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Development of a New Implant System for the Correction of Coxofemoral Luxation in Canines

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DEVELOPMENT OF NEW IMPLANT SYSTEM FOR CORRECTION OF
COXOFEMORAL LUXATION IN CANINES

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

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Approved:

Prof. Glenn Gaudette, Advisor

1. Toggle rod
2. Coxofemoral luxation
3. Novel implants



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2. Introduction	NP
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4. Project Approach	NP, JS
5. Design	All
6. Methods	All
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1 Abstract

The goal of this project was to improve both the success and ease of use of the toggle pinning procedure currently used for treating hip dislocation in canines. Through interviews with veterinarians and orthopedic surgeons across the country, the major limitations with the current procedure were identified as suture breakage, complicated instrumentation, and difficulty in the hole alignment between the femoral head and the acetabulum. Suture breakage was addressed through the design of a new implant which features rounded edges and an increased surface area. Results from uniaxial tensile testing showed that the suture held 30% more load when wrapped through our novel design as compared to the toggle rod. In addition, the current aiming guide was redesigned to reduce the mechanism to a two part system with increased clearance, thereby simplifying the device while making it easier to use. Finally, the difficulty of hole alignment was addressed through the design of a novel suture sheath to protect the suture from the sharp edges of the bone. We believe the system we have developed makes the procedure easier to perform while remaining cost effective.

2 Introduction

In the past decade, much has changed in the attitude and mentality of a family towards its pets. In a survey conducted in 2006, it was found that nearly 49% of households consider animals a part of their family. In addition, the survey found that the number of households with pets has increased from 58.3% in 2001 to 59.5% in 2006 (1). These statistics show that in addition to becoming more popular, pets are being treated with almost as much care and attention as a child.

With this new mentality towards the family pet, it is not a surprise that there has been a significant increase in the amount of money a household will spend to keep pets healthy. In 2001, Americans spent \$22.4 billion on veterinary expenditures. A survey conducted five years later, in 2006, showed that the total amount of money spent on the care of household pets rose to nearly \$24.5 billion, an increase of \$2.1 billion (1). This increase was due solely to an increase in expenditure, rather than a product of inflation.

With more money being spent to care for family pets, the past decade has shown an increased drive to improve veterinary treatments. With dogs in particular, this push has led to many significant breakthroughs in surgical procedures and medical care. Ron DeHaven, a member of the American Veterinary Medical Association, commented that, “Diseases that once would have been difficult to treat –diabetes, heart disease, cancer – today are very treatable. We are even putting pacemakers in dogs (1).” The statistics show that DeHaven’s claim is true. In 1987, only 32% of dogs were above the age of six. Currently, of the 72 million dogs nationwide, 44% of them are older than the age of six which indicates that these improved treatments are helping dogs live longer and healthier lives.

One of the companies that has played a significant role in this growth of veterinary medicine is Securos®. Securos® started with a single product in 1997 and has expanded to seven major product lines, including five current USA patents and three patent applications. Harry Wotton, President\CEO of Securos®, stated that “the veterinary orthopedic profession needed change and Securos® was born (2).” With the help of Securos, as well as other veterinary medical supply companies, the injuries and diseases that previously resulted in the euthanization of a pet can now be successfully treated.

The drive to improve veterinary medicine has resulted in the design and implementation of many successful treatments. There is a current effort to provide these treatments less

invasively as well as more successfully. Additionally, these new treatments are targeted at general practitioners and veterinary surgeons alike, such that all veterinarians are capable of performing these procedures.

A common canine injury, due to trauma and old age, is hip dislocation, also known as coxofemoral luxation. This injury occurs when the round ligament ruptures, which causes the femoral head to be dislodged from the acetabular cup. Coxofemoral luxation often occurs after prolonged hip dysplasia has remained untreated, or a traumatic injury in which the hip joint is subjected to a large impact (3). Treatment options for this injury include both invasive and non-invasive means. Non-invasive means are much simpler and cheaper; however, relaxation is much more common following a non-invasive correction. Although numerous invasive techniques have been identified as treatment options, none have been proven to be more successful than any other. The main aim of our project is to create a new system of implants and instrumentation which will increase the success rate of current toggle pinning procedure, while making less invasive and easier to complete.

3 Background

3.1 Anatomy of a Dog

This chapter will introduce information necessary for the understanding of our project. The background includes the anatomy of a dog (pertaining to the hip), information on coxofemoral luxation and current methods of treatment.

