For Surgeon
        i. No sharp edges, etc
    b. For Patient
        i. Easy Removal/Re-entry
        ii. Limit osteonecrosis and stress shielding
        iii. Lower post-operative complications
4. Market Potential
    a. Simple parts easy to manufacture
    b. Surgical consistancy

i. Able to repeatedly produce similar results
ii. Maintain mechanical integrity

c. Low material cost
d. Reproducible but still able to be specialized to individual patient

3.4 Pairwise Comparison Chart

These objectives were then ranked by the client in order of importance using a Pairwise comparison chart seen in the table below. Scoring was completed by entering a 1 for the objective in which the scorer felt was more important. If the scorer feels they are of same importance, the score can be split into 0.5 each.

Table 1: Pair-wise Comparison Chart for Sternal Fixation

Objectives	Safe	“Rigid”Sternal Fixation	Ease of Use	Market Potential	Total
Safe	X	1	1	1	3
“Rigid”Sternal Fixation	0	X	0	0	0
Ease of use	0	1	X	1	2
Market Potential	0	1	0	X	1

As can be seen in the figure, safety and ease of use were marked as the most important design objectives. This does not mean that the other objectives are not important, it just simply implies that the client feels that it is more important to optimize the safety and ease of use to create a better device. During the interviews, the surgeon provided some explanations for this reasoning. He felt that if one was to maximize the safety and user friendliness of the device that it would automatically translate into an improvement of marketing potential and rigid fixation. After all, the device cannot be considered safe and offered to patients if it does not supply fixation. The doctor felt that as long as the device works as well as current devices in reducing sternal displacement that optimizing other parameters would be more beneficial to the device.

3.4 Functions

After creating the list of objectives, the project team created a list of functions which describe the means in which to maximize these objectives. There are four separate functions, each of which plays an important role in the development the design system.

1. Mechanical
    a. Rigidly holds sternum halves together
        i. Minimizes sternal displacement and limits screw movement (anti-wobble/locking)
        ii. Achieves strong cortical purchase in bone
        iii. Alignment is maintained throughout full sternal healing
    b. Allows easy removal in emergency reentry situations
    c. Increases bone-plate interaction
    d. Applies compressive and locking force

2. Biological
    a. Does not destroy periosteum
    b. Enables bone formation and growth
    c. Limits Osteonecrosis

3. Manufacturing
    a. Machinability
        i. Correct part sizes, not too small
        ii. Allows for limited number of overall parts
        iii. Ability to be sterilized
    b. Increase speed of production with design simplicity

4. Surgical
    a. Minimize necessary tools
    b. Reduce operation time
    c. Increase ease of screwing

3.5 Constraints

The list of constraints shown below represents the parameters in which the design of the device must follow. These constraints must be followed in order for the design of a successful device. The device must be safe, fit within the given budget for the project, and must be able to reduce sternal displacement as well as current devices on the market. In order to validate the design, the device must be tested using cadaveric sterna. Time constraints such as deadlines, deliveries and machining all must be remembered during the design process in order to create a successful device.

1. Safety
    a. Biocompatible
    b. Quick and easy re-entry into chest
    c. Overall safety, no sharp edges, etc.
2. Time
    a. Project deadlines
    b. Machine shop openings
    c. Machining turn-around time
    d. Parts delivery
3. Budget
    a. Amount given for project
    b. Cost of materials
4. Must reduce sternal displacement as well as current devices
5. Must be tested on cadaverous sterna.

With these objectives, functions, constraints and overall needs identified, a final client statement was created.

Final client statement:

Design and build an ideal anti-wobble screw-plate sternal fixation device capable of reducing sternal displacement post sternotomy comparable to recent devices. The device must supply "rigid sternal fixation" in the stabilization of two full hemi-sterna, and should only allow for minimal amounts of screw loosening. The device must contain both a locking and compressive mechanism that will enhance the bone-plate interface. A quick and easy installation and re-entry method should be determined. The device must not endanger the patient or surgeon. Overall the device should be fairly simple, easy to use and easy to manufacture. Validation testing on the device must be done using cadaverous sterna.

3. 6 Device Design

The goal of the project is to design a screw-plate system that not only performs as well as current models, but can also significantly reduce screw loosening caused by the inefficiency in other models. The lack of current devices to be able to supply both a compressive and locking force at the bone-plate interface allows for a breadth of design ideas that could be possibly used. Using the objectives, functions, constraints, literature and imagination, the project team was able to create four alternative designs. Each design represents a different mechanism in which a locking and compressive force can be applied to the bone plate interface to achieve an anti-wobble effect. Each device was brainstormed, drawn in SolidWorks, and then analyzed by the team for overall advantages and disadvantages. The top design was then chosen and will be used for prototyping and testing.

3.6.1 Design Alternative I

The first design alternative utilizes a two piece screw that arrives as one assembled part to the surgeon as part of a plate/screw system. The design utilizes standard sternal fixation plates and will only require one tool for surgical installation. The screw is also unicortical and of both the compression and locking type. The two part design is essentially a screw within a screw and functions . This alternative was designed to optimize two important functional considerations: ease of use by the surgeon and manufacturability.

3.6.1.1 Detailed parts description

The outer screw functions identically to a compression unicortical screw with the exception of the screw head-plate interface. As seen below in Figure 7, the outer screw has a countersunk head with radial expansion slits around its circumference. The bottom of the countersunk hole will have receiving threads for the internal screw. A standard unicortical thread pattern on the distal bone interfacing screw body will be employed as well as a self-tapping and self-drilling tip. The bottom of the outer screw head will also have a roughened surface that will interface with the bottom of the plate welling.

Figure 7: Exploded design

The inner screw of the design will fit into the top of the outer screw with its wedge pitch being the same angle as the outer screw's receiving countersink, but the wedge length will extend past the top of the outer screw. A standard Phillips head surgical tool can be used to interface with top of the internal screw.

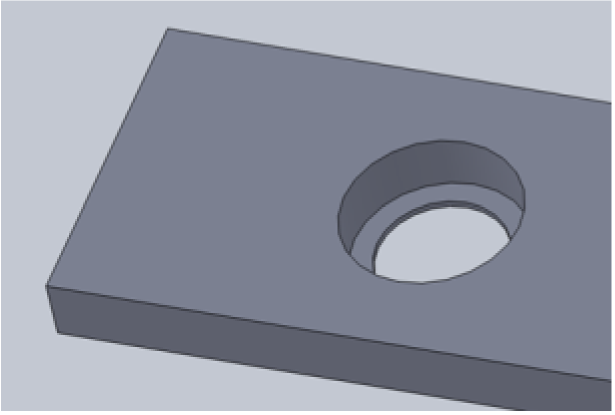

Figure 8: Standard fixation plate compatibility

3.6.1.2 Device Functionality

When the inner screw is mated with the female threads on the inside of the outer screw, and gently tightened, it is pulled down into the body of the outer screw. This is the state of the device at which the surgeon will receive it. The screw is then inserted into the plate and bone through normal surgical procedure. When the screw has reached a tightness determined by the surgeon for compression fit of the plate to the bone, the surgeon will exert a downward force to engage the roughened outer screw head's bottom surface with the fixation plate's well surface. This will create enough of a frictional force to allow the inner screw to continue to rotate into the outer screw internal body (and without stripping the bone), thus creating an outward wedging force on the outer screw head. The expansion slits will allow the head of the outer screw to expand into the walls of the plate, causing a force induced locking mechanism that will hold the screw tightly at the plate interface. Figure 8 shows a cross-sectional view of the design that details the forces produced by the inner screw on the outer screw.

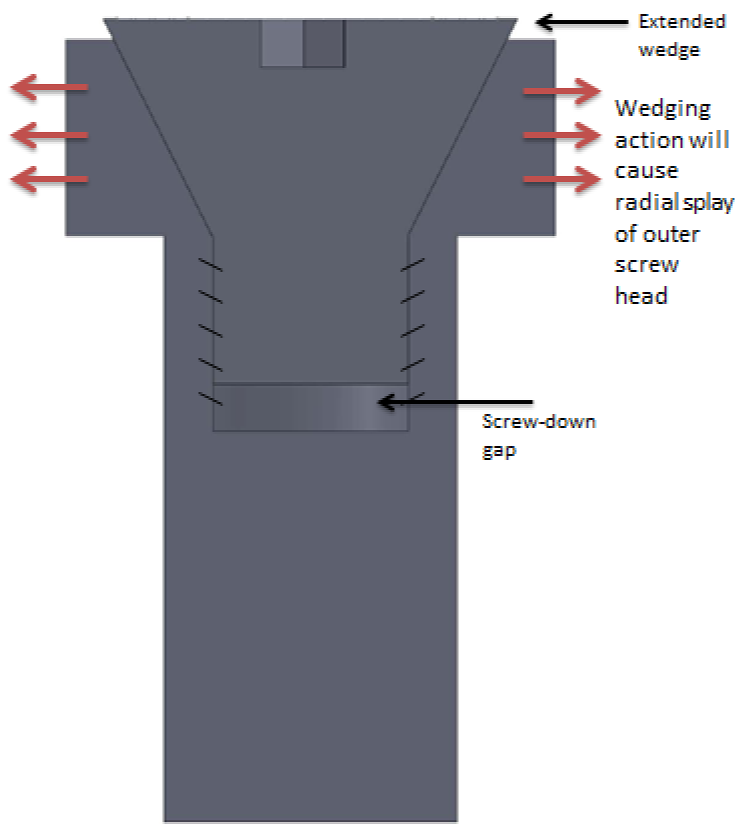

Figure 9: Cross sectional view of assembled design

3.6.1.3 Device Advantages/Disadvantages

This two part screw design aims to allow for the functional requirements of rigid sternal fixation, while optimizing the ease of use for the surgeon and manufacturability. Based on interviews with the client it was determined that the design needed to be one piece and easy to install for a cardiac surgeon. This design is very advantageous to that respect because it allows for the surgeon to utilize the screw exactly how he would use a normal compression screw. The only added motion required for locking is a downward press that engages the rough bottom surface. This design requires one tool and a very minimal learning curve for the surgeon. The second advantage is the simplicity of the design that will facilitate manufacturing and lower costs. A standard inner screw could be utilized in the design and the outer screw could even be machined from a standard screw itself.

The disadvantages of this design are related to the material design and emergency removal considerations. First, if both parts are made out of titanium, the force required to outwardly splay the screw head into the also titanium plate may be too high for the surgeon to exert by hand. Second, the emergency removal of the screw will most likely require a second tool that can hold the outer edge of the outer screw while the inner screw is removed. The outer screw could then be backed out safely.

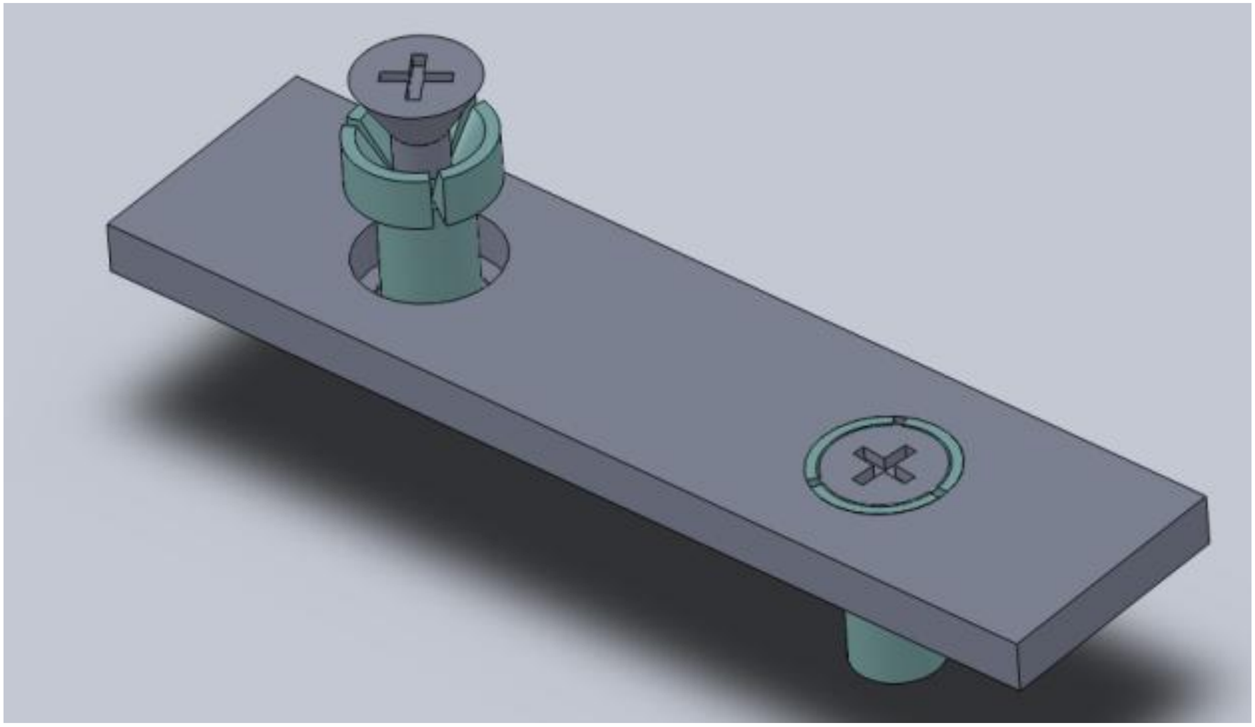

Figure 10: Complete screw and plate model

3.6.2 Design Alternative II

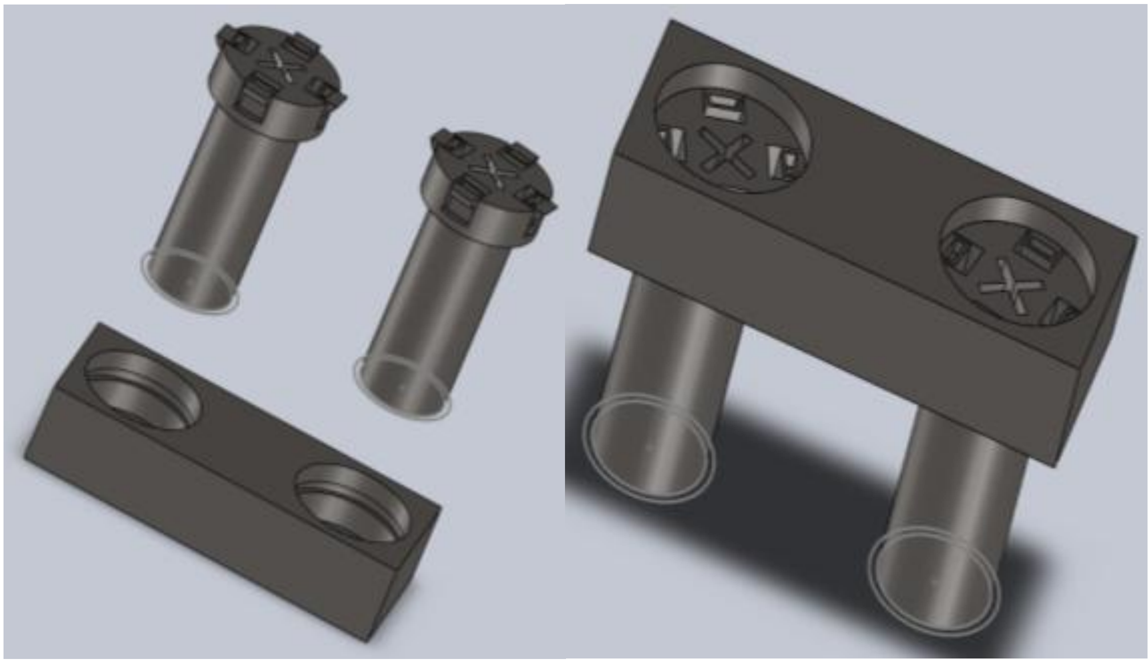

Figure 11 Overview of Design

From our client statement, our system for rigid sternal fixation needed a single piece screw having both a lag component, and a locking component. The lag component would ensure a press fit of the plate on the bone, while the locking component would prevent screw loosening.

