Comparison of Cancellous and Cortical Bone Screws for Sternal Application

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Abstract

The sternum is comprised of predominately cancellous bone encapsulated by a thin cortical shell. Currently, rigid fixation methods for sternal closure following open-heart surgery utilize plates secured with cortical screws. We hypothesize cancellous screws will be superior to cortical screws for sternal fixation due to the sternum’s high fraction of cancellous bone. Screw pullout and cyclic loading tests were conducted using both screw types to test this hypothesis. Pullout forces were recorded to observe the maximum holding strength of each screw in the sternum. Bisected porcine samples were used for pullout testing and were subjected to an increasing load of 5mm/min until the screw was torn from the bone. Cyclic fatigue analysis was conducted to better mimic in vivo conditions. Separate samples of bisected porcine sternum were fixed and subjected to cyclic loading of low-magnitude forces in order to simulate breathing. A servohydraulic testing system applied low forces (9-45N, 2-10lbs) at a low frequency (2Hz) for a high number of cycles. Failure was determined as a 2mm distraction between opposing bone faces as measured by an extensometer. The mean pullout force for cancellous screws was determined to be significantly higher (67.2±10.23N) than the pullout force for cortical screws (28.9±11.74N). Successful tests of limited number also indicated superior fatigue resistance for cancellous bone screws when compared to cortical bone screws for cyclic testing. After 25,000 cycles, the cancellous screw/plate system showed a 1.16mm distraction, whereas the cortical screw/plate system reached 1.55mm distraction. The results of these tests show promise that under conditions in the body, cancellous screws will perform more efficiently than cortical screws; however further research is needed to confirm trends.
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I. Introduction

According to the American Heart Association, about 709,000 open-heart surgeries were conducted in 2002 in the U.S. alone (Association 2005). Open-heart surgery requires the sternum to be bisected, in a procedure known as median sternotomy, such that access to the heart may be obtained. As a result, following surgery, sternal closure is required.

The risk of major wound complications after a median sternotomy is low, approximately 2% (Culliford 1976; Serry 1980; Farrington 1985; Wilson 1987; Newman 1988). However, major median sternotomy wound complications are associated with significant morbidity, prolonged hospital stay, and a mortality rate of approximately 30% (Culliford 1976; Serry 1980; Bor 1983; Newman 1988). In some cases, the sternum does not heal completely or the sternal fixation device fails. These problems normally occur in patients with risk factors such as osteoporosis and emphysema, resulting in poor bone healing (El Oakley and Wright 1996). Disruptions and separations in the healing process can even lead to post operative complications such as mediastinitis (posterior infection), dehiscence (poor closure characterized by infection), or nonunion (sternal pain and non union in the absence of infection) (Karp 1996).

Currently, two fixation methods are used clinically to fix the sternum following open-heart surgery; non-rigid and rigid. Non-rigid fixation techniques secure the sternal halves through the use of stainless steel wires, which have been shown to frequently fail in high risk patients, while rigid fixation methods use plates secured with cortical bone screws, which have also exhibited a limited success rate in clinical applications. This
I. Introduction

study suggested the success rate of sternal fixation would be improved through redesign of rigid fixation systems.

The sternum is predominately cancellous bone encapsulated by a thin cortical shell. Cancellous bone is more porous and spongy than cortical bone and therefore requires a different method for fixation. Cancellous screws have been designed for and are used in various locations throughout the body. However, they have yet to be applied to the sternum. We hypothesized application of cancellous screw technology to the sternum would improve fixation over the cortical screws currently used, thereby increasing the success rate of sternal fixation for all patients.

Two evaluation methods were used to test this hypothesis: an axial screw pullout test and a cyclic fatigue test. Axial screw pullout is a standardized ASTM test used by screw manufacturers to determine the degree of hold between a given screw and the material being tested. Both cortical screws and cancellous screws were to be evaluated in this test and the cancellous screws were predicted to require a higher axial force to pull from the sternal bone.

Cyclic fatigue tests were then conducted to more specifically test the conditions under which the sternum would be loaded in the body. Cyclic testing is a novel approach for evaluating sternal fixation, and was intended to more closely replicate the forces applied to the sternum during respiration. In this test, a given range of cyclic forces was applied to the sternum and the distraction between sternal faces was measured over time, and as the number of cycles increased. As with the axial pullout tests, cancellous screws were also predicted to perform better than cortical screws currently used for sternal fixation in this evaluation, resisting the applied forces for a larger number of cycles.
II. **Background and Literature Review**

Due to the growing number of open-heart surgeries performed each year, successful re-fixation of the sternum following these surgeries has become increasingly important. This fact has been compounded by the aging population of American baby-boomers; who, as they age, become more susceptible to a number of different pathologies. It is these problems which have been shown to complicate sternal fixation and limit its success rate. The subsequent section is intended to serve as an introduction to clinical need for improved sternal fixation, the gross anatomy of the sternum, the sternotomy procedure, the complications which arise following this surgery, and the currently accepted methods for fixing the sternum. Limitations to the current clinical approaches of sternal fixation will then be discussed, serving as an introduction to the hypothesis and specific aims of this study.

II.1. **Overall Clinical Problem**

The number of cardiovascular operations has increased by nearly a factor of five in the past twenty years. According to the American Heart Association, about 709,000 open-heart surgeries were conducted in 2002 in the U.S. alone (Association 2005). Open-heart surgery requires access to the thoracic cavity, making it necessary to cut through the sternum. As a result, once surgery is complete, the bisected sternum must be stabilized and secured such that healing can occur. Currently, common practice for realigning and fixing the sternum following surgery involves the use of stainless steel wires, twist-tied around the sternal bone. While this method has been the standard since 1957 (Julian 1957) and is successful in a large fraction of the population, patients with pathologies
II. Background and Literature Review

characterized by poor bone healing are more prone to experience sternal fixation failure after surgery. For these patients, sternal fixation is more successfully achieved through the use of plate/screws systems; however, this success rate has yet to reach 100% (Cash 1999; Cohen 2002; Song 2004; Pai 2005). As a result, physicians and patients are left with few other options if screw/plate systems also fail.

II.1.1. General Sternum Anatomy

The sternum, commonly called the breastbone, is the flat bone which forms the midline portion of the anterior wall of the thorax. Integral to the protection of the vital organs of the chest cavity, the sternum is approximately 17cm in males (Standring 2005) and generally shorter in females. Downward and slightly forward sloping in natural stance, the sternum has a convex anterior face and a convex posterior face (Standring 2005).

The segmented sternal bone is comprised of three parts; the manubrium, the body (gladiolus), and the xiphoid process (Figure 1).
II. Background and Literature Review

![Diagram of Sternum Anterior (human)](image)

Figure 1: Sternum Anterior (human)

The manubrium is the upper portion of the sternum and is cranially located. The manubrium fuses with the clavicle bones of the pectoral girdle. Below the manubrium, the sternum connects with the second through seventh ribs. The xiphoid, the lowest point of the sternum, does not articulate with any ribs. Instead, the xiphoid serves as an attachment point for a number of ligaments and muscles, including the rectus abdominis muscle and the linea alba. The sternal angle, which occurs at the junction of the body and manubrium segments, and the xiphoid-ster nal junction, which occurs at the junction of the body and xiphoid segments, are contained along the length of the sternum and allow for minimal sternal flexure. The sternum, although primarily cartilaginous at birth, ossifies and fuses into one continuous body segment throughout childhood and early adulthood (Grant 1972; Langebartel 1977; Spence 1986).
II. Background and Literature Review

II.1.2. Median Sternotomy

The full median sternotomy is a commonly performed procedure due to the technique’s relative simplicity and the substantial access it provides to the thoracic cavity. First, an incision is made into the skin and tissue covering the sternum. Next, a sternal saw or specialized knife is used to longitudinally cut down the middle of the sternum, separating the bone into two halves. Once the sternum is successfully bisected, the rib cage is then spread apart, optimally exposing the heart. A sternal retractor may then be inserted to maintain the opening and allow maximum manoeuvrability during surgery (Figure 2). After surgery is completed, the sternum is realigned and positioned for post-operative healing (Busick 2005).

![Figure 2: Schematic of Midline Sternotomy with Retractors](image)

While a full sternotomy is efficient and successful in most cases, there remains room for improvement. The physical separation of the sternum and spreading of the ribs places abnormal forces on the anterior and posterior configurations of the rib cage (La
II. Background and Literature Review

Pier 2002). Furthermore, the surgery is highly invasive. Finally, because this procedure completely divides the sternal bone, all natural stability is disrupted.

II.1.3. Complications

The risk of major wound complications as a result of median sternotomy is low, usually less than 2% (Culliford 1976; Serry 1980; Farrington 1985; Wilson 1987; Newman 1988). However, these complications are associated with significant morbidity, prolonged hospital stay, and an attendant mortality rate of up to 30% (Culliford 1976; Serry 1980; Bor 1983; Newman 1988). In some cases, the sternum does not heal completely, or the sternal fixation device fails; characterized as sternal nonunion. These difficulties are most frequently associated with patients who suffer from other pathologies, such as osteoporosis or emphysema, which are characterized by poor bone healing (El Oakley and Wright 1996). Disruptions and separations in the healing process can lead to post operative complications such as mediastinitis, dehiscence, or nonunion (Karp 1996). Failure of sternal fixation is characterized by a number of qualitative symptoms including the presence of infection, sternal clicking, or painful sternal motion (Chase 1999).

Quantitatively, failure can be characterized through the separation distance between sternal halves, usually defined clinically through x-ray or CT imaging. This failure parameter defines the maximum distance over which bone healing can occur and is generally classified as a 2mm distraction between the midline faces of the two halves of the sternum (McGregor 1999; Losanoff 2004) A number of other studies have also investigated the significance of a 2mm gap between bone faces. Chakkalakal et al.
observed no new bone formation in rats after a 2mm gap had been made in the rat’s fibula (Chakkalakal 1999). Claes et al. investigated the effects of micromovement within 2mm gaps and showed that while small amounts of micromotion promote healing, larger separation distances lead to more fibrocartilage formation and significantly less bone formation (Claes 2002).

II.2. Current Fixation Approaches

Over 40 methods for sternal fixation following median sternotomy have been described by researchers (Casha 1999). Although different in material and geometry selection, these techniques most commonly fall into one of a number of general categories; traditional wiring, banding, plate/screw systems, clips, or pins. Of the above techniques, wiring and screw/plate systems are most commonly used clinically and are most frequently referred to as non-rigid and rigid fixation respectively.

II.2.1. Non-Rigid Fixation: Wires

Since the median sternotomy was re-popularized in 1957 by Julian et al., sternal wiring has been the accepted method of sternal re-fixation. Sternal wiring is still preferred among surgeons as a result of its long established clinical history, the ease and speed with which fixturing can be accomplished, and the relatively low cost associated with wiring (Ozaki 1998; Losanoff 2004). Traditionally, most non-rigid fixation techniques use 5mm stainless steel wire.

A number of different wiring methods have been investigated both in vitro and clinically. In 1999, Casha et al. assessed the rigidity of sternal fixation for six different
II. Background and Literature Review

wiring configurations using a steel jig as a sternal model. This study concluded the maximum force on the sternum (while coughing) was 1500N, a force best withstood by two straight wires. Although the validity of a steel model for the sternum is contestable, the investigation used unit samples to test each wiring techniques thus simplifying unwanted force variation which may occur over test specimens of similar length to a natural sternum. In 2003, Dasika and his colleagues compared three sternal wiring techniques on a polyurethane bone analog model (Dasika 2003). The group found that under increasing loads (from 100 to 400N) the lower sternum is the site of greatest instability and that a more complicated figure of eight wiring technique was not statistically superior to traditional simple wiring. Finally, Losanoff et al. in 2004 utilized a cadaver model also to test six different closure techniques. The findings of the group again suggest superiority of simple peristernal wiring under cyclic forces ranging from 0 to 800N.

Although a number of different wiring techniques have been investigated, as suggested by the studies above, traditional peristernal wiring is both the simplest and the most reliable (Figure 3). In this procedure, twenty-gauge (5mm) wire is passed under both halves of the sternum, the wire is then crossed on the ventral side of the sternum, grasped with forceps, and twisted until the twists are secured against the face of the sternum (personal correspondence Dunn 2005). Excess wire is then clipped and bent downward toward the ventral face of the sternum to prevent unnecessary tissue damage; the stitch is repeated between six and eight times depending upon sternal length (personal correspondence Dunn 2005). The following image illustrates the straight wiring technique.
II. Background and Literature Review

II.2.2. Rigid Fixation: Screws/Plates

Rigid fixation systems are comprised of two components: screws and plates. Each of these elements and their interaction are integral to the functioning and success of the entire system. Plates are used to increase stability and load sharing (Stryker 2004). Screws determine the holding strength of the plate to the bone via the amount of screw threads purchased in the bone (Lee 1999). Both components of this system are traditionally fabricated using either stainless steel or titanium.

