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Comparison of Alternative Rigid Sternal Fixation Techniques

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By

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Abstract

Sternal malunion is a complication resulting in displacement of the sternal halves following open heart surgery. Currently, little is known about the effectiveness of alternative fixation systems under physiologically relevant loading scenarios. The goal of this study was to mechanically test several currently marketed sternal fixation devices and compare them to a prototype device in different loading conditions to simulate sitting up or breathing. Each system showed unique differences in cost, failure mode and efficiency; however, no statistical difference in failure load or displacement was observed between the testing groups.

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1. Introduction

As of February 1st, 2011 the American heart association estimates that 82,600,000 American adults have developed one or more types of cardiovascular disease. The same survey shows that in 2007 there were over 6,846,000 inpatient intratoracic cardiovascular operations performed in the US (American Heart Association, 2011). At the beginning of every open-heart surgery the sternum is bisected to allow access to the heart. This procedure is known as a sternotomy. This technique is essential for a vast majority of interthoracic surgeries. Following the completion of the procedure the sternum must be realigned and secured with a sternal fixation device.

In 98% of procedures the reapproximation is successful; however in the remaining 2% post operative complications occur (Casha, 1999). Usually this is due to low bone integrity caused by osteoporosis, particularly in older age groups (American Stroke Association, 2007). This osteoporosis causes the sternum to wear away at the fixation points, causing loosening. One complication associated with this condition, mediastensis, or infection of the sternum has been shown to have a mortality rate as high as 15% according to Song et al. Because this condition is closely related to osteoporosis, it is important to create a rigid fixation device that has been optimized for the low density bone of the osteoporitic sternum.

Currently the most common practice of sternal fixation utilizes stainless steel surgical wires, but studies suggest that a rigid fixation lowers the lateral displacement improving the biomechanical stability of the sterna (Ozaki, 1999). By lowering sternal displacement, the incidence of medianstinitis was shown to decrease in osteoporotic patients (Song, 2004). Rigid plate fixation has shown to be beneficial to osteoporotic patients, yet the screws and plates within the system have not been adapted to the sternum. Designing a screw-plate system specifically for the sternum would potentially lower sternal dehiscence and probability of infection. A new design for rigid sternal fixation is proposed and tested against other rigid fixation devices used on the sternum.

Various different types of sternal fixation devices will be reviewed and tested to determine precisely which parameters effect quality of fixation within the sternums unique biomechanical system. Currently new devices are only tested against the current standard practice (stainless steel wires) in order to be sold in the United States; there is no data for comparing these alternative devices to determine which design inputs have the most effect on sternal fixation (US Food and Drug Administration, 1998). Testing data for these devices are often not made public and are kept privately by the companies who design them, preventing a legitimate comparison of devices which are new to the market.

In 2009, a proof of concept was developed at Worcester Polytechnic Institute which detailed a new variety of screw and plate rigid fixation system. This proof of concept was refered to as the "AntiWobble" system. The AntiWobble system was shown to effectively resist loosening within the rigid system when compared to existing screw-plate systems (Ahn et al, 2009). This new system had a unique locking system which prevented screw movement, but allowed for maximum tightening within the bone. This AntiWobble system showed to have increased fixation within the bone, even when using screws that traditionally have decreased purchase in the bone. Since this new system increases fixation within the rigid system, it is possible that the new system would lower incidences of wound infection within osteoporotic patients.

A new iteration of the AntiWobble design is proposed and tested against current industry standards in whole, sawbone sterna to determine if the proposed AntiWobble system is a feasible replacement for current systems.

The final design was based from the AntiWobble proof of concept to feature the ideal screw type and locking mechanism identified throughout the series of experiments. AntiWobble screws were tested against currently marketed products by Stryker Medical in a dynamic loading cycle while monitoring the displacement of attached bone plates with an extensometer in cadaveric bone. Cortical threads were utilized since they provided greater resilience against displacement than cancellous threads (Ahn et al, 2009). The design would be installed with unicortial purchase; bicortical purchase was dismissed due to compromising patient safety. The screw head was also designed to achieve a full friction-fit as well as lock to limit pivoting in the plate. These tests showed that a cortical screw placed unicortically with an AntiWobble mechanism was equivalent to a bicortical screw in human cadaver tissue (Ahn et al, 2009). This new locking mechanism provides a safe way to achieve bicortical equivalence without compromising patient safety (Ahn et al, 2009)

2. Background

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

2.1 Open-heart Statistics

In 1985 less than 300,000 open-heart operations were completed. In 2007 the American Heart Association estimated 6,846,000 total open-heart operations, more than doubling the number in 20 years. Approximately 3.9 million of these procedures were performed on males, and 2.9 million on females. The estimated direct and indirect cost of these diseases is over $286.6 billion (American Heart Association, 2011).

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

The reasons for requiring an open-heart procedure vary from valvular stenosis or regurgitation, resulting in valve replacement surgery, lung or heart failure requiring transplants, clots requiring bypass surgery, or trauma cases. The standard practice for all of these procedures is to start with a sternotomy, or vertical bisection of the sternum (American Heart Association, 2011).

2.2 Sternum Anatomy and Physiology

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

The respiration cycle is a dynamic process with the lung volume changing during inspiration and expiration. The inhalation process utilizes the following muscles: scalenes, sternocleidomastoid, external intercostals, parasternal intercostals, and diaphragm (Figure 1). During expiration, the lung gas pressure is greater than atmospheric and is capable of exiting the body without additional muscles contraction. However for forced expiration the following muscles are involved: internal intercostals, internal and external abdominal oblique, transversusabdominis and rectus abdominis. Since each of the muscles provide push and pull forces in different directions and amounts, the sternum experiences multiple forces in three-dimensions (Fox, 2008).

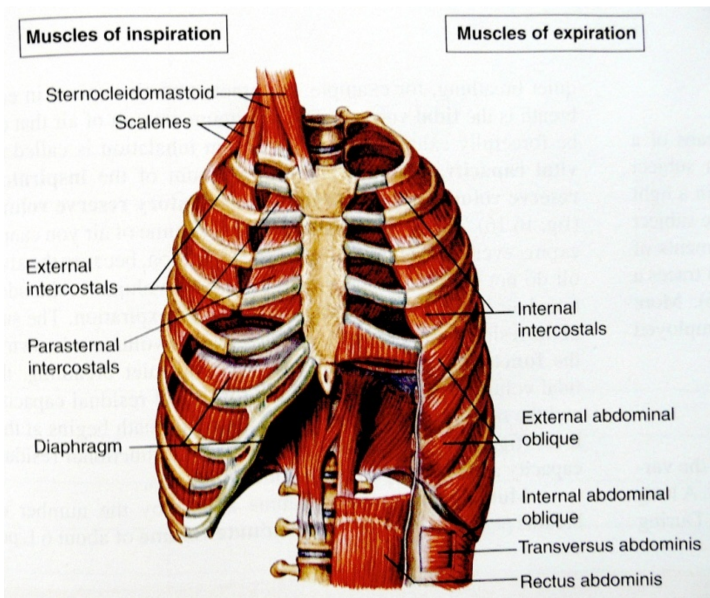

Figure 1: Muscles involved in respiration cycle

The average adult lungs at rest have between 2000 to 3000 cubic centimeters. During inhalation the adult lungs can potentially double their resting volume, as seen in a representative spirograph in Figure 2 (Fox, 2008). This continual contraction and relaxation of intercostals and parasternal muscles as the respiratory system expands and contracts between its tidal volumes results in cyclic tension being applied across the sternum (Hamid, 2005).

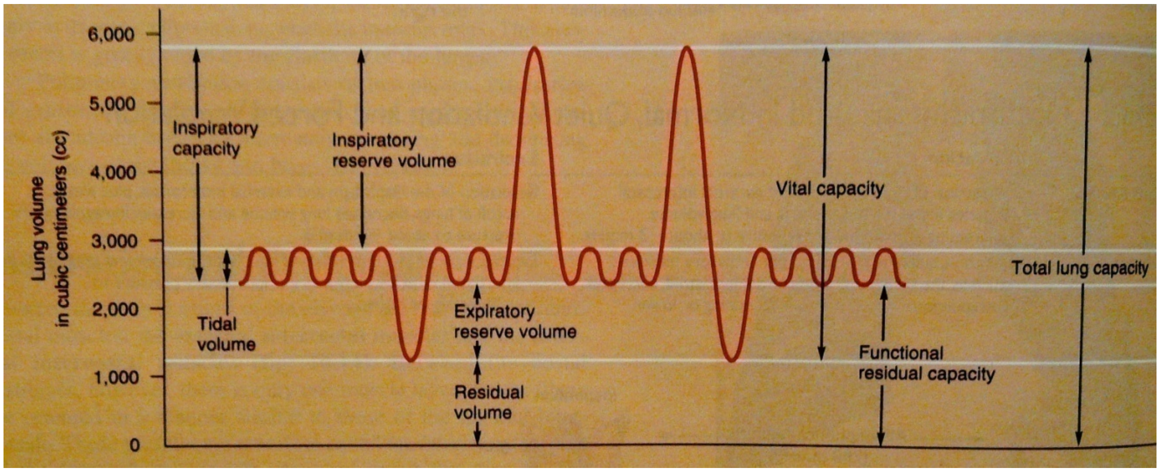

Figure 2: Spirogram of adult lung volume and capacity

The sternum is comprised of three different bone regions fused together during the body's development. A depiction of a human sternum can be seen in Figure 3. The most superior region is the manubrium which is the densest of the three. Fused below the manubrium is the corpus, where rib pairs two through seven attach. Below the corpus and not attached to any ribs is the xiphoid process. The average length of an adult sternum is approximately 17 centimeters, and typically shorter in females and longer in males.