3.1.1 Joints

Joints, also known as articulations, are formed when two or more bones are united by fibrous, elastic or cartilaginous tissue. These three classifications of joints have different functions, and are thus different in nature. The first type of joint is the fibrous joint, which allows very little motion. Fibrous joints include sutures, as found in the skull, and gomphoses, which are the tooth sockets. The second type of joint is the cartilaginous joint, which permits only limited movement, including compression or stretching. Fibrocartilage and hyaline cartilage, which is found in the epiphyseal plate of the long bones in growing animals, are two types of cartilaginous joints. The last type of joint is the synovial joint, which facilitates the greatest amount of movement. Synovial joints are characterized by a joint cavity, a joint capsule, synovial fluid, and articular cartilage.

The joint capsule in a synovial joint is comprised of an inner synovial membrane and an outer fibrous membrane. Vascular connective tissue lines the inner surface of the joint capsule and produces synovial fluid in the inner synovial membrane. Synovial fluid is a vital part of a synovial joint because it lubricates the joint, decreases friction, and increases the effectiveness of the joint. Synovial fluid is also responsible for transporting nutrients and removing waste from the joint, due to the avascular nature (3). The articular cartilage in synovial joints lines the joint end of bone, and provides the loading and unloading mechanism to resist load and shock.

Synovial joints are the most prevalent joint in the body. There are many types of synovial joints, including gliding joints, such as the carpals of the wrist that allow gliding or sliding movements; hinge joints, such as the elbow, that allow flexion and extension in one plane; pivot joints, which enable one bone to rotate about another; and finally, ball and socket joints, such as the shoulder or hip joints.

3.1.2 Hip Joint

One of the two ball and socket joints in the body is the articulatio coxae, or the hip joint. The hip joint is formed by the head of the femur articulating with a capsule within the pelvic girdle: the acetabulum. There are four bones that make up the pelvic girdle as shown in Figure 1. They include: the ilium, the ischium, the pubis, and the acetabular bone. The bones of the hip are symmetrical across the sagittal plane of the dog, and any asymmetry could indicate a pelvic fracture or hip dislocation.

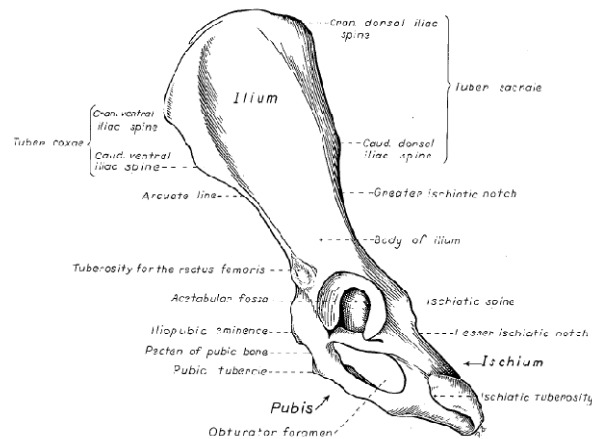


Figure 1: Left hip bone, lateral view (4)

3.1.2.1 Acetabulum

The acetabulum is a concave surface of the hip bone in which the head of the femur articulates to form the coxofemoral joint. There are three bones of the os coxae (hip bone) that come together to form the acetabulum. The ischium provides the lower and side boundaries to the acetabulum, the ilium forms the upper boundary, and the rest of the acetabulum is formed by the pubis.

In medium-sized dogs, the acetabulum is on average one centimeter deep and two centimeters in diameter (5). The acetabular lip is a band of fibrocartilage that enables the femur to have full range of motion within the acetabulum. The joint capsule attaches a few millimeters from the acetabular lip, while on the neck of the femur it attaches one to two centimeters from the head (5).

3.1.2.2 Femur

The femur is a long bone with an enlarged and smooth head. It is the heaviest bone in the dog skeleton; the femur is slightly shorter than the tibia and the ulna, and about one-fifth longer than the humerus. It articulates with the hip joint, forming a flexor angle of 110° (4). The smooth surface of the head is covered by a layer of hyaline cartilage. The enlargement of the head serves two purposes: it diminishes the risk of the dislocation of the hip, and it provides a large surface area for articulation.

The right and left femurs lie in parallel sagittal planes, with the flexor angles of the two joints facing in opposite directions (4). The head of the femur is supported by the neck and three trochanters. The fovea, a distinct landmark of the femur, is a small circular pit in the middle of the head. The fovea is important because it serves as the attachment of the round ligament of the hip joint. Depictions of the femur are shown in Figure 2.