Plates are manufactured in a number of different configurations to best suit the clinical application. In current orthopedic research, straight plates (Figure 4) are frequently tested as a comparison to wire techniques due to geometric similarities. However, as pointed out by Ozaki et al. (1998), straight plates are not used clinically because they do not allow for screw purchase into the best possible parts of the sternum. As a result, X-plates (Figure 4) and box plates are most frequently used for sternal
II. Background and Literature Review

fixation and the precise selection of plate geometries as well as size is customizable to the specific size and shape of the sternum and the specific patient (Song 2004).

![Image of Rigid Fixation Plates](image-url)

**Figure 4:** Straight and X-shaped Rigid Fixation Plates (based upon Ozaki, 1998)

The second important aspect of rigid fixation is screws; of which there are two primary types: cancellous and cortical. A number of design variables exist for each type of screw; screws may be self-drilling, self-tapping or locking in the plating system. Differences between cortical and cancellous screws are usually described in terms of outer diameters, core (root) diameters, pitch, thread width, and overall length. Self-drilling screws do not need an initial pilot hole and can simply be screwed directly into the bone without prior preparation. Self-tapping screws require a non-threaded pilot hole to be drilled; however, this pilot hole must be threaded for non self-tapping screws. Locking screws lock into the plate with which they are used ensuring that the screws are tightened to the same torque at every application (Olsen 2005).

In comparing cancellous and cortical screws according to the characteristics depicted above, parameters such as outer diameter, core diameter and length can all be manipulated to better fix different bone types. Pitch and thread width are primarily the parameters among which cancellous and cortical threads differ. Cancellous screws have
II. Background and Literature Review

larger thread widths and pitches (Lee 1999; Corwin 2001) due to the need to compress spongy cancellous bone while drilling (Lee 1999). In contrast, cortical screws have finer threads due to the greater uniformity of cortical bone (Lee 1999; Corwin 2001). The following image illustrates the ascetic differences between these two screw types.

![Figure 5: Geometries of Cortical (left) and Cancellous (right) bone screws](image)

The use of plates and screws for sternum fixation has been adapted from other orthopedic applications. Separation and nonunion difficulties analogous to those seen in the sternum have been observed by surgeons attempting craniofacial and axial skeleton fixation (Ozaki 1998). Due to the relative newness of sternal plating versus traditional wiring, the increased risk of drilling close to the heart, longer plate fixation time, and expense, plating following median sternotomy has been slow to be accepted clinically (Song 2004).

However, a number of studies have suggested the advantage of rigid fixation via plates and screws over traditional non-rigid wiring techniques. A 1991 study by Sargent et al. suggested that among 14 baboons, treated after midline sternotomy with either straight wires or miniplates, those which received rigid fixation experienced more rapid sternal union and greater stability (Sargent 1991). Ozaki et al. in 1998 furthered the case
II. Background and Literature Review

for rigid fixation following median sternotomy, indicating in a human cadaver model that titanium plating systems offered greater stiffness and less displacement to traditional wires under repetitive loading of 220.6N (49.6lb). A similar conclusion was drawn in 2002 by Cohen et al. in their investigation of three sternotomy closure techniques, wires, plates and cables. Here, the researchers suggest that the rigid fixation system offered more rigidity, a 25% greater resistance to failure, and less cutting when subjecting a synthetic polyurethane bone model to displacement controlled testing of 10 mm/min. In 2004, Song et al. compared, in their retrospective human study, 45 high-risk patients who received rigid fixation after sternotomy against 207 patients who received traditional wiring fixation. The results ultimately showed that patients who received rigid fixation were less likely to experience postoperative mediastinitis than those patients fixed with traditional wiring techniques. Finally, Pai et al, in 2005, conducted lateral distraction tests of bone analog models fixed with various plating combinations or non-rigid wires. This investigation suggested that under total forces of 180 N distributed over the length of the sternum analog, plating offered increased stability to wires.

II.3. Fixation Approach Limitations

Rigid fixation methods have yet to be specifically designed for the sternum. Instead, these screw/plate systems have been adapted from other parts of the body. As a result, these devices fail to take into account the unique loading profile of the sternum and the sternum’s distinctive bone composition. The considerable failure rate of rigid sternal fixation is largely the result of neglecting these factors.
II. Background and Literature Review

II.3.1. Mechanical Forces on the Sternum

The loading profile of the sternum is an important factor in determining the success of sternal fixation. Directly following open-heart surgery, the bisected sternum is unable to resist the loads normally placed upon it and these loads are directly transferred to the fixation device. Sternal forces have been impossible to characterize in an in vivo human model due to the degree of invasiveness involved. To circumvent this, researchers have formulated both numerical and animal models to approximate the magnitude and direction of these forces.

A number of computer derived finite element models have been created to determine the complex loading which is seen in the sternum. As part of their 1999 study, Casha et al. approximated sternal forces using a cylindrical mathematical model where acting forces were directed radially along the circular portion of the sterna. Using this model, the group calculated the force (T) required to keep the sternum closed by the following equation: \( T = r l P \); where \( r \) is the cylinder’s radius, \( l \) is the length, and \( P \) is the difference between internal and external pressures. As a result of this model, the determination was made that in coughing a force of approximately 1500N would be required to keep the sternum closed. In 2005, Bruhin et al. created a virtual thoracic model using thoracic computer topographic scans which the group then transferred into a three-dimensional finite element model of the thoracic cavity. Using this model, the group calculated forces under normal breathing conditions and under off-axis breathing (breathing while bent either laterally or dorsally) as a means of analyzing the structural response of the sternum to fixation with either plates or wires (Bruhin 2005). Under these
II. Background and Literature Review

conditions, the group calculated the effective stress on the sternum in normal breathing to be 5,504 N/mm$^2$.

Animal models have also been utilized by researchers for investigations of the sternum. Specifically, porcine models have been widely used for sternal applications (Losanoff 2002, Trumble 2004) due to the similarities between the human and porcine thoracic cavities in size and shape, characterized by a circular chest wall profile, as well as heart placement (Trumble 2004). The use of a porcine model in studies involving the sternum has prompted researchers to investigate the distribution of forces on the porcine sternum. In 2005, Pai et al. quantified the magnitude, direction, and distribution of sternal forces in a pig under various respiratory conditions. The findings of the study suggest much lower magnitude forces than previously documented, all found forces were less than 45N (~10lb), with maximum forces recorded during coughing to be only 44N (~10lb) at the manubrium and 36N (~8lb) at the xiphoid of the sternum (Pai 2005). In addition, forces in the lateral direction were higher than measured forces in other directions. As a result of these low magnitude forces, Pai suggests sternal failure is unlikely caused by catastrophic, instantaneous failure due to excess force, but rather as a function of low force applications over time.

II.3.2. Bone Composition

The sternum is a sandwich bone having an interior core of cancellous bone encapsulated by a thin cortical bone shell which is thickest in the manubrium (Standring 2005). The interface between the cortical bone of the shell and the interior cancellous bone is quite abrupt and there is no gradual porosity difference like is evident in long
II. Background and Literature Review

bones. Locations along the centerline of the sternum are generally characterized by more delicate trabeculae while lateral portions of the bone, presumably due to the interface between the sternum and the ribs, contain thicker and wider trabeculae (Standring 2005). Cortical and cancellous bone, although different in microstructure and morphology, exist in tandem throughout the skeleton to comprise all bone.

II.3.2.1. Cancellous

Cancellous bone, also known as spongy or trabecular bone, is found at the ends of all long bones and within flat bones such as the sternum. Although it accounts for only 20% of skeletal mass, cancellous bone comprises 67% of bone surface affording it a small role in skeletal strength but a large role in maintaining bone shape and fracture risk (Corwin 2001). Struts, called trabeculae, create the open irregular lattice structure of cancellous bone through the formation of three-dimensional, interconnected pores the size of which are on the order of 1mm. In vivo, trabeculae are comprised of hydroxyapatite crystals, embedded in a collagen-fiber matrix, which creates pores that are occupied with bone marrow and cells (Keaveny 2001).

Figure 6: Fundamental Human Cancellous Bone Structure
II. Background and Literature Review

Although the porosity structure is irregular, cancellous bone is oriented, thereby creating a grain along which mechanical stiffness and strength are maximized (Keaveny 2001). The structural unit of cancellous bone is the trabecular packet or hemiosteon which ideally is shaped like a hollow crescent with a radius of 600µm, a thickness of 50µm, and a length of 1mm (Corwin 2001).

II.3.2.2. Cortical

Cortical bone, or compact bone, is dense bone, comprising almost 80% of human skeletal mass, found in the shafts of long bone or as an outer shell of spongy bones (Corwin 2001). While the microstructural unit of cancellous bone is the trabeculae, the basic unit of cortical bone is the osteon, which surround the channels of the cortical bone. The orientation of a channel surrounded by layers of osteons, characterizes the “bull-eye” appearance of cortical bone, as evident in the figure below.

Figure 7: Cortical Bone

Morphologically, cortical bone exhibits a usual porosity of 5-10%. These various pore spaces can be characterized as one of following types; Haversian canals (spaces that run parallel to the long axis of the bone, designed to contain capillaries and nerves within
II. Background and Literature Review

their 50µm in diameter), Volkmann’s canals (short channels designed to connect either two Haversian channels to each other or to the outside surface of the bone that may also contain blood vessels and), or Resorption cavities (voids typically 200µm that are created by osteoclasts during remodeling) (Martin 2005). Functionally, cortical bone is responsible for support and protection of the skeleton (Corwin 2001).

II.4. Summary

As discussed in the preceding section, sternal fixation is currently accomplished following surgery with either non-rigid or rigid fixation methods. Non-rigid fixation techniques secure the sternal halves through the use of stainless steel wires, which have been shown to frequently fail in high risk patients, while rigid fixation methods use plates secured with cortical bone screws, which have also exhibited a limited success rate in clinical applications. Design revisions must be made for sternal fixation to be more successfully accomplished.

Sternal fixation designs must take into account the forces applied to the sternum as well as the sternum’s unique composition. Although the magnitude and direction of sternal forces is still under debate, the low force magnitudes measured by Pai are unique in attributing sternal failure to low magnitude forces applied over long periods of time. In addition, rigid fixation systems have failed to take into account the sternum’s unique composition of primarily cancellous bone encapsulated by a thin cortical shell. These two rather dramatic gaps in the research were addressed as part of the following study.
III. Project Approach

As discussed, successful sternal fixation has dramatic clinical ramifications. At present, sternal fixation has yet to be successfully achieved for all patients. Consequently, an improved method is required. An investigation concerning the limitations of current fixation methods was conducted and gaps in the research were identified. The following section will address these gaps by presenting the hypothesis of this study, its assumptions, and specific aims through which it will be evaluated.

III.1. Hypothesis

The main objective of this study was to investigate the current standards of sternal fixation as a beginning point to the development a superior rigid fixation technique for the sternum. Cancellous screws have been designed for and are used in various locations throughout the body. However, they have yet to be applied to the sternum, although this bone is primarily comprised of cancellous tissue. We hypothesized that application of cancellous screw technology to the sternum would improve fixation over the cortical screws currently used, thereby increasing the success rate of sternal fixation for all patients.

Two evaluation methods were used to test this hypothesis; an axial screw pullout test and a cyclic fatigue test. Axial screw pullout is a standardized ASTM test (F 543-02) used by screw manufacturers to determine the degree of hold between a given screw and the material being tested. Both cortical screws and cancellous screws were to be evaluated in this test and the cancellous screws were predicted to require a higher axial force to pull from the sternal bone.
Cyclic fatigue tests were then conducted to more specifically test the conditions under which the sternum would be loaded in the body. Our method of cyclic testing is a novel approach for evaluating sternal fixation, and was intended to more closely replicate the forces applied to the sternum during respiration. In this test, a given range of cyclic forces was applied to the sternum and the distraction between sternal faces was measured over time, and as the number of cycles increased. As with the axial pullout tests, cancellous screws were also predicted to perform better than cortical screws currently used for sternal fixation in this evaluation, resisting the applied forces for a larger number of cycles.

The results obtained from both of these test methods allowed for an initial comparison of cortical and cancellous screws to be made. The clinical implications of this preliminary comparison are significant as sternal fixation failure commonly occurs among open-heart surgery patients. Although the two evaluation methods used in this study provide a baseline for cancellous screws assessment for the sternal application, future evaluations of cancellous screw fixation are necessary due to the assumptions under which these tests were conducted.

