Project Number: KLB-1102

Ankle Syndesmosis Fixation Method

A Major Qualifying Report:
Submitted to the Faculty
of the
Worcester Polytechnic Institute
In partial fulfillment of the requirements for the
Degree of Bachelor of Science
by

____

Suzanna Kelley

____

Julia Krebs

____

Zachary Theoharidis

____

Prof. Kristen Billiar, Major Advisor

____

John Wixted, M.D., Co-Advisor

1) Syndesmosis
2) Loosening
3) Fixation

Acknowledgements

The authors of the design project would like to thank the following individuals for their help:

Professor Kristen Billiar and John Wixted, M.D., for their guidance and support throughout the project.

John Wixted, M.D. and the University of Massachusetts Medical School for the use of laboratory equipment and funding.

Neil Whitehouse, Thomas Hunter and Greg Overton from the WPI Machine Shop for their assistance in manufacturing fixtures needed for this project.

Professor Glen Gaudette and Benny Yin for their assistance through BME 430X.

Lisa Wall and Sakthikumar Ambody, Ph.D. for organizing the MQP project.

Authorship

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

Abstract

Screw loosening in ankle syndesmosis fixation is a major problem leading to permanent arthritis. Loosening is caused by axial and transverse loading and results in joint malreduction. Our goal was to develop a fixation method to minimize screw loosening by optimizing screw insertion angles. Finite element analysis, pullout, load to failure, and cyclic shear testing were used to find the optimal screw insertion angles. Results indicate 0˚ screws have significantly greater pullout strength than 23° or 45°, 23° screws create a stiffer fixation than 0°, and a two-screw system with 0˚ and 23˚ screws is able to withstand greater transverse loads than the current gold standard of two 0° screws. Findings indicate a screw system consisting of 0˚ and 23˚angled screws will provide better fixation.

Table of Contents

Table of Figures

Table of Tables

1 Introduction

Injury to the lower ankle ligaments, the distal tibiofibular syndesmosis, has been reported to account for 13% of all ankle fractures and 20% of all operative ankle fractures (Klitzman R, et al., 2010). It has been estimated that an ankle injury requiring fixation of the ankle syndesmosis occurs every 20 minutes (Stuart K, et al., 2011). These injuries are common in contact sports such as football and hockey.

There are currently many different surgical methods of fixation that allow for the healing and stabilization of the syndesmosis; the two most commonly used are the screw fixation method and the suture-button fixation method. The screw fixation method, using two parallel screws and a plate, is the current gold standard ankle syndesmosis fixation method. This screw fixation method, although providing stability while allowing the ankle to heal, does not allow for weight bearing (Klitzman R, et al., 2010)). Premature weight bearing on the ankle accumulates shear stresses on the screws which can cause screw loosening and widening of the tibiofibular space (Needleman RL, et al., 1989). According to Pai, et al. vibration caused by axial and transverse loading leads to screw loosening (Pai, et al., 2002). A new fixation method is desired to withstand greater axial and transverse loads to be able to account for the inevitable, non-compliant, weight bearing of the patient.

The goal of this project was to design a new fixation method for the ankle syndesmosis that accounts for less occurrences of screw loosening. The fixation method was designed to fixate the tibia and fibula together post interosseous ligament rupture and was compared to the current gold standard in transverse loading. The engineering design process will be followed in order to ensure that these goals were addressed. Alternative designs were created to incorporate and explore different means to accomplishing the project goals. Preliminary evaluations were conducted to examine the alternative designs. Once a design was justified as a viable method to be used for the project, it was tested and compared against the current gold standard. The fixation method designed in this project is an innovative method to hold the tibia and the fibula together after the interosseous ligament ruptures in the ankle syndesmosis; by creating this method able to withstand greater axial and transverse loading the occurrence of screw loosening should be decreased.

2 Literature Review

2.1 Ankle Syndesmosis Anatomy and Functionality

The distal tibiofibular syndesmosis is responsible for the stabilization of the ankle mortise (Norkus SA and Floyd RT, 2001).

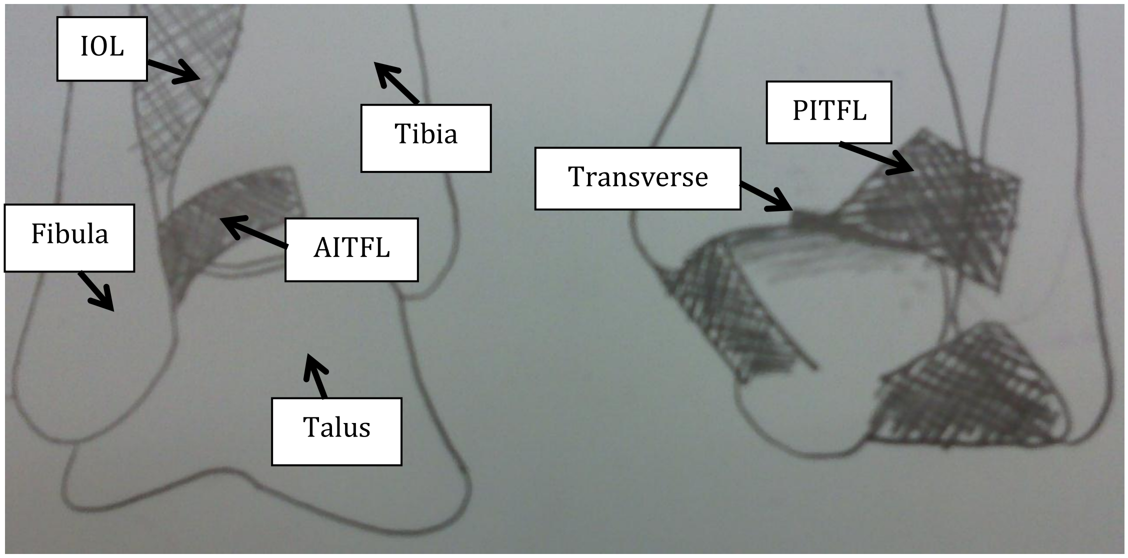
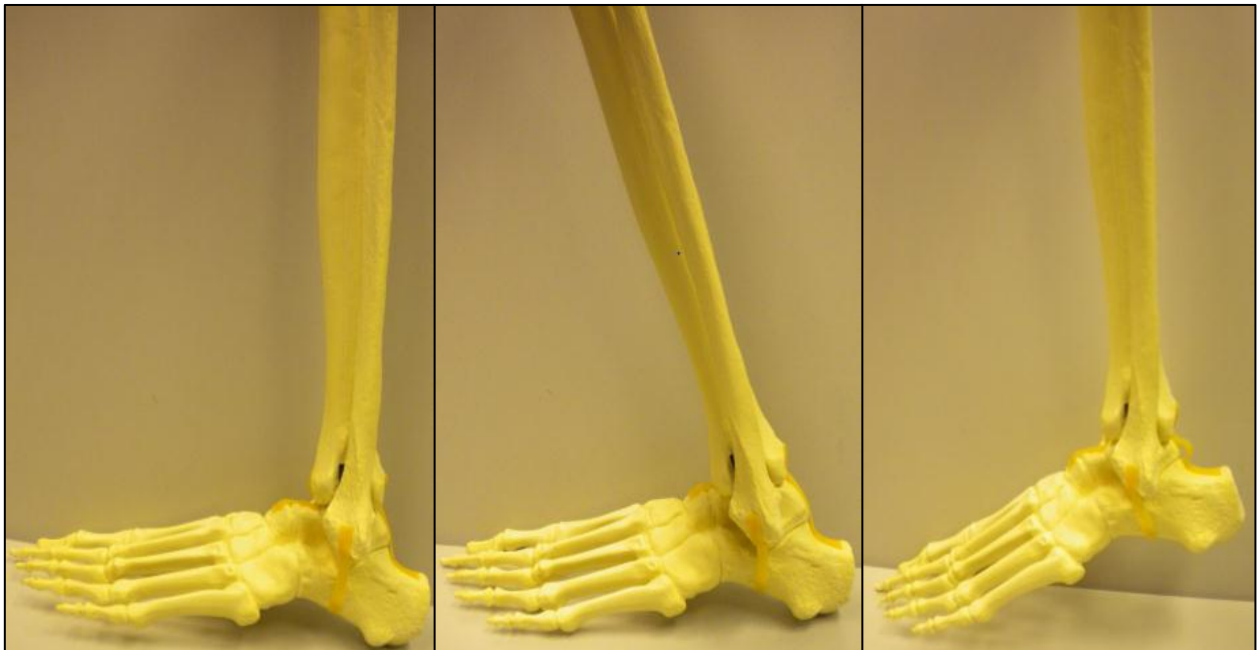


Figure 2-1: Ankle Syndesmosis

Diagram of the major ligaments of the syndesmosis

This syndesmosis is a fibrous articulation; the distal ends of the tibia and fibula are fixed together by a group of four syndesmotic ligaments (Figure 2-1). These ligaments attach the tibia and fibula from in front of and behind the ankle and between the two bones; they, respectively, consist of the anterior inferior tibiofibular ligament (AITFL), the posterior inferior tibiofibular ligament (PITFL), the transverse tibiofibular ligament, and the interosseous membrane (IOL) (Norkus SA and Floyd RT, 2001).

2.1.1 Normal Ankle Movement



Neutral View	Ground Reactive Dorsiflexion	Plantar Flexion

Figure 2-2: Ankle Movement

Normal ankle movement is in sagittal plane. From the left: neutral view, dorsiflexion and plantar flexion.

Movement of the ankle occurs in the sagittal plane: dorsiflexion and plantar flexion (Figure 2-2). Dorsiflexion, ankle flexion, is seen as moving the foot and ankle towards the anterior of the tibia; whereas, plantar flexion, ankle extension, is seen as moving the foot and ankle away from the tibia. A normal ankle is allowed 15^0 to 20^0 degrees in active dorsiflexion and 45^0 to 55^0 in plantar flexion. Full weight bearing on the ankle can lead to 40^0 in passive dorsiflexion; the passive ranges can supersede active ranges in joints (Norkus SA and Floyd RT, 2001).

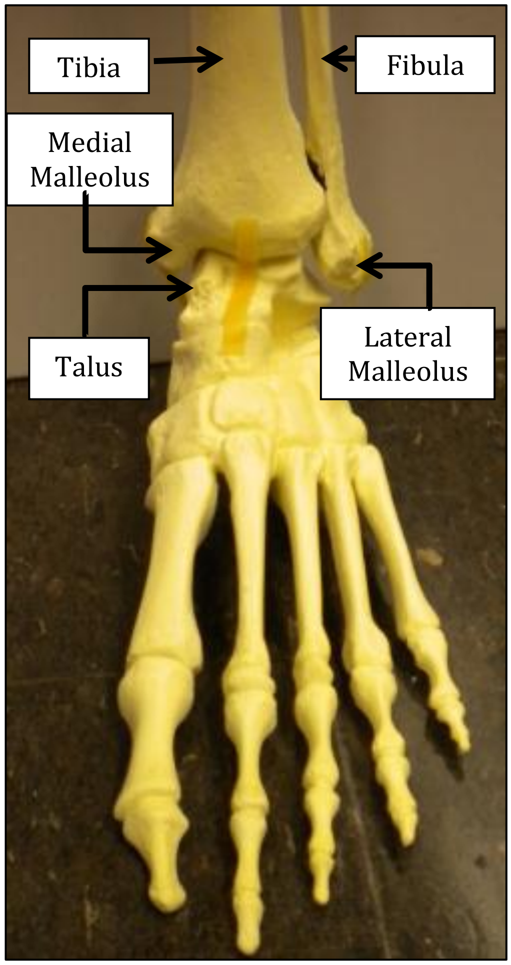


Figure 2-3: Ankle Bones

The bones that make up the ankle joint: tibia, fibula, and talus.

The different ankle bones can be seen in Figure 2-3. The talus' articular surface remains in contact with the malleoli during both movements in the sagittal plane. When the ankle moves into dorsiflexion, the anterior portion of the talus pushes up between the medial and lateral malleoli. The anterior portion of the talus separates away from the malleoli to return to plantar flexion. Due to the close bone packing and surface contact, dorsiflexion is considered to be the safest position for the ankle. Dorsiflexion creates a more stable joint than plantar flexion. Also, the talus has been seen to rotate 5° to 6° during dorsiflexion. During plantar flexion the talus both rotates and supinates, causing talus trochlea to wedge posterolaterally. Due to the posterolateral wedging of the talus trochlea from plantar flexion the talus needs to pronate during dorsiflexion (Norkus SA and Floyd RT, 2001).

When the foot moves from plantar flexed to dorsiflexed there is a 1 to 2 mm widening of the distal tibiofibular syndesmotic mortise. In dorsiflexion, the lateral rotation of the fibula is 3^0 to 5^0 and in plantar flexion the medial rotation of the fibula is also 3^0 to 5^0 (Norkus SA and Floyd RT, 2001).

2.1.2 Fibula

The fibula is responsible for maintaining ankle mortise stability during weight bearing activities. In a study by Scranton PE et al., it was found that during normal weight bearing the fibula displaces 2.4 mm inferiorly due to the contraction of foot flexors. When the fibula displaces downwards, the ankle mortise deepens; resulting in the interosseous membrane fibers tightening. A deepened mortise support and tight interosseous membrane fibers work to increase the ankle's lateral stability during gait (Scranton PE, et al., 1984).

According to a study by Takebe et al., the fibula bears about 6.4% of applied bodily loads. It has been found that depending on whether the ankle is in dorsiflexion or plantar flexion the percentage of weight bearing on the fibula increases or decreases, respectively (Norkus SA and Floyd RT, 2001).

2.1.3 Tibia

The tibia is the larger of the two lower leg bones and is responsible for bearing about 85% of the weight in the lower leg (Penn Medicine, 2012). The tibia articulates with the talus on the inferior surface of the distal end (Shier D, et al., 2009). During level walking, there is approximately 5-6˚ vertical rotation between the tibia and talus (Dettwyler M, et al., 2004).

2.1.4 Interosseous Membrane

The interosseous membrane reaches from the tibia periosteum to the fibula to hold the two bones together; the membrane continues for almost the length of the two bones (Figure 2-1). The anterior parallel fibers of the membrane run obliquely down to 15^0 to 20^0 from the tibial interosseous ridge and the posterior fibers stretch vertically. The membrane stabilizes posterolateral bowing that may be seen in the fibula during weight bearing. According to experimentation by Skraba & Greenwald, the interosseous membrane keeps the fibula active during weight bearing (Norkus SA and Floyd RT, 2001).

2.2 Mechanism of Injury

External rotation and hyperdorsiflexion are the two most accounted for mechanisms of injury to the ankle syndesmosis. Other mechanisms of injury: eversion, inversion, plantar flexion, pronation, and internal rotation (Norkus SA and Floyd RT, 2001).

2.2.1 External Rotation

External rotation from the neutral position of the ankle causes the most injury to the tibiofibular ligaments without disrupting other structures, such as the fibula. When a great enough force accompanies external rotation, the talus is forced to rotate laterally and, consequently, forces the fibula to move away from the tibia. In the occurrence of a high force external rotation the AITFL, PITFL, transverse tibiofibular ligament, or multiple of these may tear or rupture. External rotation may also tear the IOL or fracture the fibula (Norkus SA and Floyd RT, 2001).

External rotation is thought to be responsible for most ankle injuries associated with football and slalom skiing. In football, there are two noted mechanisms for such injury: a blow to the lateral leg of a player that is on the ground with his/her foot in external rotation and a blow to the lateral knee when the player’s foot is grounded in external rotation. Slalom skiing can lead to excessive external rotation and injury to the syndesmosis.

The ligaments experience maximum tension when the ankle is fully dorsiflexed or fully plantar flexed; however, in slalom skiing the boot restricts the ankle from dorsiflexion and plantar flexion. As the foot rotates externally the talus is forced to push on the lateral malleolus. This external rotation will affect the AITFL and, if the application of forces is continued, will injure the IOL and the PTFL (Norkus SA and Floyd RT, 2001).