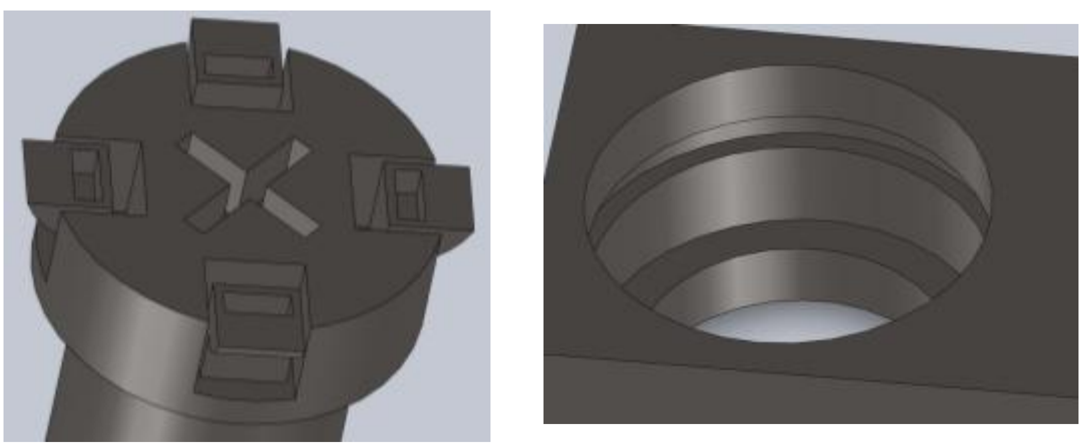

Figure 12 Close up view of winged screw head and grooved plate

In this design alternative, the locking mechanism involves 4 wings that are pinched back during installation. This can either be done with a special tool or the screw can be preassembled with the wings pinched back, having a clip to hold them in place. The screw then functions as a standard screw during surgery. Once the press fit is obtained, the user would remove the clip holding the wings back and they would lock into place. If the screws needed to be removed, the wings could be pinched back using a specialized tool, and remove the locking mechanism so the system could be uninstalled.

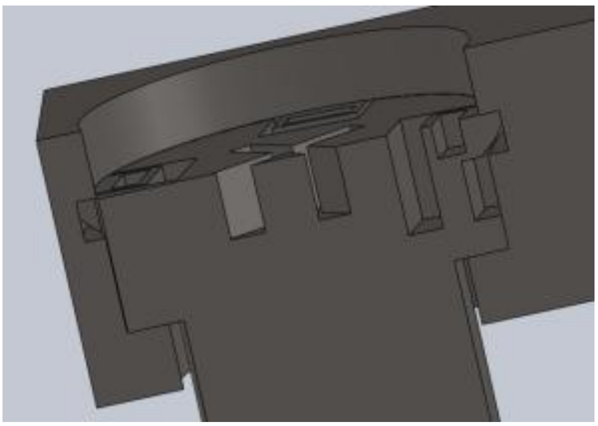

Figure 13 Cross Section view of system after installation

Advantages of this design are it uses a single piece screw, has an emergency release mechanism, would be simple to use, and no similar designs were found in patent searches. Disadvantages include manufacturability as these screws would be millimeters in diameter, and the necessity of a specialized tool to pinch the wings back during installation.

3.6.3 Design Alternative III

This design alternative is a screw-plate system with locking wing clips on the screw. The three-piece screw is preassembled and the head can rotate freely to lock into the plate. The plate has two screw holes, one for each half of sternum, and a series of notched sides for the locking cap to fit into.

The three-piece screw consists of a screw head, rotating middle piece with wing clips to lock into the plate, and a screw shaft that will go in to the sternum, as seen in the figure below. The screw shaft is 2.3mm in diameter while the cap is 3.0mm in diameter. The screw will be unicortical, so varying screw lengths will be used. As the top piece is screwed down, it will tighten with the bottom shaft piece and lock the whole system into the screw. The screw system will be 3 pieces but come pre-preassembled. The middle piece needs to be rotated by the surgeon so the wings can lock and be tightened against the plate.

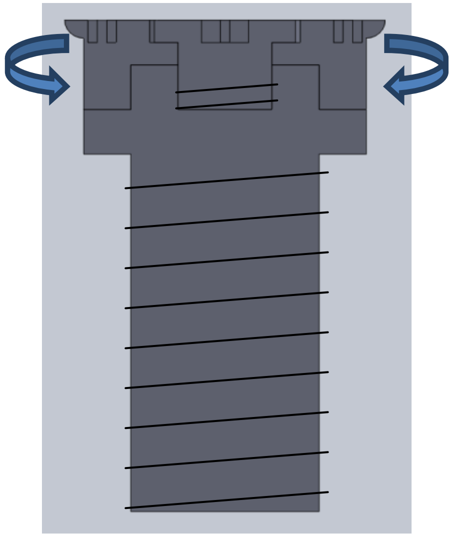

Figure 14: Schematic of three piece screw.

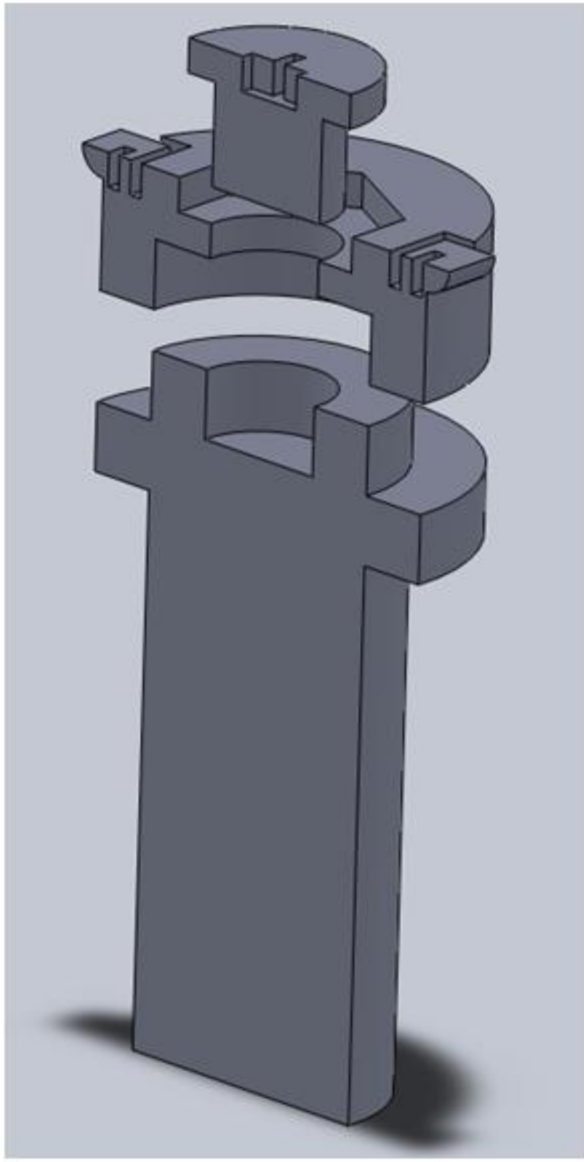

Figure 15: Exploded cross-section view

The advantage of this design is the increased stability from the three points of contact to the screw; the wings, threaded plate, and the bone. This will minimize the sawing motion created by the screw. The notches allow for different levels of screw entry based on the contour of the sternum, if there is a curvature of the bone, the plate can’t get close to the bony surface. The plate designed used is not limited to a straight plate; an X-plate could offer much more stability of the entire system. This screw system is also a novel anti-wobble design so there is a lot of market potential. The disadvantage of this system is the complexity of the screw parts. The pieces are very small and could prove hard to manufacture. Because our final implantable device will be titanium, the wing clips need to be compliant enough to snap in to each individual groove in the plate.

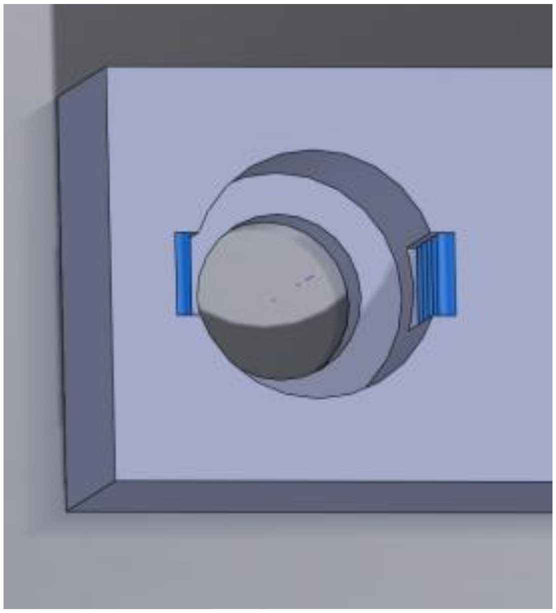

Figure 16:3D model of the plate interface.

3.6.4 Design Alternative IV

The next design alternative involves a one piece, two part screw in which the top of the screw is able to be locked and wedge into place due to its shape fitting properties.

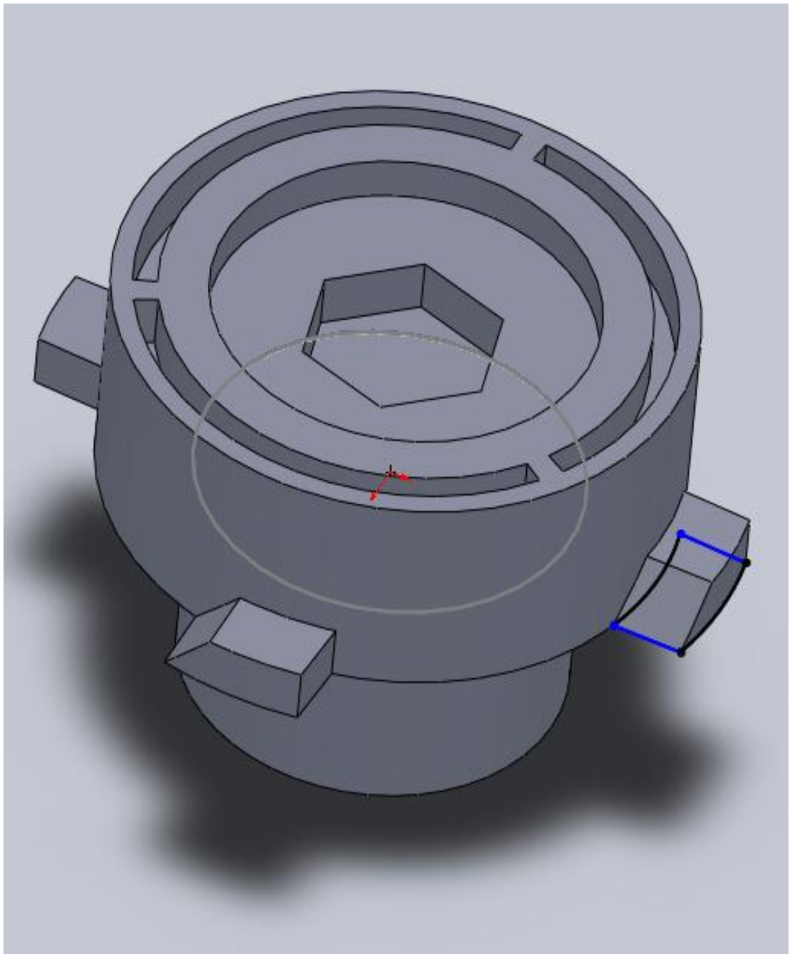

Figure 17: Screw and Cap head

Figure 17 shows the cap that will be used for the top of the screw. On the bottom and side faces are angled wings that allow the screw to be pushed down into the plate to allow for a compression force to be added downwards. Although not seen in the picture, only the top half of the inside circumference will be threaded, as this will allow the surgeon to push the screw top down into the hole before twisting the notched wings, locking them into place.

The inside screw, which has a hexagonal shaped head, will be completely threaded as a normal bone screw would be. The screw should be self-tapping as well as self-drilling. The middle screw will be the first part of the screw material to be entered into the plate. The plate can be seen below in figure 18.