III.2. Assumptions

A number of assumptions were made in developing the evaluation methods used to test the hypothesis of this study. These assumptions were necessary to sufficiently simplify the testing conditions; ensuring that all objectives could be determined within the scope of this project. Assumptions were made both within the creation of this study’s hypothesis and in design of the methods used to evaluate this hypothesis.
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III.2.1. Hypothesis Assumptions

Assumptions were made while developing this study’s hypothesis. A list of these assumptions is presented below;

**Assumption 1**: It is possible to apply cancellous screws, which have proven efficacy in other areas of the body, to the sternum.

**Assumption 2**: Rigid fixation methods provide superior sternal fixation than non-rigid fixation methods

III.2.2. Experimental Assumptions

Assumptions were made while determining the methods used to evaluate this study’s hypothesis. A list of general assumptions which pertain to both evaluation methods is presented first below followed by assumptions made of each of the two specific evaluation methods.

**General Assumptions:**

**Assumption 1**: It is possible to quantify screw performance based upon the results of axial screw pullout and cyclic fatigue testing.

**Assumption 2**: The material properties of porcine model sterna are similar to that of human model sterna.

**Axial Pull Test Assumptions:**

**Assumption 1**: Force required for axial pullout directly correlates into screw bite in the sternal bone.

**Assumption 2**: Sternal bone properties were consistent between cortical and cancellous tests.
III. Project Approach

Cyclic Fatigue Test Assumptions:

Assumption 1: Magnitude of forces applied in *in vitro* tests accurately represent the *in vivo* loading on the sternum.

Assumption 2: The predominant force exerted on the sternum is in the lateral direction, allowing upward force due to the differential pressure of the thoracic cavity. Shear forces are to be neglected, and the lateral force is simplified as uni-axial.

Assumption 3: The lateral force is caused as result of the ribs pulling the sternum apart during breathing.

Assumption 4: Sternal bone properties were consistent between cortical and cancellous tests.

III.3. Specific Aims

The ultimate goal of this project was to compare cancellous screws for rigid sternal fixation with cortical screws which are currently in use clinically. The specific aims which were to evaluate this objective are presented below:

- To select a test system whereby axial pullout force could be applied.
- To design a custom grip whereby axial pullout forces could be transferred to the screw being tested.
- To determine the magnitude of force required to pull screws from the sternal bone.
- To select a test system whereby cyclic forces could be applied to simulate breathing conditions *in vivo*.
- To design a gripping method such that sternal specimens could be successfully interfaced with the sternal bone.
III. Project Approach

- To select or design a plate for use in conjunction with screws for cyclic fatigue testing.
- To determine the number of cycles to failure of sternal test specimens as a function of cancellous and cortical screw fixation under lateral, uni-axial, applied forces.

With these specific aims determined, development of design and testing methodologies could be established.
IV.  Design

The hypothesis, specific aims, and evaluation methods previously discussed were established in compliance with the project’s three major stakeholders; the designers (students and advisors), the bone screw industry, and clinicians and patients. Although establishing these design objectives to suit the needs of each of these primary groups required numerous amounts of revision of our project hypothesis, as reflected in Appendix A, once these ideas were firmly established selection of basic design components ensued. Basic design components included the cancellous and cortical screws to be tested as well as the required hardware necessary to evaluate these screws in the selected test methods. As a result, objectives for each of these components were established and selections were made for cancellous and cortical screws, testing devices with specialized gripping systems to conduct cyclic and bone pullout tests. Also, a plate was selected to be used in accordance with cyclic fatigue testing of the two screw types. This section discusses the selection process for each of these testing components.

IV.1. Cancellous and Cortical Screw Selection

To successfully evaluate the hypothesis predicting the superiority of cancellous screws over cortical for the sternal fixation application, it was necessary to first select the screws which would be tested. Screw differences are generally discussed based on a number of geometrical attributes. These attributes include thread and core diameter, head height and radius, and thread pitch and thread number among others. In addition, more macroscopic considerations such as overall screw length, the ability of the screw to thread directly into the bone or the need for pre-drilling (self-tapping), screw diameter,
configuration of screws in plate, and the ability of the screw to lock with the plate (locking) must also be considered. The pairwise comparison chart, reproduced below (Table 1), evaluates the relative importance of one screw characteristic versus another and was used to determine the screw attributes most important in sternal fixation.

### Table 1: Pairwise Comparison of Screw Characteristics

<table>
<thead>
<tr>
<th></th>
<th>Screw Length</th>
<th>Screw Diameter</th>
<th>Plating Configuration</th>
<th>Self-Tapping</th>
<th>Locking</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screw Length</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Screw Diameter</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Plating</td>
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<td></td>
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<tr>
<td>Configuration</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Self-Tapping</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Locking</td>
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</tbody>
</table>

The results of the pairwise comparison chart indicated that screw length and diameter were the most important attributes to be considered when selecting screws for use in pilot sternal fixation fatigue tests. Additionally, it was determined that unnecessary variation between the cortical and cancellous tests needed to be minimized. As a result, aside from the fundamental geometrical design differences of thread pitch and outer diameter which largely account for the fixation differences between cortical and cancellous screws, geometrical attributes such as inner diameter and length were made the same.

The dimensions of these controllable parameters were largely determined as a result of collaboration with Stryker Corporation, from whom both the cancellous and cortical screws were obtained. Both types of screws are manufactured in standard diameters and lengths, constraining the selection process. Optimal screw length was determined to be 10mm due to the fact that screws are manufactured in 2mm increments, but more importantly because the average thickness of the porcine test specimens used
IV. Design

was 12mm. As a result, it was determined that a 10mm screw length would afford maximum purchase into the bone while avoiding the risk of piercing through to the underside of the bone; a condition which is undesirable in the clinical application because of the heart’s proximity.

The selection process was further restricted in the selection of screw diameter. Because cancellous screws have not been designed specifically for the sternal application and are generally used in long bone fixation, where long bones are much larger than the sternum, cancellous screws are generally not manufactured in small diameters. As a result, the smallest diameter of cancellous screw which could be obtained was 3.5mm. Fortunately, this diameter was able to be matched for a cortical screw and a set of cortical screws of 3.5mm diameter were also able to be obtained.

IV.2. Axial Pullout Testing

Axial pullout tests were first conducted to assess the differences between cortical and cancellous screws in the extent in which they gripped the sternal bone. The Axial Pullout Test is an ASTM standard test which can be used to compare the strength of different screws by measuring the axial force required to pull the screw out of a given material. To successfully perform these tests it was necessary to determine a testing setup and a grip design which complied with the standards set forth by the ASTM method (F 543-02).

IV.2.1. Testing Setup Selection

The ASTM (F 543-02) method dictated that a testing device should be used which could place a tensile load on the bone screw, transferring this load to the screw directly
IV. Design

through its head. The testing device had to be able to apply the tensile load at a rate of 5mm/min and then record both this applied load (in Newtons) and the displacement (in millimeters) of the screw from the testing material. The maximum load achieved by each screw before it pulled out of the bone thus determined how well it gripped the bone.

With these objectives determined, the testing device to be used for this test had to be selected. For this test, selection was limited between two different materials testing machines. Although both machines were capable of conforming to the setup parameters determined by the ASTM (F 543-02) method, differences between the size of each machine’s load cell (50 pounds or 1000 pounds) and their gripping systems which interfaced with the test specimen necessitated careful selection. As a result, preliminary tests were performed to determine the approximate magnitudes of the cortical and cancellous screw pullout in the sternal bone and therefore which machine should be used. From these tests, it was determined that the Q Test/5 materials testing system manufactured by MTS Systems Corporation (Eden Prairie, MN) possessed the appropriate sized load cell for the approximately 20 pound loads which were determined through preliminary tests. Consequently, the MTS system (Eden Prairie, MN) was used to conduct the remainder of the axial screw pullout tests.

IV.2.2. Grip Design

The axial screw pullout test also dictated the need for a custom designed grip to transfer the applied load to the screw’s head. As with the testing device, the ASTM (F 543-02) standard axial pullout test was used to define the design objectives for this custom grip, as summarized in the following bulleted list:
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- Grip must transfer applied load directly through screw head
- Grip must align longitudinal axis of the screw with the center of the testing device crosshead
- Grip must capture the head of the screw without contacting the screw shaft
- Grip must lay flat along the surface of the bone being tested

With these objectives determined, a custom grip was designed as reproduced in the image below.

![Figure 8: Custom designed axial pullout testing grip: a.) tab to be gripped by testing device, b.) U-shaped aluminum plate; c.) screw resting in U-Plate to be inserted into specimen](image)

As evident in the schematic above, the custom grip was designed such that the tab could be gripped by the testing device. The screw is then captured by the U-shaped aluminum plate which is connected to the testing device gripping tab. This grip was then manufactured and used for the remainder of the axial pullout tests.

IV.3. Cyclic Fatigue Testing

Cyclic fatigue tests were conducted to assess the differences between cortical and cancellous screws in test conditions which better mimicked the environment experienced clinically. In these cyclic tests, breathing forces and frequencies needed to be simulated by a testing device on a bisected section of the sternum fixed with either cortical or cancellous screw/plate systems. As a result, it was necessary to determine an appropriate
testing device, in addition to selecting an appropriate screw/plate system as well as develop an appropriate interface between the specimen and the chosen testing device. The following section first discusses the selection of a testing setup and then proceeds through the design of the screw/plate systems as well as the specimen-testing setup interface.

IV.3.1. Testing Setup Selection

To conduct sternal cyclic fatigue experiments, it was necessary to determine a testing system which could subject specimens to the desired testing inputs and effectively measure resulting outputs. To achieve these aims, major design attributes for the testing device and the measuring system were identified, as were design functions and objectives. Ultimately, a testing system and a measurement system which met these criteria were selected.

IV.3.1.1. Objectives, Functions, and Constraints Determination

To determine desired attributes of the testing system, the necessary functions, objectives, and constraints of the device were first generated through brainstorming. An initial list of required attributes is reproduced in Table 2, this table also separates each of these attributes into the category under which it falls; function, objective, or constraint.
IV. Design

Table 2: Preliminary Identification of Design Attributes

<table>
<thead>
<tr>
<th>Objective</th>
<th>Function</th>
<th>Constraint</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Cost effective</td>
<td>• Accurately apply lateral forces over a large number of cycles</td>
<td>• Testing conditions must be sustained over a large number of cycles</td>
</tr>
<tr>
<td>• User-friendly</td>
<td>• Measure distraction between bone faces</td>
<td>• Accurately input forces and export strain</td>
</tr>
<tr>
<td>• Affordable and easy to manufacture</td>
<td>• Display measured distraction</td>
<td>• Exported strain must be able to be measured</td>
</tr>
<tr>
<td>• Accurate and efficient</td>
<td>• Hold specimens such that forces may be applied</td>
<td></td>
</tr>
<tr>
<td>• Adaptable to other sternal models, i.e. human cadaver</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Easily repeat testing method</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Allow for frequency to be adjusted</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Allow for force to be adjusted</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Maintain proper in vivo conditions (pH, temperature, moisture, etc.)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Easily allow for specimens to be gripped</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Minimize damage to specimens</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

To better focus the objectives of the testing system, the next logical step in the design process was to determine the main categories into which each of the brainstormed objectives fell. To achieve this, an Indented Objectives List (Figure 9) was created.

Affordable
• Device should be inexpensive compared to other systems
• Device should have cost-effective repairs

User-friendly
• Device should be easy to operate
• Data acquisition should be simple and effective

Accurate and Efficient
• Device should enable inputted frequency and loading conditions to be adjusted accurately
• Device should collect and display count cycles to failure
• Device should measure and display distraction between bone faces

Mimic In Vivo Environment
• Device should simulate breathing conditions
• Device should maintain physiochemical and physiological environment (pH, temperature, moisture, etc.)

Repeatable
• Device should be able to accommodate with other sternal models
• Device should be consistently apply imputed force

Specimen Interface
• Device should minimize damage to specimens while gripping
• Gripping of specimens should be easily accomplished

Figure 9: Indented Objectives List
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From the Indented Objectives List, six main objective categories were established. To better determine the importance of each of these objective categories, a Weighted Objectives Tree was created.

![Weighted Objectives Tree](image)

**Figure 10: Weighted Objectives Tree**

The goal of the weighted objective tree was to allow for objectives to be easily compared based upon their importance to the testing system. As shown here, the weight of each level of the tree was made to equal one. The number to the left of the backslash indicates the weight of each individual objective in relation to the sub-objectives which comprise it.
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and the number to the right indicates the weight of each objective normalized over the whole tree.