2.2.2 Hyperdorsiflexion

The anterior part of the talus is wider than the posterior portion. In normal cases of dorsiflexion, the interosseous ligament is caused to tighten. In cases of severe dorsiflexion, the anterior part of the talus pushes the malleoli apart and the anterior and posterior ligaments can sprain or rupture (Norkus SA and Floyd RT, 2001).

Cases of hyperdorsiflexion can be seen in running and jumping athletes and in hockey players. When the athlete has to come to an abrupt stop, his/her weight may be thrown forward forcing hyperdorsiflexion (Norkus SA and Floyd RT, 2001).

2.3 Ankle Syndesmosis Fixation Methods

In the case of injury to the ankle syndesmosis, the talus can push up through the malleolus, between the tibia and fibula. The increased movement of the talus can cause instability, pain and a greater chance of developing permanent arthritis of the ankle. Depending on the location and the gravity of the injury, surgical fixation of the syndesmosis may be chosen to allow for the healing of the bone and or ligament(s) (Norkus SA and Floyd RT, 2001). Screw fixation and the suture-button are the state of the art fixation methods.

2.3.1 Screw Fixation

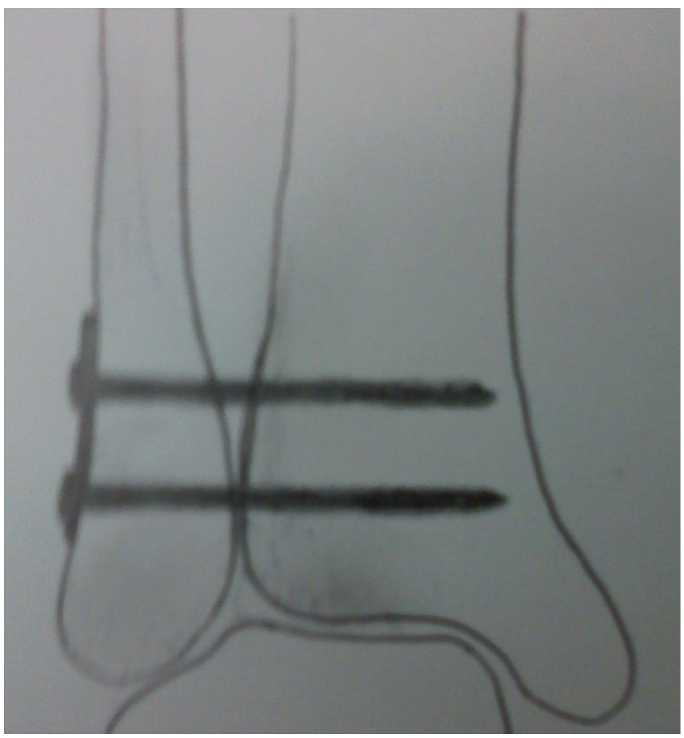


Figure 2-4: Screw Fixation

The gold standard syndesmotic screw fixation: a bone plate and 2 parallel screws.

Screw fixation is the current gold standard and most widely used method of fixation for the syndesmosis (Figure 2-4). There are many different controversial variables, such as the number of screws and the placement of the screws in relation to the joint (Porucznik

MA, 2008). Other variables include how many cortices and how, when, or if the screws should be removed. Bava E, et al. conducted a survey which found that 75% of surgeons surveyed use syndesmotic screws to fixate the joint with 51% of the surgeons using 3.5 mm cortical screws and 24% of the surgeons using 4.5 mm cortical screws. Of the surgeons that responded to the survey, there was a 1:1 ratio of surgeons that use one screw for syndesmosis fixation and surgeons that use two screws for syndesmosis fixation (Bava E, et al., 2010).

The screw fixation method varies from case to case and patient to patient. Generally, one or two 3.5-4.5 mm cortical screws are inserted parallel 2-5 cm above the joint. The screw(s) can be used in conjunction with a fibular plate. The screw(s) are not lagged or used to compress the bones. The screw(s) are positioned at a 30^0 angle from posterior to anterior and go through three to four cortices between the fibula and tibia (DiDomenico L and Garchar D, 2007). Two parallel cortical screws through a plate are thought to provide a stronger fixation between the tibia and fibula (Stannard J, et al., 2007)Screws that are tricortical have been found to have a lesser occurrence of loosening; whereas, quadricortical screws have been found to have a decreased chance of breakage (Stuart K, et al., 2011). Normal postoperative care consists of four to six weeks of a non-weight-bearing below-the-knee cast; this time may be extended for an additional two to four weeks if clinical and radiographic show it to be necessary (DiDomenico L and Garchar D, 2007). Screw diameter also has a part to play in screws loosening or breaking in the body. The 4.0 mm screws were seen to have a loosening percentage of 3.7% of all patients compared to the 3.5 mm diameter which had a percentage of 5.8%; however, the increased size of the screw generally causes more bone loss and is not suitable for use in all patients (Stuart K, et al., 2011).

2.3.1.1 Screw Parameters

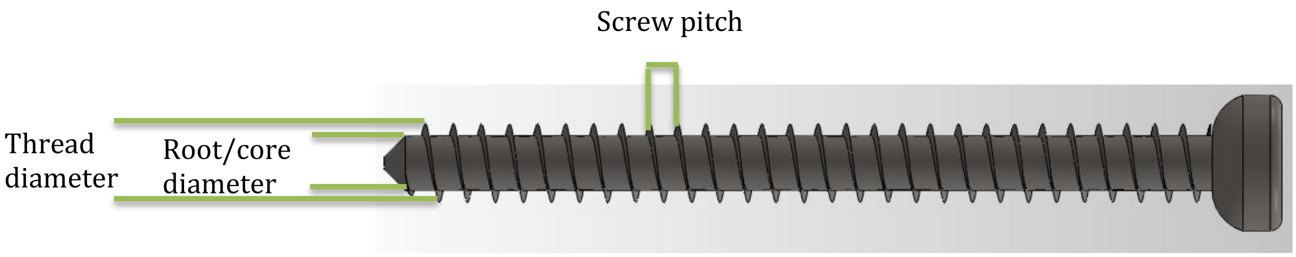


Figure 2-5: Bone Screw with Labeled Components

A labeled bone screw to show screw components: root/core diameter, thread diameter and screw pitch.

There are four main components of a screw: the root/core diameter, thread diameter, screw pitch and lead (Figure 2-5). The root/core diameter is the minimum diameter of the screw. The tensile strength of the screw is proportional to the square of the root/core diameter and the shear strength of the screw is proportional to the cube of the root/core diameter. The thread diameter is the maximum diameter of the screw; the threads can be asymmetric or symmetric. The screw pitch is the distance between two consecutive threads. The lead is the distance that the screw covers in one full rotation (DiDomenico L and Garchar D, 2007).

Bone screws can be either self-tapping or non-self-tapping. Self-tapping screws are drilled into the bone after a pilot hole is made that is larger than the core of the screw. These screws cut their own threads into the bone; therefore, these screws are subjected to resistances. Self-tapping screws are not used as lag screws. Non-self-tapping screws are not inserted until a pilot hole is made and a tap has precut threads the size of the screw into the bone (DiDomenico L and Garchar D, 2007).

Screws can be cortical or cancellous. Cortical screws are fully threaded; they can function as positional or lag screws. Positional screws fixate plates and lag screws wield compression. Cortical screws range from 1.5-4.5 mm in size. Cancellous screws have a thinner core and larger threads. Unlike cortical screws, they can be either fully threaded or partially threaded; the fully threaded screws are used for plate fastening and the partially threaded screws are used as lag screws. Cancellous screws are non-self-tapping screws, but they only need the near cortex of pilot hole to be tapped (DiDomenico L and Garchar D, 2007).

Lag screws are only threaded on the far cortex of the screw. Lag screws are designed to allow compression between two bones. Fully threaded cortical screws can act as lag screws only if the near cortex of the hole is over drilled to ensure that the size of the hole is at least greater than the thread diameter (DiDomenico L and Garchar D, 2007).

2.3.1.2 Plate Parameters

The shape of the plate only relates to the location that it is designated to be fixated; the shape does not serve any other function. There are a number of different types of plates to be used for different purposes: protection/neutralization, compression/locking compression, buttress, blade and reconstruction (DiDomenico L and Garchar D, 2007).

The protection/neutralization plate protects lag screws from all torsional, bending and shearing forces; as a result, interfragmental compression is protected. This type of plate allows early mobilization and limited loading. Protection/neutralization plates are deemed antiglide plates when used on the posterior fibula (DiDomenico L and Garchar D, 2007).

2.3.2 Suture-Button Fixation

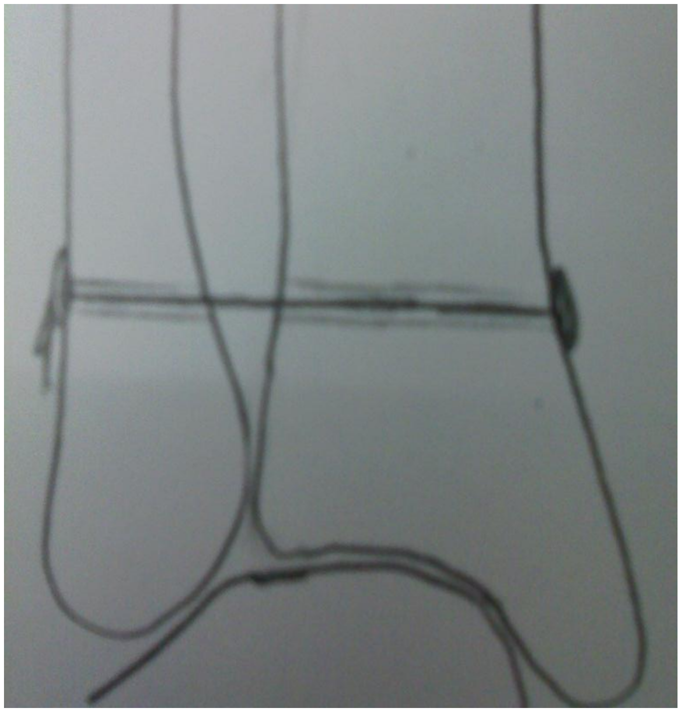


Figure 2-6: Suture-Button Fixation

A wire travels through the tibia and fibula holding the bones together.

Another method of treating ankle syndesmosis is the suture-button (Figure 2-6). The suture-button consists of suture material and two terminal metallic end buttons. One end button is tightened against the lateral fibular cortex and the other is tightened against the medial tibial cortex while the suture passes through 4 cortices: lateral and medial of the tibia and lateral and medial of the fibula (Qamar F, et al., 2011). Fibular plating is added for support. This device is designed to not interfere with the natural ankle motion, thus accelerating rehabilitation. The suture-button does not require a second surgery to remove it. However, compared to the screw fixation the suture-button is not as suited to maintain reduction of the syndesmosis (Qamar F, et al., 2011).

2.4 Problem Identification

The screw fixation method, although providing stability while allowing the ankle to heal, does not allow for weight bearing (Klitzman R, et al., 2010). Bearing weight while the screws are still inside the ankle may attribute to screw loosening and screw fatigue (Needleman RL, et al., 1989)In the incident of premature weight bearing on the ankle, the current fixation method is not able to overcome the shear stresses to prevent the screws from loosening; when the screws loosen, the syndesmosis widens and the talus is able to push up between the tibia and fibula (Beumer A, et al., 2005).

In the case of malreduction of the syndesmosis, there may be a need for a revision surgery which greatly increases the chance for infection. A fixation method is needed for the syndesmosis which decreases the cases of screw loosening. A new method that decreases the occurrence of screw loosening should increase the cases of proper reduction of the syndesmosis and eliminate the need for a revision surgery.

3 Project Strategy

The overall goal of this project is to develop a fixation method to reduce screw loosening in syndesmotic fixations. The device should withstand greater axial loading and withstand greater transverse loading. Under the direction of the client Dr. John Wixted, an orthopedic surgeon at the University of Massachusetts Medical School in Worcester, MA, the following objectives, functions, constraints and client statement were developed for the project.

3.1 Initial Client Statement

A phone interview with Dr. Wixted was conducted to obtain an initial client statement. Dr. Wixted was interested in the development of a new fixation device or method to use on the syndesmotic joint of the ankle. Dr. Wixted treats many syndesmotic injuries and the current fixation devices and methods are not fully reliable. These current methods are observed to break or loosen during the healing process, allowing the ankle to move around which can cause arthritis. Not only does the failure of the device have negative effects on the health of the patient, but the failure also adds to more surgery and increased insurance bills. The goal of this project was to design a device or method that would minimize screw loosening.

An initial client statement was developed based off of the information obtained through the phone interview with Dr. Wixted:

> *Design, develop and test a syndesmotic screw fixation method to better hold the tibia and fibula together to allow the proper regrowth of the syndesmotic ligaments after rupture.*

3.2 Objectives

A series of objectives that the device or method should meet have been comprised. The four main objectives are effectiveness, reliability, reproducibility and marketability.

Each of these areas have been defined and broken into secondary objectives, as seen in the Objectives Tree (Appendix A).

Table 3-1: Pairwise Comparison Chart

The pairwise comparison chart ranking the main objectives.

	Effective	Reliable	Reproducible	Marketable	*Total*
Effective		1	1	1	*3*
Reliable	0		1	1	*2*
Reproducible	0	0		1	*1*
Marketable	0	0	0		*0*

The main objectives were ranked by means of a pairwise comparison chart (Table 3-1). The first objective listed in the top row was compared against all of the objectives listed in the columns. The objective in the row was given a 1 for being more significant than the objectives in the column, a 0.5 for having equal significance and a 0 for being less significant. This was repeated for each of the remaining objectives in the top row. From these results, we determined a ranking of the objectives. The rankings of the sub-objectives are available in Appendix B.

The second ranked objective was to create a reliable device. Reliability was defined as the design's resistance to failure, such as screw loosening or breakage due to fatigue. Factors in resistance of failure can include material strength, loading and orientation. Optimizing these factors should increase the reliability of the design.

The third ranked objective was to create a reproducible design. The results and procedure of the device should be easily replicated. If the results obtained from the device are not reproducible, the device will not meet industry standard. A standardized testing method was created to be used to ensure that the device has reproducible results.

The fourth ranked objective was marketability. This includes minimizing the number of surgeries, cost effectiveness and ease of use. To make the design marketable, innovation should be used to improve upon previous methods. Attributes from current devices and methods may be used to create a new fixation device or method.

3.3 Constraints

Constraints need to be met in order to have a successful fixation method. First, the fixation method must be safe. The materials used in the method cannot be rejected by the body and cannot produce byproducts that will harm the body. Also, the fixation method should not harm the user or cause any unnecessary harm to the patient. In addition, testing procedures followed in this project must fall within the allowed budget by Dr. Wixted. Finally, this project must be completed before the CDR date, April 26th, 2012.

The new fixation method must be able to withstand greater axial and transverse loading than the gold standard fixation method. The two fixation methods, the newly designed method and the gold standard, must be tested under the same conditions in order to compare the effects.

3.4 Functions

In order for the device to meet the set objectives, there are several mechanical and surgical functions it must do. Mechanically, the device must hold the tibia and fibula together; this will minimize tibiofibular displacement. Also, the device should not fail inside of the patient; device failure will be defined as device loosening. In order to design against screw loosening it is important to consider the effects of axial and transverse loading on the fixation system.

3.5 Revised Client Statement

The client statement was reviewed after addressing the objectives, constraints and functions with Dr. John Wixted:

Design, develop and test a method to fixate the tibia and fibula at the syndesmosis after interosseous ligament rupture. This fixation should be capable of withstanding normal body forces of 800 N for at least 10 weeks. This method should also be able to *withstand greater axial and transverse loading than the gold standard screw fixation method.*

This new client statement was developed after much consideration. To focus the scope of the project, Dr. Wixted thought it most important to focus on fixation in the case of only rupture of the interosseous ligament. The interosseous ligament is thought to account for 21% of the strength of the syndesmosis and accounts for a great deal of its stability. A ruptured interosseous ligament is a severe instability and pain issue. The force of 800 N was chosen, as it properly reflects the forces during normal weight bearing (Cox S, et al., 2005). The duration period of 10 weeks accounts for normal ligament healing. Finally, in order to be able to see less screw loosening, the fixation method must account for the different cases of loading that lead to loosening: axial and transverse loading.

