# Design of a Unicortical Screw-Plate System for the Optimization of Sternal Fixation

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# Abstract

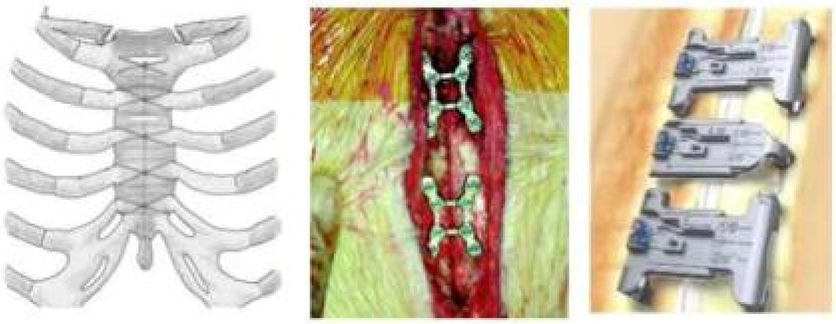
Current screw-plate fixation systems used for sternum closure after open-heart surgery require bicortical purchase which is disadvantageous due to the proximity of the heart. The goal of this project was to design, model, and test a single-unit unicortical screw and plate system which provides both compression and locking functionality. The final design utilizes a novel reverse expansion mechanism to provide a delayed lock following initial tightening. The design enables a surgeon to properly locate and secure the bone to the plate prior to engagement of a locking mechanism. Cyclic shear loading will be used to compare the effectiveness of this screw design with standard non-locking unicortical and bicortical screws.

# Chapter 1. Introduction

Cardiovascular disease (CVD) is defined by the American Heart Association as a condition in which plaque buildup prevents normal blood flow through the heart (American Heart Association, 2011). Cardiovascular disease affects approximately 1 in 3 Americans and was responsible for 1 in every 6 deaths since 2009 (Lloyd-Jones, D et al., 2009). Of the roughly 80 million Americans affected by CVD nearly 700,000 required open-heart surgeries and this number has only been increasing (Heart Disease and Stroke Statistics, 2010).

During open-heart surgery, a median sternotomy must be performed. Median sternotomy is a procedure which requires surgeons to vertically bisect the sternum, or breast bone, to gain access to the organs within the thoracic cavity. Upon completion of the procedure, sterna halves are secured in their original position to enable healing and reestablish mechanical stability required for respiration. Failure to securely close the sternum may severe complications. Such complications include mediastinitis, the separation of the sternum along its sutures, and dehiscence. Studies have shown that up to 8% of sternotomies performed result in sternal dehiscence due to limitations of their fixation. The mortality rate for patients with cases of dehiscence is 10-40%, due primarily to incurred infection and inflammation of tissue surrounding the incision, or mediastinitis, swelling and infection in the sternal area. Cases of both dehiscence and mediastinitis increase in patients that are over 75 years of age, suffering from obesity or have osteoporosis (Bek, Yun, 2010). Effective fixation methods are necessary to improve the sternum's healing process and reduce patient risk.

Most surgeons performing sternotomy procedures prefer to use a wire fixation technique; however, new methods for sternal closure are becoming increasingly popular. Fixation with cerclage wire (Figure 1a) affixes the two hemi-sterna together by looping wires around the sternum and twisting the ends for security. Although wire fixation is simple and cost-effective, its lack of mechanical stability often results in dehiscence, mediastinitis, and sternal nonunion (Ozaki et al, 1998). Fixation using plates and screws (Figure 1b) is another method used for sternal closure. This form of rigid fixation reduces sternal nonunion and other complications associated with wire fixation. Screws used to fixate the plate to the sternum loosen over time under cyclic loading caused by respiration (Lalikos Personal Interview, 2011). Other products currently available for sternal fixation includes the Talon System produced by KLS Martin (Figure 1c), a set of adjustable clamps that attach to each hemi-sterna and are pulled together. The Talon System is not widely used due to its bulky profile, high cost, and difficulty of installation (Ostrovsky, 2008). Although all current forms of fixation achieve a common goal, each product has its limitations.



(a) (b) (c)

**Figure 1: Methods of Sternal Fixation (a: Usui, A. et al., 2006, b: Song, 2004, c: KLS Martin, 2006)**

Our goal is to modify existing designs and optimize previous proofs of concept to produce a rigid sternal fixation system that overcomes as many of these limitations as possible. The main limitation associated with current plate and screw fixation systems is their inability to simultaneously:

1. Obtain a friction fit between the bone and the plate.
2. Lock the screw into the plate.
3. Prevent dorsal puncture of the screw due to bicortical design.

All functions are necessary to ensure effective sternal closure. Obtaining a friction fit between the sternum and plate is imperative because a gap between the two surfaces may result in sternal nonunion, plate displacement, or infection. Locking the screw into the plate minimizes screw loosening due to cyclic loading associated with breathing forces. Bicortical bite of the screw is a common desire of surgeons in order to increase the stability of the device. By making a unicortical device that has the same ability to hold the bone as a bicortical device, surgeons will not put the patient at risk for dorsal puncture of the screw through the sternum. Further, a unicortical delayed locking system would enable a surgeon to first fit the plate onto the bone before locking the screw into the plate. The focus of the design of the screw-plate interface is to achieve an optimal locking mechanism.

# Chapter 2. Background

## 2.1 Clinical Statistics

Cardiovascular Disease (CVD) is a condition that affects millions of Americans with numerous associated complications. Approximately one in three Americans suffer from one or more types of CVD and of these people, 38.1 million are estimated to be greater than 60 years of age (American Heart Association, 2009). This age group, which is also at risk of developing osteoporosis, has seen an increase in incidence of CVD of about 47% from 1985 to 2006. Many complications of CVD require the patient to undergo an open-chest procedure. Patients requiring open-chest procedures have increased by 43% from 1985-2006 and continue to increase today (American Heart Association, 2007). Cardiac Surgery is becoming increasingly more common, with roughly 6 million procedures completed in 2008 alone (Kun, 2009).

Any open-chest procedure requires the bisection of the sternum in order to access the heart during an open-heart procedure. This procedure is called a sternotomy. Complications due to sternotomy are seen in 0.7-0.15% of cases, many of which are caused by flaws in the method for sternal closure. These complications include sternal instability, nonunion, and infection (Kun, 2009). The sternum is a very complex structure; the fixation of the sternum must accommodate its complexity in order to be successful in both fixating the sternum and preventing its infection.

## 2.2 Sternum Anatomy

The sternum is the bone located in the center of the human chest. The sternum attaches to and provides functional support for the ribs as well as the clavicle. As a structural component of the chest wall, the sternum serves the purpose to help protect the organs located within the chest cavity (Encyclopedia Britannica, 2012).

### 2.2.1 Structure and Function

The sternum is characterized by three main components that are fused together as seen in Figure 2.

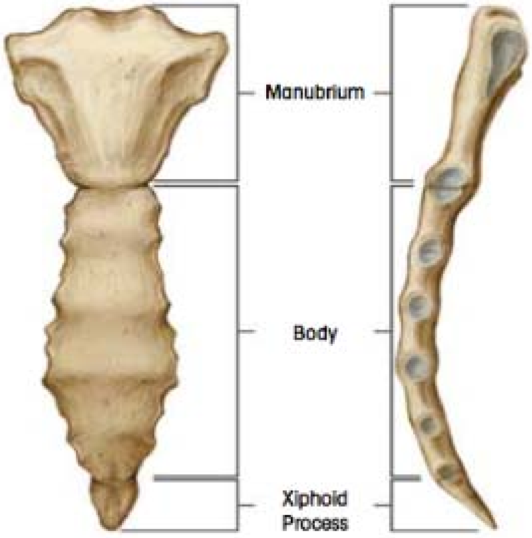


Figure 2: Human Sternum Anatomy (Ferguson, 2010)

The manubrium is the upper portion of the sternum, the body, or mid portion, is the bulk of the sternum, and the xiphoid is the lower portion of the sternum. The manubrium tends to be the region where bone is thickest and most dense.

The average size of the sternum varies slightly from person to person, with the main differences found between genders. The standard length of the female manubrium is approximately 5.24cm, compared to 5.52cm in males. The average length of the body portion of the sternum is approximately 9.42cm in females, and 10.97cm in males. The total overall length of the female sternum is approximately 18.29cm, whereas the length of the male sternum is 20.86cm. The average thickness of the sternum body is approximately 1.0cm (Gray, 2009).

In addition to the small size of the sternum, its bone density is variable, as seen in Figure 3. Cancellous and cortical are the two bone types composing the human sternum. Cancellous bone makes up the interior portion of the sternum and supplies nutrients to the outer layers of bone from the blood vessels within. Cancellous bone is spongy, porous, and less dense than cortical bone. Cortical bone makes up the outer layer of the sternum. Cortical bone is dense, rigid, and provides a hard shell around the cancellous interior. This variation of density enables the sternum to withstand forces associated with respiration due to its rigid support and elasticity provided by the two sternal components (Ozkaya & Nordin, 1998).

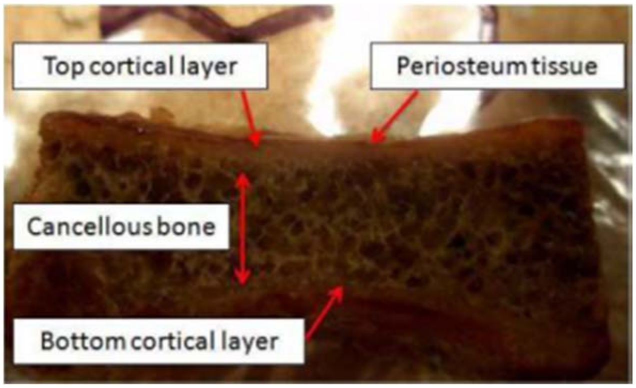


Figure 3: Cross-Section of Human Sternum (Ozkaya & Nordin, 1998)

There are seven different muscles associated with respiration. Muscles associated with inhalation exert their maximal forces on the sternum at the end of the respiratory cycle, while the exhalation muscles maximize their force load at the opposite point in time. Additionally, the sternum must withstand the forces exerted by the diaphragm, a muscle located below the rib cage (Ratnovsky, 2005). During inhalation the scales, sternocleidomastoid, external intercostals, parasternal intercostals, and the diaphragm muscles are used. During the expiration process, gas pressure within the lungs is greater than atmospheric air; thus no muscles are involved. If expiration is forced, however, internal intercostals, internal and external abdominal oblique, transverse abdominis, and rectus abdominis muscles are used. Due to the variety of muscles involved, forces in all three dimensions are exerted onto the sternum and must be taken into consideration during the development of a product to fixate the sternum (Fox, 2008).

### 2.2.2 Osteoporosis

Currently, about 10 million Americans have osteoporosis and 34 million more are at risk. Osteoporosis is a condition causing bones to weaken and increase their risk of fracture (National Osteoporosis Foundation, 2011). The National Osteoporosis Foundation estimates that about half of all women over the age of 50, as well as one in every four men, will break a bone due to the disease. Osteoporosis can lead to other health complications, from those as simple as pain, to death. Because bones are so fragile in osteoporotic patients, many precautions must be taken to ensure optimum health post open-heart surgery (National Osteoporosis Foundation, 2011). Designing products for patients with osteoporosis is challenging, particularly when working with bones that are as thin as the sternum. Special considerations have to be made in order to accommodate the difficulties presented with osteoporotic bone.

### 2.2.3 Anatomical Challenges Associated with Sternal Fixation

Sternal fixation many times requires drilling and placing screws in an extremely dangerous location in the body. If a screw penetrates through both cortices of the bone there is a chance the tip of the screw could cause serious damage to the organs located below the sternum, namely the heart. The pericardial covering over the heart is not compliant and provides the heart with limited space to move. Any scratch or tear to the pericardium may fill it with blood, preventing the heart from beating. The fixation device that is designed to fixate the sternum therefore faces a unique challenge to hold the sternum in place while greatly reducing the ability of the surgeon to make a mistake and puncture the dorsal side of the sternum, potentially putting the heart in danger (Dunn. Personal Interview, 2012).

## 2.3 Sternotomy

A sternotomy must be performed to begin any open-heart procedure. Surgeons are required to separate the sternum along its vertical axis into two halves using a high frequency saw. A sternal retractor is then positioned between the hemi-sterna to prop open the thoracic cavity and allowing surgeons to complete the surgical procedures necessary. Upon completion of the procedure, the sterna halves are secured together to enable healing and reestablish mechanical stability required for full function. Failure to securely close the sternum may lead to both long and short-term complications. Up to 8% of sternotomies result in sternal dehiscence or the lateral separation of the sterna halves. The mortality rate for patients with cases of dehiscence is 10-40%, due primarily to mediastinitis, surrounding the incision. Cases of both dehiscence and mediastinitis are more common in patients over 75 years of age, obese patients or those suffering from osteoporosis (Bek, Yun, 2010). More effective sterna closure and fixation methods should be explored to improve the sternum's healing process and reduce post-sternotomy complications.

### 2.3.1 Closure Methods

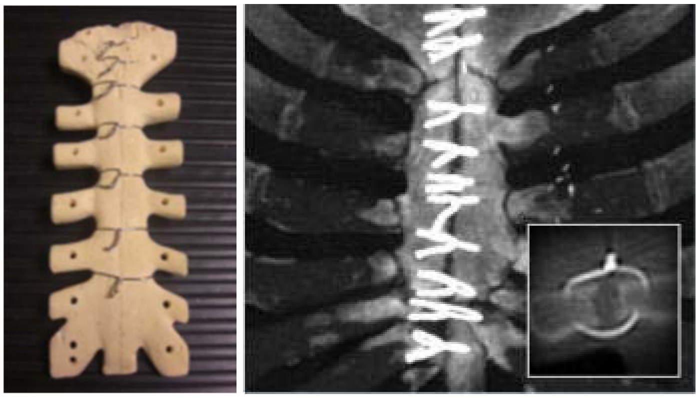
Proper sternal closure after a sternotomy can yield improved healing, decreased incidence of dehiscence, and increased patient comfort. There are two kinds of sternal fixation, rigid and non-rigid, each having associated advantages and disadvantages.