Comparing the normalized weights of each objective in the Weighted Tree allowed for the creation of a Pruned Objectives List which is shown below.

<table>
<thead>
<tr>
<th>Accurate and Efficient</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Device should enable inputted frequency and loading conditions to be adjusted accurately</td>
</tr>
<tr>
<td>• Device should collect and display count cycles to failure</td>
</tr>
<tr>
<td>• Device should measure and display distraction between bone faces</td>
</tr>
<tr>
<td>Repeatable</td>
</tr>
<tr>
<td>• Device should be able to accommodate with other sternal models</td>
</tr>
<tr>
<td>• Device should be consistently apply imputed force</td>
</tr>
<tr>
<td>Specimen Interface</td>
</tr>
<tr>
<td>• Device should minimize damage to specimens while gripping</td>
</tr>
<tr>
<td>• Gripping of specimens should be easily accomplished</td>
</tr>
</tbody>
</table>

Figure 11: Pruned Objectives List

The Pruned Objectives Tree reflected which objectives were deemed most important following weighting and therefore most vital to the attributes of the testing device. As evident, the main objectives determined from the Pruned Objectives List were that the device:

- Should be both accurate and efficient
- Minimize damage to test specimens when gripping
- Have repeatable testing methods

Clarification of these main objectives allowed for a more focused assessment of testing systems.

IV.3.1.2. Testing Setup Selection

After establishing the primary objectives of the testing device, previously used testing apparatuses for cyclic testing were researched in the literature [Appendix B]. Although differences in the design of testing systems varied from study to study to reflect the specific objectives of testing, it was seen that while a number of studies fabricated
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	heir own testing apparatus many others manipulated standard material testing machines
to suit their specific needs (through specialized grips, testing conditions, etc.). From the
information gained through evaluation of the previous literature and through the approach
determined for this experiment, a set of technical objectives for the testing device was
established as follows.

- Device must be frequency adjustable (2-10 Hz)
- Device must accurately exert forces between 2-15 lbs.
- Device must be able to simulate 100,000+ cycles
- Device must be able to mimic \textit{in vivo} sinusoidal breathing conditions
- Device must be able to run tests overnight, when necessary
- Device must record cycles, strain, and local distraction as a function of real time

These technical device attributes, in conjunction with the primary objective defined
earlier, were the primary factors taken into consideration during testing device selection.

Due to time and expertise limitations, it was established that fabrication of a novel
testing apparatus was beyond the scope of this project. As a result, an appropriate testing
system was chosen after establishing a partnership with Instron Corporation (Norwood,
Massachusetts). Collaborating with Instron resulted in access to a variety of mechanical
testing equipment. After consideration of technical and primary objectives, selection of
the appropriate testing device resulted. The specifications of the testing device selected
are shown below, Figure 12.
The Instron FAST TRACK 8841 mechanical testing system was selected for a testing device because its attributes coincided with the highest number of established testing device objectives (Appendix C). The FAST TRACK 8841 was not only capable of recording the cycles of each bone specimen to failure over the large number of cycles necessary; it was also capable of applying imputed force values and export strain values. Most importantly, this system could be easily interfaced with an external device which could accurately determine the local distraction of the opposing bone faces. In addition, this testing device used a servohydraulic power system to enhance the cyclic simulation of *in vivo* forces and breathing frequencies. While other considered testing systems possessed appropriate load cells, the abilities to import force values and export strain values, and the ability to interface with an external device to measure local displacement, they did not have the hydraulic driven actuators necessary to mimic the sinusoidal breathing conditions found in the body.
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IV.3.1.3. Local Distraction Measurement System Selection

The data acquisition system integrated with the FAST TRACK 8841 was capable of measuring the percent strain in the grips of the device. However, due to possible slack within the testing setup and the small lateral distraction between opposing bone faces which needed to measured, it was necessary to measure local displacement on the actual bone specimens precisely at the site of separation. A formal brainstorming session was not conducted as the primary objectives on the displacement system were already well known. These objectives are displayed in the following list:

- Device must be able to measure displacement locally at the precise point of separation
- Device must be able easily integrated into the testing system
- Device must be relatively self-sustaining and self-regulating
- Device must be also to continually run for a large number of cycles

These attributes were taken into consideration during measurement device selection.

Five different methods of measuring local displacement at the site of specimen separation were evaluated. The following is a list of pros and cons associated with each considered method.
Table 3: Summary of pros and cons for each distraction measurement method

<table>
<thead>
<tr>
<th>Method</th>
<th>Pros</th>
<th>Cons</th>
</tr>
</thead>
<tbody>
<tr>
<td>Extensometer</td>
<td>• Can be easily integrated into data acquisition program</td>
<td>• Size of device may be bigger than available bone area to attach to</td>
</tr>
<tr>
<td></td>
<td>• Can measures real time of local distraction as a function of cycle</td>
<td>• Device may fall off during cyclic testing</td>
</tr>
<tr>
<td></td>
<td>• Can be placed directly onto bone sample</td>
<td>• Device may not measure distractions greater than 2mm</td>
</tr>
<tr>
<td>Video Extensometer</td>
<td>• Can be easily integrated into data acquisition program</td>
<td>• Markers must be placed on bone specimen and can detach during testing</td>
</tr>
<tr>
<td></td>
<td>• Can record real video of the experiment</td>
<td>• There must be enough room for device to be set up next to testing system</td>
</tr>
<tr>
<td></td>
<td>• Can measure local distraction as a function of time</td>
<td>• Device is frequently used at Instron and may not always be available</td>
</tr>
<tr>
<td>Digital Camera</td>
<td>• Can record local distraction at specified time intervals</td>
<td>• Pictures must be taken manually and will be time consuming</td>
</tr>
<tr>
<td></td>
<td>• Can take pictures of bone specimen during testing</td>
<td>• Local distraction will not correlate with cycles</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Measurements will not be as frequent or accurate as video recording</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Markers must be placed on bone specimen and can detach during testing</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Local distraction must be measured from digital pictures using a computer</td>
</tr>
<tr>
<td>Video Camera</td>
<td>• Can record local distraction over time</td>
<td>• Local distraction will not correlate with cycles</td>
</tr>
<tr>
<td></td>
<td>• Can take real time images of cyclic testing</td>
<td>• There must be enough room for device to be set up next to testing system</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Markers must be placed on bone specimen and can detach during testing</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Local distraction must be measured from video images using a computer</td>
</tr>
<tr>
<td>Strain Gauges</td>
<td>• Can be placed directly on bone specimens</td>
<td>• Must be integrated into data acquisition program</td>
</tr>
<tr>
<td></td>
<td>• Can measure local distraction over time</td>
<td>• Programming is time consuming</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Must calculate local distraction from strain measurements after each test is complete</td>
</tr>
</tbody>
</table>

Following generation of the local displacement measurement system advantages and disadvantages, an extensometer was selected to measure local distraction of the opposing bone faces. The rationale for this selection was based upon the fact that the extensometer was self-sustaining and self-regulating and thus could be left for the long periods of time which the test was required to run. In addition, the cons associated with the extensometer were determined to be most easily overcome, making the extensometer the simplest device to use. Finally, due to the ability of the extensometer to directly
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interface with the data acquisition system, data collection was efficient and could be accrued throughout the entire duration of the test.

IV.3.2. Plate Selection

To successfully reproduce the rigid fixation method performed clinically, the selected screws needed to be tested in conjunction with a plate. This plate was secured using both types of the selected Stryker screws and was used to hold the two halves of the bisected sternum together. To determine the plate used, its necessary characteristics were first determined.

It was understood that to best understand screw failure in the cyclic application, the complexity of the model should be minimized as much as possible. To this end, it was established that screw failure could best be characterized if only one screw was used to fix each side of the bisected sternum. Although this approach is seldom used clinically, because multiple screws provide better rigidity to a secured plate, it was felt that in a pilot test setup this point could be overlooked. As a result, the model was simplified and a straight plate possessing only two holes for screw fixation was desirable.

To maintain clinical relevance, a straight plate also manufactured by the Stryker Corporation was first used in conjunction with both the cancellous and cortical screws to fix the sternum. A schematic representation of the one-third tubular plate selected is depicted below.

![Schematic Representation of Stryker One Third Tubular Plate](image-url)
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This plate obviously contained three screw holes; however, only the two at either of the plate’s extremities were used in fixation. The third was used to center the plate over the bisecting line between the two sternal halves.

Although a number of preliminary tests were conducted using the Stryker plate (Appendix C), it was soon evident that a number of the plate’s characteristics were undesirable in the application in which it was used, Figure 13. For one, the elliptical holes designed to accommodate the screw heads allowed for the screw heads to slide. As a result, as soon as the test setup was pre-loaded, the screw heads slide to the extremities of the holes and loosened significantly within the bone. Additionally, although it is difficult to discern from the schematic, the tubular plates also possessed a curved, as they were designed to fit the concave shape of long bones. Consequently, the curved plate did not lay snuggly on the flat sternal bone, decreasing the length of the screw which purchased the bone and reducing the quality of fixation.

Once these limitations were established, a simple custom plate was designed. The profile of this custom plate was minimized to allow screws maximum purchase into the bone. Bone purchase was also supplemented by countersinking the screw heads into the plate whereby more screw threads would contact the bone. Additionally, the countersunk holes were designed to snuggly fix with the circular geometry of the screw heads which eliminated the sliding seen with the elliptical holes of the Stryker plate. The following diagram indicates the geometrical changes which were made in the manufacture of the custom plate.

![Figure 14: Custom Designed Plate](image-url)
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The manufactured custom plate was then used in conjunction with the Stryker screws to evaluate the success of fixation under cyclic fatigue.

IV.3.3. Specimen Potting and Grip Design

Although a testing device had successfully been determined, it was also necessary to determine how the interface between the Instron FAST TRACK 8841 and the test specimen would be accomplished. To determine successful methods used by other researchers, a literature review of gripping bone specimens was conducted. One study, by Losanoff and colleagues in 2004, designed specialized clamps with which to grip their full sternal specimens. These grips were comprised of two rows of 1 cm stainless steel nails which were designed to puncture the sternal bone and thus hold it securely. Although innovative, this method was very destructive to the sample and less applicable when using smaller sternal specimens as nail puncture would unnecessarily deteriorate sternal properties and interfere with testing.

Other studies, such as Ozaki et al., 1998, used a method of potting, which was found to be popular in gripping bone specimens, to interface sternal samples with a mechanical testing machine. In this study, the group potted sterna and ribs segments in custom rectangular aluminum molds which were subsequently filled with polymethyl methacrylate (PMMA). Although it was determined that a similar potting method would be the best for interfacing the samples to the testing device, amendments to the Ozaki study had to be made as custom rectangular molds were unavailable and PMMA is a toxic material.
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As a result, a potting material and mold had to be determined. The following lists were formulated to determine the objectives for each of these potting components.

<table>
<thead>
<tr>
<th>Table 4: Potting Material and Mold Objectives</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Potting Material Objectives</strong></td>
</tr>
<tr>
<td>• Affordable</td>
</tr>
<tr>
<td>• Easy to work with</td>
</tr>
<tr>
<td>• Non-toxic</td>
</tr>
<tr>
<td>• Able to bond to both Bone and Mold material</td>
</tr>
<tr>
<td>• Strong</td>
</tr>
<tr>
<td>• Stiff/ Rigid</td>
</tr>
<tr>
<td>• Easily obtained</td>
</tr>
<tr>
<td><strong>Potting Mold Objectives</strong></td>
</tr>
<tr>
<td>• Affordable</td>
</tr>
<tr>
<td>• Ready made/ Minimize need to customize</td>
</tr>
<tr>
<td>• Easily obtained</td>
</tr>
<tr>
<td>• Interface with standard Instron grips</td>
</tr>
<tr>
<td>• Interface with selected potting material</td>
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</tbody>
</table>

With these objectives determined, a number of potting materials and molds were tested for feasibility. Due to limited bone availability, feasibility studies were first performed using a bone analog material. Liquid Nails (MACCO, Strongsville OH) and Quikrete (Quikrete Companies, Atlanta GA) were the first two potting materials tested due to their ease of handling and availability at any local hardware store. Two inch, PVC plumber’s rings were used as molds in which to pot these first samples and ¼” thick, 1 ½” long, rectangular, stainless steel tabs were used to provide an interface between the potted specimens and the standard grips of the FAST TRACK 8841 (Appendix C). Three test setups were prepared using these materials and were fixed with wires for ease and simplicity. The following image depicts this first setup.
IV. Design

As the above image indicates, tabs were unaligned due to an oversight in considering spatial alignment when potting, making samples difficult to load into the testing machine. In addition, samples fixed with Liquid Nails did not harden and as a result preliminary tests failed during preloading. Consequently, Liquid Nail setups were abandoned and only Quikrete setups underwent design iterations.