4 Designs

4.1 Limitations of State of the Art Fixations

Approximately every 20 minutes there is an ankle injury that requires fixation of the syndesmotic joint (Stuart K, et al., 2011). Two parallel syndesmotic screws used with a bone plate is the current gold standard for securing syndesmotic injuries. These screws are used to reduce the space between the tibiofibular joint and stabilize the area until it is completely healed; however, these screws sometimes fail due to fatigue or loosening during healing which can result in the need for revision surgery. Screw loosening failure is when the screw loosens inside of the bone and eventually begins to back out of the hole, resulting in the fibula and tibia being able to pull apart (Stuart K, et al., 2011). Stuart, et al. conducted a study on 137 patients with syndesmotic fixation to examine fixation failure mechanisms. From this group, 30 patients (22%) were found to have failed hardware with 14 (10%) patients having broken screws and 13 (9.5%) patients having loosened screws. The study found that the resulting screw loosening allowed for 1.2 – 2.4 cm of movement between the tibia and the fibula (Stuart K, et al., 2011).

Screw loosening is generally believed to be caused by vibration or shock. Vibrational induced loosening can occur through axial loading of transverse loading. Axial loading is the vibrational forces acting parallel to the screw and transverse loading is the forces acting perpendicular to the bone. Axial loading is thought to cause deformation in the bone material, lowering the frictional forces which hold the screws in place. Transverse loading causes internal stresses which, when high enough, can overcome the frictional forces holding the screws in place and force them to back out of the bone. Transverse loading is known to cause the most severe cases of vibrational loosening (Pai NG & Hess DP, 2002). 90% of the patients that experience screw loosening develop permanent arthritis (Stuart K, et al., 2011).

A fixation method is needed to withstand vibrational induced loosening. Failure to reduce the space between the tibia and fibula allows the talus to push up between the two bones; upwards movement of the talus can lead to discomfort, instability and severe arthritis. With more than a fifth of treatments failing due to screw loosening or fatigue, a new device needs to be created as an alternative to this method to prevent malreduction of the syndesmosis (Stuart K, et al., 2011). A device is needed to hold the tibia and fibula together while withstanding predetermined axial and transverse loads.

4.2 Preliminary Design

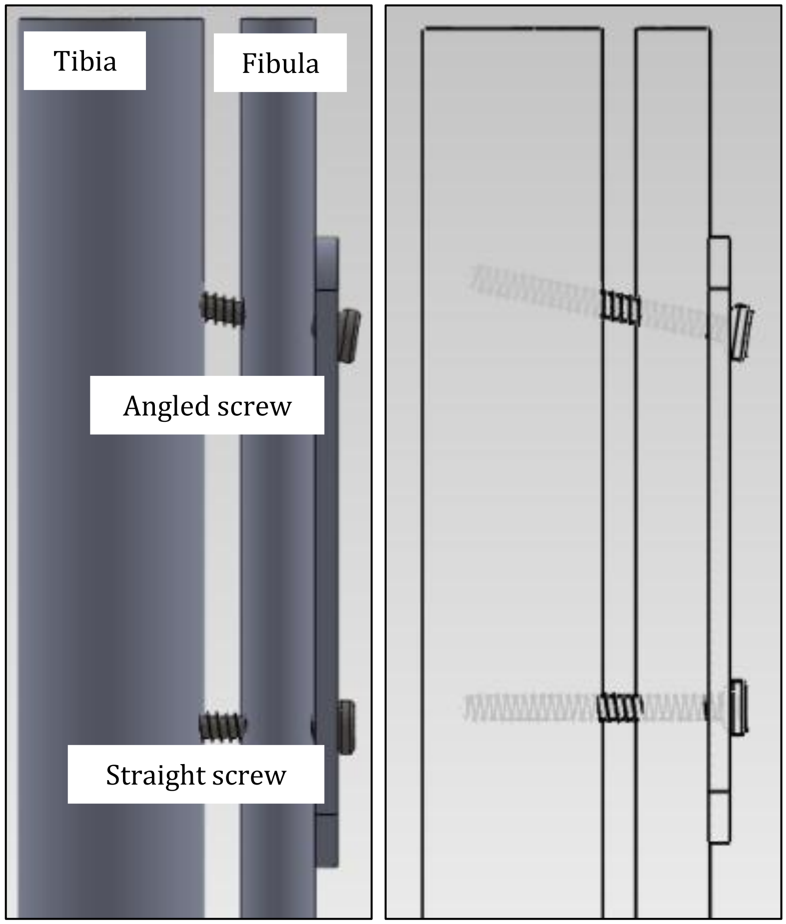


Figure 4-1: Preliminary Design

This is the concept model for a screw system with one angled screw and one straight screw. Solid model (left) and displaying hidden lines (right)

The preliminary design was a variation on the current screw and plate fixation method. Varying the angle that the screws are inserted into the bone may change how the forces of the body affect the screws and could prevent loosening. Since a screw and plate variation is similar to the current method, surgeons would not need to be trained on how to implant the device. The preliminary design can be seen in Figure 4-1.

4.3 Alternative Designs

In addition to the preliminary design, several alternative designs were developed. The alternative designs were created to explore other methods of holding the tibia and fibula together.

4.3.1 Alternative Design 1

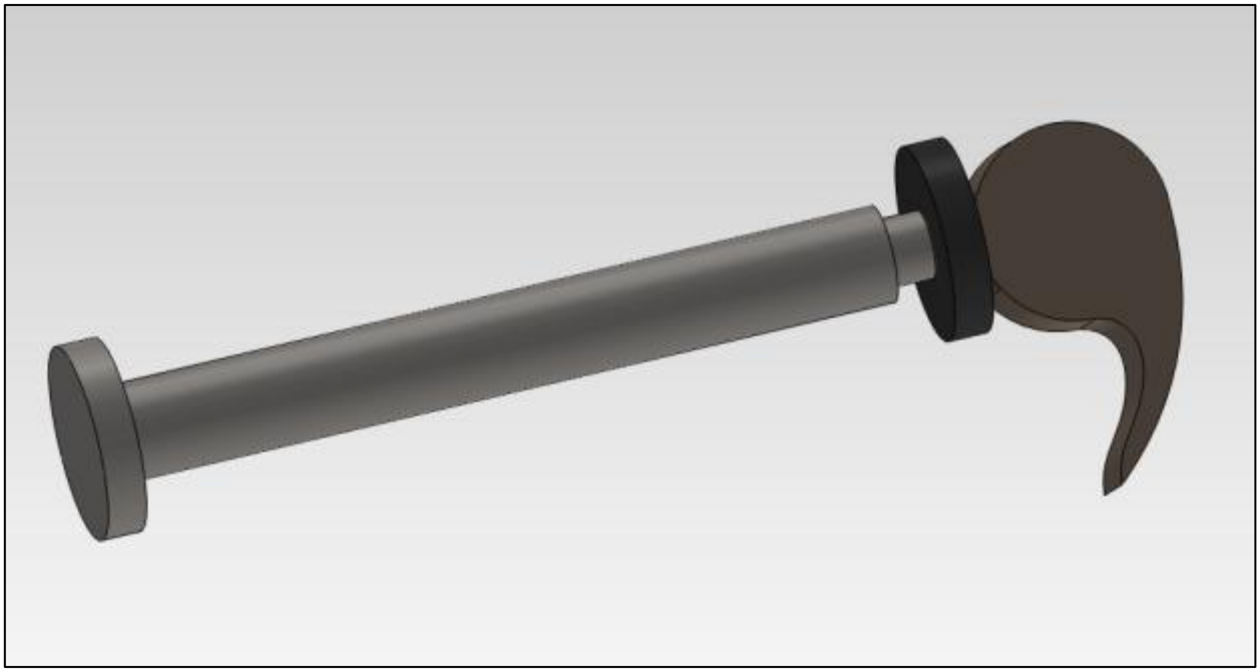


Figure 4-22: Alternative Design 1

This is the concept model for a latch system.
When the latch is pushed down, the washer is pushed down and clamps the two bones together.

A possible alternative is to use a latch device that would go through the bone and compress two plates together (Figure 4-2). This design may account for increased pullout strength and stability. The washers on either side of the rod may prevent the rod from pulling through the bones. This design may be adapted to make it easy to fixate by pushing down on a lever to pull the plates together. The disadvantage of this design is that it is more invasive; there may need to be multiple incisions and the device would be more bulky than the current method. More incision sites would increase the risk of infection.

4.3.2 Alternative Design 2

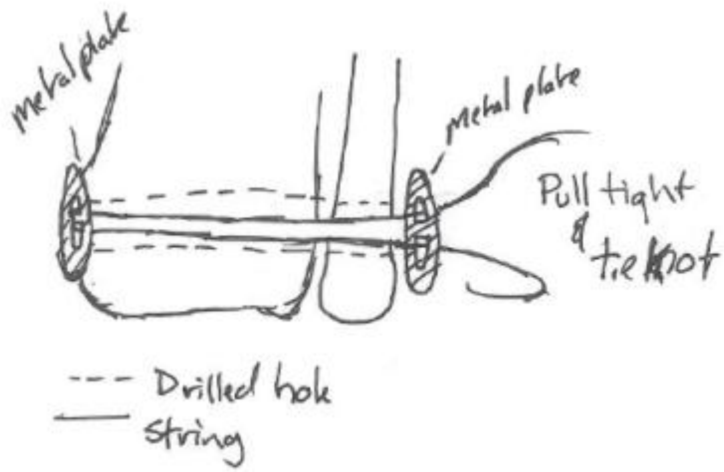


Figure 4-33: Alternative Design 2

Two strings are threaded through a drilled hole, wrapped around the bones and is used to tighten the two plates together and hold the bones in place.

The next design is an adaption of the suture-button. This device (Figure 4-3) is essentially a string that passes through the two bones and pulls them tightly together. The suture-button method is said to withstand rotational forces but does not have very good holding strength. One possibility is to change the string into wire and make stronger fixation points to allow the device to withstand greater forces.

4.3.3 Alternative Design 3

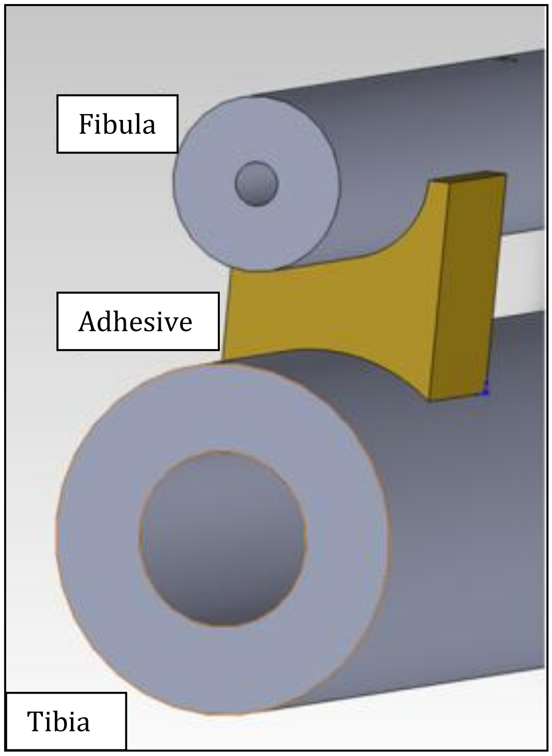


Figure 4-44: Alternative Design 3

This is a model of an adhesive holding the tibia and fibula together.

Another alternative design is using a bioadhesive to hold the two bones together (Figure 4-4). The advantages of this design are that it would require less surgery time and would eliminate screw loosening as a means of failure. The problem with this design is that the adhesive may easily be broken and could degrade before the syndesmosis is properly healed. Also, the bioadhesive may damage the bone upon application.

4.3.4 Alternative Design 4

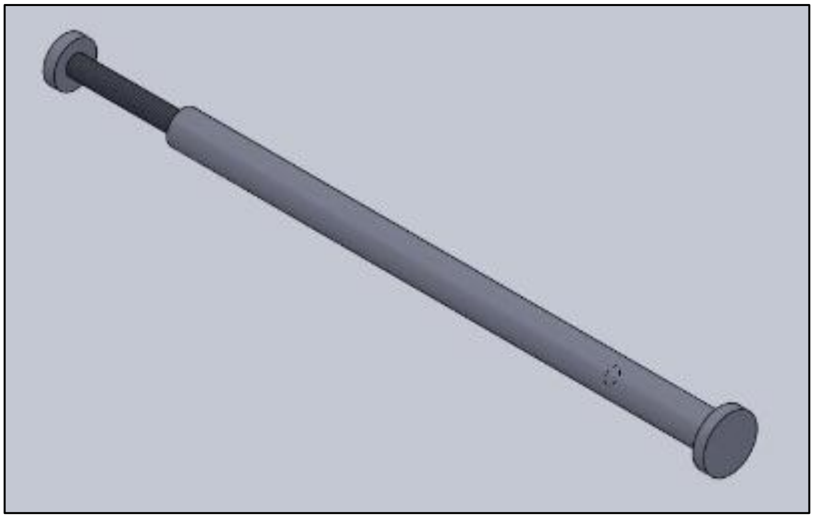


Figure 4-55: Alternative Design 4

This alternative design consists of two rods that screw together between the tibia and fibula.

Alternative design 4 (Figure 4-5) consists of two rods that screw together. One rod is inserted into the tibia and the other is inserted into the fibula. The rods screw together between the two bones. The washers on the outsides of the rods should prevent the rods from pulling through the bones. This alternative design would require the surgeon to make two incisions which would increase the chances of an infection.

4.4 Conceptual Final Design

To select a conceptual final design, the preliminary design and the alternatives designs were evaluated using a patent search, surgical practicality and stability evaluation.

4.4.1 Patent Search

A patent search was performed to see if any of the alternative designs already existed as a patent or pending patent. The patent search yielded an application filed in March 2008 (Pub. No.: US 2009/0228049 A1, Pub. Date: Sep. 10, 2009) that was similar to Alternative Design 4 (Figure 4-5). The patent application was for two cannulated screws. The screws have different diameters that correspond to the diameter of the bones. The smaller diameter screw inserts into the larger diameter screw and holds the bones together (Park, 2008). This patent search ruled out Alternative Design 4.

4.4.2 Surgical Practicality

The alternative designs were examined for their surgical practicality. This included minimal parts, minimal incisions and ease of use in a surgical environment. Alternative designs 1 and 2 did not meet these requirements.

Alternative design 1 was not a practical design for surgical implantation. This design would require the surgeon to make two surgical incisions on either side of the ankle, one for the part of the device with the washer that prevents pullout and the other for the latch part of the device. In addition, the latch is a bulky component. Two incision sites increases the amount of the time the patient is in surgery and increases the chance of the patient developing an infection.

Alternative design 2 also requires the surgeon to make an incision along both sides of the ankle in order to thread the device through the bones and wrap it around the outside of the bones. The client agreed with the decision to not use Alternative Design 2; this design was not something he was interested in using.

4.4.3 Stability Evaluation

The alterative designs were examined for their stability. Alternative Design 3 is not a stable design. The bioadhesive is not strong enough to hold the tibia and fibula together for a prolonged period of healing. In addition, the bones are being pulled together by the glue. A design that pushed the bones together would provide the most stable fixation. The bioadhesive could be a good addition to another design but would not be strong enough by itself.