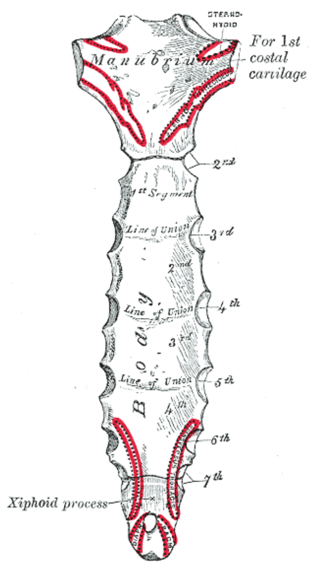

Figure 3: Anatomy of an Adult Human Sternum (Sandring, 2004)

There are two forms of bone, the dense compact cortical bone and spongy cancellous bone, also called trabecular bone. The cancellous portion is also made of bone marrow responsible for generating new blood cells (Ozkaya & Nordin, 1998). Bones throughout the body vary in the percentage of cancellous and cortical bone based upon the bone's physiological function. Because the sternum encloses the lungs, it must be capable of flexing during inhalation and expiration. Thus the sternum contains a higher percentage of spongy trabecular cancellous bone, and a thin cover shell of cortical bone (Ozkaya & Nordin, 1998). Figure 4 shows the cross-section of a human sternum with the type of bone labeled.

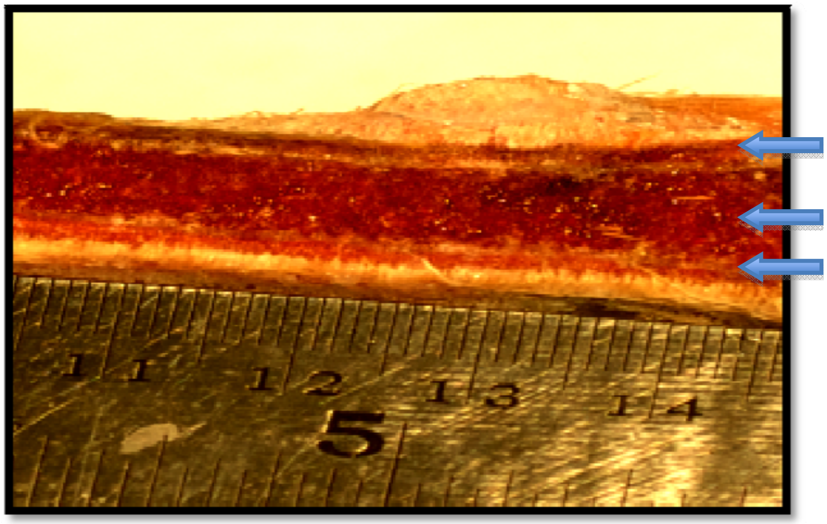

Figure 4: Cross-section of Human Sternum

2.3 Sternotomy Procedure

Cardiothoracic surgeons begin performing an open-heart procedure with separating the tissue superficial to the sternum. A high frequency saw on is used to bisect the sternum longitudinally along the center. By creating a clean linear cut the possibility of sternal complications during recovery, such as bleeding and fracturing, is minimized. With the sternum bisected a sternal retractor is situated between the bisected halves. Surgeons are able to adjust the size of the opening into the thoracic cavity. Once the primary operation is complete, surgeons must "close" with sternal fixation. Though the sternum may not be the primary subject of operation, approximately 2% of post open-heart complications are due to poor sternal closure (Dupak, 2004).

2.4 Sternal Fixation Methods

The final part of the median sternotomy is to fix the halves of the sternum together so that the bone can heal properly. There are a number of parameters that need to be considered for sternal fixation including fatigue strength, sternal separation, speed of procedure, speed of re-entry and cost, all of which are used to judge which sternal fixation method is to be used. Three major techniques for sternal fixation are wire circulation (Casha, 1999), the KLS Talon system (Levin, 2010), and the rigid screw-plate fixation systems (Cicilioni, 2005).

2.4.1 Wire Fixation

Since the mainstream birth of the sternotomy in 1957 the use of stainless-steel wire to circle the sternum has been used as the standard method of closing the sternum (Julian, 1957). A vast majority of inter-thoracic surgeries are closed using this technique. During the procedure four to seven parasternal sutures of stainless steel wires are wrapped around the sternum, with two wires placed through the manubrium, then the ends are twisted together securely to prevent loosening. The twisted ends are then buried in the sternal tissue. The pectoral fascia and lineaalba are then secured using a PGA (Poly-glycolic Acid) suture (Shields, LoCicero, Ponn, & Rusch, 2004). The wire placements can be seen in Figure 5.

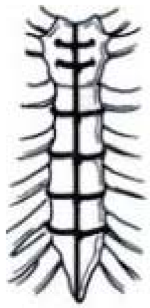

Figure 5: Sternum Closed by Wire Fixation (Shields et al, 2004)

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

2.4.2 Rapid Sternal Closure "Talon" System

A new alternative to plating and wiring developed by KLS Martin, LP (Jacksonville, FL) called the Sternal Talon has recently been developed. This system utilizes a titanium double hook design ("talons"), where the hooks are placed between the ribs on either side of the sternum (Figure 6). This system uses a sophisticated ratcheting mechanism with a cam lock to adjust the distance between sternal halves and holding them together, essentially combining fixation and reduction of the hemisterna. The devices themselves are simple to apply, but require a significant amount of measuring (talon depth and lateral length for each device used) in order to determine proper implant size. These devices are also significantly more expensive than standard plates and screws or circlage wires.

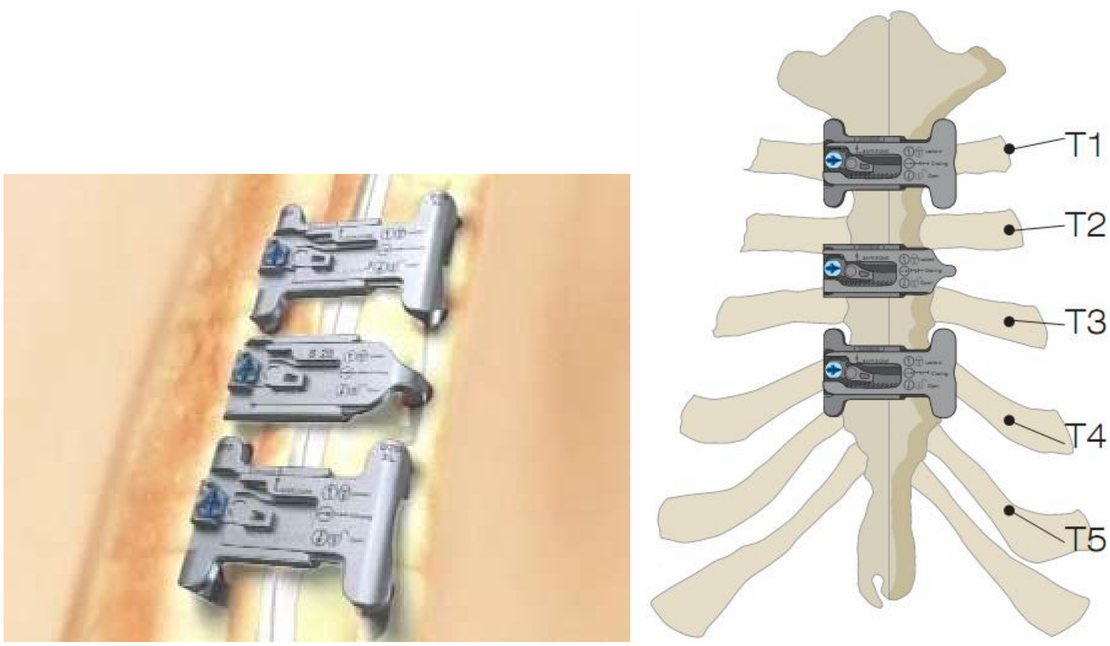

Figure 6: Talon system and Placement (rapidsternalclosure.com)

2.4.3 Rigid Fixation via Plate and Screw System

Rigid fixation was first developed by Robert Danis in 1949, when he demonstrated that bone fractures could heal without fibrous tissue formation if the movement of the bone fragments is minimized and held in position with compression (Mostofi, 2005). He is considered to be the father of the now common compression plating technique. Internal compression plating offers huge advantages over other techniques because it physically holds bone fragments together during the healing process, limiting their movement and not disrupting the blood supply in the region (An Y. , 2002). There are many different varieties of these plates, with many bones having their own unique plate configurations.