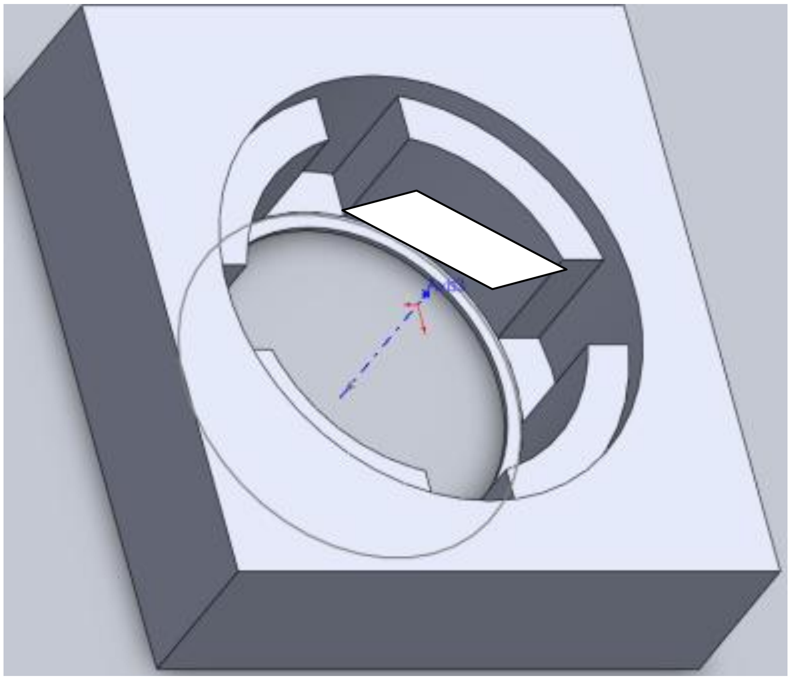

Figure 18: Plate design

Once the middle screwed is screwed in, and the cap has reached the top of the plate, the wings should be arranged in a fashion so that they fit the shape of the hole exactly. Once down to the bottom of the grooves, the cap can then be rotated and locked into the track that is located circumferentially around the bottom of the plate. The track will decrease is size by a slight angle, allowing the tapered edges of the wings to be wedged into the plate.

There are several limitations with a device like this. First of all, the plate holes are already very small and it would be very hard to manufacture such detailed plate holes. There is also the limitation in the possibility that the surgeon will not be able to get a full compressive fit before rotating the cap creating the locking mechanism. Another disadvantage is shown by the fact that more than one tool will be necessary to screw down the different parts. This will make it necessary to make extra tools, which is not cost effective. Overall the device has a strong theoretical concept, but does not seem to be able to be used in a practical manner.

3.7 Experimental Design

The project group designed an anti-wobble screw-plate system but the screw loosening performance needs to be compared to a standard unicortical screw-plate system to successfully validate the design. The goal of the experimental testing is to show a lower displacement of the screw-plate system after uniaxial cyclic loading tests in sawbone sterna and human sterna. A screw plate system will be tested on a single section of sternum to generate multiple data sets and while conserving testing specimen. Uniaxial cyclic loading will first be performed on sawbone sterna in order to obtain preliminary results for each screw-plate system and optimize the experimental protocol. After screw-loosening data is obtained in sawbone sterna, the cyclic loading tests will be repeated on human sterna. Results from human sterna testing will help validate the success of our anti-wobble design.

3.7.1 Methodology

The following methods were used for validation testing for the anti-wobble design. An Instron Electropuls E-1000 uniaxial testing device was used to perform cyclic loading tests to simulate respiratory forces. The Instron Console and Wavematrix programs were used to set the testing parameters including: force, frequency, and number of cycles. The program recorded displacement data over the testing time.

Measuring the displacement produced from the low force cyclic loading will help assess the performance of the screw-plate system. An extensomer was used to measure the displacement locally to remove any noise from the potting and fixation methods. A schematic of the testing can be seen in Figure 18.

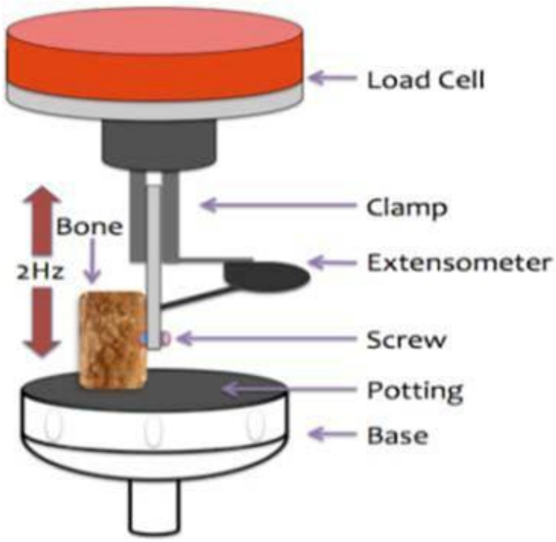

Figure 19: Schematic of testing setup

KLS Martin titanium mandibular reconstruction plates were used with 2.3mm cortical titanium screws. Due to manufacturing complications and time constraints, initial testing was performed using a similar anti-wobble device designed by John Dieselman. This device consisted of a two piece screw and cap system to achieve the delayed locking effect, similar to our one piece system. As seen in Figure 19, the anti-wobble system used for initial validation testing consisted of a thicker plate to accommodate the screw cap and used the same 2.3mm standard screw.

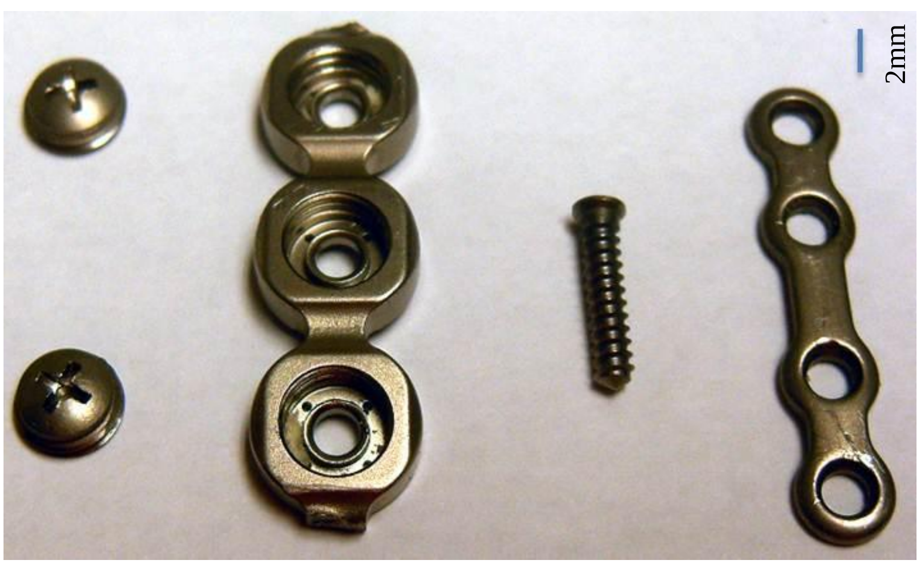

Figure 20: Cap and plate for anti-wobble system on the left. Screw for both systems in the middle. Standard plate on the right.

Initial testing was performed in Sawbone Sternal models. This testing was used to assess the testing protocol and make any necessary adjustments. Also this served as initial proof of concept testing to validate the "locking" mechanism before moving on to further validation in cadaveric sternum. In this low force cyclic testing, a 50N force transducer was used to apply a force of 50N at a frequency of 2Hz for 15,000 cycles. Each test took approximately two and a half hours.

Prior to testing, the sawbone sternal models were bisected laterally, and sectioned off by rib pairs. Two tests were performed on each piece of sawbone. For proper pairing, one standard system and one anti-wobble system were tested on each sawbone piece. Prior to testing, the sawbone piece was potted in a modified 1 inch PVC endcap using epoxy. Samples were offset to allow for proper uniaxial alignment in the Instron machine. Epoxy polymerization took approximately 30 minutes. After this, the sternal piece was rigidly secured in the cap. Then the sample was fixed into the gripper of the Instron using a custom made grip to grasp the plate. The setup can be seen in Figure 20.

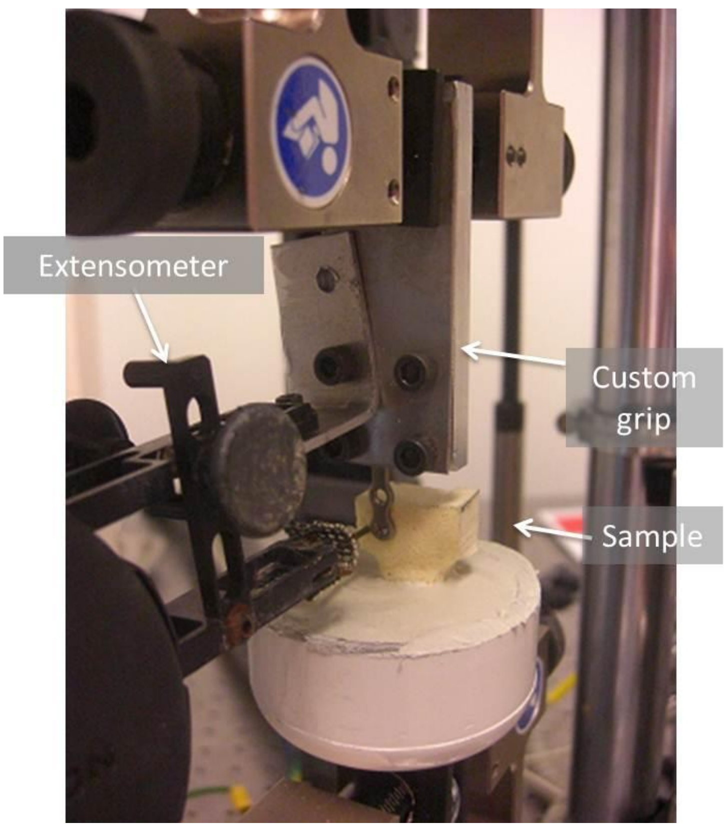

Figure 21: Actual instron testing setup.

3.7.2 Instron Electropuls Setup

In order to hold the sawbone pieces for testing, each sample was fixed into a PVC endcap using epoxy putty. 1.5in diameter PVC end caps were obtained from Lowe's Home Improvement and cut with a bandsaw so the final height was approximately 1.5 inches. This was done to make room for the extensometer while leaving enough space for the rib of each sternum sample. A 3/16" threaded hole was drilled and tapped into the end cap to screw in a 3/16" eye bolt and tightened with a complementary nut on the other side. The eye bolt allows the Instron machine grips to hold the sternum samples.

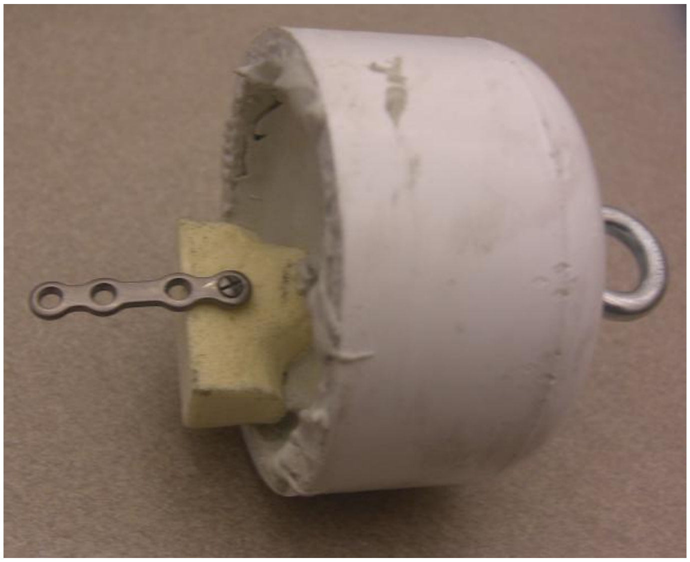

Figure 22: Setup of sample fixed in PVC endcap with eyehook.

Since the screws were not self-drilling, two holes were predrilled using a 1.9mm drill bit to accommodate the 2.3mm screws being used and prevent micro fractures from being produced in the sawbone during this initial setup. A wood screw was also screwed into the rib section of the sternum to more rigidly secure the sample in epoxy and prevent the sawbone from pulling out of the epoxy during testing. Sternum samples were fixed in the epoxy endcap by first screwing a bone plate into the sternum sample into one of the pre-drilled holes. The plate was attached to the upper grip on an Instron machine and lowered down to make sure there was enough clearance from the eye bolt inserted into the PVC endcap. Epoxy putty was then mixed and put into the end cap and the sternum sample was lowered again, this time into the hardening epoxy. The sternum sample was held in place for 30 minutes to allow the epoxy to cure fully. The fixed sample and epoxy endcap can be seen in Fig 22.

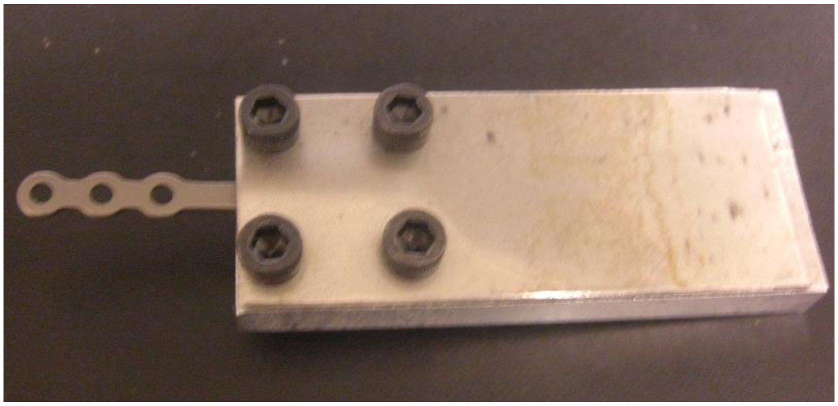

Figure 23: Custom grip to hold bone plate.

Because there is very little surface area to hold the bone plate, a custom grip was designed to withstand 15,000 cycles of testing. Two aluminum plates were used to rigidly secure the bone plate without. Four holes were drilled and tapped into the plates and four 8-32 hex screws were used to tighten the aluminum plates with the bone plate in between (Fig 23).

In order to set up the custom grip and fixed sternum sample, the bone plate is first inserted into the custom grip and tightened. Then a pilot hole is drilled into the sternum sample and the bone plate is secured onto the sternum sample with a single screw. The entire set up is then carefully placed into the Instron grips making sure the plate is parallel with the force transducers. Finally the Instron grips are tightened and testing begins. An image of the testing setup can be seen in Fig 20.