4.4.4 Chosen Design

After completing the patent search, surgical practicality and stability evaluation, varying the screw angle of the current screw and plate fixation method was selected as the final design. Varying the screw angle of the current design is practical for surgery. Surgeons are familiar with inserting screws and plates into the body and would not need to be trained on a new surgical procedure. In addition, a screw and plate design would only require one surgical incision, resulting in a lower risk of infection than having two incisions. In addition, a screw and plate design would be able to hold the tibia and fibula together. A patent was not found that ensured repeatable insertion of a bone screw at one fixed angle. The conceptual final design was determined after the preliminary testing. The preliminary testing was used to determine the angle at which to place the screws to minimize the screw loosening. Screw loosening has been found to correlate to the shear stresses on a screw. Testing was conducted to determine the best screw angle combination to limit the shear stresses on the structure. From the results of the testing, a locking plate with set angled screw holes was designed to ensure proper screw angle orientation.

The designed fixation method incorporated 3.5 mm diameter, tricortical, Ti-6Al-4V cortical screws. Several papers have shown conflicting evidence on what diameter screw has less occurrences of loosening. A 3.5 mm diameter screw was chosen based on its small size which has been shown to take less material out of bone than the 4.5 mm screw. The 4.5 mm screw damages the bones more, causing them to weaken. Inserting the screws into only three cortices, instead of four cortices, was chosen due to four cortices screw fixation has been shown to have an increased incidence of screw loosening compared to three cortices fixation (Stuart K, et al., 2011). Also, the nature of four cortices screw insertion causes protrusions which cause patient discomfort.

5 Design Verification

Computational modeling and experimental verification was used to determine the ideal angle of the screw and compare the design against the current state of the art screw and plate fixation. Computational modeling was used to examine the design with stresses on the screws at each angle. Experimental verification included pullout testing to examine axial loading and load-to-failure testing and cyclic shear testing to examine transverse loading.

5.1 Computational Modeling

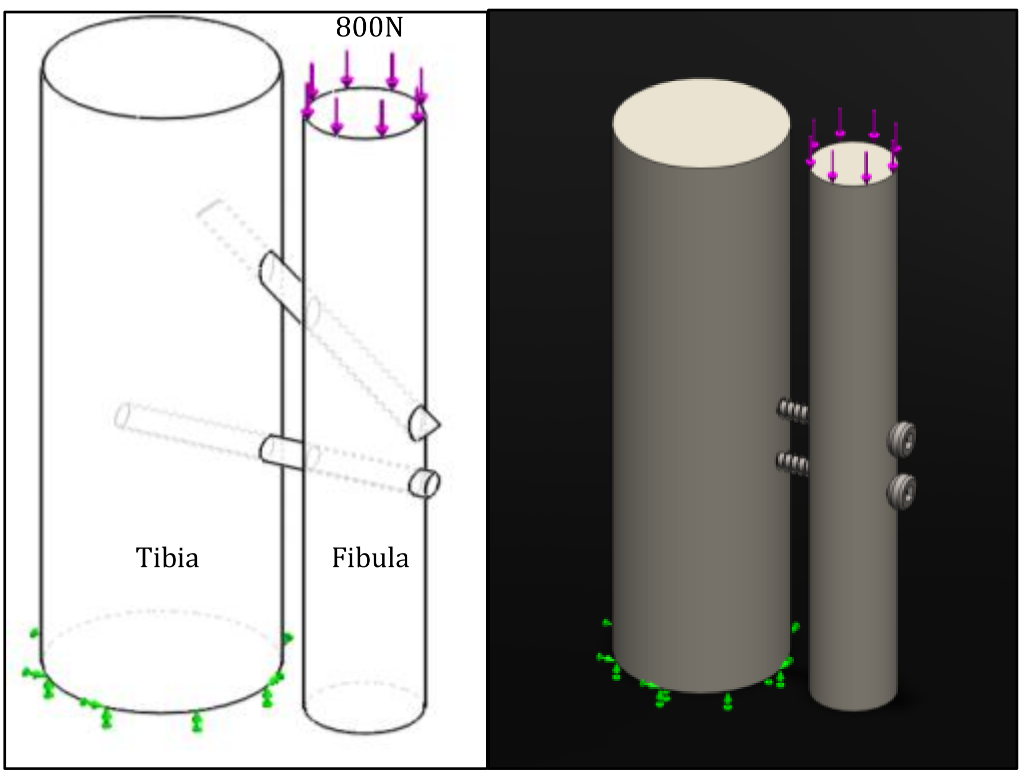


Figure 5-1: CAD Simulation

CAD simulation used to determine the maximum von Mises stress. The larger cylinder represented the tibia while the smaller cylinder represented the fibula.

Solidworks was used to create a computer aided design (CAD) model of the tibia and the fibula (Figure 5-1). Similar mechanical properties of cortical bone were applied to the bone models. Modeled Ti-6Al-4V screws were inserted into the model bones at three different angle combinations: two parallel screws perpendicular (0°) to the bones, the bottom screw perpendicular (0°) to the bones with the top angled up 23°, and the bottom screw perpendicular (0°) to the bones with the top screw angled up at 45°. In each scenario, the two screws were inserted 1 cm apart as to stay consistent between testing groups. Finite element analysis (FEA) was conducted on the different screw system models using a Solidworks simulation package to examine the effects of each angled screw under equal shear loads.

Each CAD model was subjected to simulated stresses. The tibia, the larger diameter cylinder was fixed at its distal end. Forces of 800 N were applied to the proximal end of the fibula, the smaller diameter cylinder. The bones were fixed and loaded in this to mimic the effects of shear loading on the syndesmosis (Hansen M, et al.). The von Mises showed the shear stresses on the screws and where they were most likely to fail. The von Mises stress obtained in the screws were recorded and compared for analysis. The results from this simulation analysis were studied to compare how the different screw angle combinations withstand shear stresses through transverse loading.

5.2 Pullout Testing

Pullout testing was conducted using 3.5 mm diameter, 40 mm long, Ti-6Al-4V cortical screws in 0.32 g/cc density closed-cell polyurethane (PU) foam blocks with a 2 mm thick 1.64 g/cc short fiber filled epoxy (Pacific Research Laboratories, 2011).

Table 5-1: Mechanical Properties of Simulated Bone Materials

This table shows the mechanical properties of the PU foam and the short fiber filed epoxy sheet.

(Pacific Research Laboratories, 2011)

	Compressive		Tensile		Shear	
	Strength	Modulus	Strength	Modulus	Strength	Modulus
0.32 g/cc PU	8.4 MPa	210 MPa	5.6 MPa	284 MPa	4.3 MPa	49 MPa
	Compressive		Longitudinal Tensile		Transverse Tensile	
	Strength	Modulus	Strength	Modulus	Strength	Modulus
1.64 g/cc epoxy sheet	157 MPa	16.7 GPa	106 MPa	16.0 GPa	93 MPa	10.0 GPa

The foam blocks were obtained in 120 x 170 x 42 mm sheets and were cut down to 45 x 60 x 42 mm. The 0.32 g/cc closed-cell PU blocks have been tested to have similar mechanical properties as normal cancellous bone (Table 5-1). These blocks meet the ASTM standard specification F-1839-08 for screw pullout testing using PU foam blocks (ASTM International, 2010). The short fiber filled epoxy sheets have similar properties to normal cortical bone (Laboratories, 2011).

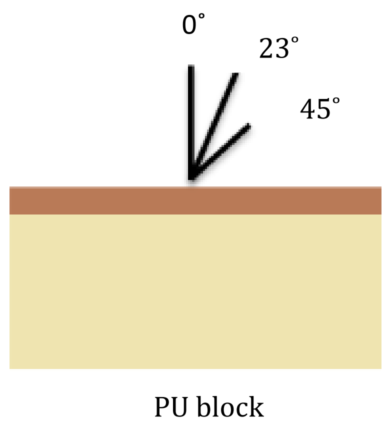


Figure 5-2: Angles used for pullout testing

Screws were tested in pullout at three angles as depicted in this diagram.

Testing protocol was followed according to a procedure by Patel PS, et al. Three different groups were tested: screws were inserted into the testing blocks at 0˚, 23˚ and 45˚ from perpendicular (Figure 5-2). Patel PS, et al. conducted the same tests with 4.5 mm cortical screws; however, they did not have the short fiber filled epoxy cover to simulate cortical bone on the PU foam block (Patel PS et al., 2010).

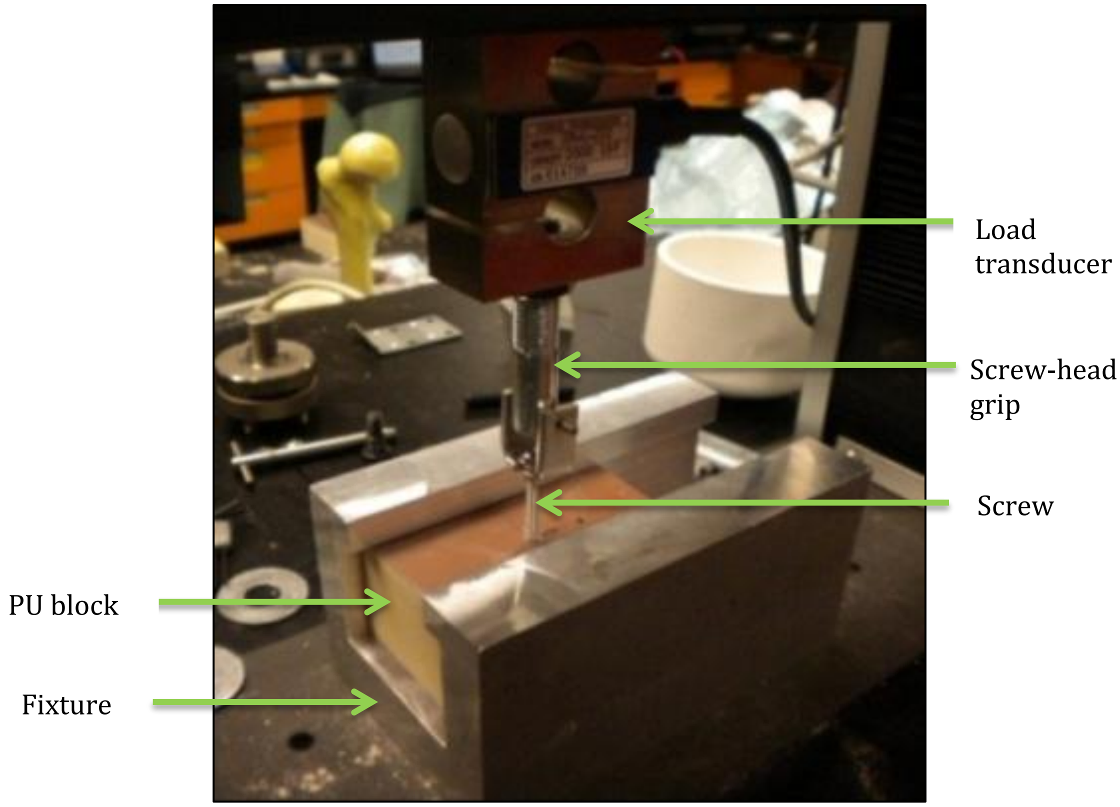


Figure 5-3: Pullout Test Set-Up

The fixture held the testing block in place while the screw-head grip pulled up on the head of the screw.

A 2.5 mm drill bit was used to make a pilot hole in each block at the respective group angle. A guide block was created for each angle using an angled drill press and was used to drill the pilot hole in each block at the chosen angle. Each screw was inserted into the pilot hole to a depth of 30 mm. A custom fixation apparatus was designed to hold the PU block with the screw rigid during the testing (Appendix C). The apparatus was attached to the base of an ADMET uniaxial testing machine with a 2000 lb-ft load transducer (Interface, model SSM-AJ-2000). The load transducer of the machine was attached to a custom made device that held the screw head (Figure 5-3). Each sample, regardless of what angle the screw was placed at, was pulled straight up perpendicular to the base of the machine and preloaded to approximately 33 N. The screws were all pulled under displacement control at a rate of 0.10 mm/sec. The pullout strength was recorded as the maximum generated load during the test (Patel PS et al., 2010). Pullout testing was done in accordance with ASTM standard F543-02 (ASTM International, 2002).

During initial testing it was observed that slipping of the blocks occurred in both samples of angled screws. In order to prevent slippage a metal stop was inserted to prevent the blocks from being able to slide horizontally inside the jig. In addition, a washer was used on the angled screws to allow for the grip to hold onto a greater surface area to ensure that the screw head did not slip out of the grips during the experiment.

A MATLAB script was written to analyze and plot the data (Appendix D). A one way analysis of variance (ANOVA) and a Tukey honest significant difference (HSD) were conducted to determine any significance between the pullout strengths of the three different insertion angles of the screws.

5.3 Load-to-Failure Testing

Load-to-failure testing was conducted using commercial bone analogs (Pacific Research Laboratories, 2011). Testing was conducted to observe the effects of transverse loading on straight versus angled screws.

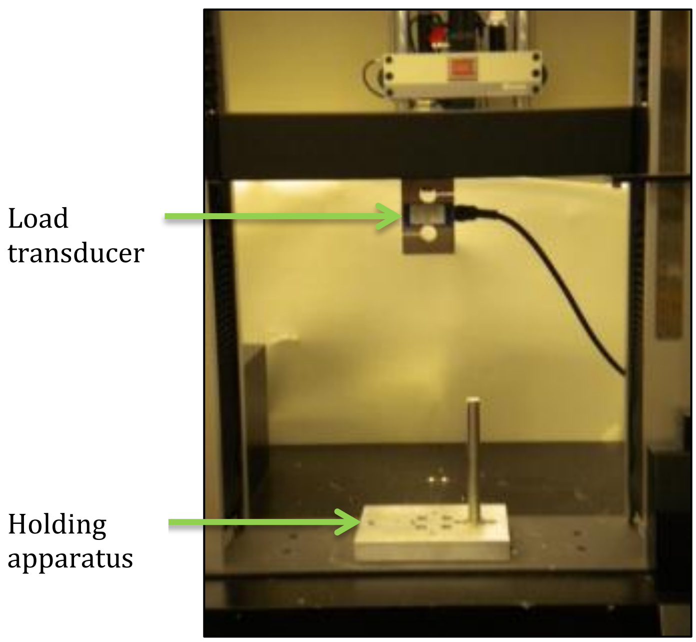


Figure 5-4: Test Set-Up for Shear Testing

Test setup for the shear testing. The fixture held the tibia while the load transducer applied a load to the sample.

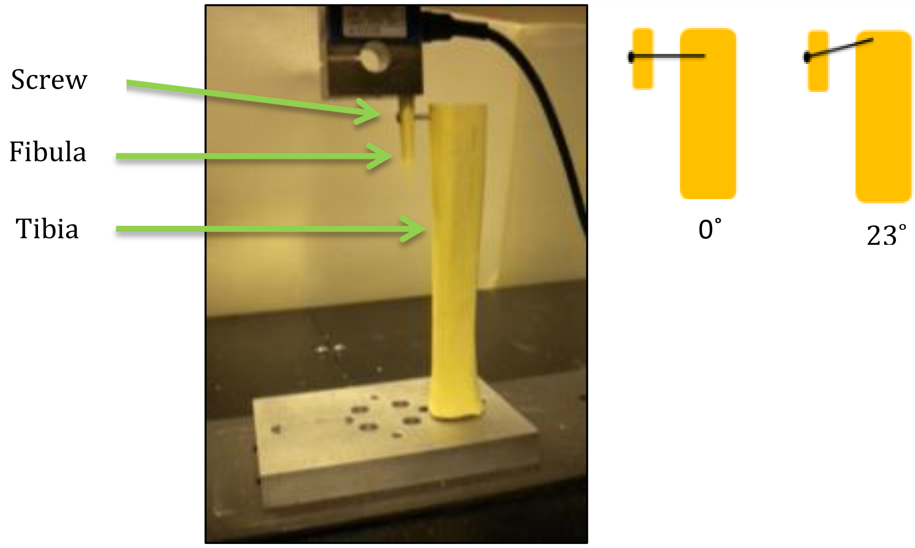


Figure 5-5: Load-to-Failure Single Screw Angles

Single screws were tested at two angles, 0° and 23°, in load-to-failure testing.