The sternum is the only bone in the body where rigid fixation is not the commonly used fixation method. Rigid fixation techniques use plates and screws to hold the halves of the sternum in place while it heals. Initially published by Dr. David Song of the University of Chicago in 2004, this technique is often used in high risk patients where the wire ties may fail or cut through the bone (Song, 2004) . During the procedure four small “X” shaped plates are screwed into the sternum horizontal to the manubrium using Titanium screws that are sized according to the size of the sternum. The final product of this can be seen in Figure 7 below.

Figure 7: Sternum Closed by Rigid Plate Fixation (Song et al, 2004)

This technique is mainly performed in situations where wire closure is not recommended (0.5% - 3% of cases, (Breyer, 1984); (Demmy et al, 1990); (Loop et al, 1990)). This is most common in osteoporotic patients where the wires may cut through the brittle bone of the sternum. Rigid plate fixation takes slightly longer to perform than wire closure because the plates have to be positioned and screwed into place properly. It also requires more skill on the part of the surgeon because the screws must be the proper length to hold in the sternum and not extend into the thoracic cavity, possibly damaging organs (Breyer, 1984). Another reason why this technique is not widely adopted is cost. The cost of the plate and screw system is substantially more than the wire, costing between $700 and $1400, however when considering that the average hospital bill for wire related mediastinitus is approximately $500,000; the plate system becomes a more sound investment (Huh, 2008 ; Song, 2004) (Huh, 2008), (Song, 2004).

2.5 Types of Rigid Fixation: Plates

Due to the large variety of bone shapes and sizes within the body, there are several different types of rigid fixation plates that can be used, each with their own pros and cons. Plates are usually manufactured and designed specifically for a clinical application. In general, there are Straight plates, X-shaped plates, wave plates, and friction plates. Figure 8 gives an example of straight and X-shaped plates and friction plates.

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

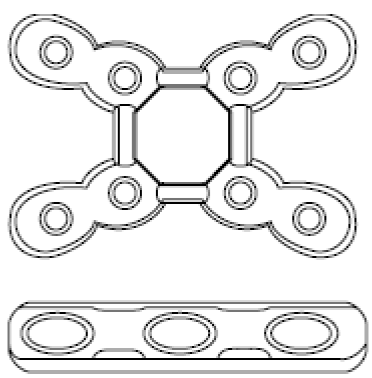

Figure 8: X shaped plate and Straight plate (Based on (Ozaki, 1999))

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

Wave plates are a variation of the straight fixation plate (see Figure 9) and are widely used in long bone compression fixation. These plates are beneficial because they do not apply compressive forces directly to the fracture site. Applying extensive compressive forces to the wound site has been shown to increase vascular disruption to the wound site, limiting the blood supply to the wound site and increasing healing time (An, 2002). Although this design is usually applied to large cortical bones, it may be useful for decreasing the healing time of a very vascular bone such as the sternum

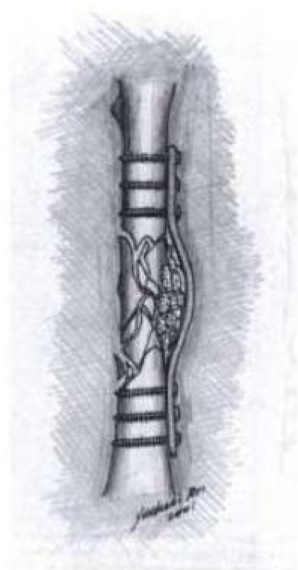

Figure 9: A wave style compression plate (An, 2002)

The friction (or adhesive) plate system (Figure 10) was developed by Meyrueis in 1977, but has not been widely used or documented (An, 2002). This plate and screw system comes in a variety of shapes and sizes, and can be added to almost any plate and screw system, creating a very versatile system. The system adds ridges to the undersurface of the plate, increasing the plate-bone contact area and effectively decreasing the stresses on the screws used in the system by as much as a third (An, 2002). By minimizing the motion between the plate and the bone, stress protection in that region of bone can be greatly reduced. Although this system has not been widely accepted, it could potentially be very advantageous in the sternal system since the screws that are used are much smaller and have much more cyclic loading than plate systems elsewhere in the body.

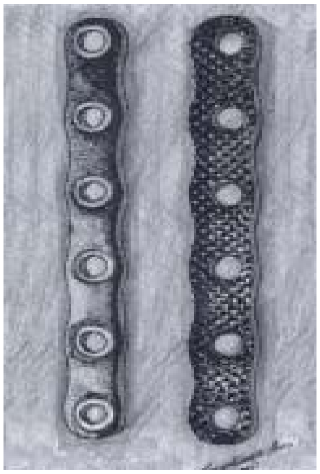

Figure 10: A Meyrueis friction plate (An, 2002)

2.6 Types of Rigid Fixation: Screws

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

The cortical or cancellous properties of the screw are decided based on the density of the bone that the screw is being applied to. Cortical screws are very similar to metal screws found in your local hardware store; they have a very high thread count, with a very low thread depth and pitch. Because they are used in the hardest, highest density type of bone, thread penetration is not very important, but it is vital that the threads stay in constant contact with the bone surrounding it. Conversely cancellous screws are very similar to wood screws, boasting deeper thread penetration to maximize stabilization in the low-density cancellous bone (An, 2002; Shields et al, 2004).

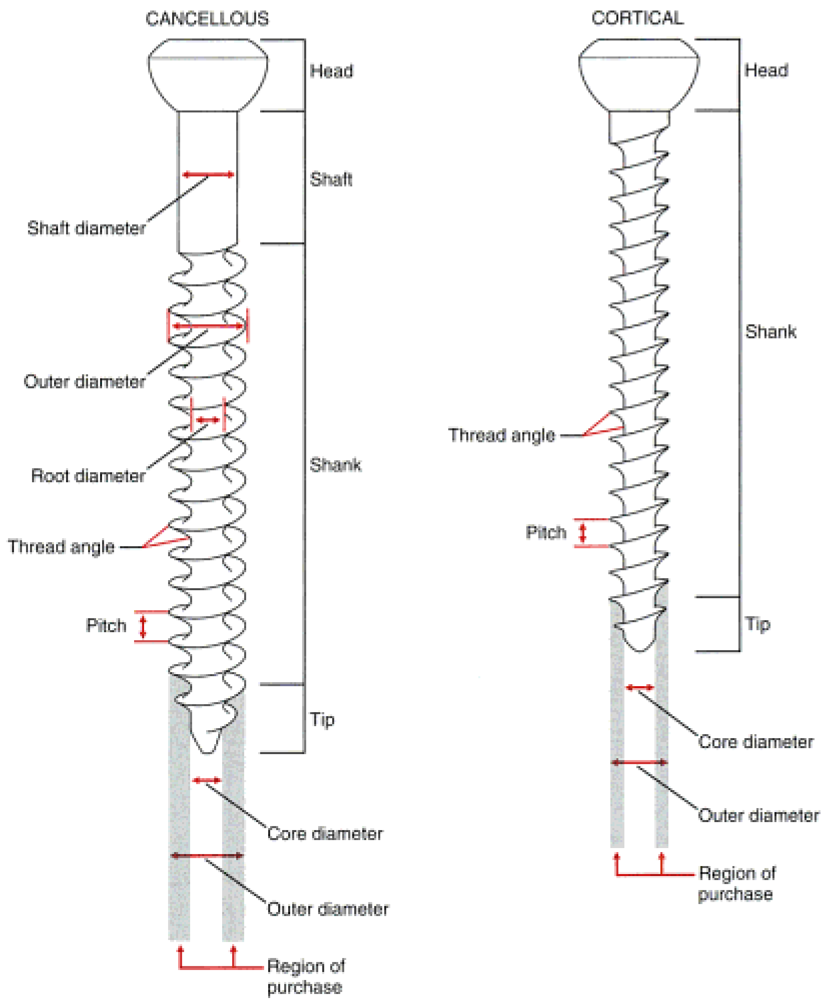

Figure 11: Anatomy of a bone screw (Akbar Bonakdarpour, 2009)

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

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

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

2.6.1 Screw Design

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

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

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

A screw's thread is defined by its depth (difference between the major and minor diameter) and its pitch. The thread depth is what responsible for thread purchase as it represents the area of the screw that is interacting with the bone. The thread is a helical ridge that is wrapped around the core. Its function is to convert rotation into translational movement. As can be seen in Figure 11, the cross section is a series of ramps. Together with the helical shape, when rotated the triangular cross section functions as an inclined plane that provides a mechanical advantage in moving through the bone and to maintain a compressive force. The thread pitch is defined as the distance between threads on the screw (An & Draughn, 2000)

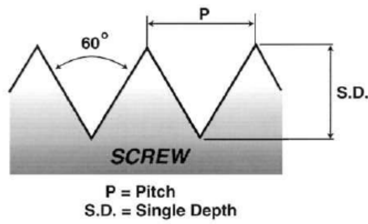

Figure 12: Screw Pitch Parameters (An &Draughn, 2000)

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

2.7 Sternal Loading

Current techniques for testing sternal fixation devices fall into two categories: dynamic testing and static testing (Cohen, 2002). Dynamic testing loads the sternum repeatedly in a lateral direction to simulate the tension placed on the sternum during breathing, while static testing applies a steadily increasing load until failure. These different testing methodologies can be used to determine various failure mechanisms of sternal fixation devices, depending on the direction the load is applied (Wangsgard, 2008).