#### *2.3.1.1 Non-Rigid Fixation*

Non-rigid fixation is most popularly used in sternal closure procedures today. Non-rigid fixation allows the sternum to deform due to numerous forces associated with patient movement and respiration, resulting in a variety of potential complications.

##### Cerclage Wire Fixation

Cerclage Wire Fixation is the most common method of sternal fixation, rigid or non-rigid. Use of cerclage wires was popularized in 1957 and has since become the standard method of fixation. During the procedure, five to seven stainless steel wires are wrapped around the sterna halves, and wire ends are twisted and buried in the tissue (Ozaki et al, 1998), as seen in the sternum model in Figure 4.



(a) (b)

**Figure 4: Cerclage Wire Fixation (a: Bakalova et al. 2010, b:Biomet Microfixation, 2011)**

Figure 4 (a) shows a Sawbone sternum fixated with wire. Figure 4 (b) shows an x-ray image of sternal separation after wire fixation was used.

There are many advantages to using wire fixation. Relative to other products currently in the market, wires are the least expensive. The installation process is also well known by surgeons, therefore making the overall procedure faster and less expensive. Over the years, wire fixation has been proven moderately successful, but is not without complications (Ozaki et al, 1998).

Despite benefits of wire fixation, approximately 0.7-1.5% of patients will experience complications after the procedure. Sternal separation, lateral displacement, and tissue damage are common. Osteoporotic bone is at a higher risk for these, as well as additional problems such as mediastinitis or sternal nonunion (Pai, 2005). Because many of the patients undergoing open-heart procedures are greater than 65 years of age and therefore have a high probability of osteoporosis, a high risk of these complications is prevalent (Ahn et al., 2009).

One of the most prominent and preventable failure modes of cerclage wire fixation is sternal nonunion. Limiting motion between the sternal halves increases healing and reduces incidence of the stated complications. After significant cyclic loading, sternums fixated with wire show a much higher separation rate than those fixated with a plating device, as seen in Figure 5 (Pai, 2005).

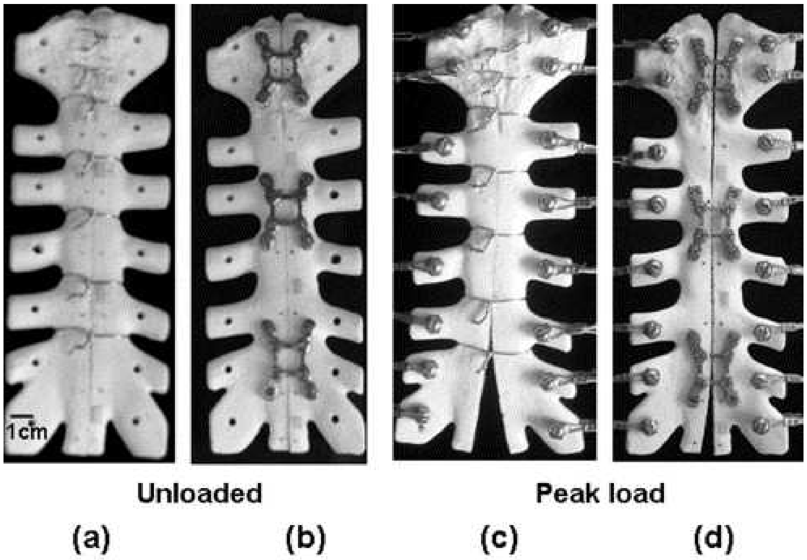


**Figure 5: Results of Cyclic Loading on Wire and Plate Fixation Systems (Pai, 2005)**

By changing the sternal closure method from non-rigid to rigid fixation, surgeons can decrease the number of post- sternotomy complications.

### *2.3.1.2 Rigid Fixation*

Rigid fixation is an increasingly used method of sternal closure and is characterized by the products that rigidly support the sternal halves. Rigid fixation products currently on the market include the Sternal Talon, developed by KLS Martin as well as numerous screw and plate systems, which will be explored later in this chapter.

#### Sternal Talon

The KLS Martin Group, a global surgical products company, has introduced an innovative design to sternal fixation: the Rapid Sternal Closure Talon System. Unlike other fixation methods, the Sternal Closure system uses titanium talons, or hooks, to pull both sides of the sternum together, as seen in Figure 6. The ratchet mechanism within the talons is then secured by a screw, and pressure is thus applied to compress the hemi-sterna in their original position.

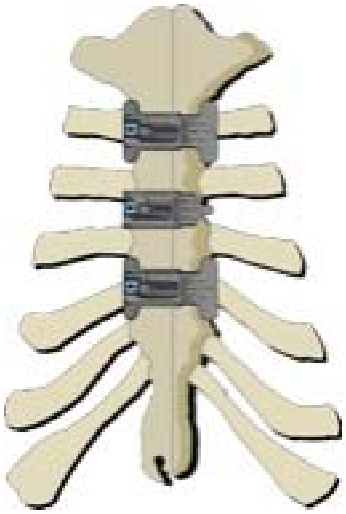


**Figure 6: Sternal Closure Talon System (KLS Martin, 2006)**

This method is especially suited for high-risk patients, including those with diabetes and osteoporosis (KLS Martin, 2006). Although the Rapid Sternal Closure Talon System efficiently secures the sternum and prevents non-union, it is not commonly used. The system's high profile and bulkiness deem it a less appealing fixation method for patients. The high cost and complicated installation method result in sparing use in clinical practices.

## 2.4 Screw and Plate Systems

Sternal fixation by plates and screws is becoming more popular due to the reduction in complications associated with the procedure. One study proved an increased ease of installation of plating devices over wire fixation, as well as the ability of screw-plate systems to reduce the incidence of mediastinitis (Kun, 2009). Plates have also been proven effective at rigidly holding the hemi-sterna intact over time, as well as decreasing the rate of their separation (Pai, 2005). An example of a human sternum closed by rigid screw and plate fixation is shown in Figure 7.

**Figure 7: Human Sternum Closed by Plate-Screw System (Song, 2004)**

The variable-density nature of the sternum, in addition to its small size and potential for osteoporosis, are challenges that must be taken into consideration when choosing an appropriate method of fixation. Due to the porous nature of osteoporotic bone, it is difficult for a screw to make purchase within both layers of the bone without inducing bone stripping or other excessive damage to the tissue. Shear stresses exerted on a fixated osteoporotic sternum can result in an increased risk for screw pullout failure. The cyclic forces associated with respiration can cause screw loosening. Small system parts can cause difficulties in installation, since the screw is no more than 15-20mm in length (Egol, 2004).

Regardless of their orthopedic applications, current screw and plate systems lack the ability to create a friction fit between the plate and bone while simultaneously locking the screw head to the plate. Obtaining a friction fit is necessary in order to maintain stable fixation and to reduce post-surgical complications (Dunn, Lalikos. Personal Interview, 2011). Ultimately, locked plate and screw systems that obtain a flush fit to the sternum have yielded optimal testing results on osteoporotic bone, and are therefore viable methods of sternal fixation. There are many devices currently on the market that address one of these problems, but not both.

### 2.4.1 Screw Design

The design of screws changes their overall function. There are many factors that govern the functionality of screws as well as change the application they are used for.

#### *2.4.1.1 Components of a Screw*

The three primary components of the screw are the head, core, and thread. The head functions to transfer applied torque to the core and thread. It also serves as a surface of contact with the plate which stops the screw from being inserted further; as the head reaches the plate, torque is transformed into compressive forces which flush-fit the fixation system onto the respective bone (An & Draughn, 2000).

The core is the central shaft of the screw around which threads are wrapped. The length of the core varies from screw to screw, depending on the physical characteristics of the bone to which it is applied, to provide the necessary purchase. A screw is characterized by the diameter of the shaft at the base of the screw, the minor diameter, and the diameter between the outer edges of the threads, the major diameter (An & Draughn, 2000).

The thread is a helical ridge wrapped around the core which functions to obtain purchase within bone tissue. The difference between the major and minor diameters of the screw defines the thread depth, or the cross-sectional surface distance in contact with the bone. As torque is applied to the screw, rotational motion is converted into translation motion due to the helical configuration of the thread. Similarly to a series of ramps, the threading mechanically facilitates the screw's insertion into the bone. The thread pitch is the distance between each subsequent thread along the core of the screw as seen in Figure 8 (An & Draughn, 2000).

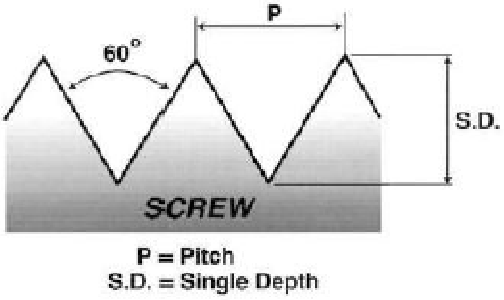


**Figure 8: Screw Thread Parameters (An & Draughn, 2000)**

### *2.4.1.2 Bone Screw Types*

Bone screws are specifically designed to function effectively in the bone into which they are installed. Bone health and density, wound location, and fracture type are considered to determine the appropriate design of the screw used.

#### Cortical and Cancellous

Cortical and cancellous screws are classified by the layers of bone that they interact with. The cortex of a bone is the hard outer shell covering the entire bone. The human sternum is very shallow and both cortices of the bone can easily interact with a screw. A bicortical design is desired by surgeons due to the mechanical stability it provides the system; however, a bicortical screw puts the organs under the sternum at risk of being punctured by the screw tip. Developing a device that maintains the mechanical stability of a bicortical screw in a unicortical design is ideal in the situation of sternal fixation (Dunn. Personal Interview, 2012).

Cortical screws have a high thread count, and low thread depth and pitch. The cortical section of the bone is harder and denser than the cancellous portion; thus, less thread penetration into bone tissue is needed for stability. Cancellous bone screws have a lower thread count and pitch, but higher thread depth (Figure 9).

**Figure 9: Cortical Screw (left) and Cancellous Screw (right) (Crown Metal Works, 2009)**

Due to the soft, less dense, and more porous nature of cancellous bone, cancellous screws require more surface area to be in contact with tissue for mechanical stability (Shields, LoCicero, Ponn, & Rusch, 2004).

There are two variations of cortical screws: bicortical and unicortical. These differ by the number of bone cortices they puncture during insertion, as seen in Figure 10.

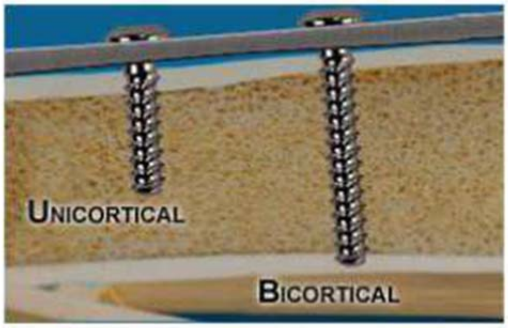


**Figure 10: Unicortical and Bicortical Screw Systems (Bakalova et al, 2010)**

Bicortical screws are commonly used in bone and yield more mechanical stability by obtaining purchase through both cortices. Unicortical screws only puncture one cortical layer: the surface of their insertion point. Unicortical screws also impact the median layer between cortices. Although less mechanically stable, unicortical purchase prevents accidental puncture of tissues or organs near the impacted bone (Ahn et al., 2009).

### Self-Tapping and Pre-Drilled

Self-tapping and non-self-tapping, or pre-drilled, screws vary by their means of insertion. Self-tapping screws have deeper, sharper threads that interact with the bone tissue to create grooves when the screw is subjected to applied torque. A sharper screw tip enables the screw to be inserted without pre-drilling holes. Unlike self- tapping screws, pre-drilled screws require tapping after drilling before insertion into the bone. Although a less sharp tip may reduce the risks of excessive tissue damage, drilling into the bone prior to screw insertion is an additional procedure requiring more time (An & Draughn, 2000). Self-drilling screws do not require any drilling prior to insertion. They are characterized by a sharp conical threaded tip and an engraved cutting flute at the end of the screw body which enable the simultaneous insertion and the removal of bone particles (Gibbons & Hodder, 2003).

#### Standard and Locking

Standard and locking screws differ by the clinical need to lock the screw head into the plate. Locking screws come in numerous shapes and sizes with just as many variations of locking mechanisms. Locking screws function primarily to lock the screw into the plate and reduce screw loosening. Standard screws are simply those without locking mechanisms. Figure 11 shows one form of standard and locking screw.

**Figure 11: Standard Screw (left) and Locking Screw (right) (Stryker, 2011)**

The screw head in the locking example (right) is threaded, allowing it to lock into place by fitting into corresponding ridges in the plate well. Conversely, the standard screw (left) does not have a threaded head and therefore would not lock into a threaded plate. The orthopedic applications of both screws are extensive, however the technology of locking screws is not yet developed to its full potential.

### 2.4.2 Plate Design

Plates used in sternal fixation can be any number of shapes and sizes to accommodate variable sternum anatomy. The topography, geometry, and locking mechanism of the plates change the force distribution, amount of pressure on the sternum, and forces exerted on the screw and plate. Plates used in sternal fixation must compliment the screws used in the system in order to have a successful fixation (Bakalova et al., 2010).

#### *2.4.2.1 Plate Configurations*

Straight plates are the first-generation alternative to the wire-fixation method. A straight plate is a linear fixture with holes strategically placed throughout the plate for screw entry (Figure 12).

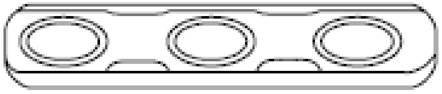


Figure 12: Straight Plate (Ahn et al, 2009)

When testing wires compared to four-hole titanium straight plates, no statistically significant difference in the stiffness or lateral displacement was shown (Ozaki, 1998). One factor this study did not account for was the pain associated with wire fixation, as the wires have been proven to cut into osteoporotic bone during respiration, causing the patient both pain and tissue damage.