Testing was setup in accordance with the procedure proposed by Hansen M, et al. (Figures 5-4 & 5-5) (Hansen M, et al.). A holding apparatus (Appendix E) was designed and manufactured to hold the tibia perpendicular to the base of an ADMET uniaxial materials testing machine. The holding apparatus was designed with a 12 cm-long steel rod with a 1.27 cm diameter that was inserted in to the tibia to hold the bone perpendicular to the base. A 5 cm sample of the fibula was used. Two different screw orientations were tested: one single screw at 0° from perpendicular and one single screw at 23° from perpendicular (Figure 17). Guide blocks were used to create 2.5 mm diameter pilot holes in the bone samples. Screws were inserted in to the same part of the bones each time. The head of the fibula lined up with the load transducer and a displacement control of 20 mm in 6 sec was applied.

A MATLAB script was created to read, analyze, and plot the data (Appendix F). A two-tailed unpaired t-test was used to determine statistical significance between the maximum withstood loads of the two different screw systems. A p-value < 0.05 signified statistical significance.

5.4 Cyclic Shear Testing

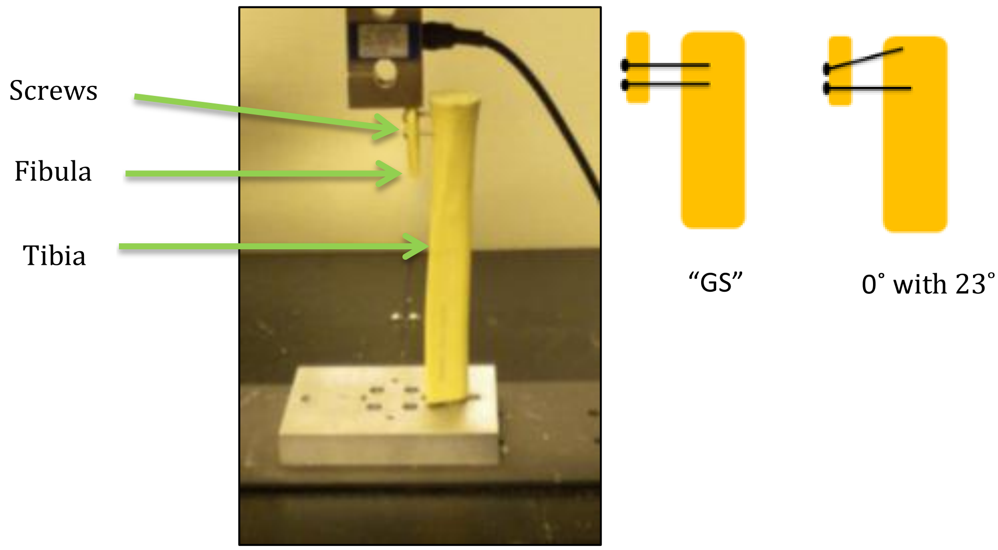


Figure 5-6: Cyclic Shear Screw System Angles

Two screw systems, the Gold Standard ("GS") and a 0˚ with 23˚ system, were compared in cyclic shear testing.

The test setup described above was also used to test the two parallel screws that represented the, gold standard, current fixation method against the experimental group, one straight screw and one angled screw at 23˚ (Figure 5-6). Samples were subjected to a preload of approximately 17 N and a load displacement of 5 mm in 2 sec for 75 cycles, adapted from Hansen M, et al. (Hansen M, et al.). A MATLAB script was created to read, analyze, and plot the data (Appendix F).

6 Results

The results from the computational model analysis along with the pullout, load-to-failure, and cyclic shear testing were observed and analyzed.

6.1 Computational Modeling

Table 6-1: Magnitude of Stresses on Screws

Representation of the magnitudes of the shear stresses accrued on the screws in the FEA simulation.

Screw Systems	Maximum Stress (N/m²)
2 at 0˚	3.3×10^{8}
1 at 0˚, 1 at 23˚	2.3×10^{8}
1 at 0˚, 1 at 45˚	1.8×10^{8}

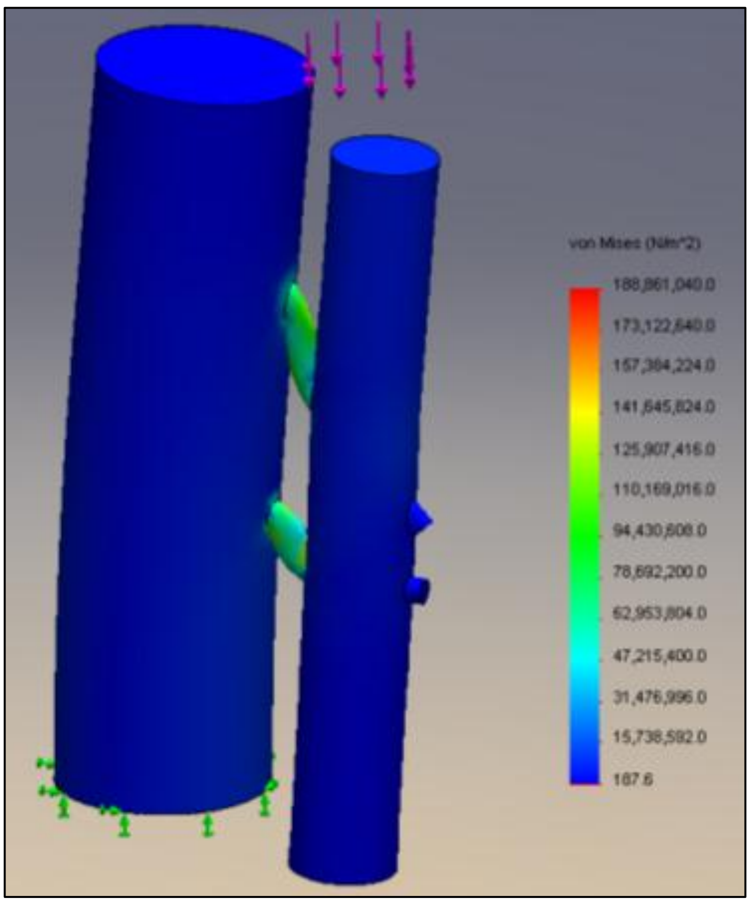


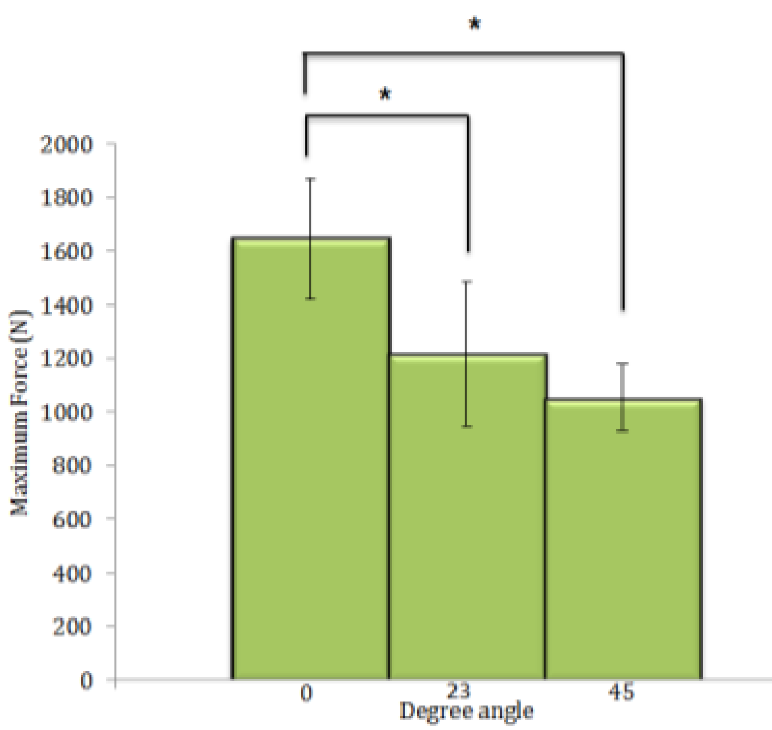
Figure 6-1: FEA simulation

A representation of the FEA simulation showed the von Mises stress on a two screw system with one screw at 0˚ and one angled screw.

Von Mises stresses from the 0˚, 23˚ and 45˚ angled screw combinations obtained from the FEA were compared (Table 6-1). A representation image of the FEA simulation is displayed in Figure 6-1. Results showed that the screw system consisting of two screws at 0˚ provided the highest maximum stresses in the screws, the 0˚ 23˚ screws provided the second highest maximum stresses in the screws, and the0˚ and45˚ screws had the lowest maximum stresses in the screws.

6.2 Pullout Testing

Pullout testing was conducted on three screw angles: 0˚, 23˚ and 45˚. This testing was performed to examine the maximum force the different angles could produce; this is an indication of the amount of axial loading each angle can sustain. The full results for the pullout strength for each sample can be found in Appendix G. The average force (N) and standard deviation for each angle was calculated and analyzed against the others.



* $p < 0.05$

Figure 6-2: Graph from Pullout Testing

The averages of the pullout tests showed a significant difference between 0˚ and 23˚ angled screws as well as between the 0˚ and 45˚ degree angled screws with $p < 0.05$. A trend that the 0˚ angled screws have the highest pullout strength, followed by the 23˚ angled screws is also shown.

The graphical representation of this is seen in Figure 6-2. The 0˚ screws averaged pullout strengths of 1650N with a standard deviation of 244. The 23˚ samples had an average of 1210N and standard deviation of 268. The 45˚ had an average 1050N and standard deviation of 124 Sample sizes were $n = 5$ for the 0˚ and 23˚ angled screws and $n = 8$ for the 45˚ angled screws.

A one way analysis of variance (ANOVA) and a Tukey honest significant difference (HSD) were conducted (Appendix H). The ANOVA showed that there was a significant difference between the three angled groups, $F(2, 15) = 14.62$, $p = 0.000$. The Tukey HSD comparison of the three groups showed a significant difference between the 0˚ and 45˚ degree screws as well as the 0˚ and 23˚, where $p < 0.05$. A significant difference was not found between the 23˚ and 45˚ angled screws, but the graph of the results demonstrated a trend that the 23˚ angled screw has a higher pullout than the 45˚ angled screw.

6.3 Load-to-Failure Testing

Load-to-failure testing was conducted to examine the effects of shear stresses, maximum loads and stiffness, caused by transverse loading on a single angled screw of 0˚ and 23˚. Sample size was too small ($n = 2$) for statistical analysis. However, the load-displacement graph was analyzed for trends.

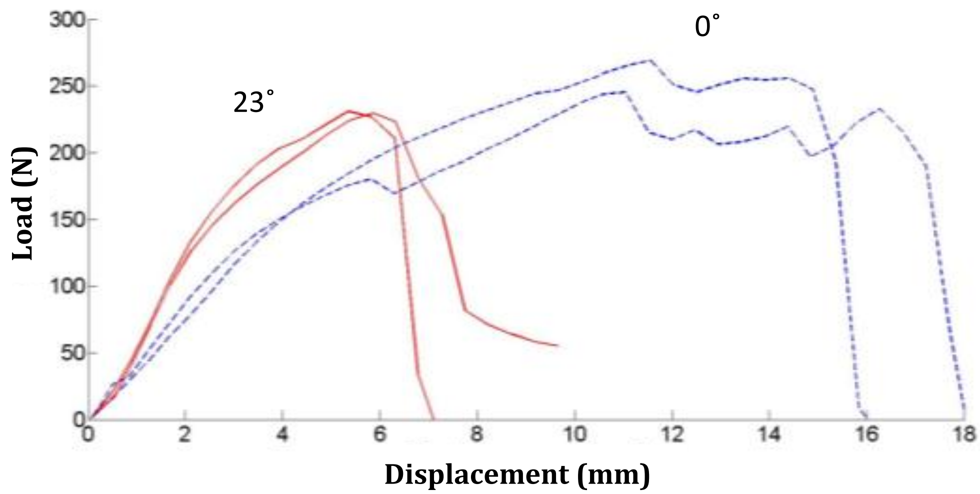


Figure 6-4: Load-Displacement Graph for Load-to-Failure Testing

The load-displacement graph of the 0˚ angled single screw and 23˚ angled single screw showed a comparable maximum load.

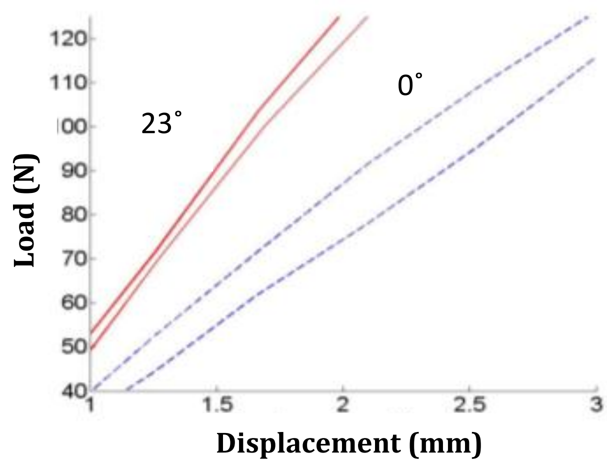


Figure 6-3: Elastic Region of Load-to-Failure Testing

The elastic region of the 23˚ angled screw showed a higher stiffness than the elastic region of the 0˚ angled screw.

The load-displacement graph for load-to-failure testing is in Figure 6-3. To eliminate the effects of plastic deformation in the screws the elastic region of the two angled screws was further examined for stiffness. Figure 6-4 shows only the elastic regions of the graph. The stiffness of the two angled screws were compared and the 23˚ angled screw showed to have a 66% increase in stiffness compared to the 0˚ angled screw.

6.4 Cyclic Shear Testing

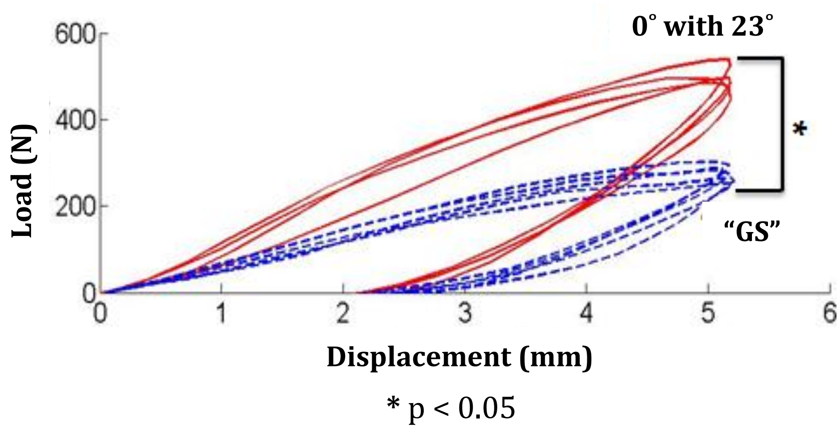


Figure 6-5: Load-Displacement Graph of a Single Cycle of Cyclic Shear Testing

The load-displacement curve for the Gold Standard ("GS") of two screws at 0˚ and the screw system consisting of a 0˚ with a 23˚ angled screw showed a statistical difference; the 0˚ and 23˚ screw system was able to withstand a significantly load.

Cyclic shear testing was conducted to examine the shear stresses caused by transverse loading on two screw systems: the current gold standard screw system of two 0˚ angled screws and the screw system consisting of a 0˚ angled screw with a 23˚ angled screw (Figure 6-5). The full results for the maximum forces on each sample can be found in Appendix I. The average maximum load for the two 0˚ angled screws was 277 ± 19.1 N and the average maximum load for the screw system consisting of a 0˚ angled screw with a 23˚ angled screw was 503 ± 24.3 N. The maximum loads absorbed by the 0˚ angled screw with a 23˚ angled screw was 80% greater than the maximum loads absorbed under these loading conditions by the gold standard. The apparent stiffness of the 0 ˚ angled screw with a 23˚ angled screw was twice the stiffness of the gold standard. A sample size of n = 5 was used for the two 0˚ angled screws and a sample size of n = 4 was used for the screw system consisting of a 0˚ angled screw with a 23˚ angled screw. A two-way unpaired t-test was used to compare the maximum loads. The t-test showed a significant difference between the maximum loads of the two screw systems, with $p < 0.05$.