3.7.3 Testing Parameters

Instron Console and Wavematrix were used to program the cyclic testing for the Instron Electropuls machine. A 50Nload transducer was used and machine safety limits were set to 51N with the Instron Console program. A cyclic load testing method was programmed with Wavematrix. The test began with a 5-second ramping phase to set the sample load to zero. Cyclic testing starts when the samples are loaded from 0 to 50N, and then repeated for 15,000 cycles at a rate of 2Hz. Testing ends when the sample fails or 15,000 cycles are completed.

3.7.4 Modifications for Cadaveric Sternum Testing

A few modifications were made to the testing protocol for testing using cadaveric sternum. The human sternum was sufficiently weaker and had more irregular mechanical properties compared to the sawbone, so during potting in epoxy, the back of the sample had to be covered in epoxy to better stabilize it for more accurate results. This process can be seen in Figure 23.

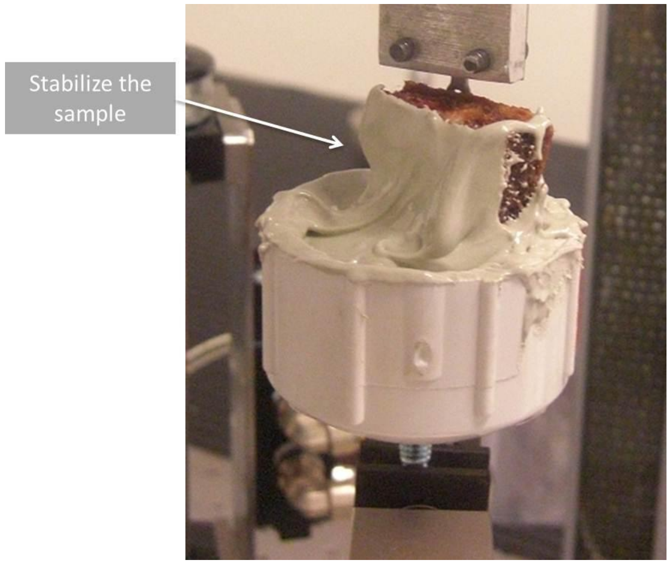

Figure 24: Cadaveric sternum with backside epoxied.

Also, during the 5 hours of testing on each sternal piece, the samples would dry out, affecting their mechanical properties. A humidifier and container were added to the testing setup to keep the sample moist for more uniform mechanical properties throughout the testing duration. This can be seen in Figure 25.

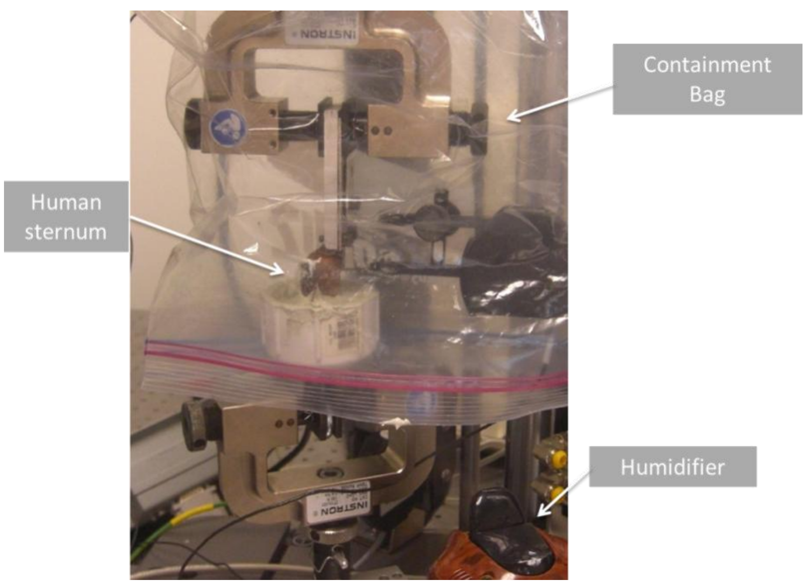

Figure 25: Testing setup with humidifier and containment bag.

4.0 Manufacturing

4.1 Prototype Manufacturing

To ensure the designed locking mechanism successfully prevents the screw from wobbling in the plate, a 5x prototype was manufactured. A steel 3/8-16 (0.375”) socket head cap machine screw was chosen as the ideal size for the outer screw. This was chosen because of the both the available tooling and the ease of manufacturability. A steel 10-24 (0.19”) countersunk flat head machine screw was chosen for the inner screw.

The head of the outer screw was first center drilled to half the screw depth with a #25 (10-24 standard) drill on the manual drill press. The blind hole was then threaded manually with a 10-24 tap drill and the top of the hole was countersunk to accommodate the seating angle of the inner screw. Finally, as seen in Figure 26 three cross-diameter cuts were made with a band saw through the thickness of the outer screw head down to the thread post. The inner screw only needed to be shortened to be fully screwed into the outer screw.

Figure 26:Manufactured outer screw, inner screw, and assembly prototypes.

Two pieces of aluminum stock were used to fabricate a prototype plate and representative bone. The plate was first drilled through with a 5/16 drill to allow the threaded part of the screw to clear the plate. A larger diameter three-quarter depth hole was then milled on the same center point as the 5/16 hole into the aluminum plate. This larger hole allows the outer screw to sit flush within the plate with the threads extruding from the bottom. As pictured at the bottom of Figure 27, the representative bone was manufactured by drilling and tapping a 3/8-16 hole to accept the threads from the outer screw.

Figure 27: Milled plate (top), threaded bone plate (bottom), screw assembly (right).

The prototype was validated by placing the representative aluminum bone in a vice and placing the milled plate on top of the “bone”. The screw assembly was then screwed into the bone using a single tool until the bone and plate were compressed. At this point, a downward force was applied to the inner screw as it was turned, causing it to continue to screw down into the outer screw without movement of the outer screw. As pictured in Figure 28, this caused the head of the outer screw to be wedged into the plate, locking it from further movement.

The entire prototype was then removed from the vice and the bone was removed. Repeated blunt force hits to the protruding thread post of the outer screw did not dislodge the assembly from the plate. The “bone” was then reattached to the plate and put back into the vice. The original tool was used to remove the inner screw, thus removing the wedging force from the outer screw head. The outer screw was then removed from the “bone” with a separate tool to interface with the cross-diameter cuts.

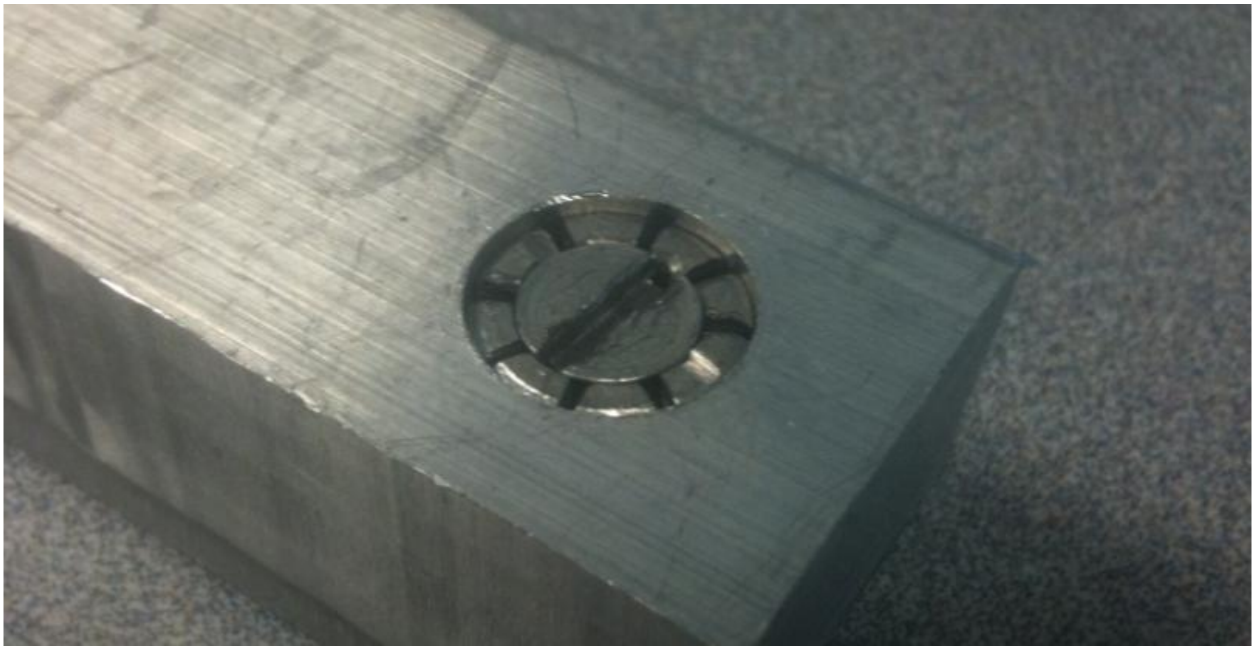

Figure 28: Validation of the locking mechanism. Inner screw has been tightened and the head of the outer screw has engaged the plate. After removal of the bone plate from below, blunt forces to the screw thread post did not dislodge the part.

4.2 Production Model Manufacturing

The manufacturing of an implantable screw plate system that ensures rigid, locking sternal fixation would be complicated from raw materials. The project team decided to modify a currently available sternal fixation system through micromachining. A 2.3mm KLS Martin mandibular bone screw, seen in Figure 29, was chosen based on its head design. The screw has a flat circumferential edge that will mimic the wedging action of the prototype. The plate supplied with this particular KLS Martin sternal system is a standard non-locking bone plate and can be seen in Figure 31.

Figure 29: KLS Martin screw adjacent to a nickel (left) and a close-up of the thread pattern and head profile (right).

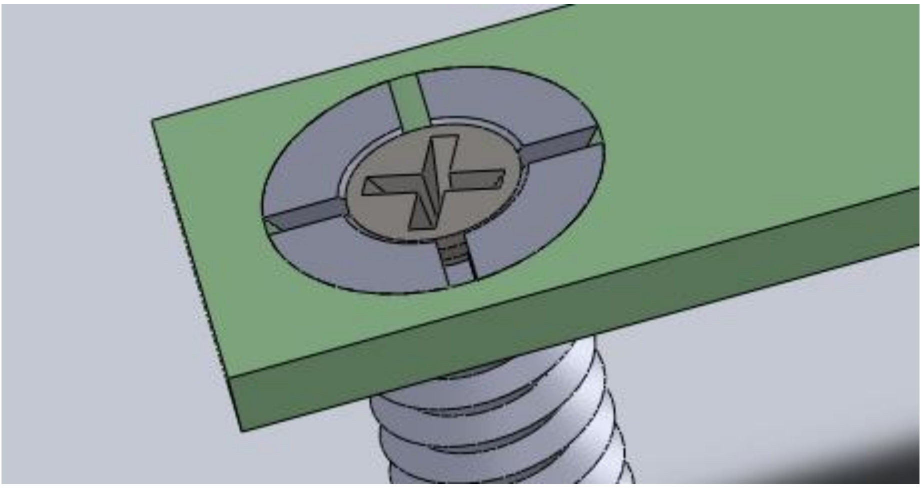

Figure 30: A CAD model of the miniaturized assembly.

4.2.1 Machining Titanium

The KLS Martin bone screws are a medical grade titanium alloy, a difficult material to work with. Titanium has a low thermal conductivity, making heat buildup in the tooling an issue. Stronger tooling with advanced flute design allows efficient removal of material without sacrificing cutting precision. Many titanium compatible tool bits are made of solid carbide because of its resistance to failure at higher temperature. Coatings can also be applied to the carbide tools to increase reliability. Titanium aluminum nitride coated carbide tools (grade F8 or B8 carbide) are an example of this and are the tool material that will be used for our machining purposes.

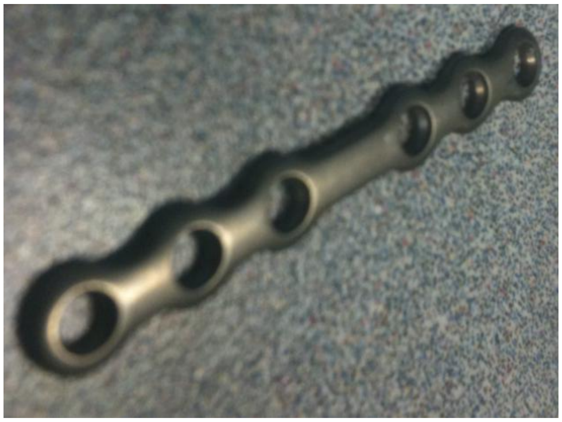

Figure 31: KLS Martin mandible bone plate.

4.2.2 End Milling

Before milling can be started, a custom grip to rigidly hold the titanium bone screw perfectly centered and without damaging the screw threads must be used. A circular aluminum slug will be used as a holder for the screw to allow a rigid grip of the screw necessary for machine milling. Any part vibration or wobbling during machining can lead to catastrophic failure of a tool and possibly the screw itself. The aluminum slug will also allow for accurate center probing of the screw, ensuring that the milling operations are done at the exact center. To safely drill the titanium bone screw to the desired diameter and depth, a carbide end mill bit is the preferred tool. A standard centerplunge method will be used with a 3/64" four-flute solid carbide end mill to incrementally remove small amounts of the titanium. This approach minimizes tooling contact time with the screw, reducing friction and cutting temperatures.

4.2.3 Single Profile Thread Mill

Single Profile Thread Mills (SPTMs) are the ideal thread cutting tool for titanium applications. They are made of solid carbide and employ multiple flutes with a single thread form on the bit. This allows a significant reduction in side cutting pressure on the tool, which when tapping titanium, is a significant concern. An 0-80 internal thread will be cut into the end milled hole of the bone screw. A CNC program provided by Scientific Cutting Tools, the manufacturer of the SPTM, will allow proper cutting of titanium.

4.2.4 Wire Electrical Discharge Machining

Wire electrical discharge machining (wEDM) will be used in order to make the specialized, high accuracy cuts into the small screw head. In this machining process, a very thin piece of brass wire is electrically charged and used to cut into the titanium. The cutting guides are accurate up to 0.004 mm. The smallest cuts possible use a 0.1mm wire, creating a 0.12 mm cut. For overall industrial manufacturing, the most economically and time efficient wire is a 0.25 mm creating a .335 mm cut. Over-cutting occurs due to the sparking that is created, causing erosion. Overall, the additional amount cut out due to erosion is sufficiently predictable and will be compensated for. Wire diameters can be created as small as 20 micrometers. The overall energy necessary per pulse is relatively low and will not affect the mechanical properties of the material.