X and H-Plates are very similar to straight plates. These plates differ in the overall shape of the plate as well as the location of the screws throughout the plate (Figure 13).

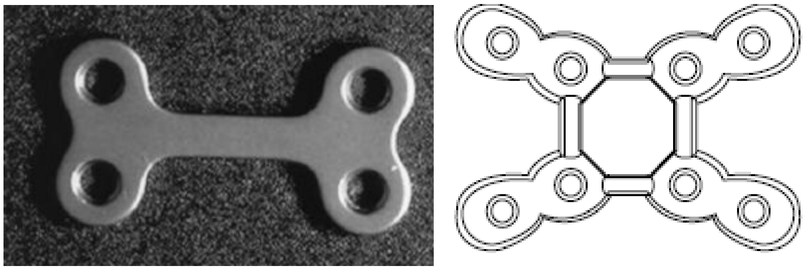


Figure 13: H-Plate (left) and X-Plate (right) (Ahn et. al, 2009. Ozaki, 1998)

X and H-Plates tend to be more effective than straight plates because they distribute forces to a larger surface area and use more screws for added security and stability. During comparative testing between the straight plate and the four-hole titanium custom H-Plate, the H-Plate resulted in statistically significant greater stiffness ($p < 0.05$) and less lateral displacement ($p < 0.05$) than both wire fixation and straight plate. Testing procedures were done using human cadavers (Ozaki, 1998).

### 2.4.3 Current Screw and Plate Designs

Screw and plate systems are not new to the market, and numerous iterations of designs have been produced over the past 5 years. The screw and plate systems seen below utilize a locking mechanism between the head of the screw and the plate. Although locking systems are beneficial in securing the system, they often do not allow the surgeon to ensure a tight fit between the plate and bone.

Threaded screw heads are seen in many locking mechanisms. Threaded heads are beneficial in the physical locking of the device; however, if they are not paired with a system that awards the surgeon more control, they can cause more harm than good.

### Anti-Wobble Design

The Anti-Wobble proof of concept is a concept that identifies the delayed locking system between a screw head and plate to eliminate the ability of a screw to “wobble” out due to cyclic loading (Ahn et al., 2009). The anti-wobble concept has been explored through various projects completed by students at Worcester Polytechnic Institute (WPI) as well as other designs on the market.

### BioMet Microfixation Design

BioMet Microfixation developed the SternaLock sternal fixation mechanism. The SternaLock product is a plate and screw system that allows the surgeon to choose from multiple shapes of fixation plates in order to meet the needs of individual patients. The SternaLock device still requires the surgeon to attach a reduction wire to the sternum to set the hemi-sterna in place. The plate section that crosses the midline of the sternum can be cut in order to gain re-entry into the sternum and is a double-sided plate design that allows surgeons to use either side of the plate to optimize bone contact. SternaLock screws are a cancellous design with a threaded head locking mechanism (BioMet Microfixation, 2011).

### Smith & Nephew VLP Foot Plating System

Smith & Nephew makes a plating system called the VLP Foot Plating System. Although the orthopedic applications of the VLP Foot system are different than sternal fixation, the device still rigidly fixates bone. The VLP system has a variable angle insertion mechanism that allows surgeons more freedom in choosing placement of the system. Numerous plates and specialty screws cater to patients with low bone density and challenging anatomical shapes. The heads of the VLP Foot system’s screws are threaded in order for them to easily lock into the plate at multiple angles of up to 15 degrees as seen in Figure 14.

**Figure 14: Smith & Nephew VLP Foot Plating System (Smith & Nephew, 2010)**

This system is similar in design to other locking systems in that a fully threaded screw shaft and head are used as a locking mechanism. This is appealing to surgeons because they enable application at a variety of angles and ensure locking (Smith & Nephew, 2010). As previously state, premature locking due to threaded screw heads can result in a significant gap between the plate and bone.

## KLS Martin Threadlock TS System

The Threadlock TS System by KLS Martin is primarily used for mandible fixation. Much like previous designs, the plates and screws available cater to individual patient needs. This fixation system allows the surgeon to deploy the screw at an angle of up to 20 degrees. The full length of the screw is outfitted with uniform threading and pitch to allow for easy installation, and a locking plate configuration secures the screw head into place (KLS Martin USA, 2010).

## Synthes CLSP Quick Lock System

Synthes produced a nested screw design that comes pre-loaded to emulate a single unit design. The multi-unit function of the preloaded screw is achieved by using tooling to rotate the outer screw and inner screw independently. The application of the Synthes system is in the spine; however the concept of a delayed locking mechanism is realized in this design. The head of the inner screw of this device is used to expand the outer screw in order to fixate it within the plate as seen in Figure 15.

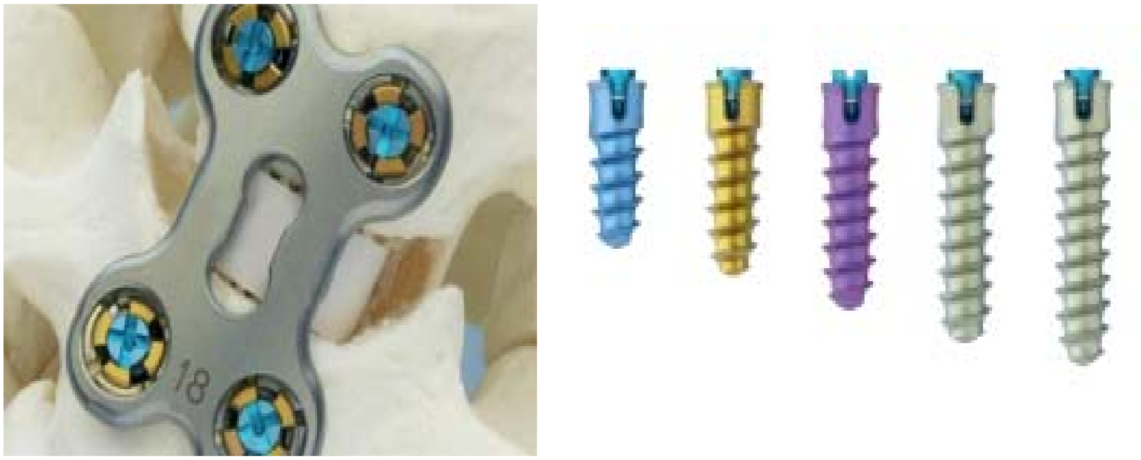


**Figure 15: Synthes Nested Screw and Plate System (Synthes, 2007)**

This screw and plate system has been available since 2007, but has not been widely used in clinical practices. The complexity and cost of a nested screw design may be the main contributor to the lack of use in a clinical setting.

### 2.4.4 Previous WPI Designs

Based on the benefits associated with rigid fixation, prior WPI project teams have focused on designing a novel screw-plate system. In 2009, students worked to incorporate client needs with the anti-wobble proof of concept that they first developed and tested as a means for obtaining more effective screw-plate fixation. The anti-wobble system enables a user to first obtain a flush-fit between the bone and fixation plate, and then to lock the screw into the plate to prevent loosening. This concept is evident in the final design, which is comprised of a plate, bone screw, and a threaded cap. The screw and cap are first installed as a single unit; then, the cap is rotated back up and threads into the plate, thereby locking the screw in place (Figure 16). Although this design functions effectively, its multipart system is undesirable for use. The threaded cap is an additional component which increases not only the number of parts, but also overall installation time of the system.

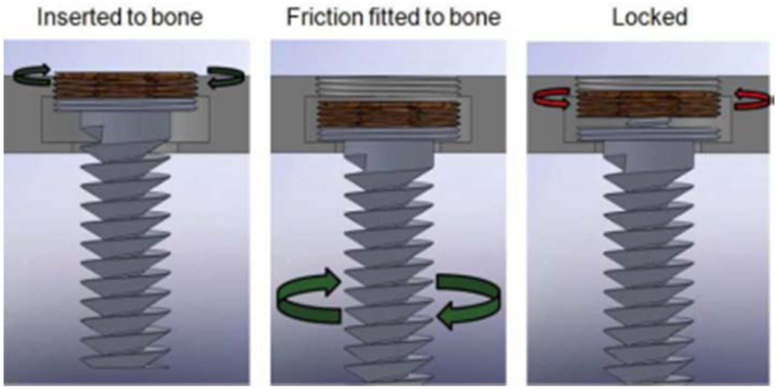


Figure 16: 2009 Anti-Wobble Design (Ahn et al, 2009)

In 2010, a bilateral cyclic testing system which mimicked human respiratory forces was developed. This device was created for testing mechanical properties of sternal fixation systems on both cadaveric and polyurethane Sawbone models. Various screw-plate models were tested to determine performance in unicortical, bicortical, locking, and standard fixation systems. Although the anti-wobble fixation device was not further developed, the findings from these test analyses yielded information pertinent to future design processes (Bakalova et al., 2010).

The design of a rigid sternal fixation device was continued in 2011. The final manufactured design follows the anti-wobble proof of concept and is comprised of a fixation plate and a set of two nested screws - an outer screw and an inner screw. In order to first obtain a flush fit, the user installs the larger outer screw. To lock the outer screw into the plate, the smaller inner screw is then installed into a threaded cavity of the outer screw head. As torque is applied to the inner screw, cross-sectional slits within the outer screw head enable it to expand into the plate and thus lock into place (Figure 17). Cyclic testing of the device proved lower displacement compared to standard screw systems. However, the excessive amount of torque applied to the inner screw may cause the outer screw to continue rotating, causing bone stripping in the sternum (Song et al., 2011).

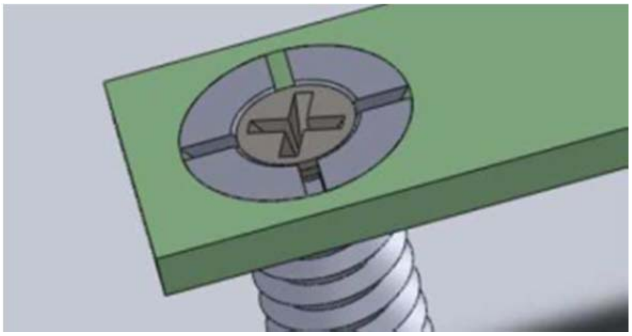


Figure 17: Assembled 2011 Anti-Wobble Design (Brunelli et al, 2011)

In order to further develop the screw-plate fixation system, the delayed-locking mechanism, or the flush-fit followed by screw locking, must be optimized to maintain the anti-wobble proof of concept. The limitations of previous designs should be reduced, and testing should yield positive performance results in appropriate sternum models.

# Chapter 3. Project Approach

## 3.1 Client Statement and Design Goals

The main stakeholders of this project are as follows:

Designers: Worcester Polytechnic Institute (WPI) Biomedical Engineers
Clients: University of Massachusetts Medical School (UMMS) Surgeons and KLS Martin
Users: Surgeons who will work with the product in the field after development

The needs and opinions of stakeholders involved with this project will weigh accordingly within the design process.

This project and the associated designs are based off of previous research and project work completed by WPI Engineers in conjunction with UMMS surgeons. Past projects including studies of screw type in cortical and cancellous bone, rigid stabilization of the sternum with a screw and plate system, and research in screw stability in both cadaveric and substitute bone material have evolved the need for a new screw design to minimize bone stripping during the installation of current screw-plate systems, as well as a more effective locking mechanism in the screw-plate interface.

### 3.1.1 Initial Client Statement

*Redesign and test a screw head for a Rigid Sternal Fixation device that maintains the anti-wobble concept established in previous renderings of the sternal fixation system. Create a single tool to implant the screw into the sternum through the sternal fixation plate. Provide drawings to KLS for manufacturing of the final design.*

### 3.1.2 Design Goals

The goals of this project are to ultimately design a screw that maintains the anti-wobble proof of concept approved by KLS Martin in May of 2011, but that eliminates the failure modes seen by previous designs. In order to achieve this goal, there are numerous sub-goals that need to first be accomplished. We must first examine limitations of existing screws to develop an understanding of the design challenges we need to overcome. We then can proceed with optimizing the screw-plate interface, and simplifying the locking mechanism that will hold the screw in place. Finally, we plan to complete competitive testing to evaluate the effectiveness of our design compared to designs currently on the market. In addition to the development of a new screw, we hope to design a pre-loaded tool that will allow for consistent, easy installation of the product if there is time.

### 3.1.3 Objectives, Constraints, Functions and Specifications

The following is a breakdown of the main components of the design process that were put into place prior to initially designing our product.

### *3.1.3.1 Objectives*

Development of a locking screw-plate fixation system for the prevention of post-sternotomy displacement is guided by the following objectives (Figure 18).