A second round of preliminary tests was slightly more successful than the first largely due to a revision of the gripping tab. Instead of a stainless steel tab, a ¼” thick eyelet hook was bolted to the center of PVC endcaps through which a hole had been drilled. This new technique not only prevented the tab from pulling out of the potting, but also enabled better alignment of the eyelets to ensure they could be accurately loaded into the Instron machine. Although these design revisions appeared promising, testing was again unsuccessful due to the material properties of the Quikrete potting material.
IV. Design

Quikrete, like all concrete, is strongest in compression and relatively weak in tension, making a tensile loading application ill advised. As a result, although the objectives of the potting mold had been met by the eyehook/endcap combination, a potting material had yet to be successfully determined.

Success was finally achieved the third preliminary testing attempt. Epoxy Putty (Oatey Epoxy Putty, Cleveland OH), was tested and met all of the primary objectives brainstormed for a testing material. The putty was easy to work with and significantly simplified the potting procedure. The Epoxy also hardened to ‘steel’ in a very short amount of time and successfully held the bone analog model. The following image depicts the first successful preliminary test of a wired analog bone specimen. The Epoxy putty not only simplified the ease of potting, but also securely held the bone analog. Preliminary data of bone analog samples fixed with wire were able to be obtained. As a result, this potting procedure was confidently applied to porcine bone. The following image depicts the successful preliminary attempt of a potted sawbone fixed with wires.
IV. Design

Figure 16: Successful Third Test (Epoxy Putty Setup)

The Epoxy Putty/endcap with eyehook setup (Appendix E) was deemed a success and this testing gripping interface was used in the remainder of cyclic fatigue testing on porcine bone sections in combination with the manufactured custom plate and the chosen cancellous or cortical screws.
V. Methods

To determine whether test cancellous screws would perform better in sternal fixation than cortical screws, axial screw pullout and cyclic fatigue tests were performed. Axial pullout tests were used to best illustrate the screw’s grip in the bone. In these tests, a maximum load was applied which resulted in the screw being torn from the bone. The second type of test conducted was cyclic testing where the screws were incorporated into a custom plating system. The screw pullout tests were intended to reflect the integrity of the screw in the bone under maximum loading, whereas the cyclic tests with a plating system were intended to test the screw’s performance under conditions that mimicked breathing and similar loading as seen in the body.

V.1. Preliminary Testing

Prior to conducting tests directly comparing cancellous and cortical screws, preliminary evaluations were first made using sawbone for both testing methods. For axial pullout tests, frozen-thawed and fresh porcine samples were also tested, according to ASTM (F 543-02) standards. The main aims of conducting preliminary testing were: to identify the magnitudes of force expected from actual testing and to expand upon suggestions from literature and validate them for sternal applications.

Literature suggests that sawbone, a polyurethane model, possesses similar properties to actual bone (Trumble 2002). For this reason, initial pullout tests were performed to obtain maximum pullout forces using sawbone and a cortical screw. Pullout forces were recorded using a material tester (MTS Systems Corporation, Eden Prairie, MN) and a QTEST data acquisition program. Results showed force magnitudes on the
V. Methods

order of 25lbs, which provided a 1% percent error based upon the loading capabilities of the machine. As a result, all further pullout testing was conducted using this machine. Cyclic testing to determine a preliminary number of cycles to failure was also first conducted on sawbone.

Studies have also demonstrated freezing and subsequent thawing of bone does not affect its mechanical properties, enabling mechanical testing to be performed on either fresh or previously frozen samples with comparable results (Linde 1993). However, due to the uniqueness of sternal composition and lack of history for pullout tests performed on the sternum, it was deemed necessary to validate this claim. Full fresh porcine samples were bisected, leaving half of the sternum fresh and freezing the other half (-20° C) for 48 hours. The fresh sternum was tested immediately and the frozen half was thawed (2° C for 12 to 24 hours), and then tested in accordance with literature (Borchers 1995). Results indicated that there was no statistical difference between the pullout forces of the fresh and frozen halves, confirming what literature previously stated and allowing testing to be performed on either type of sample with confidence the validity of the results would not be compromised (see Results section).

V.2. Axial Pullout Testing

Axial pullout tests (ASTM F 543-02) were conducted to assess the differences between cortical and cancellous screws in the extent in which they gripped the sternal bone. All pullout testing was performed using an MTS machine. To conduct these tests, the screw was first placed through the designated hole in the custom gripping system and fixed into the bone. A metal plate with a cutout section was placed over the screw and the bone was
V. Methods

secured to the testing stand by C-clamps. The metal tab of the gripping system was then positioned into the MTS crosshead. In accordance with ASTM (F 543-02) standards, screw pullout was recorded with the crosshead moving at a speed of 5mm/min (ASTM 2002) and maximum force was acquired using a data acquisition system. The following image depicts the test setup used to conduct axial pullout tests.

![Axial Pullout Testing Schematic](image)

**Figure 17:** Axial Pullout Testing Schematic: a.) MTS crosshead; b.) custom gripping system; c.) metal plate with C-clamps; d.) bone screw; e.) sternal half; f.) machine stand

To prepare each test specimen, full porcine sterna were obtained, defatted using scalpels, and bisected. Marks were then placed 2cm apart along the length of each sternal half so as to eliminate interference from other screw threading and reduce variability from location to location (ASTM 2002). Holes were then drilled based upon these markings with a 3/32 sized drill bit; a side was then reserved for each type of screw
V. Methods

fixation. The following image schematically represents the placement of screws along each of the bisected sternal halves.

![Figure 18: Cancellous and Cortical Screw Test Site Locations](image)

As evident in the figure, sites were labeled 1 to 5 with site 1 corresponding to the manubrium and site 5 corresponding to the xiphoid. This test setup was used for all five axial pullout tests which were performed in this study.

V.3. Cyclic Fatigue Testing

Cyclic fatigue tests were conducted to assess the differences between cortical and cancellous screws in test conditions that better mimicked the *in vivo* environment. This testing was performed using forces comparable to those found by Pai’s master thesis which determined the *in vivo* ventilation forces for a pig were on the order of 0.37N to 43.8N (1-10lbs) (Pai 2005). Therefore, forces used during cyclic testing ranged from 8.9N to 22.2N (2-5lbs) accordingly, as only small sections of the sternum were tested rather than a whole sternum. Samples, one and a half inches in length, were sectioned from the body of the sternum and positioned in the custom potting system of PVC.
V. Methods

e ndcaps and Epoxy Putty (Appendix E). The potted sternal section was then bisected to simulate a sternotomy procedure and the sections were then fixed.

Several preliminary tests were required to validate the methodology for cyclic fatigue studies. Sawbone analogs were first used in preliminary testing to compare test conditions while preserving banked porcine sterna for finalized testing. Preliminary tests were originally conducted using wires, an account of these results can be seen in Appendix F. Once the testing procedure was validated for wired sawbone samples, preliminary testing was adapted to porcine samples fixed with rigid screw/plate systems. These tests were largely unsuccessful due to the design issues associated with the Stryker one-third tubular plate which was originally used (Appendix F for results). With the subsequent design of a custom plate, two successful tests were able to be conducted.

Final cyclic testing methodology successfully secured the custom plate to the sectioned sternal samples using either cancellous or cortical screws. Holes were pre-drilled for these screws in a similar manner to pullout testing, and screw/plate fixation was performed by surgeons at UMASS Medical School or a Stryker representative. Specimens were potted and then placed in the Instron FAST TRACK 8841 testing apparatus and an extensometer was secured to the specimen in order to measure the local distraction between the bisected sections. The testing apparatus applied cyclic forces from 8.9N to 22.2N to the specimen in a sinusoidal profile at a 2Hz frequency (Michel 1993; Moore 2003). The following schematic indicates each of the components of the final cyclic testing method.
V. Methods

Figure 19: Cyclic Fatigue Test Setup

This final test setup was used for all successful screw/plate cyclic fatigue tests performed in this study.

V.4. Statistical Analysis

Maximum pullout forces for cancellous and cortical screws were recorded and the mean force and standard deviation calculated. A paired, two-tailed, t-test was used to compare screw pullout forces for the fresh and frozen-thawed group. In addition, a two-way ANOVA analysis ($\alpha = 0.05$) was performed to identify statistical differences in screw pullout force between the cancellous and cortical bone screw groups, and location-dependent variation. Statistical analysis for determination of significance was conducted in SPSS (SPSS Inc., Chicago, Illinois, USA).
VI. Results

VI. Results

Evaluation of the hypothesis that cancellous screws exhibit superior performance to cortical screws for the sternal application was conducted using the methods described in the preceding section. Results were successfully obtained for both axial screw pullout and cyclic loading tests. These results support the hypothesis of this study.

VI.1. Axial Pullout Testing

Axial pullout tests are a standardized test used to determine screw purchase into a testing material. Axial screw pullout tests were used here to indicate the statistical similarity of fresh and frozen samples and to determine the statistical difference between cancellous and cortical axial screw pullout.

VI.1.1. Fresh vs. Frozen Bone

Axial screw pullout tests were first conducted using one bisected sternum to validate literature claims (Trumble 2004). Half was tested fresh and half was tested after being frozen at -20.0°C. The following schematic illustrates this grouping by the assigned color of each tested site.
VI. Results

Screw pullout forces ranged from a minimum of 69.4N (15.6lbs) to a high of 175.7N (39.5lbs) for the fresh sternal half and from 45.8N (10.3lbs) to 125.4N (28.2lbs) for the re-thawed, frozen half. Once data were obtained, a graphical representation was created and reproduced below.

**Figure 20:** Frozen and Fresh Test Site Locations and Groupings

**Figure 21:** Screw pullout force in fresh and frozen-thawed porcine sternum
VI. Results

A paired, two-tailed t-test was conducted to determine statistical significance.

Table 5: Screw Pullout Force in Fresh and Frozen Porcine Sterna

<table>
<thead>
<tr>
<th>Force (N)</th>
<th>Fresh</th>
<th>Frozen</th>
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</thead>
<tbody>
<tr>
<td>p-value</td>
<td>123.5</td>
<td>85.9</td>
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</tbody>
</table>

No significant difference existed between the screw pullout forces in the fresh or frozen-thawed bone.

VI.1.2. Cancellous vs. Cortical Screws

Axial pullout tests of cancellous versus cortical screws were performed to quantify the screw purchase into the sternal bone. Screw pullout force ranged from 33.2N (7.5lbs) to 128.1N (28.8lbs) for the cancellous bone screws and from 7.2N (1.6lbs) to 100.8N (22.66lbs) for the cortical bone screws. In contrast to the fresh and frozen screw testing, testing comparing the Stryker screw sets evaluated screw pullout force on a site-to-site basis (Figure 18).

The following graph was prepared using the cortical and cancellous data obtained from testing and shows a comparison of average axial pullout force for each site along the sternum for both cortical and cancellous screws.
VI. Results

As indicated in the graph, cancellous screws achieved higher pullout forces than cortical screws at each site tested. The mean pullout force for cancellous screws was $67.2 \pm 10.2\text{N}$ (15.1±2.3 lbs), the mean pullout force for cortical screws was $28.9 \pm 11.7\text{N}$ (6.5±2.6 lbs). Statistical analyses for determination of significance included a 2-way ANOVA analysis and were conducted with an $\alpha=0.05$ (n=5).

<table>
<thead>
<tr>
<th>Cancellous</th>
<th>Cortical</th>
</tr>
</thead>
<tbody>
<tr>
<td>Force (N)</td>
<td>67.2</td>
</tr>
<tr>
<td>$p$-value</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

Table 7: Variation of Screw Pullout Force along Sites

<table>
<thead>
<tr>
<th>Variation of pullout Force (N) along Sites 1,2,3,4,5</th>
<th>$p$-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0.29</td>
</tr>
</tbody>
</table>

The results suggest cancellous bone screws have a significantly greater grip in the sternum compared to cortical bone screws under the conditions tested. However, no location-dependent variation in screw pullout force along the length of the sternum was observed.
VI. Results

VI.2. Cyclic Fatigue Testing

Cyclic fatigue testing was then conducted to simulate the *in vivo* forces applied to the fixation method during respiration. Data obtained from this testing produced values for local distraction and cycles to failure as measured by the extensometer. Cyclic fatigue testing was performed on three samples, one fixed with cancellous screws and the other two fixed with cortical (Appendix C).