A majority of studies looking into sternal fixation focus on three directions of loading: Lateral distraction, to simulate breathing or coughing, longitudinal shear, to simulate lateral flexion stretching, such as supporting the body on one extended arm, and transverse shear, to simulate pulling oneself upright with the assistance of the arms (Casha, 1999; Cohen, 2002; Wangsgard, 2008). Figure 12 below shows each of these directions with representative arrows to describe loading.

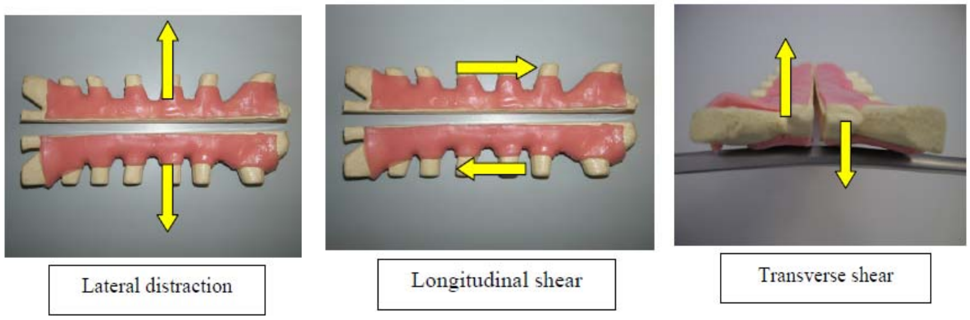

Figure 13: Visualization of loading directions, courtesy of KLS martin

Depending on the direction of loading, dynamic or static loading should be applied in order to mimic the physiological method of failure. In 2008, Pai et al proposed that low force cyclic load in lateral distraction could be the reason for failure of rigid fixation in the sternum (Pai, 2008). In the shear directions, physiological load is applied by skeletal muscles while lifting or stretching, so static loads are appropriate in these directions. Although these loading scenarios have been studied individually in the past, dynamic lateral distraction and static shear loading have never been performed in the same experimental configuration while comparing rigid sternal fixation devices.

3. Materials and Methods

Current testing has identified several different physiologically relevant failure mechanisms for rigid fixation methods. Our testing regimen has been designed to mimic the different failure mechanisms by applying different loading scenarios in their physiologically relevant directions.

3.1 Determination of Sternal Model

When establishing a testing plan, a significant amount of thought was put into determining what sternal model should be used during testing. Previous studies have used either fresh human sterna (Ozaki, 1999), polyurethane molds of different densities or animal models.

Fresh sterna offer several advantages over the artificial counterpart; it has a clinically relevant structure and size, and is definitely the best representation of the sternum *in vivo* (Ozaki, 1999). Despite this advantage, obtaining fresh sterna is expensive, and often has a high variation of bone density and cortical thickness between samples. This variation makes it difficult to build a relevant sample size when testing the whole sterna at once.

Animal models are useful in bench top testing because bone samples from pig or dog are often readily available and cost effective. Pig sterna can often be obtained for free at a local butcher as scrap. Animal bone tissue is often structurally different from human tissue, with drastically different bone density, cortical shell thickness and geometry (Pai, 2008). Standard sternal reconstruction products are not designed for use on animal bone, so animal models were not used in this study.

Polyurethane molds of the sternum are another staple that is often used in benchtop testing. Also called “Sawbones”, they have a uniform density and geometry, which is useful in designing testing fixtures and establishing statistical significance (Cohen, 2002; Wangsgard 2008). While uniform density is a benefit in some cases, sawbones lack the cortical shell, which has been shown to be important for fixation especially in osteoporotic bone.

Due to their reproducible geometry, density and low cost polyurethane sawbones were chosen for testing. These characteristics allow maximum statistical relevance, while maintaining low cost and a simple testing set up.

3.2 Lateral Distraction

Failure in lateral distraction has been associated with several different sternal loading scenarios. Unlike most bones that are traditionally fixed with rigid plates, motion of the sternum is required after surgery and cannot be restricted without causing breathing complications. Previous research at WPI has shown that the primary mechanism of failure in lateral distraction is in cyclic fatigue similar to breathing or coughing, where the screws begin to move within the bone. This decreases their contact area within the bone, lowering fixation.

To test this; sawbone sterna (Density = $10 g/cm^3$) were placed into an Instron E1000 uniaxial testing device using custom grips (detailed engineering drawings can be found in Appendix E). These custom grips cause uniform loading around the midline of the sawbone, while distributing the load on the lateral ribs. This is advantageous because it ensures that the failure location will be along the midline, and not at the edge of the grips (see Figure 14).

Figure 14: Schematic of Sternal Talon in Lateral Distraction

Determination of loading parameters is extremely important in dynamic testing. Because of the unique geometry of the test rig, and relative strength of the bone compared to the testing devices (polyurethane bone vs. titanium alloy implants), if the load is set too high the bone will fracture, and if the load is set too low the implant will be too strong and not loosen at all. Initial trial tests were run using the grips in lateral distraction at different loads in order to determine the most effective force to achieve implant loosening without total failure of the sternal model. At

100N, there was no displacement of sternal halves, while at 200N failure of the bone occurred at different time points during the test. When using 150N there was a measurable displacement between different devices, but each device was still able to last the duration of the test. This allows for a direct comparison of displacement sternal halves between devices at the same amount of time after implantation.

Once placed in the machine bone is then preloaded to 10N, and then cycled to 150N under load control 15000 times at a frequency of 2Hz. The frequency and length of the test were based on previous testing using the same machine, while the ideal force was determined experimentally (Ahn et al, 2009). At 150N maximum fatigue occurs along the midline where the load should be concentrated, and minimum stress occurs around the grips where the load is distributed. Using higher forces causes failure to occur around the ribs rather than around the fixation device. This failure mode is not physiologically relevant and therefore should be avoided during testing.

3.3 Longitudinal and Transverse Shear

Forces that occur naturally during breathing are minimal in shear directions, and therefore not relevant to the failure mechanisms. It is currently believed that failure in these directions is associated with forces generated during abrupt movement of the patient. An example of this would be a patient that slips while standing, and reaches out to catch themselves. As they catch themselves and their arms assume some of the body's weight, that load is distributed throughout the joints and muscles of the upper body, including the sternotomy wound site. These failure mechanisms are also common among obese patients who are unable to sit up without using their arms.

Due to the high energy, low time nature of this force, cyclic fatigue tests like those used in lateral distraction are inappropriate. Instead ramping loads are applied to the sterna over a set period of time. After hitting the maximum load of that cycle, the sample returns to a resting state before it is ramped again, this time to a higher force. The loading occurs over 20 seconds, starting at 100N and increasing 100N until fracture.

For shear tests is was necessary to utilize higher density sawbone than the lateral distraction testing. For the cyclic fatigue tests $10 g/cm^3$ density sawbones were used to simulate extremely osteoporotic bone. At this density it is easy to observe screws loosening in the bone at low force, as shown in lateral distraction. At higher forces, the ribs that are attached to the grips shear off the sterna before any load is placed on the sternotomy site (see Figure 15). This prevents any physiologically relevant testing of the forces applied to the fixation devices being tested. Using a #20 density sawbone, which is much similar to cortical bone, provides the ribs with enough strength to translate the force to the fixation device.

Figure 15: Example of a failure due to Rib Fracture (Left), and longitudinal shear test schematic (Right).

In the shear directions both the displacement and load at failure are measured for comparison. This is because both the movement and fracture due to load are considered to be physiologically relevant failure mechanisms. Displacement is measured via digital position (total crosshead movement).

4. Results

4.1 Lateral Distraction

The trend data taken from the Instron E1000 was used to analyze the displacement of the sternal halves over the course of the test. This data recorded the maximum and minimum displacement of each cycle, measuring using the digital position reading from the machine. Using trend data is useful because the files are significantly smaller and utilize less processing power to visualize. Figure 16: Typical loosening curve below shows a typical loosening curve, but for this analysis only the maximum displacement per cycle is relevant.