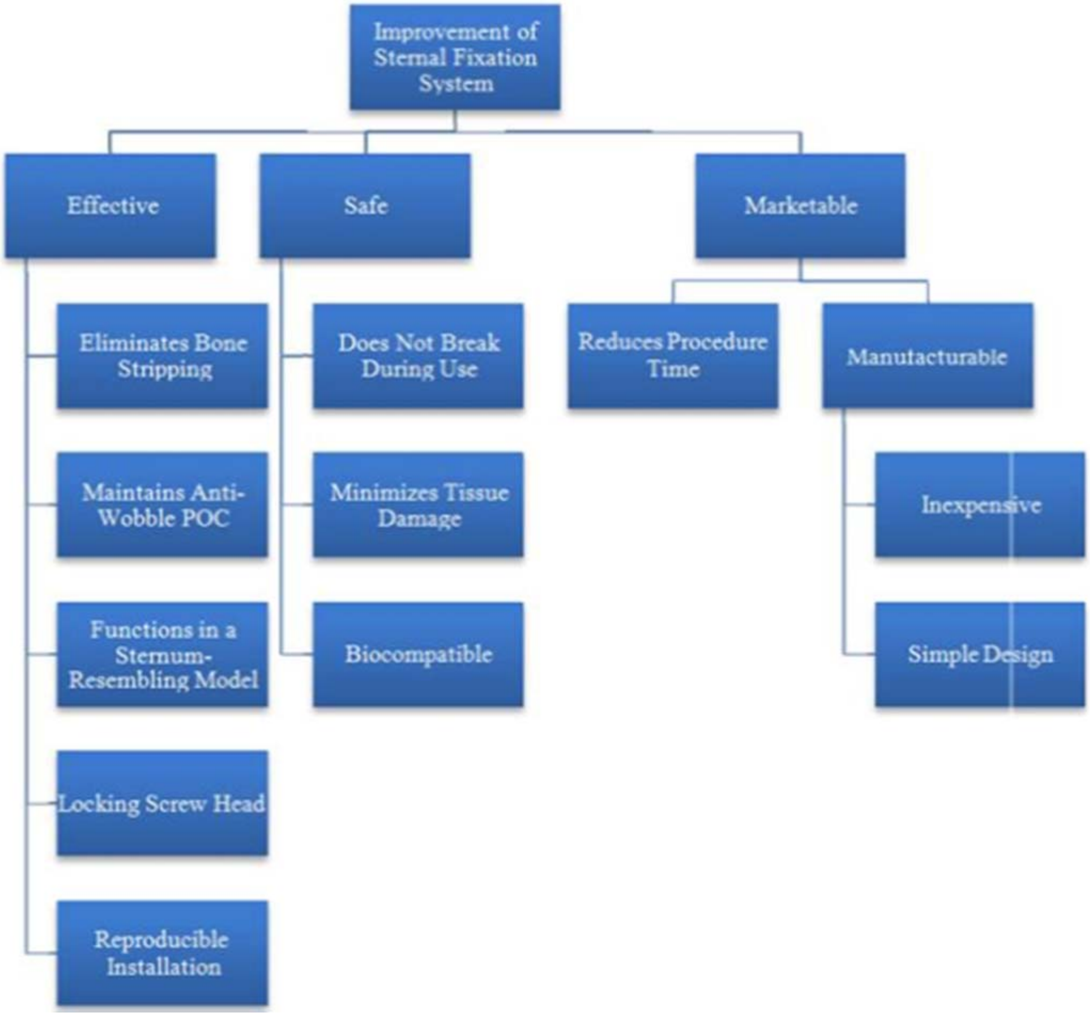


Figure 18: Objectives Tree

**Effective** – The sternal fixation system must be effective in rigidly securing the hemi-sterna together after surgery. The Anti-Wobble proof of concept must be maintained to ensure a flush fit between the bone and plate as well as the engagement of a locking mechanism between the screw and plate to minimize screw loosening during respiration. The sternal fixation system must be functional in a sternum-resembling bone model to ensure its effectiveness in the human body. According to client feedback, a delayed locking mechanism is the most important objective to optimize due to existing risks associated with screw loosening. The sternal fixation system must yield reproducible installation and effectiveness in every surgical procedure.

**Safe-** The sternal fixation system must be safe to both the surgeon and the patient. The system should have as few components as possible, and the components should be stable and effectively secured within the system, to prevent risk of breaking off during surgery. The fixation system needs to minimize tissue damage during and after installation, and must be biocompatible to avoid unnecessary interactions with tissue or physiological rejection. Additionally, the system must contain a unicortical configuration in order to prevent puncture of the dorsal side of the sternum and to minimize the risk of heart damage.

**Marketable** – The designed sternal fixation product must be marketable. A device which reduces surgical procedure duration will appeal to consumers because of time and cost savings; a simpler and faster method of installation than those available will reduce the overall cost of the operation. Additionally, the screw must be one unit in order to ease installation and to prevent component loss during assembly. The product must be manufacturable to enable mass production. An inexpensive system will create a large consumer base due to cheaper cost, and a simple design will reduce limitations of manufacturing.

*Pairwise Comparison Charts completed by a UMMS surgeon pertaining to these objectives can be found in Appendix A.*

#### *3.1.3.2 Constraints*

Development of a locking screw-plate fixation system for the prevention of post-sternotomy displacement is guided by the following constraints:

**Budget**: The budget for this project is $150 per group member, provided by WPI. UMMS and KLS Martin will provide additional funds to be determined as the project develops.

**Time**: The project must be completed by April 26, 2012.

**Safety/FDA Standards**: Any device used in conjunction with or in addition to the current sternal fixation device must meet all FDA requirements for safety.

**Maintenance of current system functionality**: The screw we design for the sternal fixation plate must maintain the elements included in the proof of concept product that was developed in past years' projects. Specifically, the screw must be "anti-wobble."

**Single Unit Design**: Upon installation, the screw must be one single unit.

**Removable**: The system must be quick and simple to remove in order for surgeons to gain access to the chest cavity in emergency situations.

**Size:** Screw length is essential due to the sternum's location near sensitive organs. According to specifications outlined by previous projects, the largest screw can be no more than 15mm-20mm in length.

**Patent infringement**: The screw market has been highly explored and patented; any product or system that we design must be clear of patent violations.

**Valid Testing Model**: There is currently a lack of a commercially available, validated, osteoporotic sternal model that our product can be tested on.

### *3.1.3.3 Functions and Specifications*

Our design must optimize the following functions and needs for effective sternal fixation: provide mechanical rigidity and stabilization to the sternum, provide a flush fit between the plate and bone to reduce shear forces associated with respiration, lock the head of the screw into the plate to eliminate device component loosening, and reduce bone stripping or other excessive tissue damage.

In order to achieve these mechanical functions, the device has to comply with the specifications set by the clients and previous studies. The screw length will vary between 11-15mm, and possess an approximate outer diameter of 3.2mm and an inner diameter of 2.0mm.

The system will need to withstand lateral forces of 43.8N and transverse forces of 9N. The screw must be composed of Ti-6Al-4V Titanium alloy. The insertion torque applied to the screw must be lower than the maximum tolerable torque for the human sternum, 0.049N-m. Additionally, our device must be biocompatible within physiological conditions. Although our project will not focus on the bio-inertness of the device, the final product must be appropriately sterilized prior to use in clinical settings. Lastly, the device must not inhibit the regenerative processes of sternal tissue.

Our design alternatives feature components that optimize the functions and follow the specifications necessary for the device. The final conceptual design is a combination of such components in order to produce the most efficient system for sternal closure.

#### *3.1.3.4 Revised Client Statement*

*The goal of this project was to design, model and test a single-unit unicortical screw and plate system that provides both lag and locking functionality. The screw must provide a flush fit between the plate and bone, lock into the plate, and reduce the potential for dorsal puncture of the sternum.*

# Chapter 4. Methodology

The goal of this project is to develop a single-unit screw and plate system that effectively closes the sternum of a patient after a median sternotomy, maintains the Anti-Wobble concept established by previous designs, and prevents dorsal puncture of the sternum. This chapter describes the methodology used to model, evaluate, and test the design. Finite Element Analysis (FEA) was used to evaluate the mechanical characteristics of the device, and large scale testing was completed to validate the proof of principle associated with the design concept.

## 4.1 Modeling in SolidWorks

The final design, the Reverse Expansion System, was modeled using SolidWorks 2011 software. The concept of this new unicortical fixation system features a single unit screw that expands as the head comes into contact with the plate during insertion. An angled circular ridge on the bottom surface of the plate well forces portions of the screw head to deflect as torque and uniaxial force are applied, seen in Figure 19. A detailed description of the final product design is included in Chapter 5.2.2 of this report.

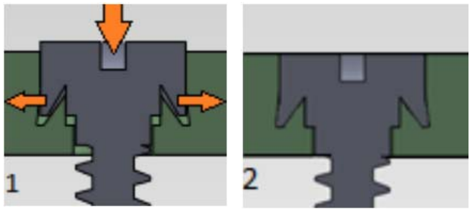


Figure 19: Reverse Expansion System Concept

Three-dimensional technical drawings of both the screw and plate were created in order to visualize the components and test the effectiveness of the screw-plate interface. Additionally, eight simplified versions of the screw were created for FEA deformation simulations. Figure 20 is one simplified version of the screw design. For simulation testing purposes, no threading was included on the shaft.

Figure 20: Simplified Reverse Expansion System Screw

Each of the simplified screws features one iterated screw head parameter. The screw versions are described in Table 1.

| Screw # | # Slits | Expanding Cross Section Thickness | Slit Thickness | Trough Angle |
|---|---|---|---|---|
| **1** | 4 | 0.278mm | 0.75mm | 30° |
| **2** | 2 | 0.278mm | 0.75mm | 30° |
| **3** | 4 | 0.478mm | 0.75mm | 30° |
| **4** | 4 | 0.078mm | 0.75mm | 30° |
| **5** | 4 | 0.278mm | 0.50mm | 30° |
| **6** | 4 | 0.278mm | 1.00mm | 30° |
| **7** | 4 | 0.417mm | 0.75mm | 25° |
| **8** | 4 | 0.124mm | 0.75mm | 35° |

Table 1: Simplified Screw Parameters

## 4.2 Measuring Screw Insertion Torque

In order to accurately simulate the expansion and deformation of the screw head, the torque and uniaxial force applied onto the screw during insertion were determined. We measured the torque by using a DSD-4 Torque Screw Driver. A hex-shank drill chuck was used to attach an appropriately sized driver to the torque meter. Ten trials to measure torque were performed by Dr. Dunn, Chief of Plastic Surgery at UMass Medical School (Dunn, 2012). During each trial, 2.3mm diameter orthopedic screw samples from KLS Martin were screwed into a Polyurethane Sawbones sternum sample of 30PCF density. Torque was recorded during maximal compression of the screw head to the sternum sample. Once the measurements were acquired, the mean value of torque was computed and compared to values found in previous studies. The average torque obtained from Dr. Dunn proved to be comparable to values found in literature (Nunmaker, Perren, 1976), seen in Table 2.

| Screw Diameter | 2.3mm (Dunn) | 2mm (Nunmaker) | 2.7mm (Nunmaker) | 3.5mm (Nunmaker) |
|---|---|---|---|---|
| **Torque** | 0.423 ± 0.006 Nm | 0.324 ± 0.122 Nm | 0.656 ± 0.238 Nm | 0.824 ± 0.340 Nm |

Table 2: Mean Screw Insertion Torque at Maximal Compression

An example of how the downward directed uniaxial force is applied to the top of the screw head during insertion is seen in Figure 21.

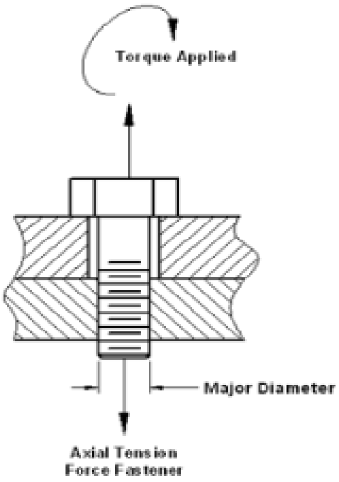


Figure 21: Torque-Axial Force Relationship on Fastener Screws (Fastener, 2011)

The mean value of calculated uniaxial force was used to measure displacement and deformation by Finite Element Analysis tools in Computer Aided Design software, SolidWorks.

## 4.3 Optimization of Screw-Plate Design

Finite Element Analysis (FEA) was performed on various iterations of the screw in order to find dimensions that yield the optimal head expansion and frictional fit to the plate while remaining in limits of manufacturability. Eight simplified screw models, as seen in Table 1, were used in conjunction with SolidWorks SimulationXpress Analysis Wizard to test head expansion. The variable screw versions depict iterations of the number of slits in the screw head, the thickness of the expanding region's cross-section, the width of the slits, and the angle of the trough. Four FEA studies were conducted to measure the displacement of the expanding screw head when the calculated force, described above, was applied. Each study focused on comparing the expansion resulting from iterations of each parameter. Material properties, total applied normal force, and screw fixtures remained constant in all FEA studies.

Upon the completion of screw head deformation studies, the parameters for optimal screw head expansion were chosen. The screw head geometry was then modified to yield the optimal expansion and frictional fit for our design.

## 4.4 Large-Scale Model Proof of Principle Testing

Simulations using a 1.5x scale-model were used to evaluate the proof of principle for the Reverse Expansion System. The effectiveness of the design was evaluated by comparative testing.

Models of the Reverse Expansion System screw and plate were manufactured in a 1.5x scale at Complex Mold & Machine using aluminum, seen in Figure 22. The experimental sample, the 1.5x screw-plate system, was assembled in two halves of a bone analog model that resembles the bicortical characteristic of the human sternum. As a comparison, a non-locking screw and plate system of the same scale were evaluated on the same bone model. Both devices were assembled in a unicortical configuration.

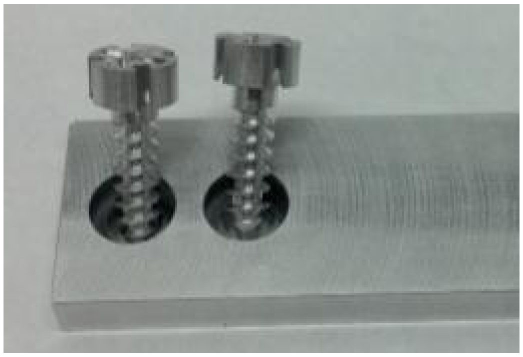


Figure 22: 1.5x Manufactured Assembly

A four-point bending test was conducted with the MTS by cyclically applying 50-150N of force at a frequency of 2Hz for 200 cycles or until complete device failure. This procedure was repeated on the control sample, standard nonlocking screws. The purpose of these tests was not to simulate breathing but rather to compare the mechanical stability of the Reverse Expansion system with that of a non-locking fixation system. The results of this testing allowed the team to evaluate the functionality and usability of the design within analogous models.

## 4.5 Testing Model

Testing models for medical devices are varied in their representation of human tissue and their ability to replicate its mechanical properties. Cadaver specimens are challenging to use because, although they are of human origin, they commonly have poor or disintegrated bone quality and thus do not accurately represent the strength or density of bone tissue found in living patients. Additionally, cadavers are very expensive to acquire (Ahn et al., 2009). The inconsistency of mechanical properties and high degree of variability between cadaveric specimens make them a challenging model to use when testing products for sternal closure (Kun, 2009).