One of the successful cortical screw cyclic fatigue tests reached a local distraction of 1.55mm after approximately 25,000 cycles whereas cancellous screws only reached a 1.16mm distraction after the same number of cycles. The fatigue trend of these two samples is indicated by the following graph where local distraction is plotted against cycles to failure. The third cortical sample is not included in this graph because it was taken from a different, larger animal and reached >100,000 cycles.

![Comparison of Cortical & Cancellous Fixation (n=1)](image)

**Figure 23:** Comparison of successful rigid fixation cyclic tests (n=1)

As shown by the graph, the specimen fixed with cancellous screws resisted cyclic failure and a lower distraction was observed.
VII. Discussion

Axial screw pullout tests were designed to evaluate the gripping capabilities of the cancellous and cortical screws in porcine sterna. Cyclic fatigue tests were used to evaluate the rigid fixation methods in a clinically applicable setting. Both of these test methods have been used by other researchers in the field. The following section reflects upon the findings of this study and compares our findings those of these researchers.

VII.1. Axial Pullout Testing: Literature Context

The effects of freezing at -20°C (one freeze-thaw cycle) of human cancellous bone have also been attempted in other studies. In research conducted by Borchers et al., freezing at temperatures of -20°C and -70°C did not appear to compromise the structural integrity of trabecular bone (Borchers 1995). Because there was no significant difference observed between the screw pullout force in frozen and fresh bone, screw pullout experiments were conducted in both fresh and frozen bone, depending on availability.

Although cancellous and cortical screw axial pullout tests were not found to have been previously attempted in the sternum, these tests have been attempted elsewhere in the body. A previous study (Asnis et al. (Asnis 1996) suggested a relationship between screw diameter and pitch to holding strength in cancellous bone. The group tested three cancellous bone screws with varying outer diameter and root diameter, in order to assess the holding power of the screws in cancellous bone analogs with two different densities. Results showed that the screws with a larger threading diameter exhibited a stronger holding power in both bone densities, and smaller core diameter had a stronger holding power in the less dense bone and no alternate affect was seen with the denser bone. Each
VII. Discussion

screw was also manufactured with various pitch levels and a range of 12-32 threads per inch, and it was determined that screws with the lowest pitch and more threads per inch held most efficiently.

Similar tests have been conducted which have indicated opposite results to those found by Asnis (Asnis 1996). These tests, however, upon close evaluation have serious experimental design flaws which might have attributed to their counterintuitive results. In 1999 Lee et al. explored the micromotion tendencies and overall pullout force of both cortical and cancellous screws in the fixation of cadaver tibial trays (the ends of long bones contain cancellous bone surrounded by a cortical shell). The fixation methods were first subjected to non-destructive cyclic testing of 10 cycles between 1 and 2mm displacements at a rate of 50mm/min to assess micromotion and then tested cyclically to failure to assess strength. The study showed that cortical screws translated to significantly lower amounts of micromotion and higher amounts of transferred energy which the authors claim suggests more stable fixation. Although these results would suggest a superiority of cortical over cancellous screws, the intrinsic properties of the screws involved in the study differed, the cortical screws were 4.0mm in diameter while the cancellous screws were 6.5mm, which indicates that the studies’ findings could have resulted due to dimensional differences between the screws.

Gausepohl et al. in a 2001 study explored the maximum holding force of cancellous bones screws versus both cortical bone screws and fine machine screws in both polyurethane and bovine cancellous bone specimens (Gausepohl 2001). The authors cite the thread pitch as the characteristic difference among the screw types. Cancellous screws are characterized by larger pitch, cortical screws have medium pitch, and fine
VII. Discussion

Machine screws have the smallest pitch. The results of this study indicated that 4mm cancellous bone screws had a significantly higher holding power in both testing media as compared to both cancellous and fine machine screws of different diameters. In contrast, after an attempted scaling to account for the variable diameters of each screw, results showed that greater holding power was had by the fine machine screws. However, the scaling method, simply multiplying the holding force by the same factored scale, is of questionable accuracy.

VII.2. Cyclic Fatigue Testing

Cyclic fatigue tests were conducted to evaluate cancellous screw fixation under testing conditions which more closely mimicked the in vivo environment. Due to time limitations and the difficulties faced when designing a cyclic testing methodology, only two successful cyclic fatigue tests were able to be accomplished, one for cancellous screws and one for cortical screws.

VII.2.1. Results Analysis

Statistical analysis could not be conducted on cyclic fatigue results because of the limited number of tests conducted. Additionally, the method of data collection did not acquire data for corresponding cycle numbers among tests. As a result, straightforward comparison studies were not feasible. However, the results obtained do indicate the superiority of cancellous over cortical screws. Cancellous screws exhibited a lower distraction over 25,000 cycles than the cortical screws at the same cycle number. Additionally, the cancellous screw trend reached a plateau, whereas the cortical screw
trend continued to steadily increase with the number of cycles. This characteristic indicates that cancellous screws better gripped the sternal bone, provided superior sternal fixation, and were therefore able to better resist fatigue.

Further testing is required over a greater number of sternal specimens to more accurately assess relationships between cancellous and cortical screw fixation. However, these pilot tests indicate the importance of such tests towards the development of future sternal fixation techniques. Additionally, the novel and simple methods developed in this study could be easily translated to industrial applications as well as clinical studies, for example evaluation of human cadaver sterna under cyclic fatigue loading.

VII.2.2. Literature Context

Few studies have been performed on the application of cyclic forces to the sternal bone. Cyclic testing of cancellous and cortical screws has also been infrequently performed. As a result, the novel cyclic approach discussed in this study has little with which to compare.

Two known studies, Hale 1999 and Casha et al. 2000, have compared the cyclic fatigue properties of various sternal wiring techniques loaded in tension (Hale 1999). Although we did not compare wiring techniques of any kind, these studies are significant because they also indicate the importance of cyclic testing of sternal closure techniques as a way of simulating the forces associated with breathing. Although these studies also evaluated different fixation methods than those in this study, some methods do apply. The Casha study used 2.5cm sectioned sheep sterna to perform their studies, similar in size to the 1.5” specimens used here. Additionally, Casha et al. used displacement as an
indication of failure, resulting in cycle versus displacement graphs similar to the one presented here. Even though the Casha study used higher loads than those applied in our study (9.8 to 98.0N) and only carried tests out to 150 cycles, the trends generated by these researchers are similar to those we obtained in this study; where displacement increases with number of cycles. Conversely, the Hale study compared bone analog models with two different wiring techniques to failure over a larger range of cycles, similar to our testing. In addition to this similarity, the force magnitude and lateral application of force used to conduct the cyclic testing in Hale’s study were comparable to the magnitude and direction used in our study; Hale used force magnitudes between 10 and 55N over the whole length of the sternum while we used forces between 10 and 22.2N over smaller sternum sections.

Ozaki et al. in 1999 have been the only known researchers to compare the cyclic loading properties of rigid fixation systems for the sternum. This group compared traditional wiring to both straight 4-hole plates and custom-designed 4-hole H-plates, although these rigid systems were fixed with standard cortical screws. Each paired sample was first subjected to wires tests then to plate tests. Both tests simulated the compressive plural pressure forces on the posterior face of the sternum by applying repetitive cyclic 220.6N (49.6lb) loads for 10 second cycles. From the tests performed by Ozaki, et al., the group was able to determine that no statistical difference in measured lateral distraction existed for straight plates as compared to wires, but that H-plates were statistically superior to wires in lateral displacement, stiffness, and number of complete failures (characterized as wire pull-through or breakage, screw pullout, plate breakage, or displacement greater than one inch).
VII. Discussion

The results of Ozaki et al. relate to our study by suggesting the importance of comparing sternal fixation methods as a function of cyclic loading in order to simulate breathing. Although this study compared the results a cyclically applied plural pressure, the potting methodology used here was similar to our own. Finally, this study also reiterates the importance of evaluating various methods of rigid fixation; although in our study we extend this to cortical and cancellous screw geometries.

VII.3. Limitations

Although statistical evidence supported the hypothesis that cancellous screws achieve superior fixation of sternal bone, this study did have some limitations. First, porcine test specimens were used in both of the evaluation methods in this study as they frequently are models for tests involving the human thorax cavity (Losanoff 2002, Trumble 2004). Porcine sterna provided a relatively homogeneous and readily available source of samples; these samples are nonetheless morphologically different than human bone. Porcine sterna are keel shaped while human sterna are not. Additionally, humans walk on two legs whereas pigs walk on four. As a result, the loading pattern on the sternum could differ.

Secondly, bone composition differences were not taken into consideration for the porcine sterna obtained and tested. Variation in bone composition can arise from differences in the age, weight, and sex of the harvested pigs. Although composition variation was minimized through the pairing of axial pullout tests, measured axial pullout forces and cycles to failure were not normalized to take into the account the density of the sternal bone.
VII. Discussion

Thirdly, forces applied during cyclic fatigue testing were simplified to the uniaxial, lateral direction. Although a complex loading pattern has been shown to result on both porcine and human models, this design decision was made consciously to reflect largest force magnitudes which have been measured in an *in vivo* porcine model (Pai 2005). Cyclic fatigue tests were performed with confidence due to the fact that the sternal specimens were loaded to simulate the most extreme cases of *in vivo*.

Finally, healing was not taken into account in either of the evaluation methods utilized. Although omitted due to the *in vitro* nature of the current study, bone healing is an important factor in determining successful sternal fixation. As the bisected sternal bone heals following open-heart surgery, and subsequent fixation occurs, the two halves begin to knit, ultimately ossifying into a whole bone which transcends the need for fixation. Although bone healing is frequently slowed among high risk patients to whom this study is catered, it nonetheless occurs. As a result, to fully characterize cyclic failure, healing must also be simulated.

VII.4. Future Recommendations

As indicated, the evaluation methods utilized by this study and the application of cancellous screw technology to the sternum are important novel approaches to rigid sternal fixation. Based upon this work, a number of future recommendations can be suggested. First, an extensive iterative process was needed to properly develop a cyclic testing methodology. There were also time constraints and a limited number of available porcine sternal specimens. As a result, a larger population of samples needs to be tested to better establish the trends suggested here.
VII. Discussion

Secondly, the cyclic fatigue forces used in this study were applied to a small section of porcine sternum in order to better determine sternal fixation failure at a fundamental and achievable level. However, sternal forces have been better characterized along the length of a whole porcine sternum (Pai 2005). As a result, the method established here should be applied to a full length sternum to better mimic loading conditions *in vivo*. This established method should also be applied to human sterna where the loading patterns and resulting failure would provide a more clinically applicable analysis of sternal fatigue failure.

Additionally, observations made during testing indicated that a screw of longer length and smaller diameter would exhibit superior holding force in the sternal bone. These observations suggest that not only sternal pitch and thread diameter are important during sternal fixation but also the thread length (which determines the amount of threads gaining purchase into the bone) and the screw diameter. These geometrical characteristics should be taken into account when establishing a more suitable screw design for sternal fixation.

Finally, although a custom plate was designed for use in our study future testing should be conducted using a plate/screw system which had been clinically accepted. Sternal plates are available on the market. However, cancellous screws have yet to be combined with these plates. In these systems, the cortical screws used are designed to lock with the plate. This technology allows for uniform insertion torque and prevents screws from becoming stripped while helping to maintain the perpendicular orientation of the screw. Future testing of this nature would allow rigid fixation techniques utilizing cancellous screws to be more clinically applicable.
VII. Discussion

VII.5. Significance

This study hypothesized sternal fixation could be improved through the adaptation of cancellous screws currently used for other orthopedic applications to the sternum. Two tests, axial screw pullout and cyclic fatigue, were used to determine the relative holding force and the failure properties under repetitive loading for each of these fixation methods. Although future work is necessary, both tests indicated the superiority of cancellous fixation for the sternal application.

The axial screw pullout tests in this study were performed in accordance with ASTM standards and indicate that cancellous screws require higher forces for axial pullout than cortical screws. This result is believed to translate directly into screw purchase within the sternal bone. No known studies have compared cancellous and cortical bone pullout in the sternum. As a result, although the outcomes of the tests performed as part of this study are statistically conclusive, further testing is required. Specifically, further testing is necessary to characterize the distribution of axial pullout force down the length of the sternum.

A limited number of studies in the field offer results for the application of cyclic loads to the sternal bone. However, breathing forces are largely hypothesized to create conditions for sternal fixation failure (Pai 2005). Consequently, novel cyclic testing approaches such as the one developed here are important contributions to furthering the field of cyclic fixation. Although the results obtained from this study were promising, the cyclic fatigue tests performed here were unable to establish conclusive evidence that cancellous screws were superior to cortical screws for the sternal application. In addition the novel approach developed here has universal applications for further sternal fixation.
VII. Discussion

fatigue testing which could ultimately help to improve current sternal fixation techniques for all patients.
References


Dunn (2005). "Personal Correspondence."