7 Discussion

7.1 Computational Modeling

Von Mises stresses analyze each point in an object and evaluate the forces acting on it in every direction. Each point is given a color by the magnitude of the forces acting on it. From this, the points in each screw where it might fail can be observed along with the overall object which has the higher stresses. In this case, the higher stresses are in the two parallel screws, meaning that the way the screws are placed in the bone is causing them to have higher stress at the surface of the tibial interface. As Pai NG and Hess DP discussed, screw loosening is mainly caused by either axial loads which cause deformation in the bone or by transverse loads which overcome the frictional forces that are holding the screws in place (Pai NG and Hess DP, 2002). This means the stresses at the screw-tibial interface can be viewed as an indicator of increased chance of deformation and/or loosening.

The FEA of the screw fixation angles in the bone models were used as proof of concept for the fixation model. The FEAs showed that the angled screw systems, 0° with 23° and 0° with 45°, were subjected to lower stresses than the two 0° screws. The results of our initial computational tests have given support to the idea that angled screws have reduced shear loads which may lead to less screw loosening. This allows us to conclude that testing needs to be done to determine what the information we received from the FEA analysis actually means. It is for this reason that we conducted further experimentation on the angled screw method which showed lower stresses.

7.2 Pullout Testing

Pullout testing was conducted to determine which screw insertion angle to use in conjunction with the 0° screw to increase the axial loading the two screw system could withstand. A pullout test is a commonly accepted measure of pullout strength in a screw fixation device; it applies an axial displacement to a screw inserted into foam or bone material (Inceoglu S, et al., 2006). Pullout testing does not accurately mimic bodily forces (Suckel, et al., 2010). The pullout test conducted in this study was similar to a test done by

Patel PS, et al.; however, in the previous study lower pullout forces were seen in samples which did not having an epoxy cover to simulate cortical bone on the PU blocks (Patel PS et al., 2010).

Table 7-1: Average Pullout Force by Patel PS, et al.

The pullout forces collected in the Patel PD, et al. study is shown in the table below. These forces are relatively lower than those found in this study. Patel PS, et al. did not use an epoxy cover to simulate a cortical bone cover.

(Patel PS et al., 2010)

	0°	**20 °**	**40°**
Average Force (N)	1110 +/- 50	970 +/- 30	790 +/- 80

Table 7-2: Average Pullout Force from this Study

The average pullout forces obtained in this study were compared to other studies to validate the results.

	0°	**23 °**	**45°**
Average Force (N)	1650 +/- 224	1210 +/- 268	1050 +/- 124

Tables 7-1 and 7-2 show the average pullout strengths for each screw insertion angle from the Patel PS, et al. study and the results from this study. An epoxy sheet has been used in previous studies on screw pullout, such as a study performed to assess the effects of loading rate on the pullout stiffness and strength of pedicle bones (Inceoglu S, et al., 2006) and a study performed to determine the difference in pullout strength between cannulated and solid-core small-diameter bone screws (Kissel CG, et al., 2003).

Results from this study showed that the 0° angled screw has the highest pullout strength compared to the 23° and 45°. This was an expected result based on the results from Hansen M, et al.

7.3 Load-to-Failure Testing

The load-to-failure and the cyclic shear results support the findings from FEA. The load to failure results suggest that a single angled screw creates a more rigid system with a greater stiffness than a single 0° screw. Hansen et al. found comparable results for a 0° screw loaded to failure (Hansen M, et al.)

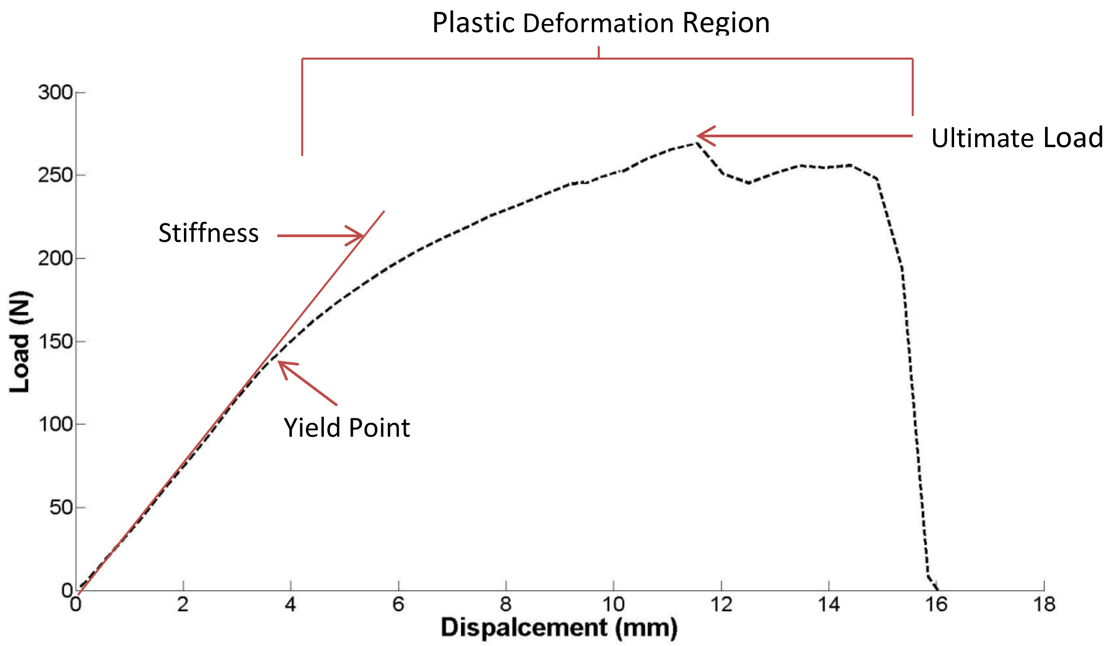


Figure 7-1: A representative plot from straight angled screw load-to-failure.

This is a graph representation from this study.
Regions of graph were adapted from a study study by Hansen M, et al.

Figure 7-1 depicts a representative graph from one 0° screw sample from the load-to-failure testing. Hansen M, et al. describes the first linear region as the stiffness. The next region, after the initial yield point, is the plastic deformation region. The plastic deformation region can be described by screw deformation or bone deformation at the screw holes or both. The same trends are seen in the load-to-failure study done in this project. The yield point and ultimate load found in this project was lower than seen in the Hansen study, this may be due to inserting the screws in different parts of the model bones. In the experimental studies done in this project, the most uniform sections of the tibia and fibula was used in order to maximize use of materials and to keep the results as precise as possible. With that said, screws were not inserted directly at the syndesmosis during this study; however, each screw system tested was tested in the same region of the bones in order to keep comparison consistent.

The results from the load-to-failure experimentation in this project suggest that the 23° screw provided about twice the stiffness than the 0° screw. Both screw systems had similar yield strengths and the 0° screw showed slightly higher maximum loads. The 0° screw also displaced over a larger range before failing than did the 23°. From this test, combining the 0° screw with the 23° screw to create one screw system fixation method seems like a viable method to decrease screw loosening. The 0° screw showed to have greater pullout strength and, therefore, may exhibit ability to absorb greater loads and the 23° screw provided greater stiffness. The results from this study cannot be compared through statistical analysis due to the small sample size for each group, n = 2; however, the results were fairly consistent and can be used to support the next test.

7.4 Cyclic Shear Testing

Comparing the two different screw systems from the cyclic testing, the two 0° screws, the gold standard, were able to absorb significantly lower maximum loads than the 0° and 23° screws under the same loading conditions. The 0° and 23° screw system was able to absorb, on average, 80% greater maximum loads. This suggested that the 0° and 23° screws would have higher shear strength and, presumably, less screw loosening (Hansen M, et al.). The 0° and 23° screw system also provided about twice the stiffness of the gold standard screw system.

This study suggested that a 0° screw with an angled screw may provide a greater holding capacity, without loosening, than the two 0° screws. A 0° and 23° screw system has been shown to withstand greater shear stresses than the two 0° screws.

7.5 Project Impacts

In any design project it is important to take into account many factors such as economics, environmental impact, societal influence, political ramifications, ethical concerns, health and safety issues, manufacturability, and sustainability. The affects from this project on each of these subjects does not differ greatly from the current gold standard fixation method used.

The results of this project suggest the new fixation method to be economically advantageous to those who need the surgery. Every minute in the operating room costs money. By designing a method that greater withstands the mechanisms that lead to screw loosening it may be assumed that less occurrences of screw loosening will be seen, which will lead to less of a need for revision surgery and money saved by the patient.

The results of this project may have a possible positive impact on the environment. The new fixation method proposed in this project uses closely the same amount of material as is currently being used in fixation of the syndesmosis; however, as the results show, the new fixation method proposed in this project addresses the mechanisms that lead to screw loosening. Having developed a new fixation method that is better equipped to withstand the mechanisms that lead to screw loosening, the need for revision surgeries should be decreased, as should the amount of materials produced for fixation. Decreasing the number of revision surgeries due to screw loosening decreases the number of overall surgeries. Decreasing the number of necessary syndesmotic surgeries can decrease the carbon footprint on the environment, either on a small or grand scale. Less screws and plates should need to be used, which could lead to less being produced. Also, fewer surgeries lead to fewer trips in a carbon emitting vehicle.

This new fixation method should be accepted into the society. This new fixation method is an innovation on the current gold standard and, therefore, should come naturally into circulation. This fixation method should be able to be easily marketed as, aside for some few but integral iterations on the current method, it is already an accepted method. The new fixation method presents obvious value over the current gold standard.

The new fixation method may infiltrate the global pool of surgeons; however, it will not have a grand influence on the global market as a whole. Companies may license the design to incorporate angled bone plates into their arsenals of products, but other than treating local syndesmotic injuries it should not expect a huge global effect. In addition to this the widespread use of this device really depends largely on surgeon’s preference on fixation method. While the device has shown to work better for the situations stated in the paper it may not be appropriate in every case.

Ethics are a major concern in most every day processes. It is important to ensure that the endpoint of the project produces means to a “good and satisfying life”. This fixation method will have a positive impact on some patients’ quality of life. This new fixation method gives the patient a better chance of ankle stability the first time around. It should give the patient better assurance that they will be healed in a timely fashion. In addition, this method was developed to help prevent patients from developing arthritis and prevent discomfort.

Manufacturability is an important aspect of a design. If a design is not manufacturable then it is useless. Even a design that is manufacturable, but is difficult to manufacture, may become useless if the cost to manufacture is too high. Creating a design that is easy to manufacture is important. The screws used in this new fixation method are already being manufactured and do not need to be altered. The new angled-hole fixation plate designed in this project may pose some complications creating the locking angled hole; however, in general it is not too far off from the standard plate currently used and should not pose too much of a problem.

Sustainability is one of the most important responsibilities that an engineer must consider. Each engineer should take responsibility in creating the most sustainable devices and processes. Sustainability is using as little from the natural environment as you need and taking no more; it is about preserving the resources of the earth. This new fixation method is relatively sustainable. Overall there should be less wasted material due to the lower number of revision surgeries that require new material. It goes without saying that doing something once is more sustainable then going back and having to fix a mistake. It uses screws that are already being made, eliminating the need to create extra “stuff”. Also, in regards to the plate, it is not too different from the current plate and so the new plate should not be drastically more or less sustainable. The final fixation method chosen in this project was much more sustainable than some of the suggested alternative designs, it uses much less materials.

8 Final Design

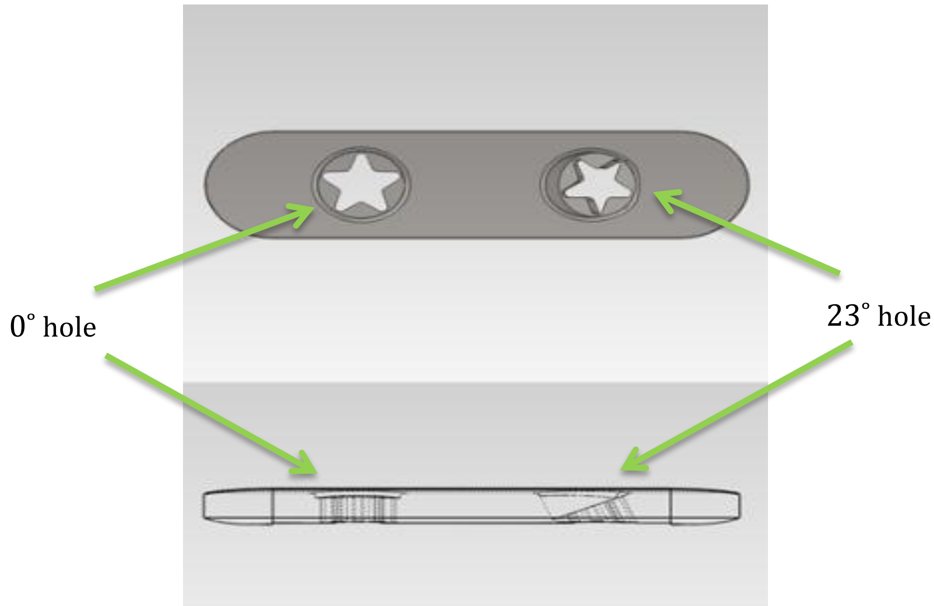


Figure 8-1: Angled-Hole Bone Plate Design

This bone plate was designed to allow surgeons to insert one screw at 0° and one screw at 23°.
Top view (top) and side view (bottom).

A bone plate was designed to allow surgeons to insert one screw at 0° and one screw at 23° (Figure 8-1). This bone plate was designed to accurately and consistently insert angled screws; the holes that hold the screws are angled to the appropriate angle. When the screw is inserted into the bone plate, the angled hole will guide the screw into the bone at 0° or 23°. Currently bone plates only allow angled screw insertion up to 15° and the bone plate does not act as a guide to angle the screw (Smith & Nephew). In order to accommodate the 23° angled hole, the thickness of the bone plate did have to be increased to 3 mm. Standard bone plates are approximately 2 mm thick (Smith & Nephew). This bone plate features a locking design, which is believed to offer superior fixation (Miller & Goswami, 2007).

9 Conclusion

The aim of this project was to design a new fixation method for the ankle syndesmosis that would hold to tibia and fibula together better than the current fixation method. The current gold standard fixation method, two parallel screws inserted at 0° from perpendicular, allows for screw loosening in about 10% of cases of syndesmotic fixation. Screw loosening is thought to be due to vibrations caused from axial and transverse loading. It was hypothesized that changing the insertion angle of the screws in the current gold standard fixation method would create a fixation that would be able to absorb greater forces in the axial and transverse directions.

Computational modeling and experimental validation testing were conducted to determine which screw angle combination could absorb the greatest maximum axial forces and transverse forces under set loading conditions. FEA analysis of the screw systems showed that the two parallel screw method had increased stresses at the screw-bone interface indicating a possible increased risk of loosening. Pullout testing was conducted as a measure of axial loading and results showed the greatest pullout strength was in the 0˚ angled screw, followed by the 23˚ angled screw. Load-to-failure and cyclic shear testing was conducted to examine transverse loading. Results showed that a single 23˚ angled screw had greater stiffness than a single 0˚ angled screw and a screw system consisting of a 0˚ angled screw and a 23˚ angled screw had greater stiffness and greater maximum loading. Based on these results, less screw loosening should be expected using a screw system consisting of a 0˚ angled screw and a 23˚ angled screw.