The final testing model that was selected was a long bone analog, short fiber spun tubing, and can be seen in Figure 23. This material is ideal for testing a bicortical versus unicortical model because of the ability to puncture a single cortex of the bone.

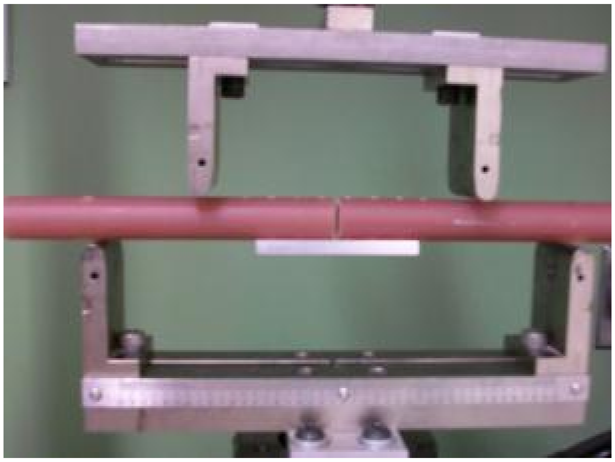


Figure 23: Long Bone Analog on the Testing Fixture

Additional testing materials explored can be found in Appendix B.

# Chapter 5. Design

This chapter will explore the alternative designs and justification for selection of the final design.

## 5.1 Needs Analysis

Due to the prevalence of open-heart surgeries performed every year in the United States, an effective method for sternal closure is needed. Although the market contains several products for sternal fixation, most devices that are currently used fail to eliminate the limitations associated with use for osteoporotic patients. A commonly used method – cerclage wire fixation – is harmful to the patient because of tissue damage caused during the healing process. On the other hand, the Talon System reduces the damage caused to osteoporotic bone and securely fixated the sternum, but is too expensive and complex for surgical preference. Plate and screw systems similar to those used for fracture fixation at other anatomical locations throughout the body are currently explored as alternatives. Although such systems either optimize the plate's flushed-fit to the bone or focus on locking the screw into the plate to limit component loosening, no current commercialized product functions to provide both outcomes.

The screw-plate system we are designing furthers the anti-wobble proof of concept demonstrated by previous WPI project teams. The Anti-Wobble system is characterized by a delayed lock mechanism which enables a surgeon to compress the plate to the sternum prior to locking the screw into the plate. Although proven effective, this system results in several modes of failure including screw loosening, dehiscence, bone stripping, and risk of heart damage due to bicortical puncture of the sternum.

Our design is effective because it reduces the limitations of previous designs and commercial products while optimizing the objectives and functions identified by engineers and clients. Our system fulfills the needs for an effective sternal fixation product by:

- Obtaining a frictional fit between the plate and bone
- Locking the screw into the plate
- Eliminating excessive tissue damage and puncture of the dorsal coritce

Additionally, our system optimizes client objectives by being:

- Safe by minimizing excess tissue damage
- Effective by maintaining the Anti-Wobble concept
- Marketable by consisting of a single-unit screw

In comparison to our system, current devices do not meet all of the needs crucial for sternal closure. Table 3 outlines alternative products not meeting these engineering criteria:

| Product | Unmet need: example |
|---|---|
| **Cerclage wire fixation** | Safety: wire cuts through osteoporotic bone<br>No locking: proven resulting dehiscence<br>No plate-bone compression: non-rigid fixation |
| **Non-locking screw-plate system** | No locking: screw does not lock into plate |
| **Locking screw-plate system** | No plate-bone compression: flush fit between plate and bone not obtained |

Table 3: Unmet Needs by Existing Products

## 5.2 Reverse Expansion Screw Head

The design developed for the 2011-2012 academic year is the Reverse Expansion Screw Head. This design is "reverse" because the expansion of the final design is opposite of the expansion in previous years' designs.

### 5.2.1 Alternative Designs

Leading up to the development of our final design, four alternative designs were developed and evaluated.

#### *5.2.1.1 Design 1: Plate Modification*

The first design we considered was an iteration of the anti-wobble fixation system presented in the 2011 Sternal Fixation MQP (Song et al., 2011). The screw-plate interface in this design alternative features a plate well which entraps the screw head as it expands and frictionally fits within the plate. As the inner screw is torqued into the outer screw, slits in the outer screw head enable it to expand. The extended plate lip, seen in Figure 24, serves as a point of contact for the screw to prevent its backing out after application. The lip ensures that the screw remains embedded within the plate as long as the head is expanded, thus enhancing the anti-wobble concept and reducing risk of screw loosening.

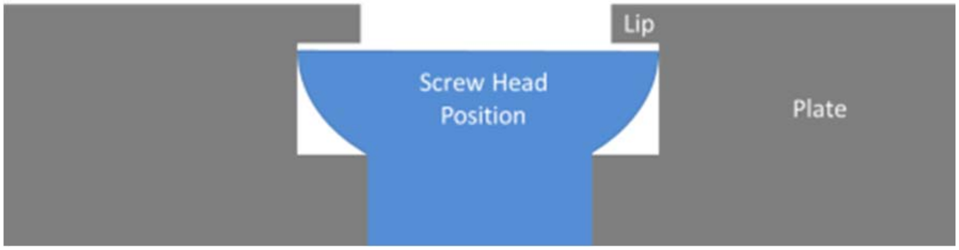


Figure 24: Expanded Screw Head under Plate Lip

Figure 24 shows how the modification of the plate with a lip will ensure the screw's locked position in the plate after expansion.

This design alternative was not chosen due to potential limitations that may result from the material properties of Titanium alloy. Because our design was restricted to materials consistent with those currently used by our sponsor, KLS, other materials could not be used for our device. With time and resource limitations of this project, we were unable to test both long and short-term elastic recovery of titanium to ensure that the screw can contract to its original geometry and be removed. The team decided to eliminate this design because of the clinical importance of guaranteed removability, which could not be ensured without proper testing.

#### *5.2.1.2 Design 2: Cap*

Previous Sternal Fixation MQP teams have investigated caps as design components to create a delayed lock necessary for the anti-wobble proof of concept. This design alternative uses a similar cap concept, or a third mechanical component which acts as the locking mechanism between the plate and the screw, as seen in Figure 25. After insertion of the screw, a threaded cap is applied over the screw into a correspondingly threaded plate well, thus securing all system components in place while providing the necessary delay in locking.

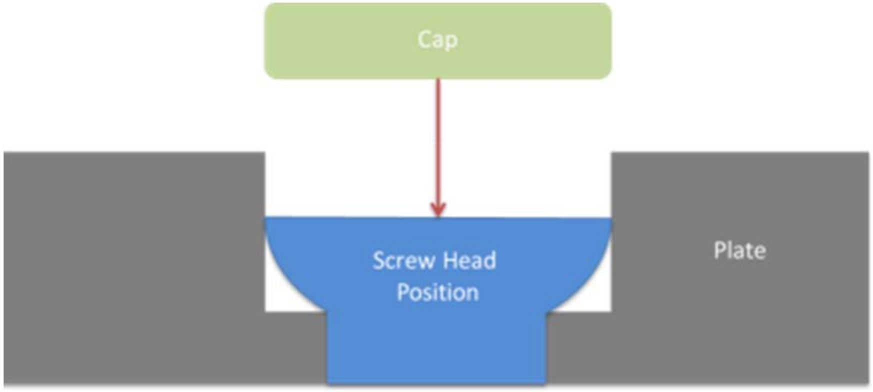


**Figure 25: Cap Used as Locking Mechanism between Plate and Screw**

Figure 25 shows the concept of utilizing a cap to lock the screw head into the plate. The cap is attached after the screw has achieved a flush fit between the plate and bone.

This concept was appealing to our team because it eliminated the ability of the nested screw design to strip the bone during installation, such as during application of an inner screw. Ideas for our locking cap came from numerous existing products, but the most successful, and easiest to install, was the Ikea Furniture assembly screw, as seen in Figure 26.

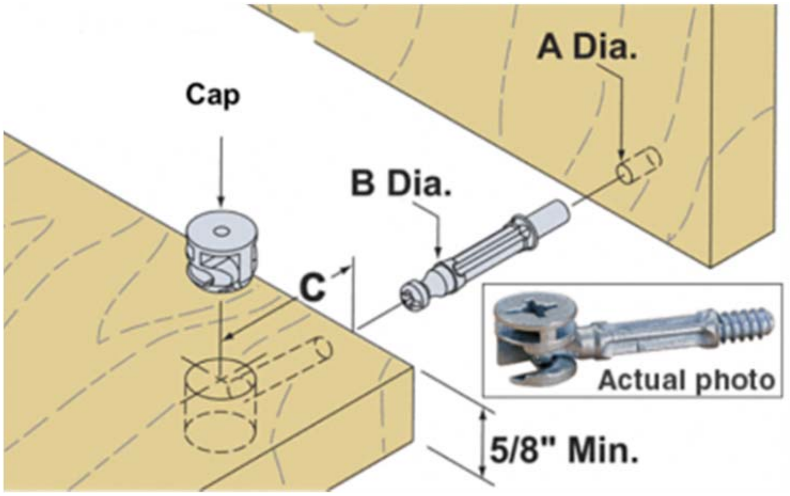


Figure 26: Ikea Furniture Assembly Screw[19]

The pin in Figure 26 is first inserted into the hole labeled "A Dia.," and then into the hole on the left. When rotated, the cap will trap the head of the pin pulling the pieces of wood together. Much like the two pieces of wood to be fixated, the bone would function as the "A Dia." component and the plate would function as the wood on the left side. The cap would, for our purposes, not join the two pieces of wood, but the head of the screw to the plate. The cap in Figure 27 uses a design similar to that of an Ikea Furniture assembly screw.

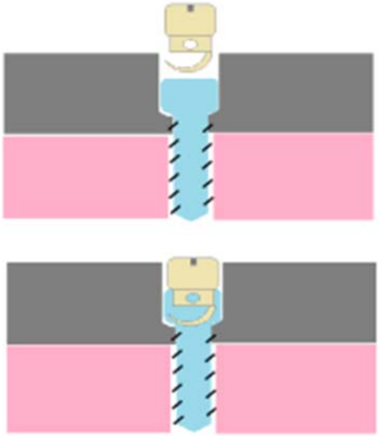


Figure 27: Utilization of the Ikea Design

This cap structure locks into the head of the screw while threading into the plate. The cap joins the head of the screw to the plate.

Ultimately, these alternative cap designs were not chosen for numerous reasons. A cap would present an additional component to the screw system, which is not ideal during surgery. In order to be functional in a plate well, the cap would have to be extremely small and thus difficult to manufacture. In order to make our final product more marketable and easier to use, this design was not chosen.

### *5.2.1.3 Design 3: Tooling*

Tooling can be used to solve numerous challenges presented by current fixation systems; however it is not the most efficient solution given the limitations of our project. We explored tooling as a means by which to eliminate bone stripping during installation of the inner screw. Potential instrumentation which was explored is presented in Figure 28; a compact tool consisting of two separate drivers functions to secure the outer screw in position while the inner screw is rotated.

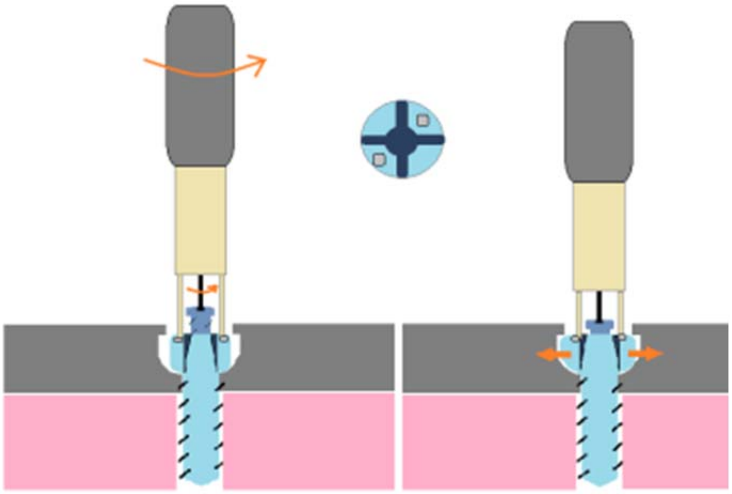


**Figure 28: Tooling for Installation of Expanding Screw Head**

The tooling shown above secures the outer screw while the inner is being inserted to expand the outer screw head. The head of the outer screw contains slots into which prongs of the tool are inserted to hold it in place.

Using tooling as an option to solve bone stripping will not be pursued in this project. Creating a self-tapping, rather than a non-self-tapping, screw will eliminate the ability of the surgeon to over-torque the screw head and cause stripping. According to the client, an effective system will reduce surgical time; therefore, the elimination of drilling holes by using a self-tapping screw will be beneficial. If using a self-tapping screw yields undesirable results, tooling will be reconsidered to accommodate the needs of the surgeons.

#### *5.2.1.4 Design 4: Expanding Head Modification*

The final design alternative explored was a series of modifications to the most recent screw design. Alternations included:

1. Evaluation and modification to number of slits in expanding head
2. Addition of reverse threading
3. Optimization of driver
4. Using a self-tapping screw tip.

These modifications, however, do not address one of the most important client needs: a single unit design. By optimizing the number of slits within the expanding outer screw head, the surgeons would need to apply less torque to obtain the same head expansion and locking. Reduction in required applied torque would also be addressed by selecting an optimal driver to insert the screw (Figure 29).

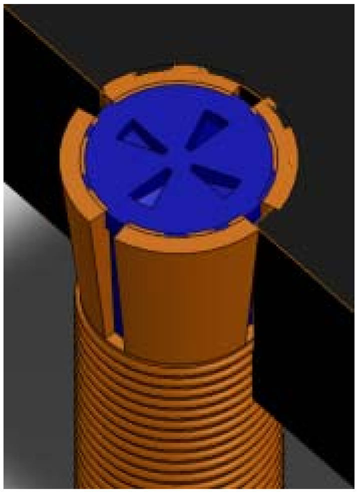


**Figure 29: Modified Head Design for Expanding Screw**

Reverse threading was explored in order to force the surgeon to perform a non-instinctual action in order to insert the screw. If the screw were only able to be tightened by turning left, than it would not be as easy for a surgeon to unintentionally over-torque the system. A self-tapping screw tip would serve as a method for reducing surgical time.