4.2.5 Manufacturing Procedure

The procedure for the manufacturing of the device is a repeatable process that can be applied to commercial batch manufacturing of the screws. This is important to the feasibility of the device both in cost and manufacturability.

1. Aluminum slug preparation. The aluminum slug serves two purposes in the manufacturing process, allowing the screw to be rigidly held during machining and also giving a larger surface over which the mill probe can acquire a center point for machining. The aluminum slug was procured from lathe scrap but any circular piece of aluminum of similar size can be substituted. The slug is prepared by first securing it into the milling machine and probing for a center point. Two drills were then used to bore out a hole for the screw to tap into, as well a clearance hole to facilitate the perpendicular starting of the screw. The stronger mechanical properties of the titanium bone screw along with its self-tapping threads allow the screw to tap the slug hole.

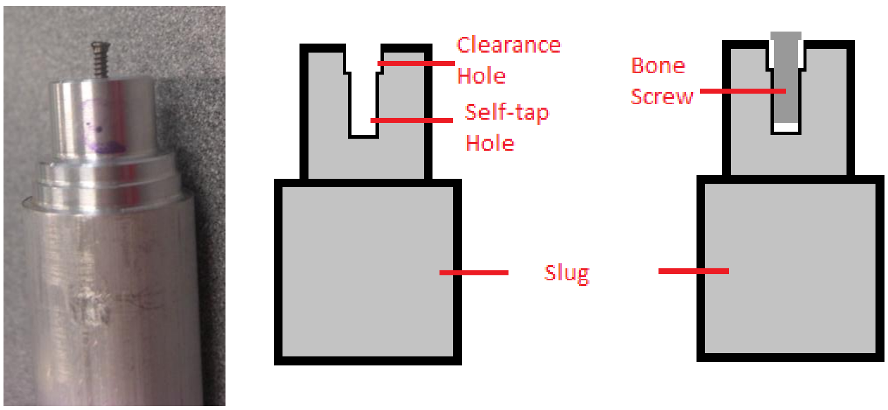

Figure 32: Aluminum slug loosely holding a bone screw (left), and schematics showing the hole setup and final position of the screw in the slug (right).

2. Screw center milling. All milling operations performed on the outer screw must be completed sequentially and without removal of the screw from the slug. This is to ensure that the screw remains centered at the same point along the axis of the machine and tool. After the slug is drilled out the screw is simply turned into the slug until the head is snug against the top plane. All mills were loaded into the milling machine and the pilot hole for the post diameter of the 0-80 screw was milled out. This was done with a 3/64" centerplunge end mill in a "pecking" operation that removes a small amount of material and then backs off to allow chips to clear the tool and temperatures to remain at a stable level. This continues until the hole is at the required 1/8" depth.

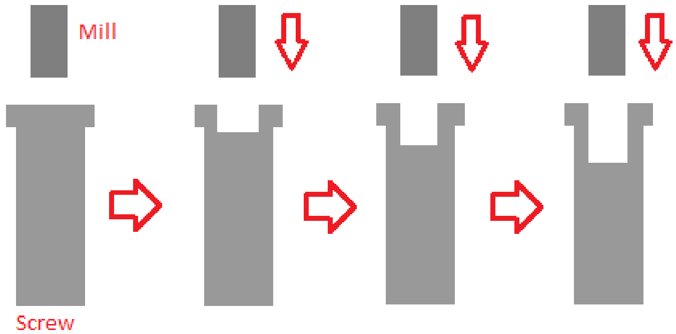

Figure 33: Schematic showing the progression of material removal by the centerplunge endmill.

3. Screw thread milling. Directly after the pilot hole is milled the tool is switched within the machine to the single profile thread mill. The thread mill program was provided by the tool manufacturer and cuts a 0-80 thread into the interior of the pilot hole from bottom to top. It accomplishes through a helical cutting pattern up the circumferential edge of the hole.

Figure 34: Screw and Thread mill close-up.

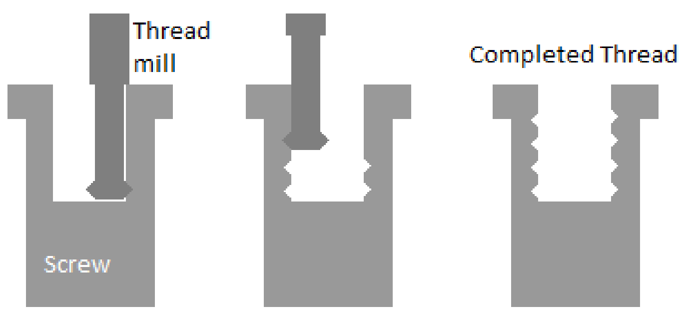

Figure 35: Schematic of the cutting of the 0-80 thread within the outer screw pilot hole.

4. Expansion cuts. The extension of the already present Philips head cut down the full length of the outer screw head was completed using the wire EDM procedure (Roger Tool & Die Co., Worcester, MA). This procedure allowed for very accurate cuts that did not damage any of the screw or previous operations work.

Figure 36: Close-up view of expansion slits that were cut using wire EDM.

Table 2: Itemized manufacturing procedure

#	Part	Operation	Tool	Description
0	Aluminum slug	Probe	Probe bore	Find center
1	Aluminum slug	Mill	0.076” drill bit	Hole for self-tap
2	Aluminum slug	Mill	0.089” drill bit	Clearance hole
3	Outer screw	Mill	3/64” 4-flute centerplunge end mill	Pre-tapping hole
4	Outer screw	Mill	0-80 Thread mill	Tapping of hole
5	Outer screw	Cut	EDM	2 full diameter expansion cuts

4.2.6 Assembly

With the finished outer screw complete, the unmodified 0-80 screw was turned into the outer screw. The pre-assembled screws can be seen in Figure 37. Final assembly of the part will require that the inner screw be turned down until it makes contact with the outer screw head but does not splay any of the expansion edges outward. The assembled screws can be seen in Figure 38. This is the state at which we will be installing the screw and also how the surgeon will ultimately receive it.

Figure 37: Pre-assembled outer screw and inner screw.

Figure 38: Assembled screw-plate system.

5.0 Results

5.1 Sawbone Sternum Verification

The experimental procedures were first performed on polyurethane sawbone sternum segments as stated in the methodology. The goal of this experiment was to compare the screw-loosening of the standard vs anti-wobble plating systems. Standard and anti-wobble tests were paired to each sternum segment and a total of 4 tests were performed in 2 groups: standard screw-plate system with n=2 and anti-wobble screw-plate system with n=2. The peak displacements during cyclic testing are summarized in Table 2.

Table 3: Peak screw displacement in sawbone

	Standard (n=2)	Anti-Wobble (n=2)
10 Cycles	0.33mm	0.18mm
100 Cycles	0.42mm	0.19mm
1000Cycles	0.50mm	0.20mm
15000 Cycles	0.57mm	0.20mm

As seen from the table, the peak displacement for the anti-wobble screw plate system is much lower than the standard screw-plate system. The final displacement after 15,000 cycles for the anti-wobble was 0.20mm compared to 0.57mm for the standard. The anti-wobble system had 65% less displacement than the standard screw system. The anti-wobble system showed low displacements at 10, 100 and 1,000 cycles when compared to the standard system. Throughout the test, the anti-wobble system showed little change in displacement throughout the 15,000 cycles while the displacement for the standard system steadily increased.

A graph displaying the average displacement for the standard and anti-wobble system can be seen in Figure 39. It can be seen from the graph that the standard screw-plate system takes about 1,000 cycles before the system starts to plateau at a displacement of ~0.4mm. In comparison, the anti-wobble system plateaus at ~100 cycles and the displacement stays steady at ~0.18mm. It can be concluded that after 15,000 cycles, the anti-wobble screw-plate system greatly minimized the screw displacement in the sawbone samples. Testing proceeded to human cadaveric sternum samples in order to provide more clinically relevant data.

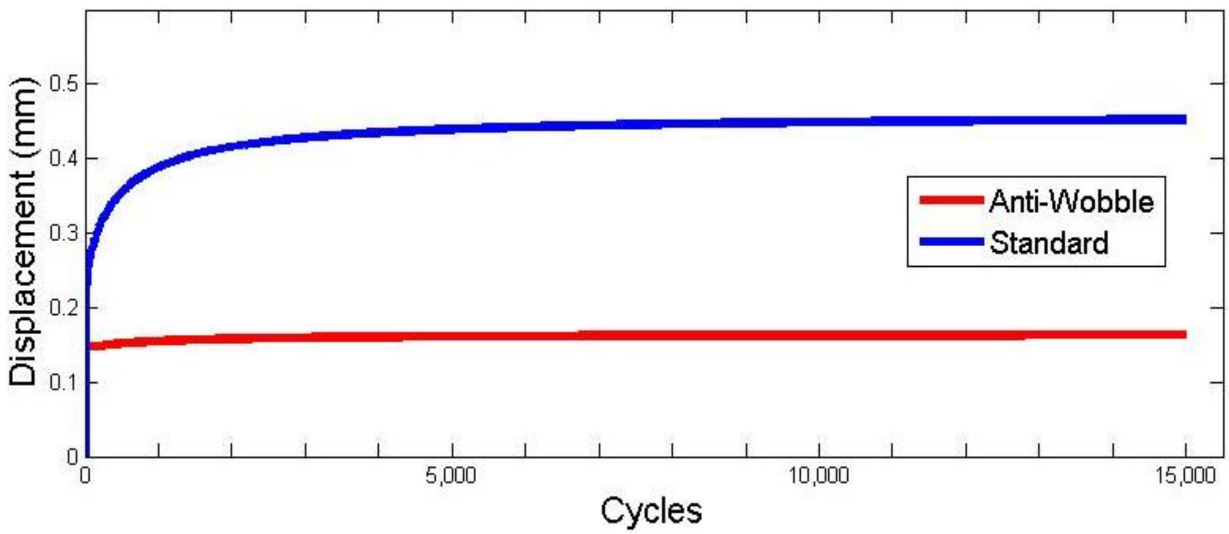

Figure 39: Average displacement values of two standard tests and two anti-wobble tests in sawbone

5.2 Human Cadaveric Sternum Verification

Following verification that anti-wobble screw-plate system minimizes screw loosening in sawbone sternum models, further testing were performed on human cadaveric sternum samples. The goal of these tests was to provide more clinically relevant data than sawbone. Testing procedures were followed as stated in the methodology but the force had to be lowered to 25N to accommodate for the weak and brittle cadaveric samples. A summary of peak displacements in human sternum can be seen in Table 3.

Table 4: Peak screw displacement in cadaveric sternum

	Standard (n=2)	**Anti-Wobble (n=2)**
10 Cycles	**0.48mm**	**0.25mm**
100 Cycles	**0.54mm**	**0.45mm**

1000Cycles	**0.78mm**	**0.57mm**
15000 Cycles	**1.45mm**	**0.65mm**

As can be seen in Table 3, the screw displacements throughout testing were much lower for the anti-wobble when compared to the standard system. A total of 4 tests were completed with n=2 for the standard and anti-wobble systems. The anti-wobble system achieved a final displacement of 0.65mm while the standard system achieved a final displacement of 1.45mm, which resulted in 55% less displacement for the anti-wobble system. The average displacement graph for the standard vs anti-wobble system can be in Figure 40.

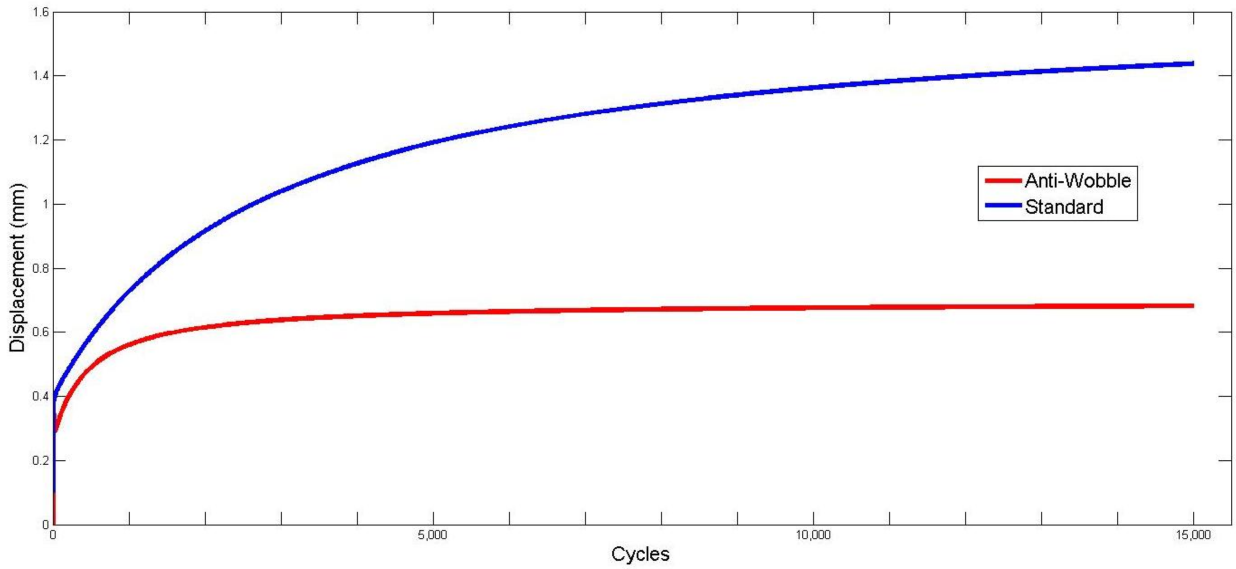

Figure 40: Average displacement values of two standard tests and two anti-wobble tests in human sternum

As can be seen in Figure 40, the standard screw-plate system has an increasing displacement and never achieves a distinct plateau as seen previously in sawbone. The initial loosening of the first 10 cycles gives the standard system a displacement of ~0.4mm, which climbs steadily throughout testing. In comparison, the anti-wobble system achieves a clear plateau at around 1,000 cycles with a displacement of ~0.6mm. The anti-wobble graph also remains steady and no displacement increase can be seen from 1,000-15,000 cycles while the standard system shows displacement increasing steadily from 1,000 to 15,000 cycles.