Future cadaver testing is recommended to verify these results using human tissue and to observe screw loosening. In addition, it is recommended that the bone plate be developed and tested to verify accurate and repeatable angled screw insertion. Cyclic shear tests should be conducted with the bone plate in order to observe screw loosening. It is recommended that this test be conducted at a lower force control and more cycles in order to see if or when each device would show loosening (Pai NG, et al., 2002). If this shows that the newly designed manufactured plate and method have less occurrences of screw loosening then the plate and method should become the new standard practice.

Works Cited

ASTM International. (2002). F543-02: standard specification and test methods for metallic medical bone screws.

ASTM International. (2010). F1839-08: Standard specification for rigid polyurethane foam for use as a standard material for testing orthopaedic devices and instruments.

Bava E, et al. (2010). Ankle fracture syndesmosis fixation and management: the current practice of orthopedic surgeons. *American Journal Orthopaedics*, 242-246.

Beumer A, et al. (2005). Screw fixation of the syndesmosis: a cadaver model comparing staineless steel and titanium screws and three and four cortical fixation. *Injury, 36*, 60-64.

Cox S, et al. (2005). Distal Tibiofibular Syndesmosis Fixation: A Cadaveric, Simulated Fracture Stabilization Study comparing Bioabsorbable and Metallic Single Screw Fixation. *The Journal of Foot & Ankle Surgery, 44*(2), 144-51.

Dettwyler M, et al. (2004). Modelling of the ankle joint complex. Reflections with regards to ankle prostheses. *Foot and Ankle Surgery, 10*, 190-119.

DiDomenico L and Garchar D. (2007). Fixation Techniques in Foot and Ankle Surgery. In L. Levy, & V. Hetherington, *Principles and Practice of Podiatric Medicine* (pp. 52:1-52). Data Trace Publishing Company.

Hansen M, et al. (n.d.). Syndesmosis fixation: analysis of shear stress via axial load on 3.5-mm and 4.5-mm quadricortical syndesmotic screws. *The Journal of Foot & Ankle Surgery, 45*(2), 65-69.

Inceoglu S, et al. (2006). Axial cyclic behavior of the bone-screw interface. *Medical Engineering & Physics, 28*, 888-893.

Kang SH, et al. (2011). A case of pedical screw loosening treated by modified transpedicular screw augmentation with polymethylmethacrylate. *Journal of Korean Neurosurgical Society, 49*(1), 75-78.

Kissel CG, et al. (2003). Comparison of pullout strength of small-diameter cannulated and solid-core screws. *The Journal of Foot & Ankle Surgery, 42*(6), 334-338.

Klitzman R, et al. (2010). Suture-button versus screw fixation of the syndesmosis: a biomechanical study. *Foot & Ankle International, 31*.

Laboratories, P. R. (2011). *Sawbones*. Retrieved October 2011, from Biomechanical Testing Materials: http://www.sawbones.com/products/bio/default.aspx

Miller and Goswami. (2007). A review of locking compression plate biomechanics and their advantages as internal fixators in fracture healing. *Clinical Biomechanics, 22*, 1049-1062.

Needleman RL, et al. (1989). Effect of the syndesmotic screw on ankle motion on ankle motion. *Foot Ankle, 10*, 17-24.

Norkus SA and Floyd RT. (2001). The anatomy and mechanisms of syndesmotic ankle sprains. *Journal of Athletic Training, 31*(1), 68-73.

Pacific Research Laboratories. (2011). *Orthopaedic and Medical Models*. Retrieved December 2011, from Sawbones: http://www.sawbones.com/

Pai NG and Hess DP. (2002). Eperimental Study of Loosening of Threaded Fasteners Due to Dynamic Shear Loads. *Journal of Sound and Vibration*, 585-602.

Park, S. (2008). *Patent No. US 2009/0228049.* US.

Patel PS et al. (2010). The effect of screw insertion angle and thread type on the pullout strength of bone screws in normal and osteoporotic bone models. *Medical Engineering & Physics, 32*, 822-828.

Penn Medicine. (2012). *Medican Animated Library*. Retrieved 03 30, 2012, from University of Pennsylvania: http://www.pennmedicine.org/encyclopedia/em_DisplayAnimation.aspx?gcid=000114&ptid=17

Porucznik MA. (2008). Screw vs. tightrope fixation for syndesmotic fractures. *American Academy of Orthopaedic Surgens*.

Qamar F, et al. (2011, September). An atomical way of treating ankle syndesmotic injuries. *The Journal of Foot & Ankle Surgery*.

Scranton PE, et al. (1984). Dynamic fibular function: a new concept. *Clinical Orthopedics*, 289-92.

Shier D, et al. (2009). *Hole's essentials of human anatomy & physiology.* New York: McGraw-Hill Companies, Inc.

Smith & Nephew. (n.d.). *Variable Ankle Locking Technology*. Retrieved 2012, from http://global.smith-nephew.com/master/40067.htm

Stannard J, et al. (2007). Ankle Fractures and Dislocations. In *Surgical Treatment of Orthopaedic Trauma* (p. 807). New York: Thieme Medical Publishers, Inc.

Stuart K and Panchbhavi VK. (2011). The Fate of Syndesmotic Screws. *Foot & Ankle International*, 519-525.

Suckel, et al. (2010). In vitro measurement of inarticular pressure in the ankle joint. *Keen Surgery, Sports Traumatology, Arthroscopy*, 664-668.

Glossary

Ankle mortise/ syndesmotic mortise: bony arch formed by the two malleoli and the tibial planfond

Anterior: at the front

Cancellous:
Cancellous Bone: also known as spongy bone; typical located at the end of long bones; has a is less stiff and dense than cortical bone
Cancellous Screw: screw used for the fixation of cancellous bone

Cortical:
Cortical Bone – harder, stiff and stronger than cancellous bone; forms outer shell of bones
Cortical Screw – screw used for the fixation of cortical bone

Distal: away from the body

Dorsiflexion: movement of the ankle; the foot and ankle move towards the anterior of the tibia

Fibula: smaller of the two lower leg bones; responsible for maintaining ankle mortise stability during weight bearing activities

Hyperdorsiflexion: mechanism of ankle injury; anterior part of the talus pushes the malleoli apart and the anterior and posterior ligaments can sprain or rupture

Inferior surface: bottom surface

Interosseous ligament: located between the distal ends of tibia and fibula; holds these bones together

Malleoli: bony prominence located on either side of the ankle

Malreduction: widening

Plantar flexion: movement of the ankle; ankle extension; movement of the foot and ankle away from the tibia

Posterior: at the back

Proximal: closer to the body

Sagittal plane: vertical plane dividing the body into left and right halves

Syndesmosis: fibrous articulation; distal ends of the tibia and fibula are fixed by four ligaments: the anterior inferior tibiofibular ligament (AITFL), the posterior tibiofibular ligament (PTFL), the transverse ligament and the interosseous ligament (IOL)

Talus: foot bone; forms the lower point of the ankle joint

Talus trochlea: part of the talus; articulates with the tibia

Tibia: larger of the two distal leg bones; responsible for bearing most of the lower leg weight

Tibia periosteum; membrane covering the tibia

Tibiofibular: between tibia and fibula

Tricortical screw placement for syndesmosis; bone screws go through medial and lateral parts of the fibula and the lateral part of the tibia

Quadricortical screw placement for syndesmosis: bone screws go through the medial and lateral parts of both the tibia and fibula

Appendix

Appendix A: Objectives Tree

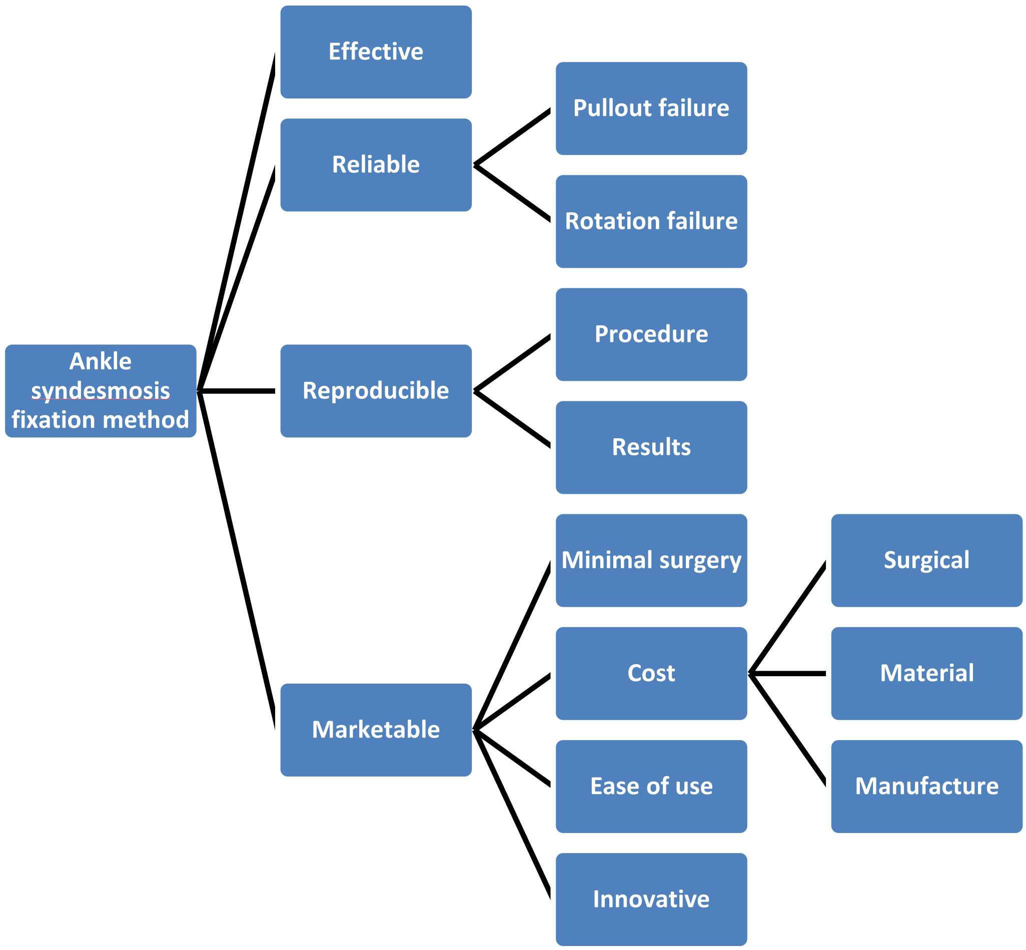


Figure 0-1: Objective Tree

The objective tree listed all primary and secondary objectives.

Appendix B: Pairwise Comparison Charts

Table 0-1: Pairwise Comparison – Reliable

This pairwise comparison chart ranked secondary objectives for reliability.

	Pullout	Back-out	Rotational	*Total*
Pullout		1	1	*2*
Back-out	0		1	*1*
Rotational	0	0		*0*

Table 0-2: Pairwise Comparison – Reproducible

This pairwise comparison chart ranked secondary objectives for reproducibility.

	Procedure	Results	*Total*
Procedure		0	*0*
Results	1		*1*

Table 0-3: Pairwise Comparison – Marketability

This pairwise comparison chart ranking secondary objectives for marketability.

	Minimal Surgery	Cost	Ease of use	Improved performance	*Total*
Minimal Surgery		1	1	0	*2*
Cost	0		0	0	*0*
Ease of use	0	1		0	*1*
Improved performance	1	1	1		*3*

Appendix C: Test Rig for Pullout Testing

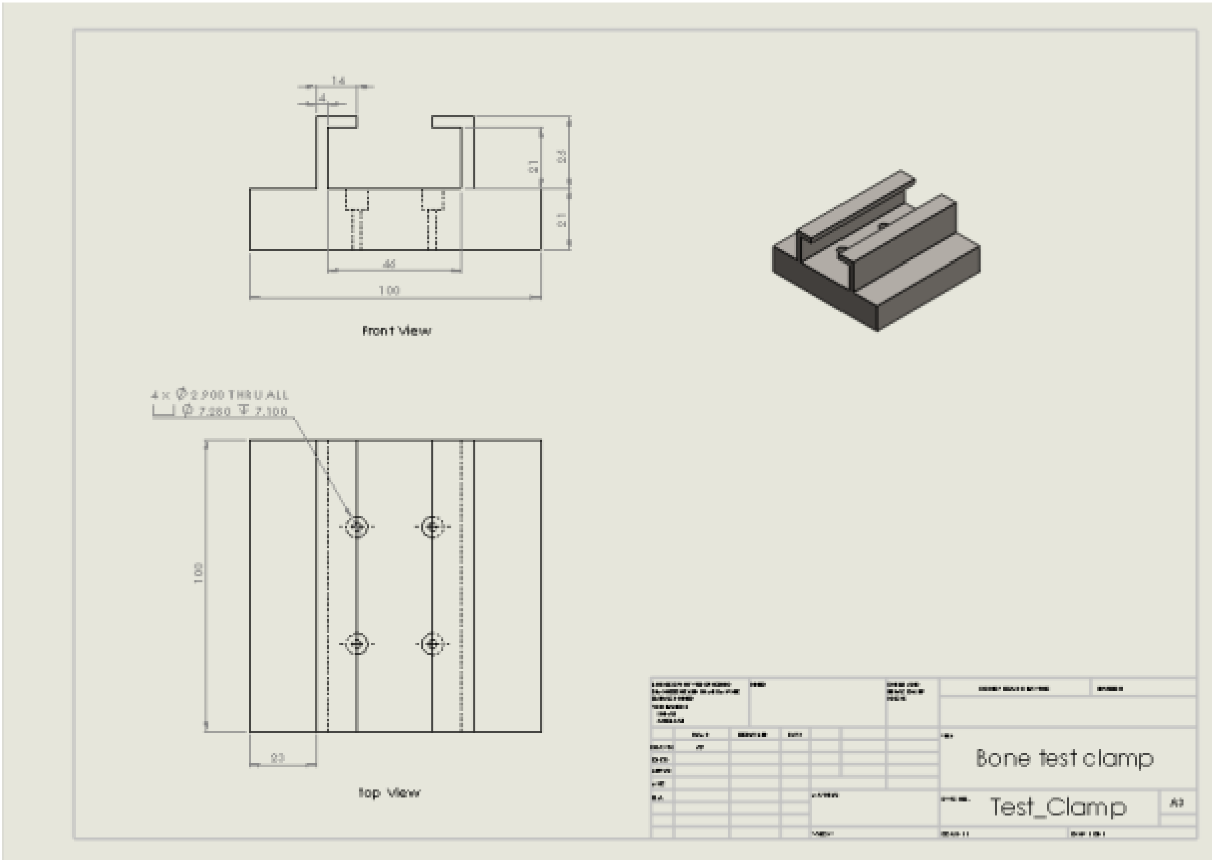


Figure 0-3: Test Rig for Pullout Testing

This test rig held the PU test block for the pullout testing.