### 5.2.2 Final Design

The final conceptual design was obtained by combining features from the preliminary design alternatives into an interdependent system, which functioned to meet all of the specified means, optimize objectives, and fall within the constraints and specifications established by clients.

### *5.2.2.1 Reverse Expansion System Concept*

The Reverse Expansion System is a single-unit screw design that enables the head of the screw to obtain a friction fit within the plate. The design features a screw and plate interface that forces the head of the screw to expand within the well upon its contact with a circular wedge within the plate well.

The concept of the new design is illustrated in the steps below shown in Figures 30 and 31.

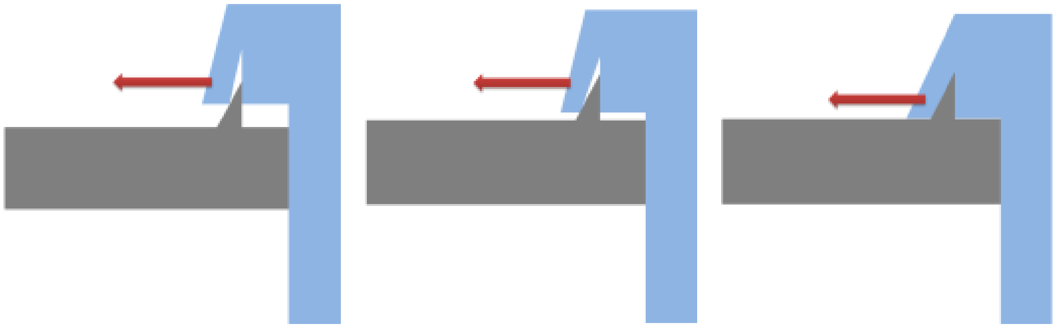


**Figure 30: Conceptual Model of Reverse Expansion Head**

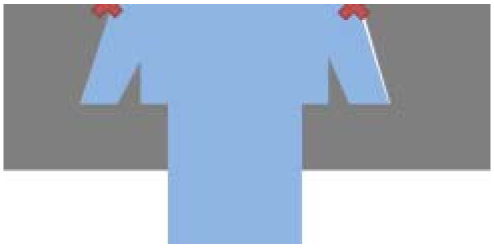


**Figure 31: Conceptual Model of Assembled Reverse Expansion System**

As the screw is inserted into bone, torque and force are applied through the driver to the screw head. Torque is transferred to the body of the screw as a uniaxial force, and the screw is translated downward as the threading obtains purchase within the bone. After the torqued screw begins to compress the plate against the bone, additional exerted force causes the head of the screw to interact with a wedge-shaped circular ridge in the plate. The corresponding circular wedge-shaped trough on the bottom of the screw head is characterized by a smaller angle than that of the plate's ridge. When the plate is compressed against the bone and uniaxial force is applied to the screw head, reaction forces normal to the angled surface of the plate's ridge are exerted on the inside surface of the trough. As a result, the head of the screw to expands outward proportionally to the difference in angularities. Slits cut around the screw head ease its expansion. This expanding action of the screw head forces it to compress and friction fit against an angled section of the plate well, locking the system together.

### 5.2.2.2 Reverse Expansion Screw

The screw features a trough underneath the distal surface of the head that interacts with a similarly-shaped ridge within the plate well. This wedge-shaped trough, with an angle of 5 degrees smaller than that of the corresponding ridge, as well as four slits cut around the outside of the head, force the head to expand outward to compress against the plate. The cross section and top view of the screw can be seen in Figure 32.

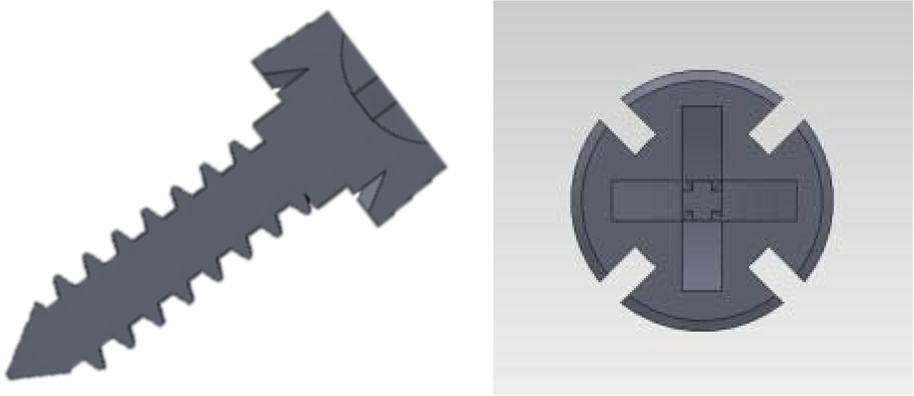


Figure 32: Cross Section (left) and Top View (right) of the Reverse Expansion Screw

The body of the screw features the geometry of a cancellous screw, as identified to be effective according to previous orthopedic research. The major diameter of the threads is larger than that of cortical screws in order to obtain more stability within osteoporotic bone. The screw is self-tapping and contains a sharp end that can pierce cortical bone without requiring pre-drilling. The head of this screw is compatible with a standard Phillips driver. The material used in the design of the screw is Titanium alloy, Ti-6Al-4V.

The dimensioned design of the screw’s cross section is seen below in Figure 33.

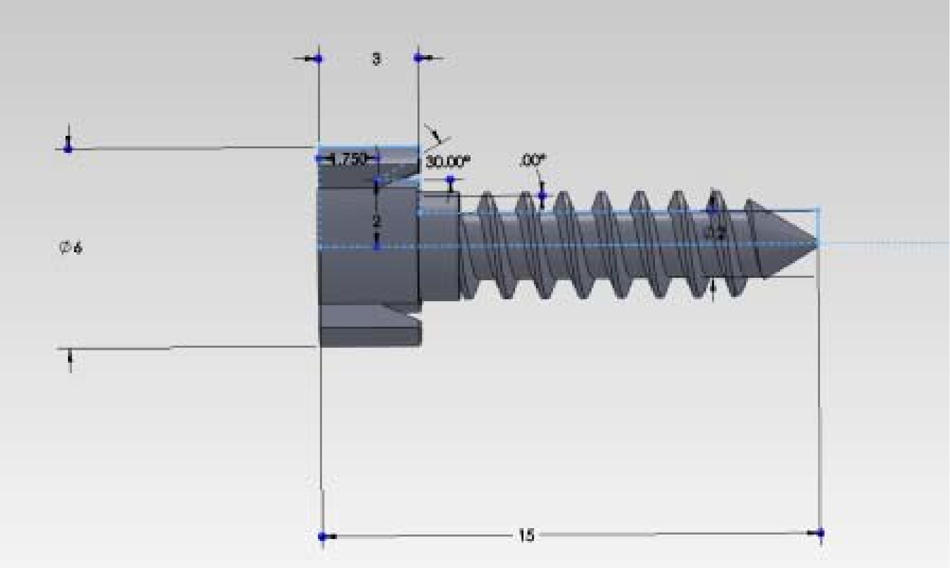


Figure 33: Dimensions of Screw Cross Section

#### *5.2.2.3 Custom Plate*

The plate required for the Reverse Expansion screw head to expand has a slight difference in geometry from the standard non-locking sternal fixation plates. The plate well features a wedge-shaped ridge that forms a circle within the plate well. The cross section of the ridge is a right triangle with its top angle 5 degrees larger than that of the screw head's trough, seen in Figure 34.

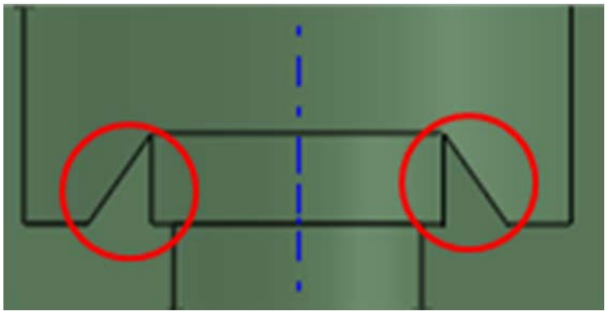


**Figure 34: Cross Section of Plate Well**

The circled portion of the diagram above shows the ridge within the plate well that comes into contact with the neck of the screw head, causing it to expand. The walls of the well are angled outward to enable the expanding components of the screw head to bend outward and obtain an optimal fit against the surface of the well. Similarly to the screw, the material used in the design of the plate is Titanium alloy, Ti-6Al-4V. The interaction between the plate and screw is shown in Figure 35.

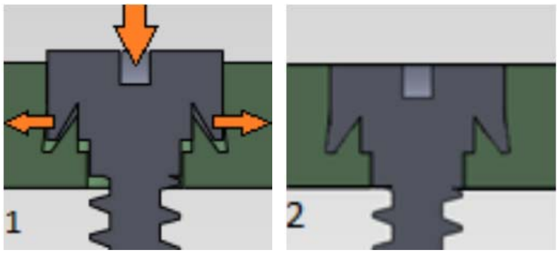


**Figure 35: Reverse Expansion Screw and Plate Interface Concept**

Two three-dimensional images of the entire screw-plate assembly design are seen below in Figure 36.

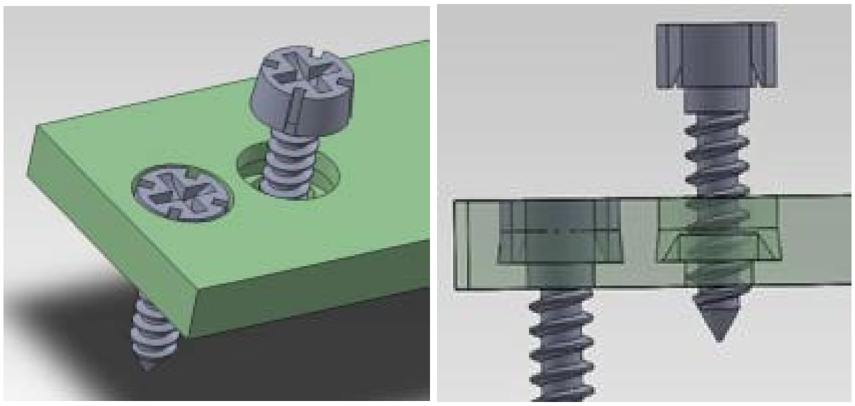


Figure 36: SolidWorks 3D Screw-Plate Assembly (Solid and Opaque)

The parameters of the final design are summarized in Tables 4 and 5.

| Length | Major Diameter | Trough Angle | Head Diameter |
|---|---|---|---|
| **15.0mm** | 3.2mm | 30° | 6.0mm |

Table 4: Screw Parameters

| Diameter | Ridge Angle | Wall Angle |
|---|---|---|
| **6.0mm** | 35° | 5.84° |

Table 5: Plate Parameters

# Chapter 6. Results

## 6.1 Screw-Plate Design Analysis

Finite Element Analysis was performed in order to study the deformation of the screw head as torque and uniaxial force are applied. Eight simplified screw models, each consisting of an iteration of a screw head parameter, were used to test the expansion resulting from a constant applied force.

After FEA was used to apply a constant normal force to each screw model, displacement results were obtained. Each screw head's displacement is visually portrayed by a color gradient that represents the amount of deflection in millimeters. Red signifies maximum displacement caused by the stress existing in the area of splay, whereas blue represents virtually no displacement, as seen in the example of a FEA deformation results legend in Figure 37.

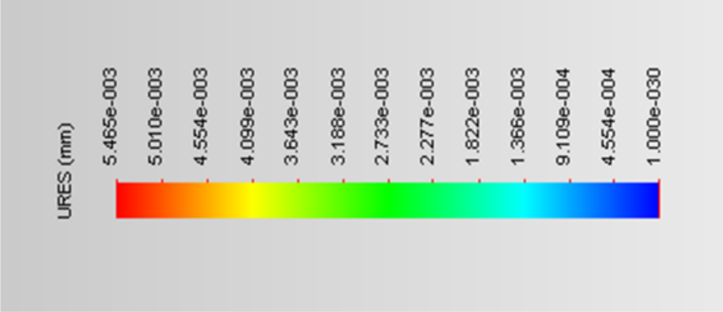


Figure 37: Resulting Displacement (mm) Represented by Color Gradient in FEA

The first study measured displacement corresponding to a different number of slits in the screw head, as seen in Figure 38. Four symmetrical slits, as opposed to two, resulted in a larger deflection when force was applied.

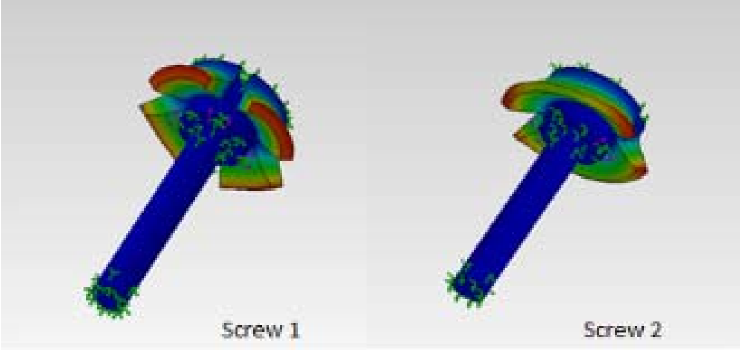


Figure 38: FEA Study 1: Displacement (mm) vs. Number of Slits;

Four slits (Screw 1) yield a greater displacement than two slits (Screw 2).