Human cadaveric sternum testing showed that the anti-wobble mechanism applies well to a clinically relevant sample. The cadaveric sternum samples are osteoporotic and have an outer cortical shell and inner cancellous region while the sawbone models have perfectly uniform density throughout. The results show that the anti-wobble mechanism can help achieve 55% less displacement and can help osteoporotic patients who are experiencing complications during the healing process after sternal closure.

6.0 Discussion

In order to test the overall validity of the final design, the screw was inserted into sawbone. The screw-plate system was successful in compressing the plate down to bone followed by the locking friction fit into the bone plate. The screw assembly was also successful in only requiring one tool to achieve both mechanisms and did not strip the sawbone. After applying multidirectional forces to the system in order to attempt to loosen the screw, it was concluded that the screw was strongly fixated into the plate and sawbone. Overall the design was successful in accomplishing the goals set out in the beginning of the project. The final design locked within the sawbone can be seen in the figure below.

Figure 41: Image showing locked device.

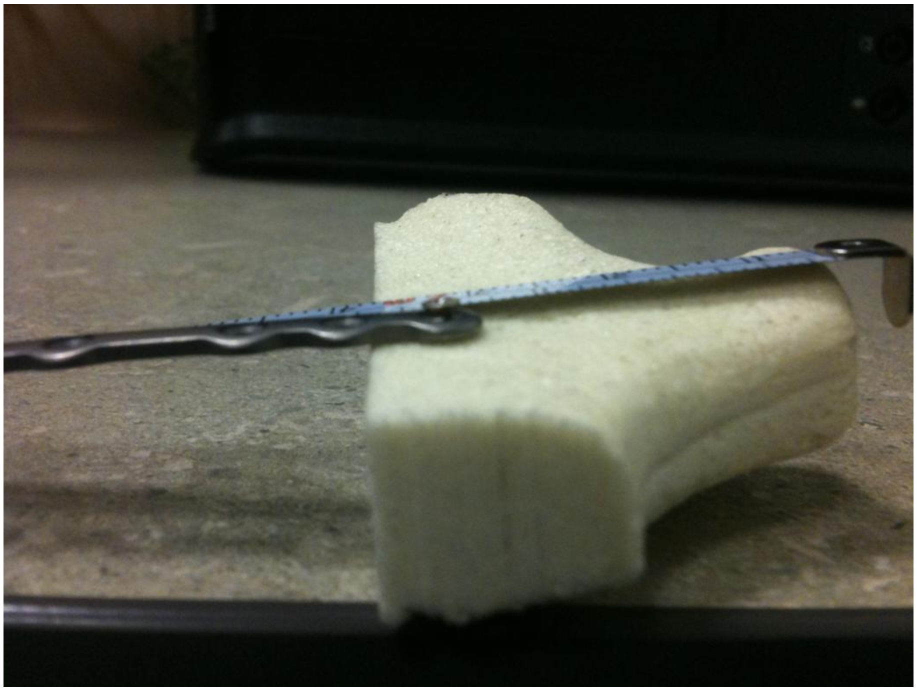

Figure 42: Side view of the screw.

In this project, the anti-wobble concept developed in previous work was redesigned and manufactured on a clinically applicable scale. The anti-wobble concept was compared to standard non-locking screw plate systems. Due to manufacturing and time constraints, initial validation testing was performed using a similar anti-wobble screw-plate system. Through initial testing in sawbone, and final testing in cadaveric sterna, the results showed that the anti-wobble system minimized screw loosening. Due to manufacturing difficulties, the design was made after the anti-wobble validation testing in cadaveric sterna. The locking mechanism was shown to work properly in sawbone. Our initial goal of designing a screw plate system to minimize screw loosening was met.

As seen from the results section, during sawbone testing the average displacement after 15,000 cycles of loading for the standard and anti-wobble screws were respectively 0.57mm and 0.20mm. In cadaveric sterna the anti-wobble screws again significantly outperformed the standard screws as the displacement of the standard and anti-wobble screws were respectively 1.45mm and 0.65mm. These results look very promising as the standard screw plate system used for comparison is one of the major types available commercially that is being used in the clinic.

When looking at the effectiveness of our device in comparison to other currently available systems, the differences are more difficult to see. Current systems such as the Talon by KLS Martin and the Titanium screw plate system by Synthes exhibit very low displacements, similar to those displayed by the anti-wobble system. The Synthes system relies on obtaining better fixation by using screws across the ribs to gain more support. While this method is effective in holding the sterna rigidly, it limits chest movement during respiration and involves the use of a lot more screws, increasing surgery time. The Talon by KLS Martin is effective at rigidly holding the sterna, but the device is complicated and expensive, and is still not optimized for osteoporotic bone.

The anti-wobble system designed in this project helps improve fixation and lower displacement while overcoming or avoiding the problems associated with other currently available devices. The anti-wobble system showed much lower displacement compared to the standard screw systems, achieving the lower displacement achieved in the KLS Martin and Synthes devices. Our system also maintained the simplicity of the standard screw for ease of use by surgeons and keeping operating times to a minimum.

Some major limitations of our design involved parameters that would need to be optimized better for proper functions of our delayed locking mechanism. The outer screw slits need to be redesigned to splay out easier and remain mechanically sound so they don't break off. The inner screw would need to be made of titanium and be made to medical grade tolerances as seen in the outer screw used. This would help prevent the inner screw head from stripping during locking, so sufficient force could be applied to achieve the locking mechanism.

The force required to splay the outer screw was much greater than expected. Because of this, a specialized tool would need to be developed to hold the outer screw during the final locking turn, to protect the bone from being stripped from the excessive force.

Overall we demonstrated proof of concept for our design, that the design is feasible on the clinical scale and would lower displacement between sternal halves caused by screw loosening. The device is currently not ready for clinical use as some redesign would be required to fix the previously mentioned limitations.

6.1 Sawbone Model

During the testing with cadaveric sternum and after reviewing the results, it was apparent that the sawbone models used for initial testing are not an accurate representation of real bone. The polyurethane sawbone models resemble the sternum in shape, but their uniform density and properties don't properly account for the properties present in real bone. While the sawbone was able to withstand testing at 50N, the 50N loading tore through the real bone after less than 100 cycles. Real bone has an irregular density and surface, and mainly is much weaker mechanically than the sawbone models. A lower density sawbone model with a hardened shell would better simulate the osteoporotic human bone used in testing. Sawbone is mainly used due to its low cost and ease, but using real bone gives more relevant data.

6.2 Anti-Wobble System

The initial sawbone testing validated our design concept as the anti-wobble screw showed less initial loosening, as well as significantly lower final displacement compared to the standard screw. The difference became more apparent during human sternum testing as the screw wobble and loosening was much more visible due to the weaker properties of the bone. During this testing, the anti-wobble system was able to plateau and maintain a displacement under 1mm while the standard screw never truly plateaued and the displacement steadily increased during testing. The lowered displacement observed in the anti-wobble system can be attributed to both the compression fit obtained between the plate and bone, as well as the locking mechanism between the screw and the plate.

6.3 Manufacturing

One of the major advantages of this device is that it does not require any new overall infrastructure, as the device is created through modifying current bone screws. The tools and technologies used to manufacture these screws would much be much easier on a commercial level. Commercial manufactures would most likely be able to use milling and EDM, just as the project group had. One of the toughest parts of the project was not having any manufacturing experience. There were several times when the project group had to reach out to outside agencies to complete the project. Out sourcing to wire EDM and thread mill companies brought up the overall cost of the product.

6.4 Future Recommendations

For future testing, we recommend using cadaveric sternum to attain statically significant results. Due to time constraints, our sample size of only four is not sufficient to make concrete conclusions but it does show promise for the concept and design. Further testing using full sternum should also be done for further validation.

While our design seemed to work well in the prototype, when moving to real bone, it is much easier to strip the bone. The final turn to lock the screw after the compression fit is obtained might risk striping the bone depending on the force required. A specialized tool would need to be developed to hold the outer screw in place during the final locking turn of the inner screw to prevent this striping from occurring and protect the bone.

While our design was shown to successfully splay out the head, wider expansion slots can minimize the force required to splay out the head of the outer screw. A redesigned screw model in comparison to the original design is shown in the figure below. From a manufacturing standpoint, this modification would use the same manufacturing techniques but requires a thicker wire EDM cut.

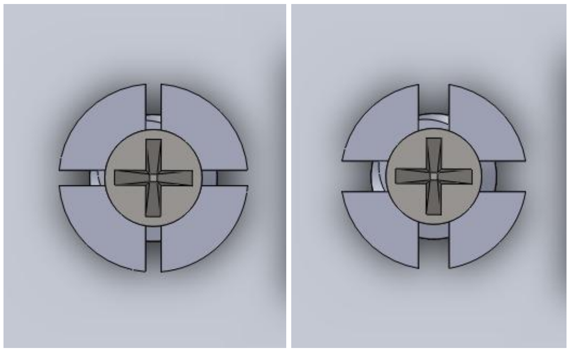

Figure 43: Original design (left). Proposed redesign (right).

7.0 Conclusion

The anti-wobble concept was compared to standard non-locking screw plate systems. Several anti-wobble designs were created based on client objectives. After analyzing the designs and considering manufacturing constraints, the final design was chosen. Due to manufacturing and time constraints, initial validation testing was performed using a similar anti-wobble screw-plate system. Through initial testing in sawbone, and final testing in cadaveric sterna, the results showed that the anti-wobble system minimized screw loosening. Due to manufacturing difficulties, the design was made after the anti-wobble validation testing.

A clinically relevant sized prototype was successfully created through micromilling and wire EDM. The locking mechanism was shown to work properly in sawbone and limitations were identified. The final prototype achieved the goal of a one-piece delayed locking screw-plate mechanism on a clinically relevant scale. While the device is not ready for clinical use, future modifications could be made to overcome the previously discussed limitations. Overall the device shows potential from our testing results and manufacturing outcomes.

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Appendix A – Instron Electropuls E-1000

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 m² (1.6ft²) 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 pad 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 ▶

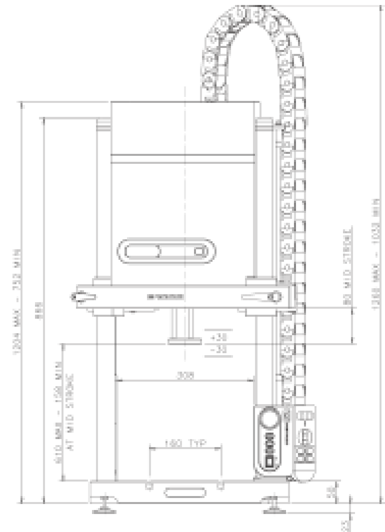
A New Wave In Testing

E1000 Electrodynamic Test Instrument

ELECTROPULS™

Specifications

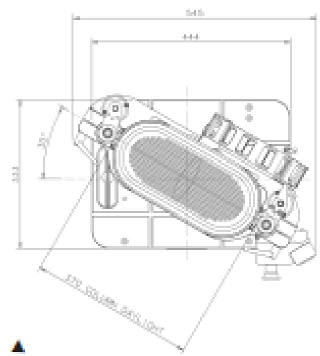
Dynamic Capacity	± 1000 N (± 225 lbf)
Static Capacity	± 710 N (± 160 lbf)
Stroke	60 mm (2.36 in)
Daylight Opening	610 mm (24 in) maximum with actuator at mid stroke
Configuration	Diagonal twin-column with actuator in upper crosshead
Orientation	Vertical (Horizontal with optional mounting kit)
Lift and Locks	Electrically powered lifts with manual lever clamps
Load Cell	± 2 kN Dynacell™ mounted to base
Weight	92 kg (202 lb) (frame only) 38 kg (84 lb) (controller)
Electrical Supply	100 VAC to 120 VAC 20 A single-phase 50/60 Hz 220 VAC to 240 VAC 10 A single-phase 50 Hz
Cooling	Temperature-controlled air cooling
Operating Temperature	+ 10 to + 30 °C (+50 to +86 °F)
INTERFACES	
Actuator	M6 x 1 right hand central thread 3 x M6 on 57 mm PCD
T-Slot Table	M6 x 1 right hand central thread 3 x M6 holes on 57 mm PCD 6 x M10 holes on 100 mm PCD 4 x M10 holes on a 280 mm x 90 mm accessory rectangle 4 x M6 T-slots spaced 80 mm from center



E1000 dimensions front view

Accessories

1300-151	Horizontal mounting kit for ElectroPuls™ E1000 test instrument
1300-121	Safety screen for E1000 test instrument
2742-102	±1 kN (±225 lbf) fatigue-rated mechanical wedge grip
2742-103	±1 kN (±225 lbf) fatigue-rated pneumatic wedge grip
2718-011	Pneumatic grip air kit for dynamic systems
8800-120	Hardware operator panel



E1000 dimensions plan view

E1000 test instrument in horizontal configuration

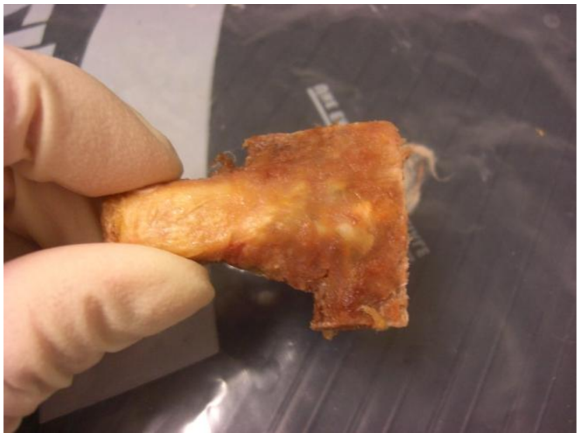
Appendix B – Materials

Materials:

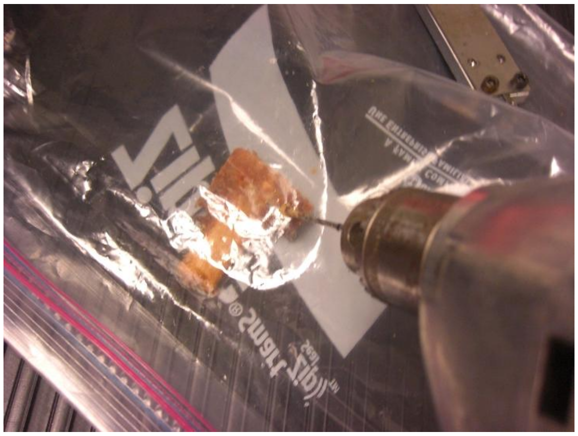
1. **Sample Fixation**
    - Epoxy
    - 1.5in Unthreaded PVC Cap
    - ¼-20 2.5in Eyehook and Nut
    - ¼-20 1.5in Wood Screw
    - Polyurethane Sawbone
    - Human Cadaveric Sternum
    - Plate and Extensometer Grip (Custom manufactured at WPI)
    - 70% Ethanol Solution
    - Gallon Sized Ziplock Bags
2. **Screw and Plate**
    - KLS Martin Mandibular 9mm screw
    - KLS Martin Mandibular Plate
    - Cap and Plate Anti-wobble system (Created by John Dieselman)
3. **Instron**
    - Instron Electropuls E-1000
    - 50N Load Cell
    - Extensometer
    - Standard Instron Grip
    - Instron Console Program
    - Instron WaveMatrix Program
4. **Tools/Instruments**
    - Philips head screw driver
    - KLS Martin precision screw driver
    - Power Drill with 1.9mm drill bit
    - Personal Protection Equipment (PPE)
        - Latex Gloves
        - Long-sleeve Lab Coat
        - Safety Goggles

Appendix C – Steps for Human Sternum Testing

Step 1: Samples were sectioned as shown in the image to the right by Dr. Ignotz at UMass Medical School. Samples are stored in -40°C freezer and thawed in a 4°C refrigerator the night before testing. Make sure to wear PPE while handling human tissue.