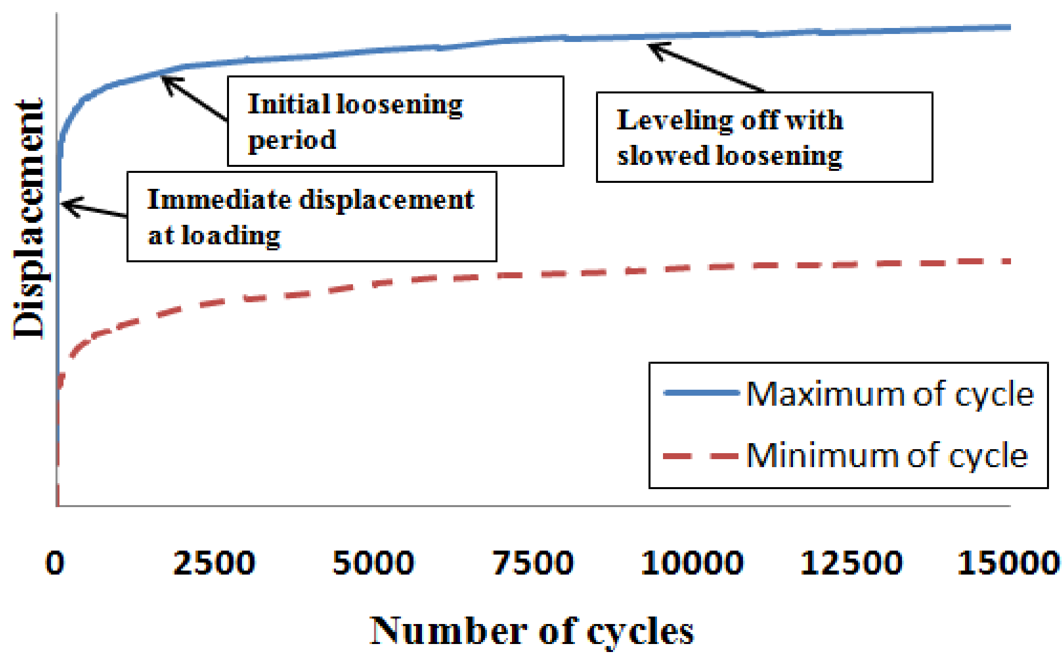

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Figure 16: Typical loosening curve

Digital position through the Instron E1000 is used to measure the displacement of the sternal halves. This measurement electronically tracks the total movement of the crosshead. Although other studies have used extensometers to show this displacement, extensometers only show displacement between two points along the sternum. Digital position allows us to visualize the total amount of displacement between sternal halves without focusing on a particular set of points.

In each test the model was first preloaded to 10N in order to remove any slack within the load train. While analyzing the data the displacement caused by the preload is subtracted from the subsequent measurements. This allows for accurate measurement of displacement even if there is a loose fixation screw or the crosshead needs to be adjusted.

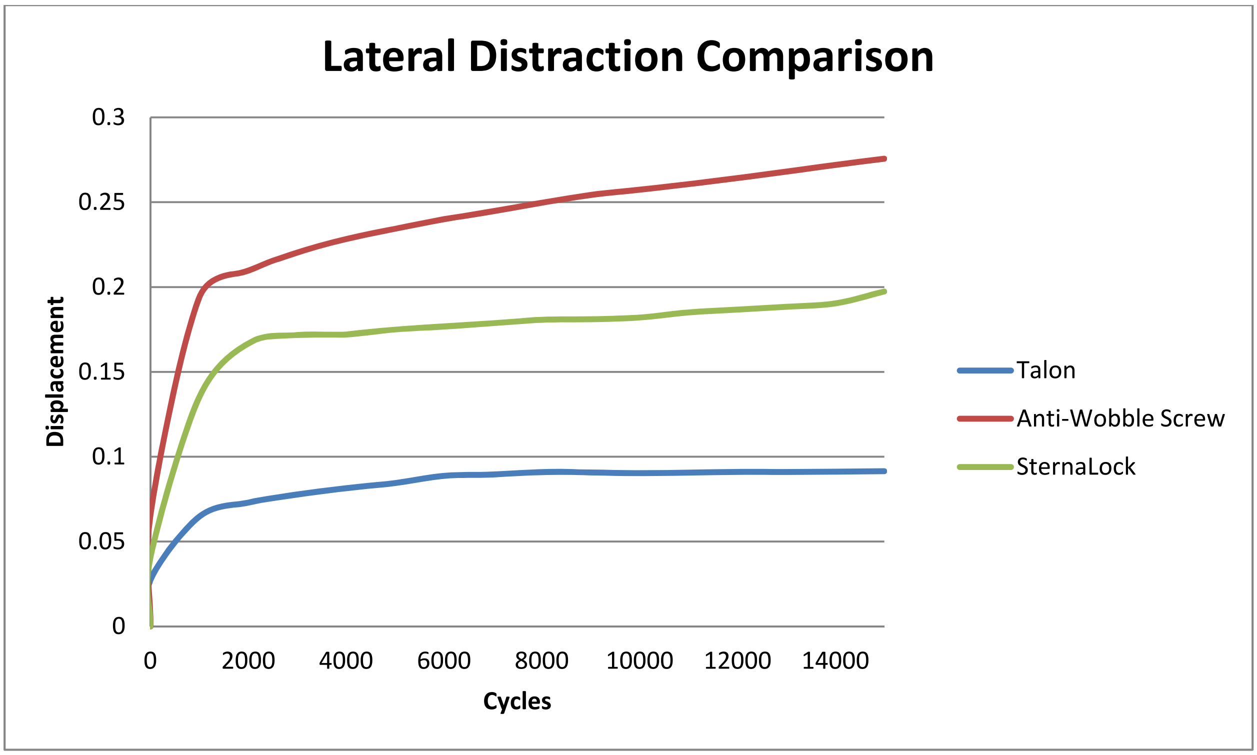

Figure 17: Comparison of the Sternal Talon (KLS Martin), Anti-Wobble Screw prototype and Biomet Sternalock systems in lateral distraction

The average displacement of the Sternal Talon is shown in Figure 17 above to be the lowest (0.092 ±0.066mm, n=3), the AntiWobble screw to be the greatest (0.276±0.175mm n=3) and the Sternalock system to be in between (0.197 ± 0.134mm, n=3). A Three-Way ANOVA was performed using SIGMASTAT V3.5 which confirms that the difference in the median values of the treatment groups were not great enough to exclude the possibility that the difference is due to random sampling variability. Therefore there is not a statistically significant difference between the treatment groups (P=0.314). More detailed information can be found in Appendix A.

4.2 Longitudinal Shear

Tracking measurements taken approximately every 0.01 seconds for load and displacement were used to analyze how each system responds to shear loading. Digital position and load at every time period was then graphed in to determine which systems were most effective at reducing the displacement of the sternal halves, as well as the load at failure. Figure 18 below shows the displacement at each loading step for each of the test groups. The black "load" line shows the force being applied at each step along the X- Axis. Each of these steps shows a change in the loading program, either ramping up, ramping down, or resting.

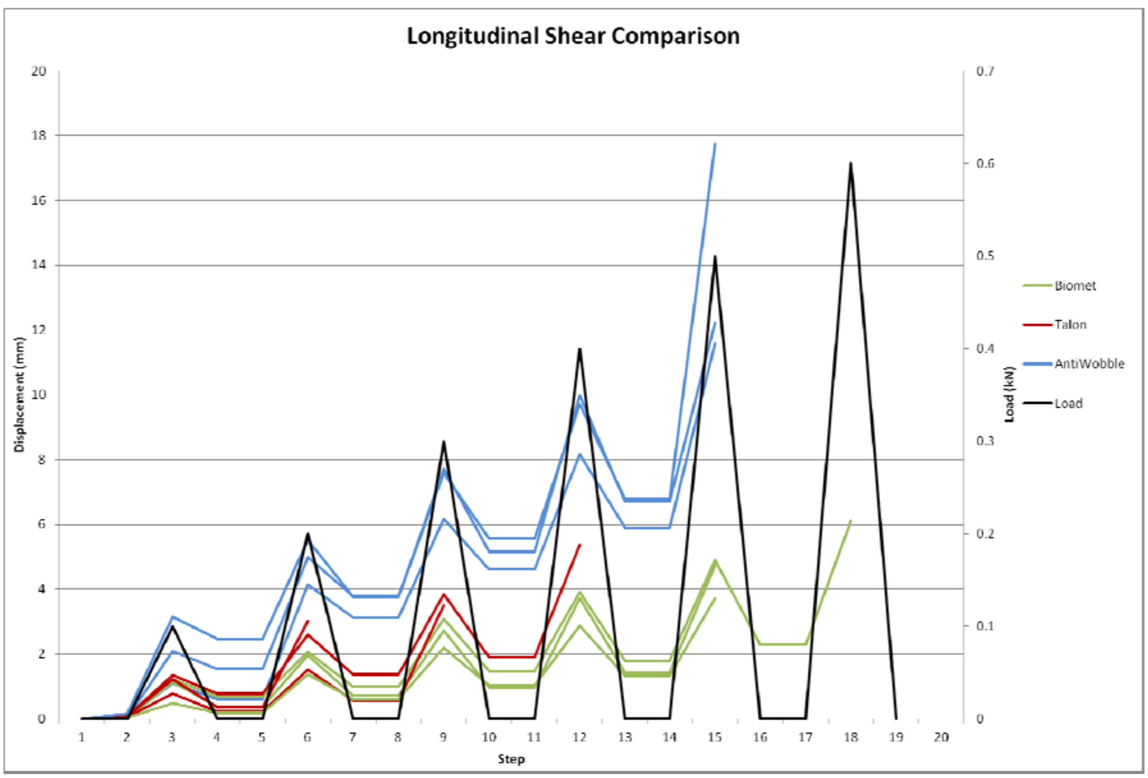

Figure 18: Force and displacement of different screw systems in Longitudinal Shear.

The AntiWobble system showed significantly higher displacement than the other systems regardless of force, however due to the linear geometry of the plates this is expected (Table 1 Below). Despite the high displacement, failure force remained similar to the Biomet screw system.