The second study measured displacement resulting from a variable cross-section thickness in the expanding portion of the screw head, seen in Figure 39. The screw model with the thickest cross-sectional thickness (Screw 3) resulted in the least amount of deflection, while the screw with the smallest cross-sectional thickness (Screw 4) yielded an increase in deflection. However, the dimensions of Screw 4 are not optimal since the thin expanding portions of the head may be too fragile to withstand applied forces during insertion.

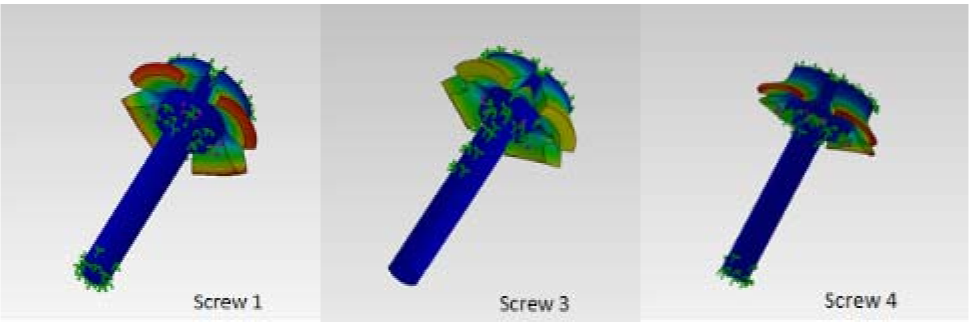


**Figure 39: FEA Study 2: Displacement vs. Expanding Cross-Section Thickness;**

**A 0.278mm thickness (Screw 1) yields a greater displacement than a 0.478mm thickness (Screw 3).**

The third study measured displacement corresponding to the width of the slits, seen in Figure 40. The largest displacement was achieved in Screw 5 where slit width was 1mm as opposed to 0.75mm or 0.5mm in Screw 1 or Screw 6, respectively.

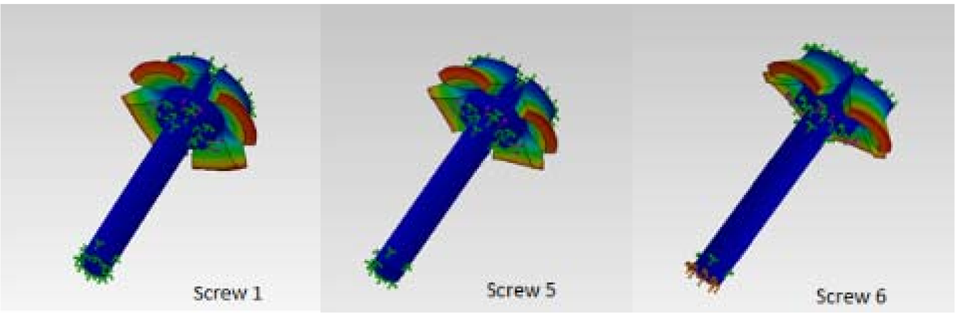


**Figure 40: FEA Study 3: Displacement vs. Slit Width;**

**The greatest displacement resulted from slits of 1mm width (Screw 5) compared to widths of 0.5mm or 0.75mm.**

The fourth study measured the displacement resulting from variable trough angles, seen in Figure 41. Although Screw 8 resulted in the greatest deflection due to its trough angle of 35°, it is neither optimal for manufacture nor application due to the thinness of the expanding cross section. The larger angle of 30° (Screw 1) yielded as increase in deflection over an angle of 25° (Screw 7) while maintaining dimensions suitable for mechanical stability and manufacturability.

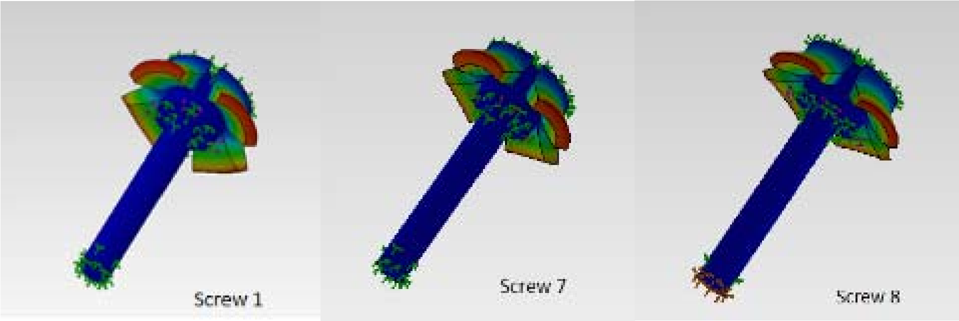


**Figure 41: FEA Study 4: Displacement vs. Trough Angle;**

**An angle of 25° (Screw 7) produced the smallest displacement whereas a trough angle of 35° (Screw 8) yielded the largest.**

The parameters that yielded optimal splay (four slits, 1mm slit width, 30° angle trough, and 0.278mm cross-sectional thickness) while maintaining mechanical stability and ability for manufacture were combined to create a modified screw head. This screw model was tested using FEA to obtain its resulting deformation, seen in Figure 42.

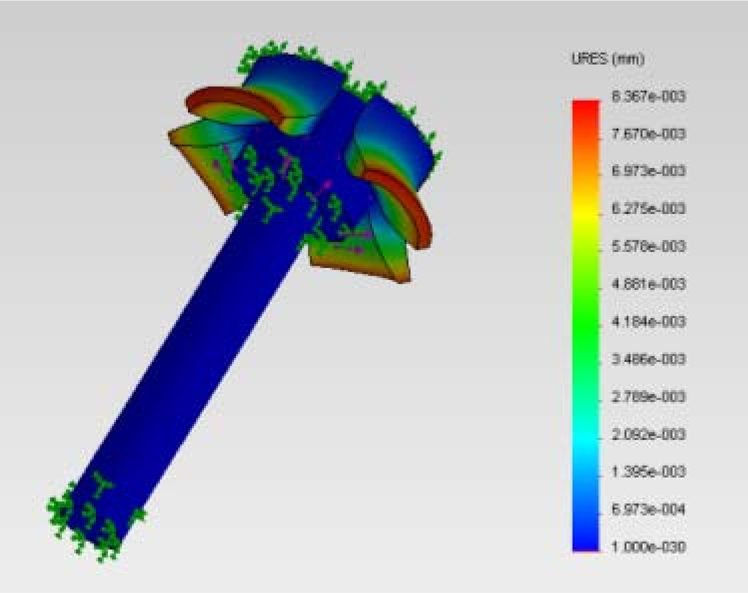


**Figure 4210: FEA Displacement Results of Combined Parameters for Optimal Expansion;**

**Maximum displacement peaked at 8.367e$^{-3}$mm.**

## 6.2 Large-Scale Model Proof of Principle Testing

Testing was completed using the MTS 858 MiniBionix. Two Samples were tested:

1. Unicortical Brass Non-Locking Screws
2. Unicortical Aluminum Reverse Expansion Locking Screws

Samples were tested for 200 cycles from 50-150N at 2Hz. The nature of this testing was not to directly replicate physiological conditions, rather to test the ability of the Reverse Expansion Screw to maintain stability in a bone model in comparison to a standard screw and plate system. Both samples were able to withstand the duration of the test. Testing raw data can be found in Appendix C.

### 6.2.1 Control Sample

The control sample is a sample comprised of a non-locking screw and plate system scaled up to 1.5x the size of normal sternal fixation systems. The assembled control screw and plate system is seen in Figure 41. Brass screws were inserted into a custom plate with the same dimensions as the complementary plate to the Reverse Expansion Screw.

Figure 411: Control Sample of Non-Locking Screw and Plate System in Long Bone Analog

The control sample completed the duration of the test without failure. Figure 42 shows the expected sinusoidal behavior of the control system under loading.

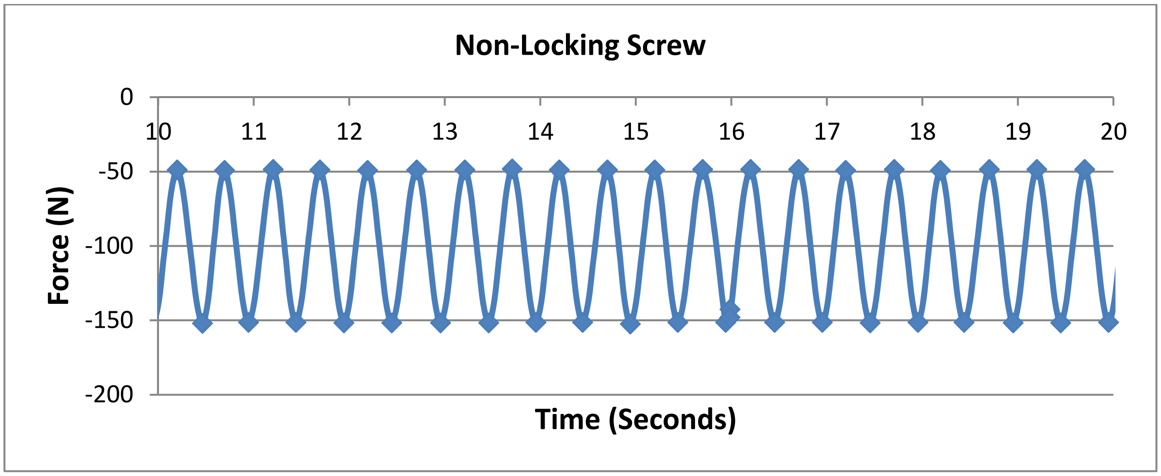


Figure 42: Behavior of Control Screw System With Non-Locking Screw-Plate System

### 6.2.2 Reverse Expansion System

The Reverse Expansion Screw system is comprised of the prototype design and the matching plate scaled up to 1.5x the size of normal sternal fixation systems sample. The assembled Reverse Expansion Screw and plate system is seen in Figure 43.

Figure 43: Expanding Head Screw and Plate System in Long Bone Analog

The prototype screw showed failure after 9 cycles, but was able to complete the desired 200 cycles of the test despite failure, as seen in Figure 44.

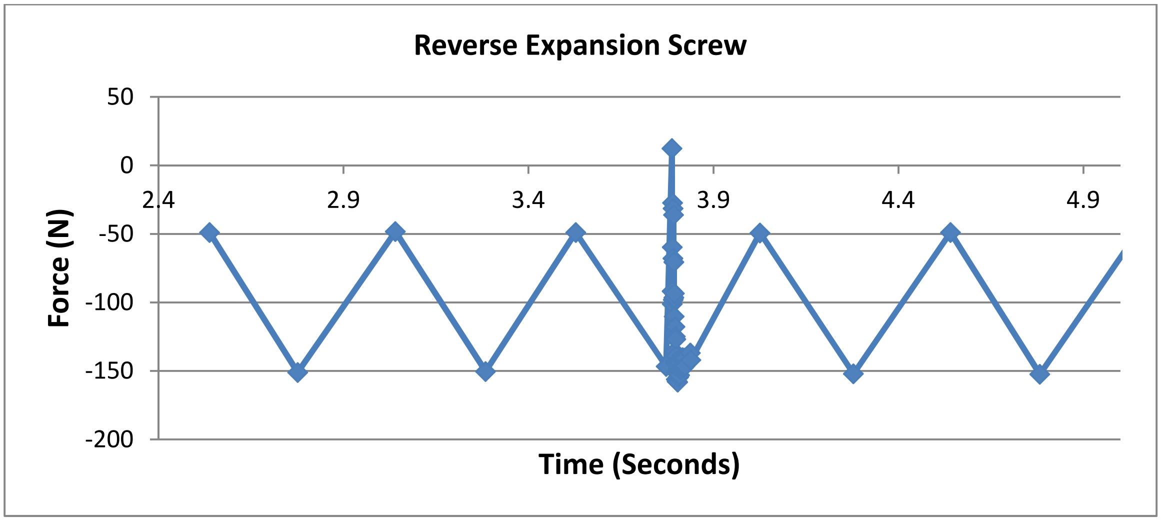


Figure 44: Behavior of Reverse Expansion Screw System

The spike in the graph at roughly 3.8 seconds is the failure point of this test. The continued sinusoidal behavior can still be seen after this point.

# Chapter 7. Discussion

The Reverse Expansion Screw and Plate system designed in this process is a positive advancement in the medical field, particularly the field of cardiothoracic surgery.  The Reverse Expansion Screw is novel because it is a single-unit design, the absence of which was identified as one of the challenges of prior designs. Furthermore, this design is relatively easy to install and will save surgeons time in the operating room during the installation process. Overall, the design achieves all the major goals identified in the initial phases of the design process.

Compared to other designs currently on the market, the Reverse Expansion Screw has a lot of potential. Wire fixation is time-consuming and comes with many complications, whereas our design will be much more easily installed and promote better healing as seen with other screw and plate fixation devices. In the realm of screw and plate systems, the Reverse Expansion screw system is significantly improved. Our design, unlike many others, does not require pre-drilling of holes in the bone. Elimination of pre-drilling decreases surgical time as well eliminates the risk associated with over drilling the sternum and puncturing vital organs below the sternum. Due to its ability to lock, the screw can be a unicortical design, reducing the ability of the distal end of the screw puncturing the dorsal side of the sternum endangering the patient’s heart.  In comparison to other rigid fixation devices, the screw and plate system is easy to install, not bulky, and much more comfortable for surgeons to use.

Our clients identified safety and effectiveness as two major considerations of the design. The team feels this design is very safe because there are not multiple parts that can be lost or become cumbersome during the surgical procedure. The device, should it be continued, will have to meet FDA regulations; however, the design itself yields a safer installation process due to its ease of use. The full effectiveness of this device will have to be further explored with comparative studies including the evaluation of other locking and non-locking devices. From our preliminary studies, the device has a significant amount of promise in this regard.

The modeling aspect of this project was extremely important to the overall success of the design. SolidWorks Finite Element Analysis (FEA) was used to display force concentrations on the screw as well as to analyze its functionality and expandability. These models were used to manufacture prototypes that were used for testing. Four Screws and two plates were created: four Reverse Expansion Screws, one Locking Plate and one standard non-locking plate. The standard non-locking plate was used with generic brass wood screws from a hardware store. These screws were chosen because they were similar to our screws in that they are self-tapping and were of a comparable length; however, they were not able to lock into the plate for comparison purposes. The prototypes were enlarged to a 1.5x model in order to make testing and concept proofs easier. If the models were in their original size to be used in the sternum, the concept would have been more challenging to demonstrate as well as manufacture. For the purposes of our testing, the 1.5x model was appropriate.