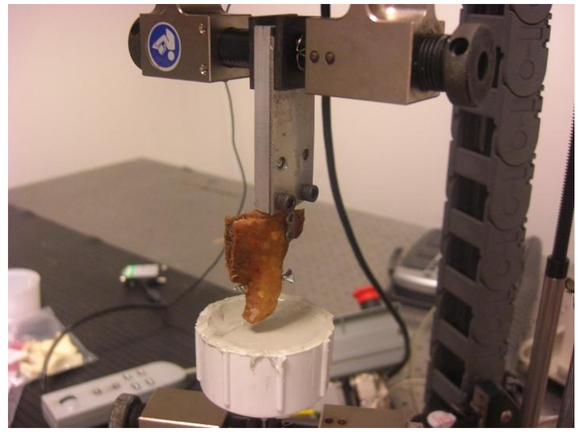


Step 2: Two holes are drilled into the sternum segments as shown. The sternum is kept in the ziplock bag to contain any biohazardous material. Another hole is drilled into the side of the rib segment for the anchoring screw.

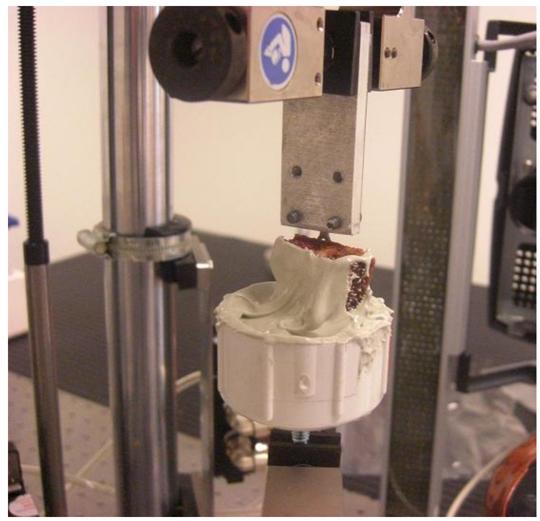


Step 3: The bone plate is inserted between the aluminum plates of the custom grip and the machine screws are tightened. The bone plate is screwed into the sternum sample as shown in the image to the right. A wood screw is screwed into the predrilled hole in the side of the rib to help anchor the sample in the epoxy.

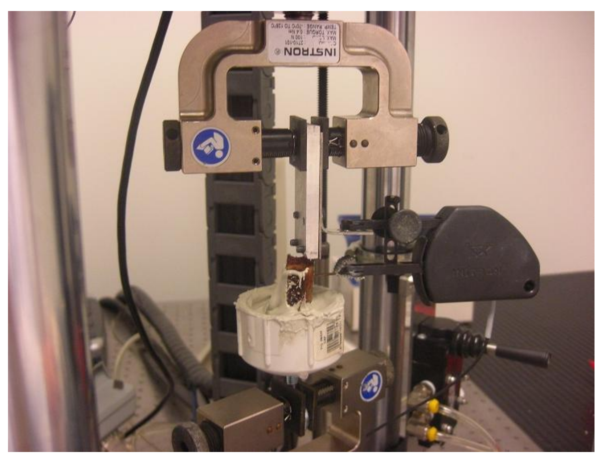
Step 4: The custom grip is attached to the upper Instron grip and an endcap with epoxy is filled and attached to the lower Instron grip. The Instron grip is then lowered into the epoxy to make sure the sample is aligned.



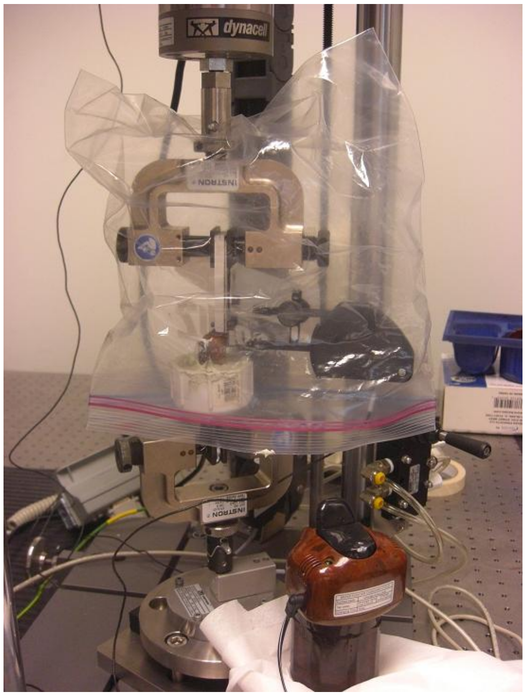
Step 5: The epoxy is spread to make sure the anchoring screw is submerged and the backside of the sternum is also covered. This prevents movement at the joint between the rib and the sternum.



Step 6: The extensometer is screwed into the custom grip while the epoxy dries for ~25mins.



Step 7: A ziplock bag is placed that covers the whole sample. A humidifier is placed below to keep the sample moist during testing. Once the epoxy is dry, the sample is ready for testing.



Appendix D – Matlab Code - Plotting Comparison Graphs Using Fit Curve

This code below will plot the data using a fit curve for each to approximate the average displacement seen at each point by removing outliers from the data. Outliers are defined as data points that are greater than 1.5 standard deviations from the estimated data fit curve.

```
close; clear; clc;
ldata1=xlsread('L4 Screw 1.csv');
time1=ldata1(:,1);
cycles1=ldata1(:,3);
extstrain1=ldata1(:,10);
ldp1=ldata1(:,7);
f1=fittype('rat33');
fit1=fit(cycles1,extstrain1,f1);
fdata1=feval(fit1,cycles1);
I1=abs(fdata1-extstrain1)>1.5*std(extstrain1);
outliers1=excludedata(cycles1,extstrain1,'indices',I1);

ldata2=xlsread('L4 Screw 2.csv');
time2=ldata2(:,1);
cycles2=ldata2(:,3);
extstrain2=ldata2(:,10);
ldp2=ldata2(:,7);
fit2=fit(cycles2,extstrain2,f1);
fdata2=feval(fit2,cycles2);
I2=abs(fdata2-extstrain2)>1.5*std(extstrain2);
outliers2=excludedata(cycles2,extstrain2,'indices',I2);

ldata3=xlsread('R2 Screw 1.csv');
time3=ldata3(:,1);
cycles3=ldata3(:,3);
extstrain3=ldata3(:,10);
ldp3=ldata3(:,7);
fit3=fit(cycles3,extstrain3,f1);
fdata3=feval(fit3,cycles3);
I3=abs(fdata3-extstrain3)>1.5*std(extstrain3);
outliers3=excludedata(cycles3,extstrain3,'indices',I3);
```

```
ldata4=xlsread('R2 Screw 2.csv');
time4=ldata4(:,1);
cycles4=ldata4(:,3);
extstrain4=ldata4(:,10);
ldp4=ldata4(:,7);
fit4=fit(cycles4,extstrain4,f1);
fdata4=feval(fit4,cycles4);
I4=abs(fdata4-extstrain4)>1.5*std(extstrain4);
outliers4=excludedata(cycles4,extstrain4,'indices',I4);

plot(fit1,'r-',cycles1,extstrain1,'k.',outliers1,'m*');
hold on;
plot(fit2,'r.',cycles2,extstrain2,'k.',outliers2,'m*');
hold on;
plot(fit3,'b-',cycles3,extstrain3,'k.',outliers3,'m*');
hold on;
plot(fit4,'b.',cycles4,extstrain4,'k.',outliers4,'m*');
```

Plotting Comparison Graphs Using Fit Curve and Removing NaNs From Data

This code below will do the same as the one above except it will remove NaNs (not a numbers) from the data subset if they are causing problems during plotting.

```
close; clear; clc;
ldata1=xlsread('Real Bone AntiWobble Avg.csv');
time1=ldata1(:,1);
cycles1=ldata1(:,3);
extstrain1=ldata1(:,12);
strain1=ldata1(:,10);
strain2=ldata1(:,11);
ldp1=ldata1(:,7);
f1=fittype('rat33');
cycles1=cycles1(~isnan(cycles1));
extstrain1=extstrain1(~isnan(extstrain1));
strain1=strain1(~isnan(strain1));
strain2=strain2(~isnan(strain2));
```

```
fit1=fit(cycles1,extstrain1,f1);
fit1a=fit(cycles1,strain1,f1);
fit1b=fit(cycles1,strain2,f1);
fdata1=feval(fit1,cycles1);
fdata1a=feval(fit1a,cycles1);
fdata1b=feval(fit1b,cycles1);
I1=abs(fdata1-extstrain1)>2.5*std(extstrain1);
I1a=abs(fdata1a-strain1)>2.5*std(strain1);
I1b=abs(fdata1b-strain1)>2.5*std(strain2);
outliers1=excludedata(cycles1,extstrain1,'indices',I1);
outliers1a=excludedata(cycles1,strain1,'indices',I1a);
outliers1b=excludedata(cycles1,strain2,'indices',I1b);

ldata2=xlsread('Real Bone Standard Avg.csv');
time2=ldata2(:,1);
cycles2=ldata2(:,3);
extstrain2=ldata2(:,12);
strain3=ldata2(:,10);
strain4=ldata2(:,11);
ldp2=ldata2(:,7);
cycles2=cycles2(~isnan(cycles2));
extstrain2=extstrain2(~isnan(extstrain2));
strain3=strain3(~isnan(strain3));
strain4=strain4(~isnan(strain4));
fit2=fit(cycles2,extstrain2,f1);
fit2a=fit(cycles2,strain3,f1);
fit2b=fit(cycles2,strain4,f1);
fdata2=feval(fit2,cycles2);
fdata2a=feval(fit2a,cycles2);
fdata2b=feval(fit2b,cycles2);
I2=abs(fdata2-extstrain2)>2.5*std(extstrain2);
I2a=abs(fdata2a-extstrain2)>2.5*std(strain3);
I2b=abs(fdata2b-extstrain2)>2.5*std(strain4);
outliers2=excludedata(cycles2,extstrain2,'indices',I2);
outliers2a=excludedata(cycles2,strain3,'indices',I2a);
outliers2b=excludedata(cycles2,strain4,'indices',I2b);

plot(fit1,'r-',cycles1,extstrain1,'k.',outliers1,'m*');
```

```
hold on;
plot(fit1a,'r-',cycles1,strain1,'k.',outliers1a,'m*');
hold on;
plot(fit1b,'r-',cycles1,strain2,'k.',outliers1b,'m*');
hold on;
plot(fit2,'b-',cycles2,extstrain2,'k.',outliers2,'m*');
hold on;
plot(fit2a,'b-',cycles2,strain3,'k.',outliers2a,'m*');
hold on;
plot(fit2b,'b-',cycles2,strain4,'k.',outliers2b,'m*');
```

Appendix E – Testing Results

Sawbone Testing:

R1 Screw 1 standard- Screw pulled out after <1000 cycles, was screwed in too close to edge

R1 Screw 2 standard- Failure after 7000 cycles

L4 Screw 1 Antiwobble- 0.23mm displacement at finish

L4 Screw 2 Antiwobble- 0.15mm displacement at finish

R2 Screw 1 standard- 0.47mm displacement at finish

R2 Screw 2 standard- 0.57mm displacement at finish

Note- sample pairing is not required on sawbone as all pieces are of fairly uniform size and density

Real Sterna:

L2 Screw 1 antiwobble- 0.96mm displacement at finish

R1 Screw 1 antiwobble- 0.57mm displacement at finish

R1 Screw 2 antiwobble- 7.16mm displacement at finish, during screw installation, stripped bone

L1 Screw 1 antiwobble- 50N force, sample failed on cycle 68, force too high for osteoporotic bone

L1 Screw 2 standard bicor- .60mm displacement at finish, screw pierced second cortical shell, data not usable

L1 screw 3 antiwobble- sample failed at cycle 1009, can't use sterna piece for more than 2 tests

L2 screw 1 antiwobble- sample failed at cycle 1, load cell tripped, improperly set up

R4 screw 1 antiwobble- sample failed at cycle 1010, screwed too close to edge, improperly set up