System	Load at Failure (kN)
AntiWobble	0.579±0.065
Biomet	0.587±0.028
Sternal Talon	0.390±0.142

Table 1: Failure forces of Sternal Fixation Systems in Longitudinal Shear

4.3 Transverse shear

Transverse shear measurements were taken using the same methodology, equipment and program as longitudinal shear, but using a slightly different orientation of the grips. Custom adapters were machined in order to facilitate this loading scenario (Figure 19 below). Analysis of the failure load and displacement show no statistically significant difference between the test groups. All test groups had approximately the same range of failure loads (all between 200N and 300N), and similar displacements.

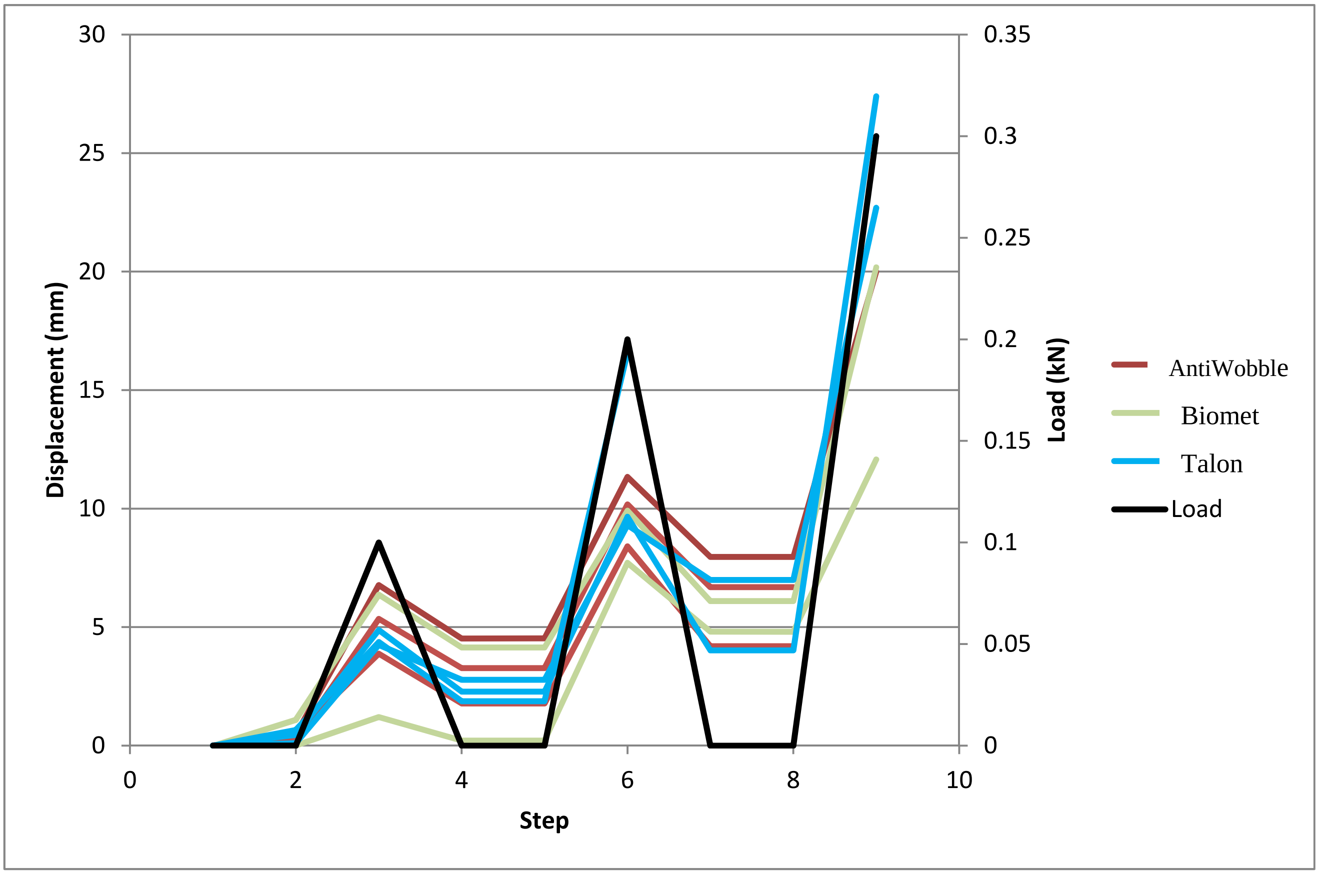

Figure 19: Comparison of test groups in transverse shear.

5. Discussion

The displacement and failure forces of the three treatment groups were shown to have no statistical difference, however this does not necessarily indicate that one system is superior to another. There are several design advantages associated with the AntiWobble system and the Talon system that could potentially allow them to be more effective in a clinical setting than is indicated by bench top testing.

In lateral distraction it was shown that there was no statistical difference between the AntiWobble System and the Biomet Sternalock system; however there are several geometric differences that could affect the clinical use of such a system. First, the AntiWobble system uses half as many bone screws as the Biomet system while utilizing the same total number of implants (including the screw caps). Because there are half as many bone contacting implants, there is significantly less boney damage during implantation which decreases healing time. The decreased number of implants also could potentially introduce significant cost saving when compared to systems that may require twice as many screws. Also, because there is no depth measurement associated with the screw caps there would be significantly reduced surgical time, which is known to decrease complications post-op.

In longitudinal shear the relevant failure modes become harder to distinguish from failure modes due varying geometries of the different devices. For example, the displacement of the AntiWobble system is significantly increased despite maintaining a similar failure load. While *in vivo* a shear displacement of 12mm is definitely considered a failure, this displacement is due to the linear geometry of the plates and not the fixation of the screws within the bone (as seen in Figure 20 below). One possible solution for eliminating plate rotation would be introducing X geometry, using 4 screws to eliminate rotation similar to the Biomet screw system. Another possible solution would be to add "cleats" to the posterior surface of the plate, similar to the design proposed in the 2009 WPI MQP (Ahn et al, 2009). These rigid cleats would add lateral stability and reduce rotation of the plate (see Figure 20, below).

The Sternal Talon had a very distinct failure mode in shear directions. This failure mode occurred at comparatively lower forces than the other treatment groups, where catastrophic failure occurred surrounding the fixation devices. These failures had so much energy that often pieces of sawbone would be found across the room. After speaking with KLS Martin marketing representatives who have access to clinical data, it is believed that this failure is caused by the dislocation of ribs from the sternum. The clinical data collected by KLS Martin confirms that in larger patients (allowing for higher forces) the rib joints separate and cause failure.

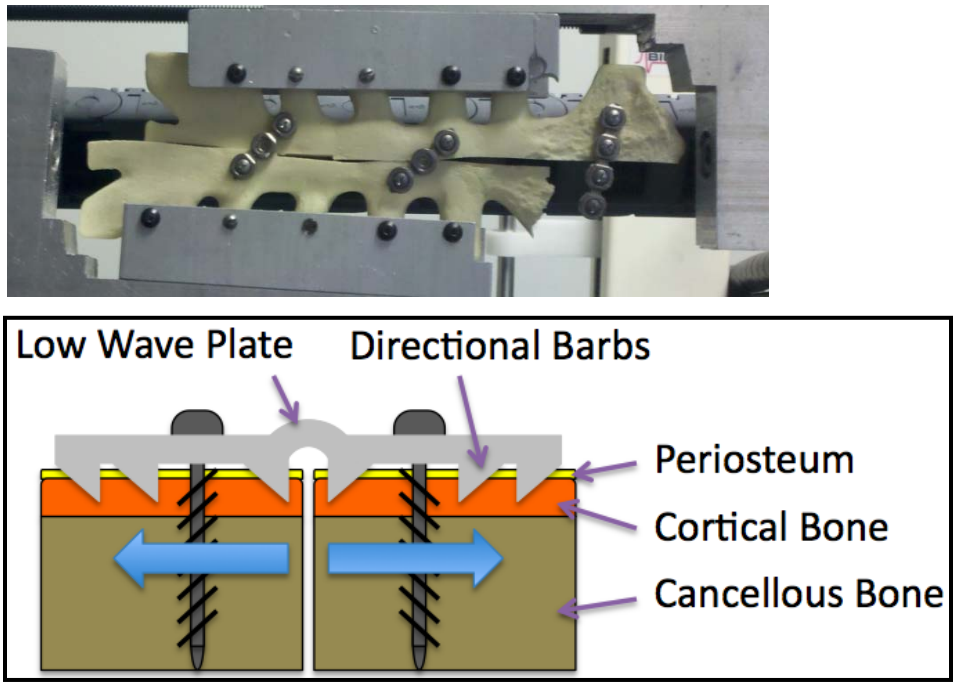

Figure 20 Top: Rotation of linear AntiWobble plates in Longitudinal Shear. Bottom: Proposed anti-rotation plate as shown in (Ahn et al, 2009)

The AntiWobble screws had additional benefits that were not anticipated based on the prior work. If the AntiWobble screw was inserted with a lateral trajectory and then the cap was tightened, the downward force on the cap would force the screw into a straight orientation. This movement of the screw created significant approximation forces between the sternal halves. This additional force on the midline could be useful clinically for reducing fibrous tissue formation between the healing pieces of the sternum (An Y. , 2002).