References


Appendix A

Appendix A: Initial Project Approach and Design

Early on in the design process, stakeholders and their respective concerns were identified. By establishing these concerns, an initial client statement was generated. This statement underwent numerous revisions and a revised client statement follows. Although this statement was further amended, as reflected in the Project Approach section of this report, these revisions indicate the application of the engineering design process to this project.

Determining Stakeholder’s Concerns

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<td>Patients</td>
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<td>Pain/ Comfort</td>
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<td>Cost/ Insurance coverage</td>
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<tr>
<td>Doctors</td>
<td>Patient Healing/ Revision Surgery</td>
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<td>Ease of implantation/ removal</td>
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<td>Cost</td>
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<tr>
<td>Cardiac-Thoracic</td>
<td>Patient Healing/ Revision Surgery</td>
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<td>Project results</td>
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<td>Cost</td>
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Appendix A

**Client, User, and Designer Clarification:**

1. **Client**: person, group, or company that wants to know which fixation technique is optimal
2. **Users**: set of people that will use the fixation devices being tested
3. **Designers**: set of people who develop a testing methodology and determine which fixation technique possess the most fatigue resistance

**Initial Project Hypothesis and Client Statement:**

After determining the primary stakeholders of our project, we referred to the design process to revise our initial problem statement such that it would meet project objectives, functions, and constraints. The initial problem statement we generated is below:

Determine the fixation technique with the greatest fatigue resistance by applying *in vivo* loading conditions as described in studies by Pai and colleagues.

The above problem statement must be revised in order to meet the needs of the stakeholders and specific aims of the project. Therefore, a statement that clearly and concisely addresses the needs and objectives of the client and stakeholders is necessary.

The revisions made to this statement are indicated below.

Determine the fixation technique with the greatest fatigue resistance by selecting an appropriate cyclic testing apparatus to apply *in vivo* loading conditions (2-15 pounds) as described in studies Pai and colleagues. The proposed apparatus should be accurate, efficient, minimize damage to test specimens, and have repeatable testing methods.

From this project statement, we were able to determine the hypothesis and specific aims of this study.

We hypothesize sternal failure after open-heart surgery is not a function of instantaneous loading, but rather a result of repetitive cyclic loading. Therefore, we believe sternal fixation plates secured with cancellous bone screws will fair better under cyclic loading in comparison with plates secured with cortical bone screws and traditional
wiring techniques (Figure 9). Although cortical bone screws are the current standard in sternal plate fixation, documented evidence suggests the sternum is largely comprised of trabecular bone sandwiched between two cortical bone shells. For these reasons, the group feels screws designed for trabecular material would perform better in the sternal setting.

Based on literature, the cyclic testing will be run under conditions chosen from the range of 2-10Hz and with a load chosen from 2-10lbs. These parameters are yet to be determined based on preliminary testing. However, our proposed results and data acquisition will be determined by two major graphs: 1) Cycles to failure vs. fixation device and 2) Displacement vs. cycles to failure.

![Figure 1: Cycles to failure versus fixation device](image-url)
Appendix A

We predict the displacement between the two bone samples is likely to grow slowly with increasing number of cycles. We based our graph on descriptions of fatigue crack growth in literature. Although our samples do not necessarily exhibit the same morphology as a cracked material, we believe that fatigue crack growth may provide a good model for the strain/displacement behavior for our samples.

**Figure 2:** Displacement versus number of cycles for each fixation device
Appendix B: Literature Review of Cyclic Fatigue Studies

<table>
<thead>
<tr>
<th>Reference</th>
<th>Hypothesis</th>
<th>Samples</th>
<th>Failure Indicator</th>
<th>Methods</th>
<th>Measurements</th>
<th>Calculations</th>
<th>Results</th>
</tr>
</thead>
</table>
| Moore and Gibson  
*Fatigue of Bovine Trabecular Bone*  
Journal of Biomechanical Engineering  
125 (2003) 761-768 | To evaluate the effect of damage accumulation under cyclic loading conditions on the mechanical behavior of bovine trabecular bone  
How do the mechanical properties (secant modulus, $E_{sec}/E$, reloading normalized modulus, $E_r/E$, residual strain, $\varepsilon_{res}$, and the change in the plastic strain during a single cycle, $\Delta \varepsilon_{pl}$) of bovine trabecular bone depend on the maximum strains reached in compressive failure | 100 tests  
4 normalized stresses ($\Delta \sigma/E$) | Tests were stopped when the samples reached one of six predetermined levels of maximum compressive strain ($\varepsilon_{max}$) (max. strain corresponded with the reduction of modulus better than the # of cycles) | Conditioning: loading for 10 cycles in strain control using a sinusoidal waveform from 0.0% strain to -0.3% at a frequency of 2.0 Hz.  
Testing: frequency= 2Hz., loaded first to a nominal compressive preload (-50N) and then to a predetermined load (= one of four normalized stress levels, $\Delta \sigma/E$)  
Post testing: one sinusoidal cycle loading in strain control form 0.0% to -0.3% strain at 2 Hz | $N$= number of cycles  
$\Delta \varepsilon_{pl}$= change in plastic strain during a single cycle  
$E_{sec}$= secant modulus of the final cycle  
$E_r$= reloading modulus= slope of the loading curve between -.1% to -.3%  
$\varepsilon_{max}$= maximum strain  
$\varepsilon_{res}$= residual strain on unloading | 35 specimens in final statistical analysis  
Mean values for: apparent density  
Volume fraction  
Initial elastic modulus  
0.2% offset yield strain | Progressive loss of secant modulus and accumulation of strain  
Number of cycles to failure was in the range of 3-439,430 |
| Haddock et al.  
*Similarity in the fatigue behavior of trabecular bone across site and species*  
Journal of Biomechanics  
37 (2004) 181-187 | The Strain-cycle curve for cyclic compressive loading of trabecular bone is independent of the site and the species | 52 cylindrical cores of fresh-frozen human trabecular bone  
5 groups of $\sigma/E_o$  
Ranging from 0.0026 to 0.0070 (n=10) | Failure: the cycle before which a specimen could no longer sustain the applied stress, as indicated by a rapid increase in strain upon the subsequent loading cycle  
Initial failure: 10% reduction in the secant modulus | Conditioning: ea. Specimen was loaded to 1500 microstrain for 10 cycles at a rate of 10 cycles per second, $E_o$= slope of stress-strain curve of the tenth cycle  
Testing: cyclic compressive stresses from 0-6 corresponding to the prescribed value of $\sigma/E_o$ were applied until failure  
Used a triangular waveform in strain rate control ( 1500 microstrain, freq. = 1.32-2.87 Hz.) | Specimen gauge length: length of bone exposed between endcaps  
Strain:  
Modulus changes: secant modulus measurements from 0 to 2000 microstrain of the current stress-strain curve  
After testing,  
Volume fraction  
Tissue density  
Apparent density | 35 specimens in final statistical analysis  
Mean values for: apparent density  
Volume fraction  
Initial elastic modulus  
0.2% offset yield strain | Progressive loss of secant modulus and accumulation of strain  
Number of cycles to failure was in the range of 3-439,430 |
<table>
<thead>
<tr>
<th>Reference</th>
<th>Hypothesis</th>
<th>Samples</th>
<th>Failure Indicator</th>
<th>Methods</th>
<th>Measurements</th>
<th>Calculations</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>S.M Bowman</td>
<td>Creep contributes to the behavior of bovine trabecular bone</td>
<td>85 waisted specimens trabecular bone</td>
<td>Fatigue failure defined as a 10 percent reduction in secant modulus compared to the initial secant modulus, or as complete specimen fracture.</td>
<td>Testing: frequency=2Hz (sinusoidal load profile), loaded first to a nominal compressive preload (~10N).</td>
<td>Nf= number of cycles to fatigue</td>
<td>40 specimens in final statistical analysis</td>
<td>No statistical difference between the moduli of the fatigue and creep specimens.</td>
</tr>
<tr>
<td>Michel et al.</td>
<td>Fatigue behavior of bone trabecular bone specimens under stress control using a sinusoidal uniaxial compressive load profile with frequency of 2 Hertz.</td>
<td>24 specimen of fresh bovine distal femoral condyles.</td>
<td>Fatigue failure was defined as a 5% decrease in secant modulus Δσ/ε.</td>
<td>Conditioning: specimens subjected to 10 strain cycles in the range 0.6-0.8% at 0.2Hz.</td>
<td># cycles to failure: 20 cycles at 2.1% to 400,000 cycles at 0.8% strain</td>
<td>24 specimens in final statistical analysis</td>
<td>Identified to failure modes: Straight transverse brittle-like fracture through trabeculae. Bucking-like failure, involving bending and splitting. Modulus degradation with number of cycles different for high-cycle and low-cycle fatigue. creep and damage accumulation contribute to fatigue failure of trabecular bone.</td>
</tr>
<tr>
<td>Reference</td>
<td>Hypothesis</td>
<td>Samples</td>
<td>Failure Indicator</td>
<td>Methods</td>
<td>Measurements</td>
<td>Calculations</td>
<td>Results</td>
</tr>
<tr>
<td>-----------</td>
<td>------------</td>
<td>---------</td>
<td>------------------</td>
<td>---------</td>
<td>--------------</td>
<td>--------------</td>
<td>---------</td>
</tr>
<tr>
<td>T.M. Keaveny</td>
<td><em>In vitro</em> mechanical testing on bovine tibial trabecular bone to obtain accurate descriptions of the elastic and yield behaviors. 1. Toe in stress-strain curve? 2. Does tension-compression preconditioning (+0.5% strain for eight cycles) affect mechanical behavior? 3. Mechanism of yielding? 4. Tensile and compressive strengths equal?</td>
<td>Reduced-section cylindrical specimens (wet w/ reduced section gage length).</td>
<td>Failure: &gt;4.0% strain; defined as obvious nonlinearity in stress-strain curve</td>
<td>Testing: Tension (n=19) Compression (n=18) Axial strain measured using miniature extensometer Preconditioning: ±0.5% strain. Apparent density measurements: volume-weighted average obtained &amp; QCT estimates of density</td>
<td>Evaluated: Linearity of initial portion of stress-strain curve (toe region) Tensile and compressive modulus before and after preconditioning Compared tensile and compressive strength</td>
<td>15 ± 14 specimens in final statistical analysis Tensile &amp; compressive moduli Apparent density</td>
<td>Mean tensile strength was approximately 70% of mean compressive strength. Strong relationship between modulus and apparent density.</td>
</tr>
<tr>
<td>Keaveny et al.</td>
<td>Trabecular bone modulus and strength can depend on specimen geometry.</td>
<td>Uniaxial compression tests on wet bovine trabecular bone to compare both modulus and strength when measured using 2:1 aspect ratio (10mm long, 5mm diameter). Correlation coefficients in resulting modulus-density and strength-density regressions.</td>
<td>Specimens: Cubes: (5x5x5 mm³) Cylinders: 5.1mm diameter x 10mm long Each group ⇒ 30 specimens each</td>
<td>Failure: Not applicable Conditioning: NOT performed (reference: Linde and Hvid, 1987) Testing: compressive fatigue stresses were conducted under load control using a sinusoidal profile at 2 Hz.</td>
<td>Local strain: measured using an optical technique. (Stained black to increase contrast). Four rows of microspheres mounted on specimens with petroleum jelly. Top and bottom rows within 1 mm from specimen ends. # cycles to failure: 20 cycles at 2.1% to 400,000 cycles at 0.8% strain % strain: 0.0, 1.0, 1.5, 2.0 and 5.0% strain</td>
<td>24 specimens in final statistical analysis Values for: Local strain distribution Initial global maximum strain Modulus degradation</td>
<td>Statistical analysis: Unpaired t-tests and ANCOVA Significant differences between groups of cubes &amp; cylinders: Mean values of density Modulus Strength Specimen geometry influences mechanical properties!</td>
</tr>
</tbody>
</table>

*Journal of Biomechanics 27 (1994) 1127-1136*  
*Journal of Biomechanics 26 (1993) 991-1000*
Appendix C: Instron FASTTRACK 8800 Technical Data Sheet