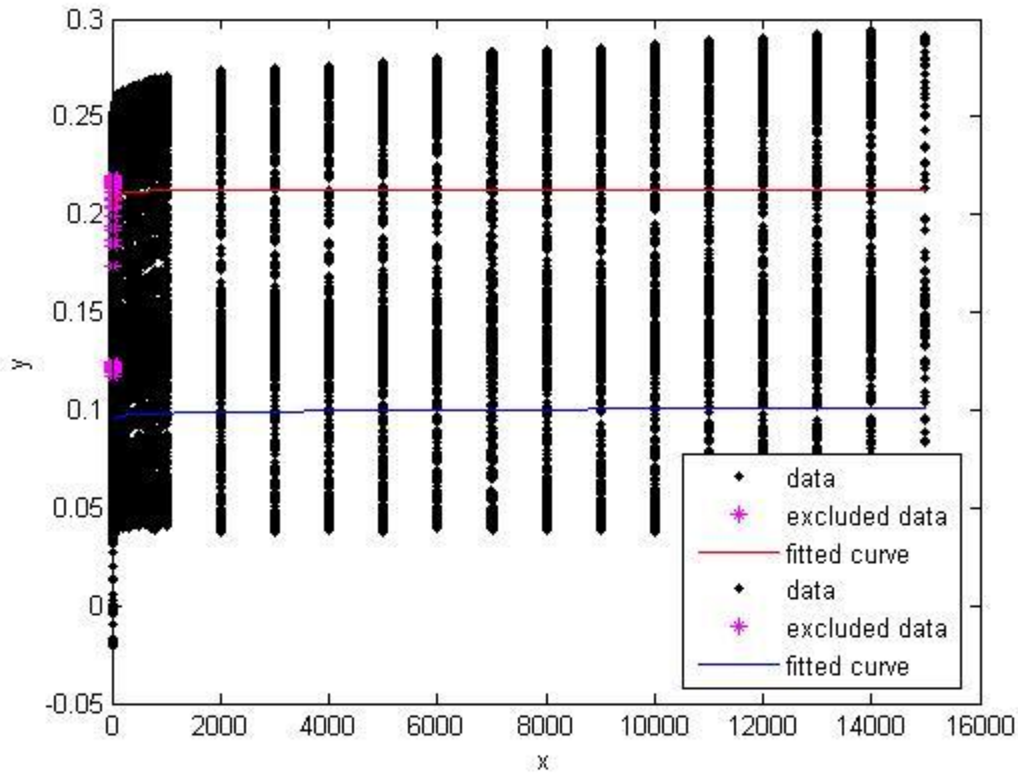
L2 screw 2 standard- 1.74mm displacement at finish

R4 screw 2 standard- 1.84mm displacement at finish

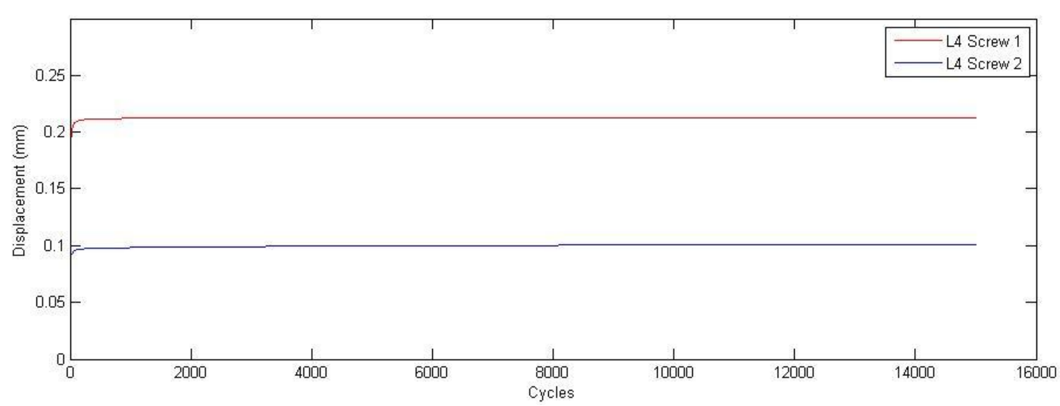
Appendix F – Data plots

Sawbone Data Plots:

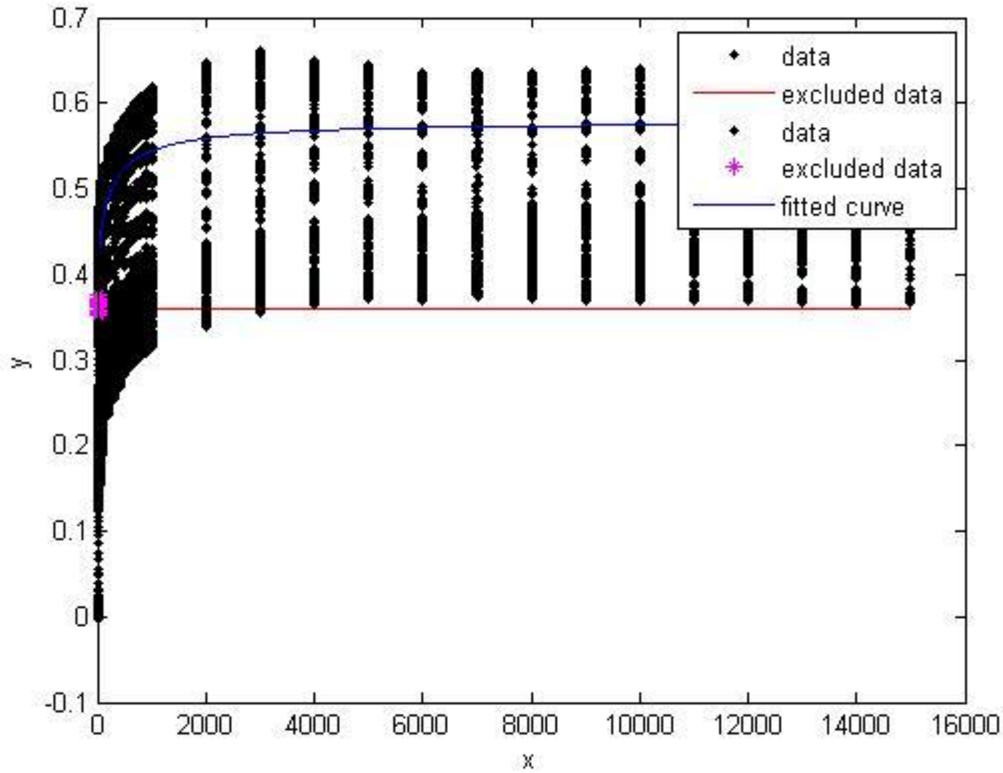
L4 Data Plots with Anti-Wobble Systems



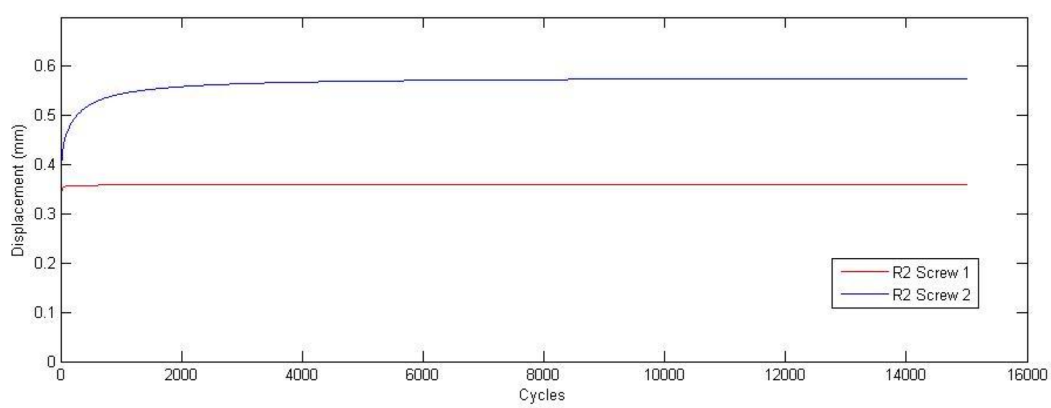
Plot with fitted curve to data



R2 Data Plots with Standard System

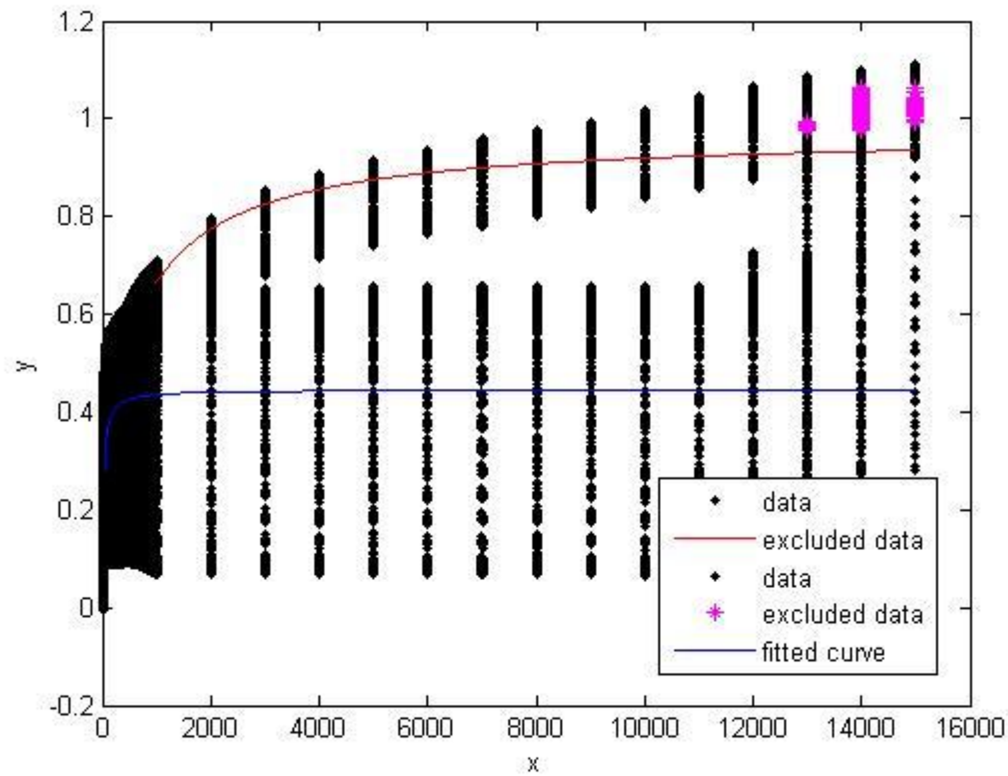


Plot with curve fitted to data

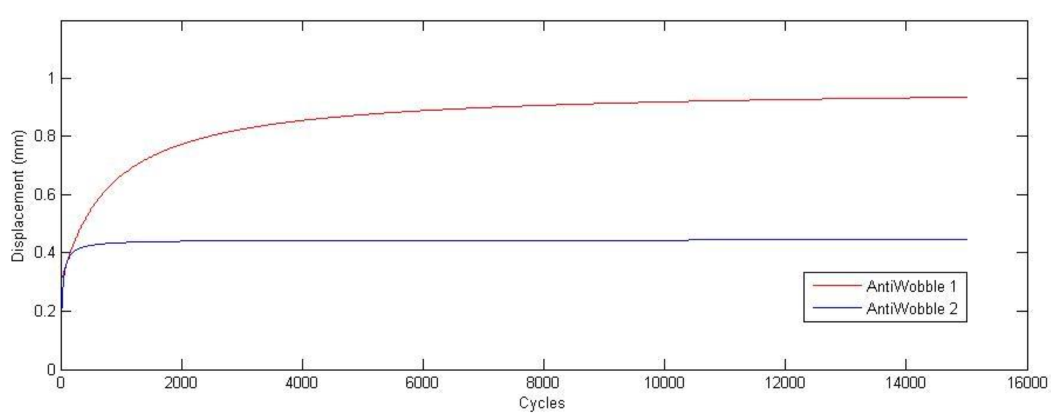


Cadaveric Sterna Data Plots:

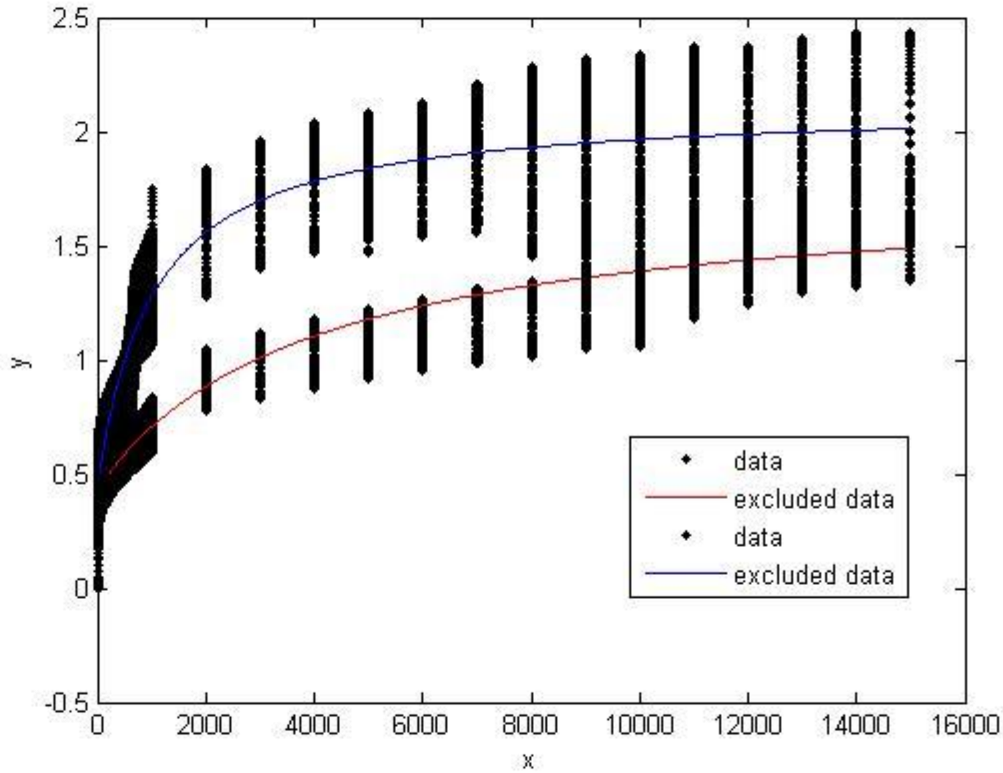
Screw-cap Anti-Wobble system



Plot with curve fitted to data



Standard System



Plot with curve fitted to data