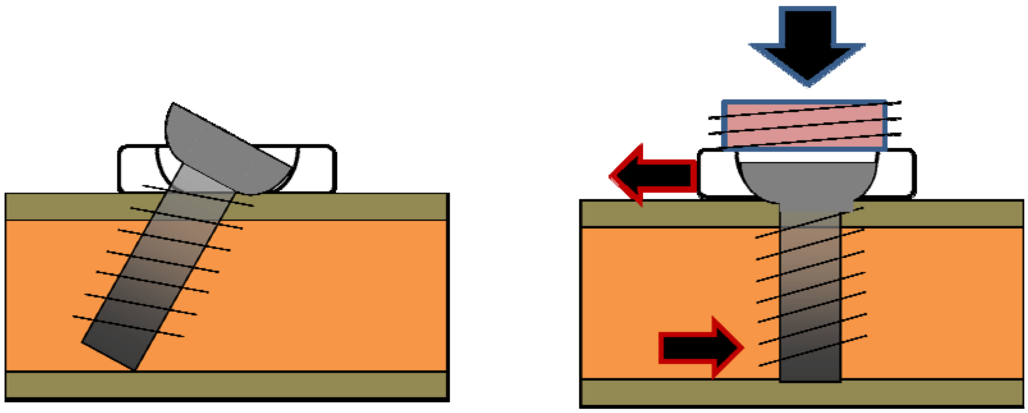

Figure 21: Reduction technique using AntiWobble screw. Left: Screw is inserted with lateral trajectory. Right: Screw is forced into alignment by AntiWobble Cap

In transverse shear there was no significant change from one test group to the other. Most of these failures were due to plastic deformation of the bone prior to device failure. This shows that regardless of the fixation method used, failure due to boney deformation remains consistent in this direction. The boney failure also occurs at a lower load than the device failure load, which could not be found given this experimental set up. Determining the failure force of the closure constructs would have required a much larger testing machine, which WPI does not possess.

6. Conclusions

Adding an AntiWobble feature to restrict head movement allows for less displacement per screw in lateral distraction than the Biomet screw system, and is not statistically different from the Biomet system or the Sternal Talon system. Due to its higher fixation per screw the AntiWobble system was shown to be not statistically different from the Talon or Biomet system in cyclic lateral distraction, even when using half as many bone screws. Using half as many bone contacting implants has several implications that could potentially affect patient outcomes. By using half as many screws, bone damage is decreased, which has potential for decreasing healing times and infection rates (An Y. , 2002).

In the shear directions it was shown that failure of the bone occurs at a much lower force than the sternal closure construct. Different styles of closure devices were shown cause boney fracture at lower forces. Specifically, a compression style device such as the Talon causes dislocation of the ribs at a much lower force than the other test groups. Failure due to displacement was only seen in the linear AntiWobble screw which shows that more than 2 points are required per plate, or significant compression. While the AntiWobble plate had significantly more displacement than the other devices, testing did show that it had a unique rotational compression technique which provided the compression along the midline like the Talon, with a higher failure load. The AntiWobble screw system could provide a low cost, simple to use alternative to the Sternal Talon.

Although the current iteration of the AntiWobble screw system is has been shown to be effective in the laboratory, the current design would be cumbersome to use in a clinical setting. This is mainly due to the "cap" that is used as an active lock to prevent backout and restrict head movement. Future iterations of the design should somehow incorporate the cap into the head of the screw. In the 2011 MQP produced by Song et al, they designed an expanding head screw used with a two stage screw driver as a possible solution (Song et al, 2011). Another possible solution could be adding an active locking mechanism to the plate, which uses the same drive feature as the screw. This would allow the surgeon to place a screw and engage the AntiWobble mechanism in two steps without needing to exchange instruments or implant additional devices.

The testing methodology used has very high statistical strength, and still yielded no statistical difference between the test groups. To help confirm these results and create a stronger argument for physiological relevance, testing using human hemisterna should be performed. These future tests will validate the results of this study and give additional insight into how the cadaver bone differs in testing from the polyurethane sawbone. In addition to continuing researching AntiWobble applications within the sternal model, investigating the in other bone systems is recommended, with possible applications in bones with underlying soft structures where bicorticle fixation is not recommended like the cervical spine, ribs or craniomaxillofacial structures. (Ahn et al, 2009)

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Appendix A: Lateral Distraction Data

Total Cycles	Talon	AW	BM
1	0	0	0
10	0.028±0.024	0.068±0.040	0.042±0.025
1000	0.065±0.046	0.194±0.109	0.135±0.099
2000	0.073±0.048	0.210±0.123	0.167±0.104
3000	0.078±0.051	0.220±0.131	0.172±0.105
4000	0.081±0.054	0.228±0.137	0.172±0.111
5000	0.085±0.058	0.234±0.142	0.175±0.111
6000	0.089±0.062	0.240±0.146	0.177±0.114
7000	0.089±0.064	0.245±0.150	0.179±0.115
8000	0.091±0.065	0.250±0.154	0.181±0.116
9000	0.091±0.064	0.254±0.158	0.181±0.117
10000	0.090±0.063	0.257±0.162	0.182±0.119
11000	0.091±0.063	0.261±0.165	0.185±0.120
12000	0.091±0.062	0.264±0.169	0.187±0.120
13000	0.091±0.062	0.268±0.171	0.188±0.122
14000	0.091±0.064	0.272±0.174	0.190±0.125
15000	0.092±0.066	0.276±0.176	0.197±0.134

Total Cycles	Talon 11/19/10 Test 3	Talon 11/19/10 Test 4	Talon 5/27/11	Tal 4/14/11
1	0.0000	0.0000	0.0000	0.0000
10	0.0100	0.0470	0.0050	0.0500
1000	0.0440	0.1290	0.0230	0.0630
2000	0.0430	0.1310	0.0250	0.0930
3000	0.0420	0.1290	0.0270	0.1130
4000	0.0440	0.1330	0.0260	0.1230
5000	0.0430	0.1390	0.0270	0.1290
6000	0.0440	0.1450	0.0270	0.1390
7000	0.0420	0.1480	0.0270	0.1410
8000	0.0440	0.1510	0.0270	0.1420
9000	0.0440	0.1530	0.0280	0.1380
10000	0.0450	0.1550	0.0280	0.1330
11000	0.0460	0.1550	0.0290	0.1330
12000	0.0470	0.1550	0.0300	0.1320
13000	0.0470	0.1560	0.0290	0.1321
14000	0.0440	0.1590	0.0300	0.1320
15000	0.0400	0.1610	0.0310	0.1340

Total Cycles	AntiWobble 3/10/11	AntiWobble 5/6/11	AntiWobble 5/13/11
1	0.0000	0.0000	0.0000
10	0.1050	0.0740	0.0240
1000	0.2600	0.2410	0.0810
2000	0.2910	0.2590	0.0790
3000	0.3100	0.2700	0.0810
4000	0.3260	0.2770	0.0820
5000	0.3390	0.2840	0.0800
6000	0.3500	0.2890	0.0810
7000	0.3600	0.2940	0.0800
8000	0.3700	0.2980	0.0810
9000	0.3790	0.3020	0.0820
10000	0.3870	0.3050	0.0800
11000	0.3940	0.3070	0.0810
12000	0.4010	0.3111	0.0810
13000	0.4080	0.3140	0.0820
14000	0.4150	0.3170	0.0840
15000	0.4220	0.3200	0.0850

Total Cycles	Biomet 5/6/11	Biomet 3/25/11	Biomet 4/27/11
1	0.0000	0.0000	0.0000
10	0.0240	0.0770	0.0240
1000	0.0250	0.2640	0.1160
2000	0.0330	0.2790	0.1880
3000	0.0370	0.2880	0.1900
4000	0.0290	0.2960	0.1910
5000	0.0330	0.3010	0.1910
6000	0.0310	0.3070	0.1920
7000	0.0330	0.3110	0.1920
8000	0.0340	0.3150	0.1930
9000	0.0340	0.3180	0.1910
10000	0.0330	0.3220	0.1910
11000	0.0350	0.3280	0.1920
12000	0.0370	0.3310	0.1920
13000	0.0370	0.3350	0.1930
14000	0.0370	0.3420	0.1920
15000	0.0360	0.3640	0.1920

Appendix B: Longitudinal Shear Data

Step	Load	AntiWobble 4/8/11	AntiWobble 3/2/11	AntiWobble 5/13/11
0	0	0	0	0
1	0	0.049	0.173	0.039
2	0.1	1.106	3.139	2.081
3	0	0.608	2.463	1.549
4	0	0.608	2.463	1.549
5	0.2	4.142	5.526	4.999
6	0	3.120	3.767	3.776
7	0	3.119	3.767	3.775
8	0.3	6.181	7.728	7.594
9	0	4.614	5.167	5.555
10	0	4.613	5.166	5.556
11	0.4	8.162	9.989	9.716
12	0	5.894	6.694	6.787
13	0	5.893	6.694	6.788
14	0.5	11.585	12.220	17.742