Due to time and financial constraints the final prototype was manufactured from aluminum. Aluminum is a relatively soft material, which required special considerations when completing testing. In order to keep the bone analog from splitting, screw holes were pre-drilled. The holes for the aluminum screw had to be slightly larger than the holes for the control screw because the aluminum material was not strong enough to withstand the force necessary for insertion into the bone analog. This is believed to be the failure mode of the final test. Upon examination of the system after loading, it could be seen that one of the screws had threading that slipped through the hole. Had the holes been more appropriately sized, we believe the system would not have failed in the manner that it did.

The materials used between the control screws and the prototype screws were inconsistent, which may be one of the reasons the control did not fail. The prototype screws were aluminum and the control screws were brass. These were used simply for comparison purposes; however, the testing may have had inaccurate results due to the strength of these materials. During insertion of each screw into the bone analog, it was much easier to apply large amounts of force to insert the brass screw, whereas the aluminum screw head began to strip with the same forces.

An unforeseen challenge in this project was the insertion angle of the screw. In our testing the material, topography was very consistent and we had difficulty inserting the screw into the plate so the head would line up with the well and successfully lock. In a surgical setting, such a small tolerance would be unacceptable. The head of the screw has to have a little room to fluctuate within the plate during the insertion process in the case that the sternum is unusually shaped. We recommend that further iterations of this device address this problem.

Overall, this project was successful in that we met the needs of the client and were able to demonstrate the ability of the Reverse Expansion System to function within an analogous setting to the sternum.

## 7.1 Project Considerations

The following sections describe the social, ethical and economic impact of the project. Also, the manufacturability and sustainability of the design will be discussed.

### 7.1.1 Economy

Every year, Americans spend millions of dollars on medical procedures that are either unnecessary or lead to preventable complications. With the cost of healthcare increasing each year, it is extremely important for devices and procedures to be developed that are both cost-effective and reduce the need for post-operative care. The best way to introduce devices that achieve this goal is by the introduction of new products that have been tested and proven to improve the quality of life for patients.

As evidenced in the Background section of this report, rigid fixation by plates and screws is one of the best ways to close the sternum for a patient after open-heart surgery. By constantly improving the products on the market that rigidly fixate patient's sterna after these procedures, not only will their quality of life increase, but they will not be faced with unnecessary medical expenses.

One of the greatest expenses in healthcare is surgical time (Lalikos, Personal Interview). By decreasing the time surgeons spend in the operating room, the overall bill the patient receives is significantly less. This device eliminates the need for pre-drilling screw holes as well as reduces the ability of the surgeon to accidentally puncture the dorsal cortex of the sternum, allowing them to work more quickly and with less risk to the patient. This ultimately decreases the overall cost to the patient.

### 7.1.2 Environment

Within the scope of this research, there were no environmental concerns to be addressed. The goal of this project was to develop a sternal fixation device to be used in patients after open-heart surgery. If anything, the only environmental impact in relation to this project would be saving energy and electricity by eliminating the need for power tools to be used during installation.

### 7.1.3 Social Influence

The purpose of this study and the resulting device is to provide knowledge to the medical community and those seeking knowledge in the field of sternal fixation. The device itself does not pose any social implications. Doctors and patients may use this information and in the future the device developed in this study to provide and receive better care.

### 7.1.4 Ethics

The major ethical concern in relation to this project is not within this generation of the study; however, it will impact the future studies of this device. Cadaveric and animal models will ultimately need to be used to complete device verification. Many non-biological materials were explored in order to replace biological models. However there were no exact models that would be able to replace the results that are obtained by using a cadaveric or animal model.

### 7.1.5 Health and Safety

This generation of screw and plate system is not yet approved by the FDA and therefore cannot be used in patients. However, in the future, for this concept to be used and tested it will be necessary for the device to be properly documented and tested by the FDA. The concepts demonstrated in previous projects addressing sternal fixation show that using a device of this variety will reduce sternal separation due to forces associated with breathing, minimize instance of infection and improve overall healing.

### 7.1.6 Manufacturability

The screw and plate system designed will be challenging, yet not impossible to manufacture. Because it is a single unit, we expect that the cost will be less than the multi-unit nested screw design developed in previous years. However, the geometry of this device is difficult and may require a large initial investment by the manufacturer to obtain the correct manufacturing tools. We did not face any challenges getting the product manufactured, even though it was larger than the devices that would be manufactured for use later on.

### 7.1.7 Sustainability

The device can be manufactured using pre-existing methods such as ASTM. We prescribe both the screw and the plate be made of a Titanium Alloy that is already commonly used in the medical field. Combined, the methods and materials increase the sustainability of the device.

# Chapter 8. Conclusions and Recommendations

The completion of this project yielded results that provided insight to the success of the final design, and led to the development of recommendations for further work regarding our design.

## 8.1 Conclusions

There were two main conclusions that resulted from the testing of the final prototype.

1. The final design is a plausible solution to the problem presented in our client statement.

The final design met the requirements of the client statement and is more advanced than previous generations of the device. The single-unit design is more beneficial to surgeons because the installation time is reduced, and is easier to handle.

2. Testing showed comparable performance between the control and the prototype.

Figure 45 is the output of the MTS testing machine. The red and blue lines represent the control and the prototype respectively; the behavior of both samples is very similar.

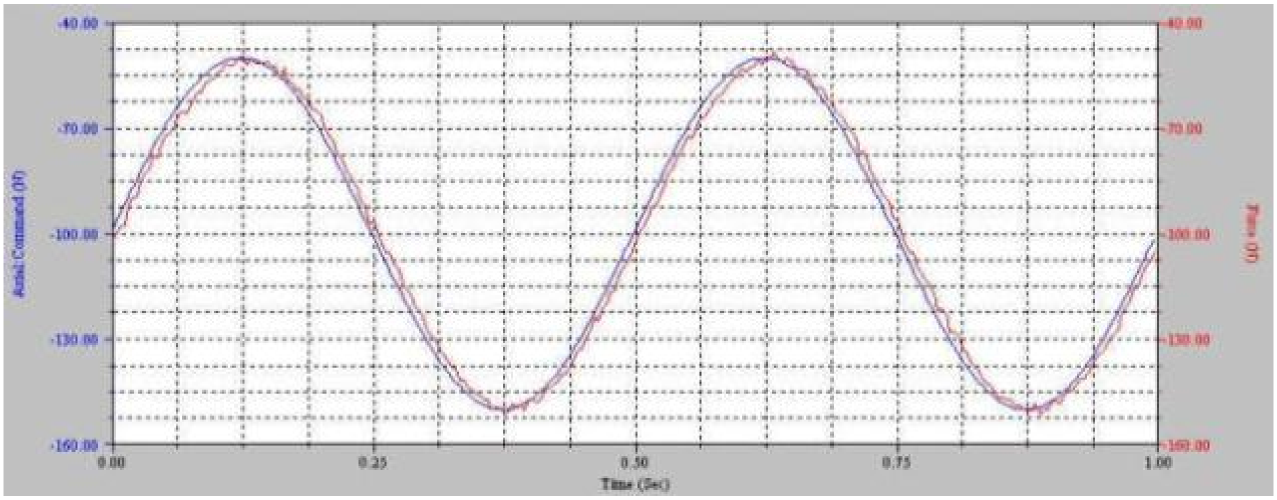


Figure 45: Image of MTS Output

Beyond the failure point seen in Figure 44, the behavior of the samples remains constant. We are able to hypothesize that based on these results, further testing would show that our prototype is able perform as well as a system that is already in use.

## 8.2 Recommendations

We recommend the following steps be taken in the future to further the success of this device. By following these recommendations the methods and approach to this problem can be improved upon and concepts can be developed further in order to create the most successful product possible.

### 8.2.1 Alter Insertion Design to Accommodate Variable Anatomy

During the installation of the prototype into the system, both initially into the sawbones and into the final testing system, there were many challenges with the geometry of the screw. The most prominent challenge was the insertion angle of the screw into the plate. Due to the head geometry, the screw has to be inserted at an almost perfect 90-degree angle in order for it to fit within the well of the plate. This is unrealistic for surgical settings. A surgeon needs to have a system that is flexible in the angle at which the screw is inserted in order to compensate for variable anatomy. We recommend that future iterations of this design take into consideration this challenge and design the next generation screw to be able to be inserted at various insertion angles.

### 8.2.2 Improve Testing Method

The testing method that was used for this project was not ideal. Although the principle of the expanding head was demonstrated, further testing should be explored using bicortical sternal models. Also, due to constraints out of the team’s control, tensile testing was not completed which is a more accurate testing method to replicate the forces associated with breathing. We also recommend using the same material for all screws and plates in order to make the testing more consistent.

### 8.2.3 Complete Further Comparisons

In order to get the most comprehensive understanding of the performance of this device in relation to other devices on the market, a more complete set of samples should be tested. We recommend that future teams test unicortical and bicortical, locking and non-locking devices.

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# Appendix A: Pairwise Comparison Charts

Pairwise Comparison Charts reflecting Objectives described in section 3.2.1.

**First Level**

| | Safe | Effective | Marketable | Total |
|---|---|---|---|---|
| Safe | ----- | 1 | 1 | 2 |
| Effective | 0 | ----- | 1 | 1 |
| Marketable | 0 | 0 | ----- | 0 |

**Second Level**

| **Safe** | Minimize Tissue Damage | Does not Break During Use | Biocompatible | Total |
|---|---|---|---|---|
| Minimize Tissue Damage | ----- | 0 | 0 | 0 |
| Does not Break During Use | 1 | ----- | 0 | 1 |
| Biocompatible | 1 | 1 | ----- | 2 |

| **Effective** | Eliminates Bone Stripping | Maintains Anti-Wobble POC | Functional in Bicortical Model | Locking Head | Reproducible Installation | Total |
|---|---|---|---|---|---|---|
| Eliminates Bone Stripping | ----- | .5 | 1 | 1 | 0 | 2.5 |
| Maintains Anti-Wobble POC | .5 | ----- | 1 | 1 | 0 | 2.5 |
| Functional in Bicortical Model | 0 | 0 | ----- | .5 | 0 | .5 |
| Locking Head | 0 | 0 | .5 | ----- | 0 | .5 |
| Reproducible Installation | 1 | 1 | 1 | 1 | ----- | 4 |

| **Marketable** | Reduces Procedure Time | Manufacturability | Total |
|---|---|---|---|
| Reduces Procedure Time | ----- | 1 | 1 |
| Manufacturability | 0 | ----- | 0 |

**Third Level**

| Manufacturability | Inexpensive | Simple Design | Total |
|---|---|---|---|
| Inexpensive | ----- | 0 | 0 |
| Simple Design | 1 | ----- | 1 |

# Appendix B: Sawbones

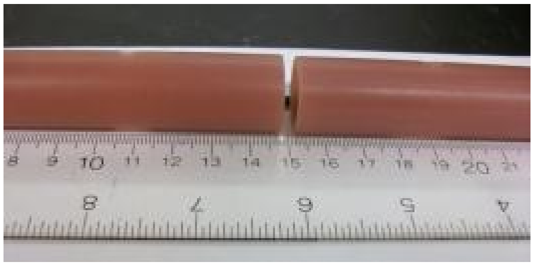
Pacific Research Laboratories: Sawbones has developed a sternum model that is designed for biomechanical testing in bone (Figure 24). The substitute bone material produced by Sawbones is generally solidified polyurethane foam of uniform density that yields results of greater consistency than does cadaveric testing. Although current Sawbones sternum models are uniformly dense, unlike human sterna, their mechanical properties typically resemble those of human bone. Numerous densities of Sawbones models are available to simulate both osteoporotic and non-osteoporotic bone (Pacific Research Laboratories, 2011). According to previous studies, using polyurethane foam was found to be more effective for detecting small differences in sternal fixation results than cadaveric bone (Trumble, 2002).

**Figure 24: Pacific Research Laboratories Sawbones Sternum Model (Pacific Research Laboratories, 2012)**

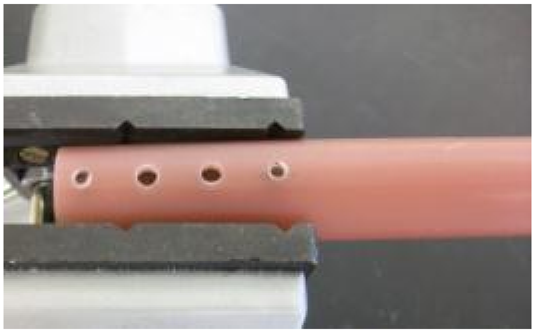
Sawbones were initially used for insertion testing and cyclic loading, however the material failed within the first load cycle. This model, however, is much better suited for the type of testing necessary to validate this device.

# Appendix C: Testing Protocol

**Step 1: Prepare the sample**
Each sample is 30cm long; cut the sample along its midline at 15cm.



Drill holes in each sample with a diameter that is slightly larger than that of the screw, using caution not to damage the sample. The holes should be located to fit the plate in a way that the sample ends touch. In this case, 1.5 and 3 cm from the midline of each side.



**Step 2: Insert the screws**
Insert the screws and respective plates into the samples

**Step 3: Prepare the MTS 858 Mini Bionix**
Place the 4-Point Bending fixtures on the machine. The bottom grips should be placed to support the sample, in this case the upper supports were 9cm apart (each 4.5 cm from midline of the sample) and the lower supports were 13 cm apart (7.5 cm from the midline of the sample).

**Step 4: Place the sample on the MTS**
Locate the sample so the top supports each sit 4.5cm from the midline of the sample, and the bottom supports sit 7.5cm from the center of the sample.

**Step 5: Begin Testing**
Locate the protective shield around the sample and run the test.