Appendix D: MATLAB code for Pullout Testing

```
%% Import Data

clear; clc; close all;
straight2='test0_2.csv';
twenty2='test23_2.csv';
twenty4='test23_4.csv';
fourty5='test45_5.csv';
fourty8='test45_8.csv';
%% Assign variables
a2=dlmread(straight2,',',[13 0 390 5]);

b2=dlmread(twenty2,',',[13 0 464 5]);
b4=dlmread(twenty4,',',13,0);

c5=dlmread(fourty5,',',[13 0 1015 5]);
c8=dlmread(fourty8,',',13,0);



% time
ta2=(-1)*a2(:,6)-0.1;

tb2=(-1)*b2(:,6)- 0.25;
tb4=(-1)*b4(:,6) - 0.25;

tc5=(-1)*c5(:,6) - 0.75;
tc8=(-1)*c8(:,6) - 0.75;

% force
fa2=a2(:,1)-200;

fb2=b2(:,1)-200;
fb4=b4(:,1)-200;

fc5=c5(:,1)-200;
fc8=c8(:,1)-200;

%% plot
figure(1);
subplot(3,1,1)
plot(ta2,fa2, 'b');
subplot(3,1,2)
plot(tb2,fb2, 'r');
hold on
plot(tb4,fb4, 'k');
subplot(3,1,3)
plot(tc5,fc5, 'b');
hold on
plot(tc8,fc8, 'r');


figure(2)
plot(ta2,fa2, 'b');
hold on
plot(tb2,fb2, 'r');
hold on
plot(tc5,fc5, 'm');
```

Appendix E: Holding Device for Shear Testing

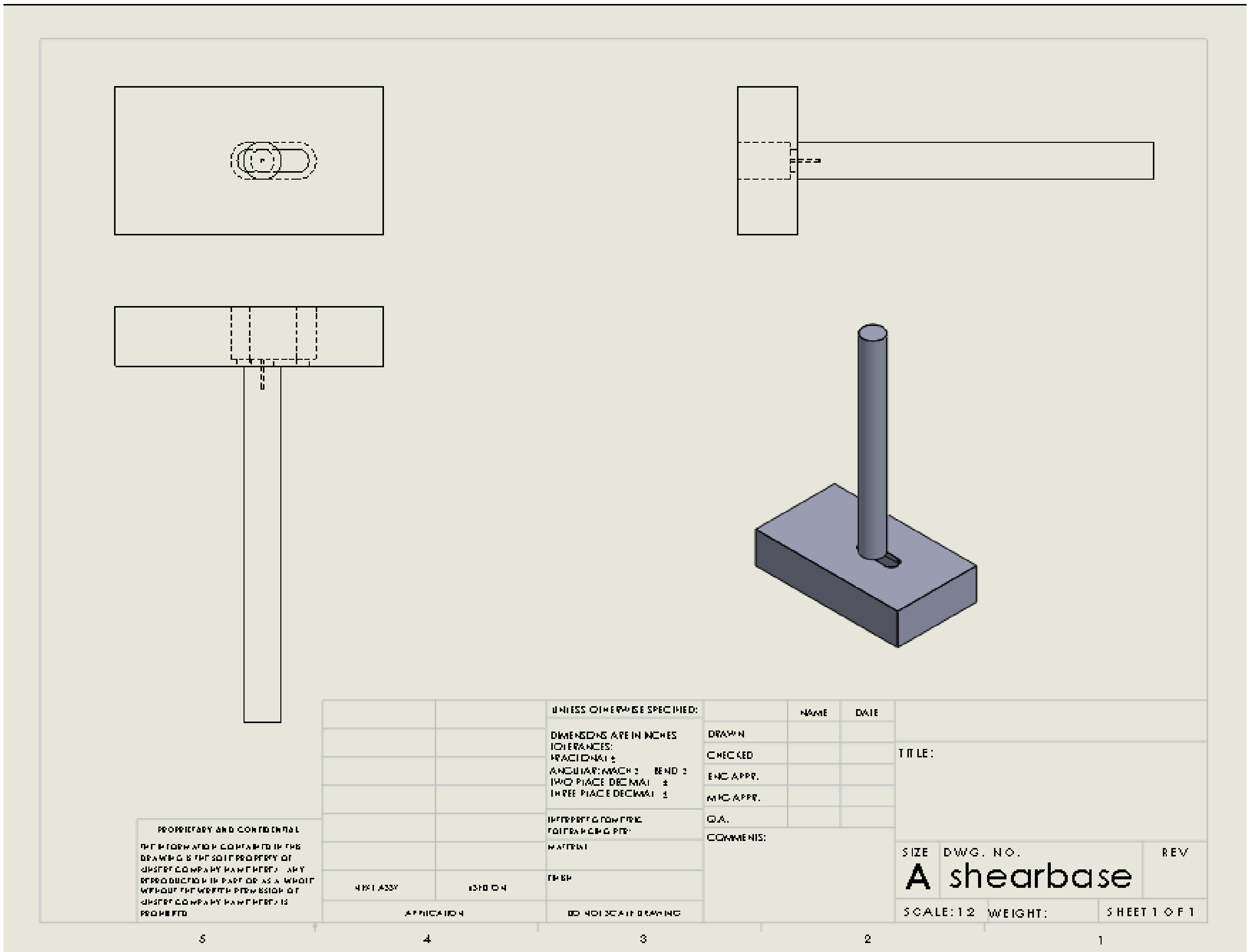


Figure 0-4: Test Rig for Shear Testing

This test rig held the sawbones for the shear testing. The rod inserted into the tibia.

Appendix F: MATLAB Code for Load-to-Failure and Cyclic Testing

```
%% Import Data

clear; clc; close all;
angle1='realangle1.csv';
angle2='realangle2.csv';
angle3='realangle3.csv';
angle4='realangle4.csv';
angle5='realangle5.csv';

straight1='straight1.csv';
straight2='straight2.csv';
straight3='straight3.csv';
straight4='straight4.csv';
straight5='straight5.csv';
straight6='straight6.csv';
straight7='straight7.csv';
straight8='straight8.csv';
straight9='straight9.csv';
straight10='straight10.csv';
straight11='straight11.csv';

%% Assign variables
a1=dlmread(angle1,',',[13 0 51 5]);
a2=dlmread(angle2,',',[13 0 51 5]);
a3=dlmread(angle3,',',[13 0 51 5]);
a4=dlmread(angle4,',',[13 0 51 5] );
a5=dlmread(angle5,',',[13 0 51 5]);

s1=dlmread(straight1,',',[13 0 51 5]);
s2=dlmread(straight2,',',[13 0 51 5]);
s3=dlmread(straight3,',',[13 0 51 5]);
s4=dlmread(straight4,',',[13 0 51 5]);
s5=dlmread(straight5,',',[13 0 51 5]);
s6=dlmread(straight6,',',[13 0 51 5]);
s7=dlmread(straight7,',',[13 0 51 5]);
s8=dlmread(straight8,',',[13 0 51 5]);
s9=dlmread(straight9,',',[13 0 51 5]);
s10=dlmread(straight10,',',[13 0 51 5]);
s11=dlmread(straight11,',',[13 0 51 5]);

% time
ta1=a1(:,6);
ta2=a2(:,6);
ta3=a3(:,6);
ta4=a4(:,6);
ta5=a5(:,6);

ts1=s1(:,6);
ts2=s2(:,6);
ts3=s3(:,6);
ts4=s4(:,6);
ts5=s5(:,6);
ts6=s6(:,6);
ts7=s7(:,6);
ts8=s8(:,6);
ts9=s9(:,6);
ts10=s10(:,6);
ts11=s11(:,6);

% force
fa1=a1(:,1);
fa2=a2(:,1);
fa3=a3(:,1);
fa4=a4(:,1);
fa5=a5(:,1);

fs1=s1(:,1);
fs2=s2(:,1);
fs3=s3(:,1);
fs4=s4(:,1);
fs5=s5(:,1);
fs6=s6(:,1);
fs7=s7(:,1);
fs8=s8(:,1);
fs9=s9(:,1);
fs10=s10(:,1);
fs11=s11(:,1);

% position
pxa1=a1(:,5);
pxa2=a2(:,5);
pxa3=a3(:,5);
pxa4=a4(:,5);
pxa5=a5(:,5);

pxs1=s1(:,5);
pxs2=s2(:,5);
pxs3=s3(:,5);
pxs4=s4(:,5);
pxs5=s5(:,5);
pxs6=s6(:,5);
pxs7=s7(:,5);
pxs8=s8(:,5);
pxs9=s9(:,5);
pxs10=s10(:,5);
pxs11=s11(:,5);
```

```matlab
%% plot
figure(1);
subplot(3,1,1)
plot(ta5,fa5, 'b');
subplot(3,1,2)
plot(ts6,fs6, 'r');
subplot(3,1,3)
plot(ta5,fa5, 'b');
hold on
plot(ts6,fs6, 'r');

figure(2);
plot(ta5,fa5, 'b');
hold on
plot(ts6,fs6, 'r');

figure (3)
plot(ta1,fa1, 'b');
hold on
plot(ta2,fa2, 'r');
hold on
plot(ta3,fa3, 'c');
hold on
plot(ta4,fa4, 'g');
hold on
plot(ta5,fa5, 'm');

figure (4)
plot(ta1,fa1, 'b');
hold on
plot(ta2,fa2, 'r');
hold on
plot(ta3,fa3, 'c');
hold on
plot(ta5,fa5, 'm');


tss1=ts1+1;
tss2=ts2+1;
tss8=ts8+1;
tss9=ts9+1;
tss11=ts11+1;

figure (5)
plot(tss1,fs1, 'b');
hold on
plot(tss2,fs2, 'r');
hold on
plot(ts3,fs3, 'c');
hold on
plot(ts4,fs4, 'g');
hold on
plot(ts5,fs5, 'm');
hold on
plot(ts6,fs6, 'k');
hold on
plot(ts7,fs7, 'y');
hold on
plot(tss8,fs8,'--g');
hold on
plot(tss9,fs9,'--m');
hold on
plot(ts10,fs10,'--k');
hold on
plot(tss11,fs11,'--y');

figure (6)

plot(tss2,fs2, 'r');
hold on
plot(ts5,fs5, 'm');
hold on
plot(tss8,fs8,'--g');
hold on
plot(tss9,fs9,'--m');
hold on
plot(tss11,fs11,'--y');


pa1=polyfit(ta1,fa1,2)
pa2=polyfit(ta2,fa2,2)
pa3=polyfit(ta3,fa3,2)
pa5=polyfit(ta5,fa5,2)

pa=[-2537.6 7222.4 -4699.8];
fa=polyval(pa,ta1);

pa11=polyfit(ta1,fa1,3)
pa22=polyfit(ta2,fa2,3)
pa33=polyfit(ta3,fa3,3)
pa55=polyfit(ta5,fa5,3)

paa=[194.15 -3369.55 5167.175 -5226.45];
faa=polyval(paa,ta1);

figure(7)
plot(ta1,fa,'b')
hold on
plot (ta1,faa,'r')

figure (8)
plot(ta1,fa1, 'b');
```

```
hold on
plot(ta2,fa2, 'r');
hold on
plot(ta3,fa3, 'c');
hold on
plot(ta5,fa5, 'm');
hold on
plot(ta1,fa, '--k');

% from basic fit
paaa=[-2707.5 43950 -159500 267500 -210000
63250] ;
faaa=polyval(paaa,ta1);

figure(9)
plot(ta1,fa1, 'b');
hold on
plot(ta2,fa2, 'r');
hold on
plot(ta3,fa3, 'c');
hold on
plot(ta5,fa5, 'm');
hold on
plot(ta1,faaa, '--k');


figure(10)
plot(ta1,fa1, 'r');
hold on
plot(ta2,fa2, 'r');
hold on
plot(ta3,fa3, 'r');
hold on
plot(ta5,fa5, 'r');
hold on
plot(tss2,fs2, '--b');
hold on
plot(ts5,fs5, '--b');
hold on
plot(tss8,fs8,'--b');
hold on
plot(tss9,fs9,'--b');
hold on
plot(tss11,fs11,'--b');

figure(19)
plot(pxa1,fa1, 'r');
hold on
plot(pxa2,fa2, 'r');
hold on
plot(pxa3,fa3, 'r');
hold on
plot(pxa5,fa5, 'r');
hold on
plot(pxs2,fs2, '--b');
hold on
plot(pxs5,fs5, '--b');
hold on
plot(pxs8,fs8,'--b');
hold on
plot(pxs9,fs9,'--b');
hold on
plot(pxs11,fs11,'--b');


%% single screws
sangle1='singleangle1.csv';
sangle2='singleangle2.csv';
sangle3='singleangle3.csv';
sstraight1='singlestraight1.csv';
sstraight2='singlestraight2.csv';
sstraight3='singlestraight3.csv';

sa1=dlmread(sangle1,',',[13 0 35 5] );
sa2=dlmread(sangle2,',',[13 0 35 5]);
sa3=dlmread(sangle3,',',[13 0 35 5]);

ss1=dlmread(sstraight1,',',13,0);
ss2=dlmread(sstraight2,',',[13 0 35 5]);
ss3=dlmread(sstraight3,',',[13 0 36 5]);

ss2b=dlmread(sstraight2,',',36,0);
ss3b=dlmread(sstraight3,',',37,0);

tsa1=sa1(:,6);
tsa2=sa2(:,6);
tsa3=sa3(:,6);

tss1=ss1(:,6);
tss2=ss2(:,6);
tss3=ss3(:,6);



fsa1=sa1(:,1);
fsa2=sa2(:,1);
fsa3=sa3(:,1);

fss1=ss1(:,1);
fss2=ss2(:,1);
fss3=ss3(:,1);

fss2b=ss2b(:,1);
```

```
fss3b=ss3b(:,1);

psa1=sa1(:,5);
psa2=sa2(:,5);
psa3=sa3(:,5);

pss1=ss1(:,5);
pss2=ss2(:,5);
pss3=ss3(:,5);

pss2b=10+ss2b(:,5);
pss3b=10+ss3b(:,5);

%% plot single screws
figure(11)
plot(tsa1,fsa1,'k')
hold on
plot(tsa2,fsa2,'b')
hold on
plot(tsa3,fsa3,'g')

figure(12)
plot(tss1,fss1,'k')
hold on
plot(tss2,fss2,'b')
hold on
plot(tss3,fss3,'g')

figure (13)
subplot(2,1,1)
plot(tsa2,fsa2)
hold on
plot(tsa3,fsa3)

subplot(2,1,2)
plot(tss2,fss2)
hold on
plot(tss3,fss3)

figure(14)
subplot(2,1,1)
plot(psa2,fsa2)
hold on
plot(psa3,fsa3)

subplot(2,1,2)
plot(pss2,fss2)
hold on
plot(pss3,fss3)

figure(15)
plot(psa2,fsa2,'r')
hold on
plot(psa3,fsa3,'r')
hold on
plot(pss2,fss2,'--b')
hold on
plot(pss3,fss3,'--b')
hold on
plot(pss2b,fss2b,'--b')
hold on
plot(pss3b,fss3b,'--b')
```

Appendix G: Full Results of Maximum Strength from Pullout Testing

Table 0-4: Maximum Strength from Pullout Testing

The maximum strengths per sample with average and standard deviation for each insertion angle.

sample	0 degrees	23 degrees	45 degrees
1	1777.6	950.3	1120.9
2	1735.1	1391.4	1075.7
3	1354.3	1593.2	922.4
4	1472.3	1122.3	1189.5
5	1890.6	1022.2	1025.5
6			1175
7			938.6
8			939.8
Average	1645.98	1215.88	1048.425
Standard dev.	223.8008	269.248746	108.357

Appendix H: One-way ANOVA test for Pullout data

Table 0-5: One-way ANOVA test

Numbers used to run the one-way ANOVA test and Tukey HSD.
If the critical value was greater than or equal to 2.18, the corresponding p-value was $p < 0.05$ and was considered significant.

0	5	1646	224					h12	5		
23	5	1215	269					h13	6.153846		
45	8	1048	108					h23	6.153846		
	SS	df	MS	F	p						
between	1114652.500	2.000	557326.250	14.620	0.000						
within	571796.000	15.000	38119.733								
total	1686448.500	17.000									

$$t_s = \frac{M_i - M_j}{\sqrt{\dfrac{MSE}{n_h}}}$$

			ts		
	0,23	Mi=1646, Mj=1215	4.9361386	sig	
	0,45	Mi=1646, Mj=1048	7.5980049	sig	
	23,45	Mi=1215, Mj=1048	2.1218509	just barely not sig	
		For the probability value to be less than or equal to 0.05, the absolute value of the t statistic must be 2.18 or greate			

Appendix I: Full Results of Maximum Loading from Cyclic Testing

Table 0-6: Maximum Loading from Cyclic Shear Tests

The maximum loads per sample with average and standard deviation for both screw systems

	0 and 23	0 and 0
	483.7	253.5
	494.9	265.1
	538.8	301.9
	495.9	288.1
		281.9
Average	503.325	277.15
Standard dev.	24.28804576	19.07249328