Step	Load	Biomet 4/8/11	Biomet 5/8/11	Biomet 5/13/11
0	0	0	0	0
1	0	0.041	0.100	0.033
2	0.1	1.133	1.230	0.482
3	0	0.375	0.701	0.195
4	0	0.377	0.701	0.195
5	0.2	1.964	2.076	1.369
6	0	0.715	0.994	0.605
7	0	0.716	0.995	0.606
8	0.3	2.727	3.085	2.198
9	0	0.967	1.482	1.027
10	0	0.968	1.482	1.028
11	0.4	3.721	3.908	2.870
12	0	1.436	1.803	1.337
13	0	1.438	1.803	1.338
14	0.5	4.737	4.911	3.723
15	0		2.272	
16	0		2.273	
17	0.6		6.101	

Step	Load	Talon 4/8/11	Talon 2/22/11 Test 2	Talon 5/28/11	Talon 2/22/11 Test 1
0	0	0	0	0	0
1	0	0.071	0.071	0.847	0.056
2	0.1	1.360	1.218	1.281	0.775
3	0	0.772	0.359	1.035	0.227
4	0	0.772	0.359	1.035	0.227
5	0.2	2.592	3.030	2.042	1.513
6	0	1.379		1.417	0.559
7	0	1.380		1.417	0.560
8	0.3	3.843		3.197	3.514
9	0	1.892		2.178	
10	0	1.893		2.178	
11	0.4	5.366		5.043	
12	0			3.548	
13	0			3.548	
14	0.5			8.168	

Appendix C: Transverse Shear Data

Step	Load	AntiWobble 4/8/11	AntiWobble 7/14/11 T1	AntiWobble 7/14/11 T2
1	0	0.005994	-0.002	0.005
2	0	0.452993	0.244997	0.484993
3	0.1	6.775024	5.349004	3.878996
4	0	4.522955	3.271973	1.778991
5	0	4.524	3.271987	1.778998
6	0.2	11.33896	10.17395	8.407023
7	0	7.960996	6.688979	4.194996
8	0	7.959995	6.688986	4.192994
9	0.3	20.00123		

Step	Load	Biomet 4/21/11	Biomet 7/14/11 T2
1	0	-0.011	0
2	0	1.087997	0.002997
3	0.1	6.369016	1.207001
4	0	4.141002	0.215993
5	0	4.14	0.215993
6	0.2	9.912965	7.712974
7	0	6.101975	4.808764
8	0	6.101982	4.802971
9	0.3	20.18439	12.07173

Step	Load	Talon 7/14/11	Talon 3/10/11	Talon 4/21/11
1	0	0.008998	0	0
2	0	0.100994	0.664995	0.454996
3	0.1	4.252009	4.372995	4.875991
4	0	2.777989	1.871989	2.278998
5	0	2.777989	1.871996	2.277996
6	0.2	9.304776	16.56366	9.658034
7	0	6.990988		4.021003
8	0	6.988993		4.019759
9	0.3	22.69571		27.39489

Appendix D: Instron E1000 information

INSTRON®

E1000 Electrodynamic Test Instrument

System Overview

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

Technical Highlights

- Patent-pending, oil-free linear motor technology for clean conditions.
- Designed for both dynamic and static testing on a variety of materials and components.
- High dynamic performance.
- ± 1000 N dynamic load capacity and ±710 N static load capacity.
- Electrically powered from single phase main supply, no need for hydraulic or pneumatic air supplies.
- Temperature-controlled air-cooling system.
- High stiffness, precision-aligned twin column load frame with actuator in upper crosshead.
- Versatile T-slot table for regular and irregular grips and specimens.
- Compact instrument - frame requires less than 0.15 m² (1.6 ft²) of desk space.

Hardware and Software Interfaces Designed to Put You In Control

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

Hidden Technology Designed to Improve Your Test

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

A High Level of Versatility

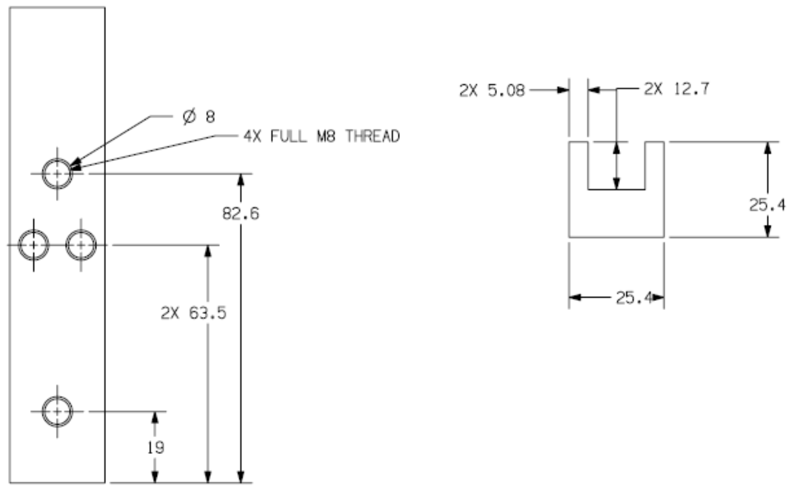
- Readily adjustable test space to suit a wide variety of specimens, grips, fixtures and accessories.
- 60 mm (2.36 in) stroke for a wide range of tests, as well as ease of specimen set up.
- Offset diagonal column configuration provides optimum access to the test area.
- Compatible with FastTrack™ suite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

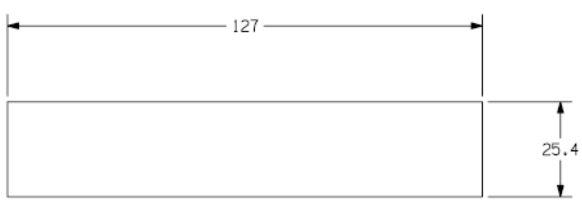
E1000 test instrument in vertical configuration ▶

A New Wave In Testing

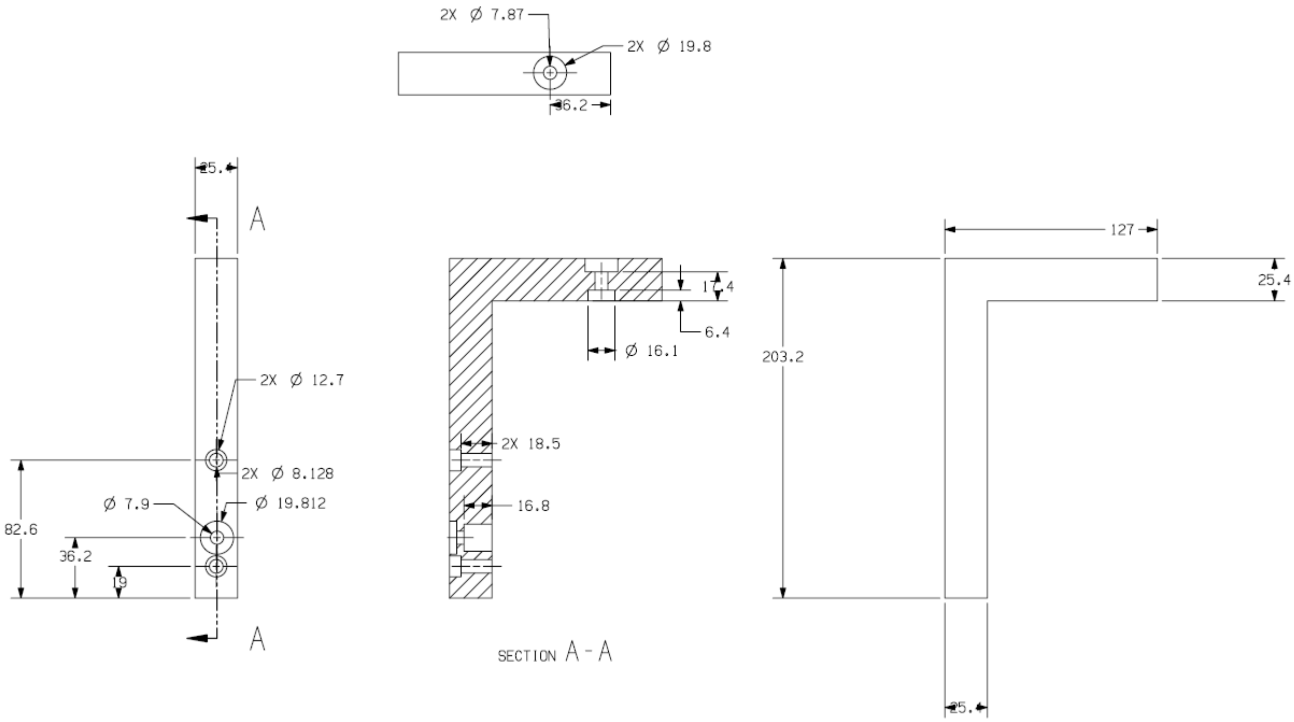
Appendix E: Custom Grip Drawings

Rib Fixation component





Transverse shear adaptor



Appendix F: Inventory

Item(Qty)	Length	Width	Type	Image
Biomet Screw (24)	10mm and 12mm	2.4mm	Self Drilling	
AW Screw (24)	10mm, 12mm and 14mm	2.3mm	Self Tapping	
AW Cap (24)	Cap	Cap	Cap	
AW Plate (8)	Variable	9mm	Plate	
Talon (4)	14XS	NA	Talon	
Biomet X-Plate (4)	35mm	23mm	Plate	
Biomet L-Plate (1)	35mm	11.5mm	Plate