Model 8841 Technical Data Sheet

8841 Dimensions

<table>
<thead>
<tr>
<th></th>
<th>Vertical Orientation</th>
<th>Horizontal Orientation</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Table to crosshead</td>
<td>108 (4.3)</td>
</tr>
<tr>
<td></td>
<td>Minimum - mm (in)</td>
<td>640 (25.5)</td>
</tr>
<tr>
<td></td>
<td>Maximum - mm (in)</td>
<td>53.6 (2.1)</td>
</tr>
<tr>
<td></td>
<td>B2 Table Mounted - mm (in)</td>
<td>38.1 (1.5)</td>
</tr>
<tr>
<td>C</td>
<td>Actuator Fully retracted - mm (in)</td>
<td>30 (1.2)</td>
</tr>
<tr>
<td>D</td>
<td>Maximum daylight</td>
<td>353 (13.9)</td>
</tr>
<tr>
<td></td>
<td>D2* Load cell, actuator mounted - mm (in)</td>
<td>547 (21.5)</td>
</tr>
<tr>
<td>E</td>
<td>Throat depth - mm (in)</td>
<td>100 (3.9)</td>
</tr>
<tr>
<td>F</td>
<td>Column Size - mm (in)</td>
<td>140 (5.5)</td>
</tr>
<tr>
<td>G</td>
<td>Column height - mm (in)</td>
<td>722 (28.4)</td>
</tr>
<tr>
<td>H</td>
<td>Table width - mm (in)</td>
<td>400 (15.8)</td>
</tr>
<tr>
<td>I</td>
<td>Table height - mm (in)</td>
<td>125 (4.9)</td>
</tr>
<tr>
<td>J</td>
<td>Feet Height - mm (in)</td>
<td>36 (1.4)</td>
</tr>
<tr>
<td>K</td>
<td>Overall width - mm (in)</td>
<td>415 (16.3)</td>
</tr>
<tr>
<td>L</td>
<td>Overall depth - mm (in)</td>
<td>515 (20.3)</td>
</tr>
<tr>
<td>M</td>
<td>Overall height - mm (in)</td>
<td>1070 (42.2)</td>
</tr>
<tr>
<td>N</td>
<td>Actuator stroke (total) - mm (in)</td>
<td>50.8 (2.0)</td>
</tr>
<tr>
<td>P</td>
<td>Load Capacity kN (lb)</td>
<td>1.0 (220.0)</td>
</tr>
<tr>
<td>R**</td>
<td>Load frame stiffness - kN/mm (lb/in)</td>
<td>14.5 (83,000)</td>
</tr>
<tr>
<td>T</td>
<td>Weight - kg (lb)</td>
<td>50 (110.0)</td>
</tr>
</tbody>
</table>

* Actuator at mid-stroke.
** Crosshead 443 mm from base.
Appendix D: Preliminary Potting Methodology

1. Definitions:

Potting: Enclosing an article in an envelope of adhesive.
Potting cylinders: circular plastic tubing used to hold the sample during mechanical testing.

2. Materials:

Extra-strength Epoxy Resin (manufacturer: Bondo)
Porcine sternal bone samples
Potting cylinders
Stainless steel rods (19mm x 19mm x 65 mm)
Aluminum paper
Polystyrene foam

3. Methods:

3.1. Preparation of materials
   3.1.1. Drill ¼ inch hole in the center of a PVC endcap.
   3.1.2. Thread this hole.

3.2. Preparation
   3.2.1. Cut a rectangular piece of polystyrene foam (35 cm x 35 cm).
   3.2.2. Wrap aluminum foil around the top surface of the polystyrene foam and fix with tape.
   3.2.3. Place potting cylinder – evenly spaced – on top of the polystyrene foam.

3.3. Prepare Bondo according to manufacturer’s directions.

3.4. Potting
   3.4.1. Push 4 stainless steel rods through the polystyrene foam. Ensure that each rod is placed in the center of each potting cylinder. Make certain that the rod extends 20 mm beyond the bottom surface of the polystyrene foam.
   3.4.2. Pour adhesive in potting cylinder until the potting cylinder is ¾ full. Ensure that the adhesive is spread uniformly. Make certain that no leaking occurs.
   3.4.3. Place the bone sample in the potting cylinder.
   3.4.4. Resume pouring adhesive until level with the top of the potting cylinder.
   3.4.5. Level adhesive off.
   3.4.6. Hold the bone sample in place for 2 minutes so that it stays upright.

3.5. Repeat for all of the samples.

3.6. Let samples dry for at least 10 hours in appropriate environmental conditions.
Appendix E

Appendix E: Final Potting Methodology

1. Definitions:

Potting: Enclosing an article in an envelope of adhesive.
Potting cylinders: circular plastic tubing used to hold the sample during mechanical testing.

2. Materials:

(Oatey Epoxy Putty, Cleveland OH)
Porcine sternal bone samples
1.5” diameter PVC end-caps
2” eyelet hook (1/4” width)
Punch biopsy
Wire
Nails
Superglue

3. Methods:

3.1. Preparation of materials
   3.1.1. Drill ¼ inch hole in the center of a PVC endcap.
   3.1.2. Thread this hole.
   3.1.3. Screw in eyelet hook until threading is flush with cap
   3.1.4. Cut the bone along the sternotomy line
   3.1.5. Cut the bone horizontally. Ensure that there are at least two ribs on each of the sternal sides.
   3.1.6. Using a punch biopsy, punch one hole in each rib.
   3.1.7. Thread a 1.5 cm length wire through this hole.
   3.1.8. Brush on superglue on the bottom of the sterna sample (make sure to cover holes).

3.2. Prepare Epoxy Putty according to manufacturer’s directions.

3.3. Potting
   3.3.1. Place one sternal halve in the hollow side of the endcap. Ensure that the sternal is centered and parallel to the direction of the eyelet hook.
   3.3.2. Pack in epoxy putty so that it surrounds sternal halve. Ensure that the sternal half is at a right angle to the bottom of the endcap.
   3.3.3. Push in nails (vertically). Push in one nail at each side of the sterna sample.

3.4. Repeat for second sample.

3.5. Once both samples have been potted, fix the sample with either: wire, cancellous or cortical screw/plate system.

Let samples dry for at least 5 hours in appropriate environmental conditions
Appendix F: Preliminary Testing Results

The cyclic fatigue testing methodology was determined following an extensive amount of preliminary testing. Pilot tests were first conducted to determine potting material. Subsequent testing was performed to determine potting methodology and expected number of cycles to failure. The following section presents the results of these tests.

Preliminary Potting Tests:

Several preliminary tests were required to select a potting material for cyclic fatigue studies. Sawbone analogs secured with wires were used to compare potting materials in order to preserve banked porcine sterna for finalized testing. Liquid Nails, Quikrete and Epoxy Putty were evaluated on their ability to withstand cyclic fatigue testing conditions. While the sample potted in Liquid Nails resulted in immediate failure, the sample potted in Quikrete reached an end cycle of 253 and a local distraction of 0.01mm. The third sample potted in Epoxy Putty displayed the most resistance to failure, obtaining an end cycle of 129,782 and a local distraction of 0.15mm. Table 1 summarizes the results of these potting materials.

Table 1: Comparison of Potting Materials using Sawbone Analog

<table>
<thead>
<tr>
<th>Sample</th>
<th>Fixation</th>
<th>Potting</th>
<th>Applied Forces(^a) (lbs)</th>
<th>End Cycle</th>
<th>Local Distraction (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Wire</td>
<td>Liquid Nails</td>
<td>2-10</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>2</td>
<td>Wire</td>
<td>Quikrete</td>
<td>2-10</td>
<td>253</td>
<td>0.01</td>
</tr>
<tr>
<td>3</td>
<td>Wire</td>
<td>Epoxy Putty</td>
<td>2-10</td>
<td>129,782</td>
<td>0.15</td>
</tr>
</tbody>
</table>

\(^a\)Forces were applied at a frequency of 2Hz.

Porcine Bone Samples with Wire Fixation

Porcine bone samples potted in Epoxy Putty yielded graphs of local distraction versus time. A summary of the testing conditions and results of the five bone specimens are displayed in
Appendix F

Table 2. The fifth test specimen reached the maximum number of cycles (315,500) in comparison to the other bone samples. The variation among bone analogs studies has been indicated by other researchers. Hale in 1999 observed a similar variation from approximately 15,000 to 134,000 cycles in his analysis of wired bone analog samples (Hale 1999).

<table>
<thead>
<tr>
<th>Sample</th>
<th>Fixation</th>
<th>Applied Forces(^a) (lbs)</th>
<th>End Cycle</th>
<th>Local Distraction (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Wire</td>
<td>10-20</td>
<td>40</td>
<td>2.07</td>
</tr>
<tr>
<td>2</td>
<td>Wire</td>
<td>2-15</td>
<td>3,200</td>
<td>2.01</td>
</tr>
<tr>
<td>3</td>
<td>Wire</td>
<td>2-15</td>
<td>3,810</td>
<td>0.42</td>
</tr>
<tr>
<td>4</td>
<td>Wire</td>
<td>2-15</td>
<td>51,417</td>
<td>1.55</td>
</tr>
<tr>
<td>5</td>
<td>Wire</td>
<td>2-15</td>
<td>315,500</td>
<td>2.00</td>
</tr>
</tbody>
</table>

\(^a\)Forces were applied at a frequency of 2Hz.

A plot of the local distraction between sternal halves (samples two through five from Table 3) versus the number of cycles is shown below in Figure 1.

![Comparison of Bone Wire Fixation](image)

**Figure 1:** Wire Fixed Porcine Sterna Preliminary Testing
Sample three exhibited the most resistance to local distraction over 3,200 cycles, while sample two possessed five times the number of distraction of sample three at the same number of cycles. However, sample five reached the maximum number of cycles (315,500), as sample three pulled out of the potting material at 3,810 cycles. The shift in data obtained for sample five represents the distraction achieved between cycles 1900 and 2000. Test results serve to illustrate the evident variation of porcine bone integrity among test specimens.

Porcine Bone Samples with Cancellous Screw-Plate Fixation

After re-evaluating our potting methodology, bone samples secured with Stryker cancellous screws were tested as a function of their resistance to local distraction over a large number of cycles. Table 3 summarizes the testing conditions and results of these experiments. All samples, with the exception of sample 5, were re-approximated and fixed with the Stryker one-third tubular plate. Sample five was testing using the custom designed straight plate. There was a significant difference in the number of cycles able to be achieved by the Stryker and custom designed plate fixation. Although testing conditions varied by ten pounds between the Stryker and custom plates, the sample secured with our plating system reached thirty-nine times the number of cycles of sample four.

<table>
<thead>
<tr>
<th>Sample</th>
<th>Fixation</th>
<th>Applied Forces (lbs)</th>
<th>End Cycle</th>
<th>Local Distraction (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Cancellous</td>
<td>2-15</td>
<td>37</td>
<td>1.48</td>
</tr>
<tr>
<td>2</td>
<td>Cancellous</td>
<td>2-15</td>
<td>117</td>
<td>0.47</td>
</tr>
<tr>
<td>3</td>
<td>Cancellous</td>
<td>2-15</td>
<td>311</td>
<td>0.60</td>
</tr>
<tr>
<td>4</td>
<td>Cancellous</td>
<td>2-15</td>
<td>644</td>
<td>0.99</td>
</tr>
<tr>
<td>5</td>
<td>Cancellous</td>
<td>2-5</td>
<td>25,087</td>
<td>1.17</td>
</tr>
</tbody>
</table>

*aForces were applied at a frequency of 2Hz.

*bCustom designed plate secured with cancellous screws. Other cancellous screws used to secure Stryker Plating system.
Porcine Bone Samples with Cortical Screw-Plate Fixation

Once we determine our custom plating system was superior to the Stryker one-third tubular plating system, we evaluated bone samples secured with cortical screws. Two specimens were bisected and potted into Epoxy Putty for testing. A summary of test results is shown below in Table 4.

**Table 4: Cortical Screw Fixation Testing**

<table>
<thead>
<tr>
<th>Sample</th>
<th>Fixation(^a)</th>
<th>Applied Forces(^b) (lbs)</th>
<th>End Cycle</th>
<th>Local Distraction (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Cortical</td>
<td>2-5</td>
<td>75,300</td>
<td>2.00</td>
</tr>
<tr>
<td>2</td>
<td>Cortical</td>
<td>2-5</td>
<td>181,300</td>
<td>0.96</td>
</tr>
</tbody>
</table>

\(^a\)Cortical Screws used to secure custom designed plate; \(^b\)Forces were applied at a frequency of 2Hz.

Sample one reached a higher local distraction at a lower number of cycles than sample two. At 75,000 cycles, sample one possessed a local distraction of 1.99mm, whereas sample two possessed a local distraction of 0.80mm, two times less than that of sample one (Figure 2). The variation in local distraction demonstrates the differences in bone integrity amongst the samples, similar to the cancellous screw-plate fixation data.

![Comparison of Cortical Screw Fixation](image)

**Figure 2:** Cortical Screw Fixed Porcine Sterna