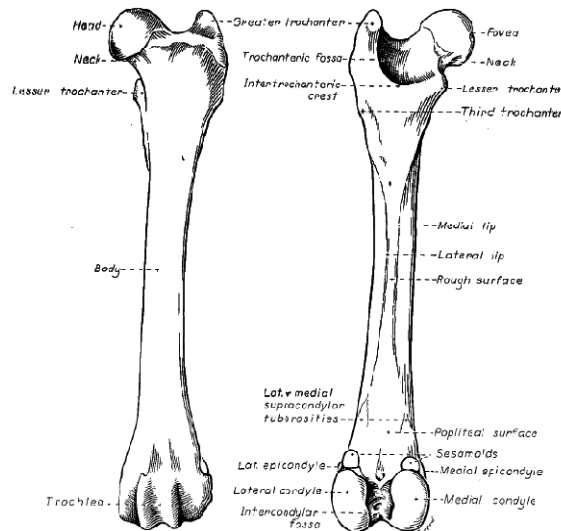


Figure 2: Left – left femur, cranial view; right – left femur, caudal view (4)

3.1.2.3 Ligaments

A ligament is a band of nearly pure collagenous tissue that connects two bones. Ligaments are very inelastic: if a tensile load exceeds the ligament's elasticity, the collagen fibers will become permanently damaged. This occurs at about 10% elongation of the ligament (3). In the hip, the ligament that attaches the head of the femur to the acetabulum is the round ligament as can be seen in Figure 3. This ligament is located at the head of the femur, and it extends from the femur to the acetabular fossa (4). The round ligament, which is covered by a synovial membrane, is not weight bearing. In fact, in the hip, the heavy muscles that transverse

the joints are more responsible for holding the femur in place than the ligaments. In large dogs, the round ligament measures 1.5 centimeters long and five millimeters wide at the femoral attachment (4). A rupture of this ligament may lead to a common injury known as coxofemoral luxation.

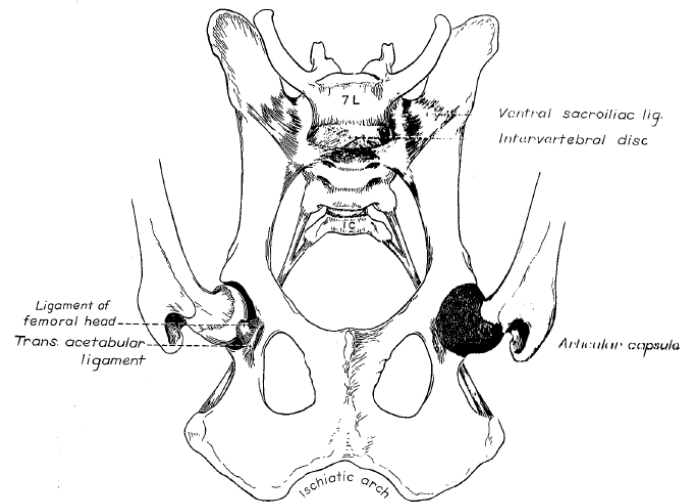


Figure 3: Ligaments of the pelvis, ventral view (4)

3.2 Coxofemoral Luxation

Luxation is often referred to as dislocation, a separation of articulating joint surfaces. Complete luxation can be defined as complete traumatic separation of co-fitting joint parts as well as complete tear of associated ligaments. Sub-luxation is a partial dislocation of the joint capsule.

Although possibly resulting from preexisting conditions such as hip dysplasia or arthritis, coxofemoral luxation in dogs is typically reported following automobile accidents (60%) or the consequence of a dramatic fall resulting with bone fracture (6). Although possible in dogs of all breeds and ages, luxation typically occurs in dogs over 10 months of age, that have been involved in some form of major trauma (7).

The hip is the most commonly luxated joint in the dog. Coxofemoral luxation accounts for 90% of all luxations in dogs (6). The hip, as described previously, is a typical ball and socket joint, but is not well protected against luxation. The lack of collateral ligaments and stabilization makes the hip prone to this disorder. Typical traumatic occurrences limit the injury to unilateral

luxation, although bilateral luxation is also possible. The luxation is typically in the cranio-dorsal direction; characterized by external rotation of the femoral head, and adducted limb position. The leg is shortened as compared to the opposing limb. The head of the femur is rotated dorsally and cranially exposing the greater trochanter towards the posterior side of the dog. Cranio-dorsal luxation, as shown in Figure 4, results in the limb adducted, with the stifle (knee joint) externally rotated. Occurrence of this luxation is a result of a longitudinal force on the long axis of the leg to drive the femur cranially and dorsally.

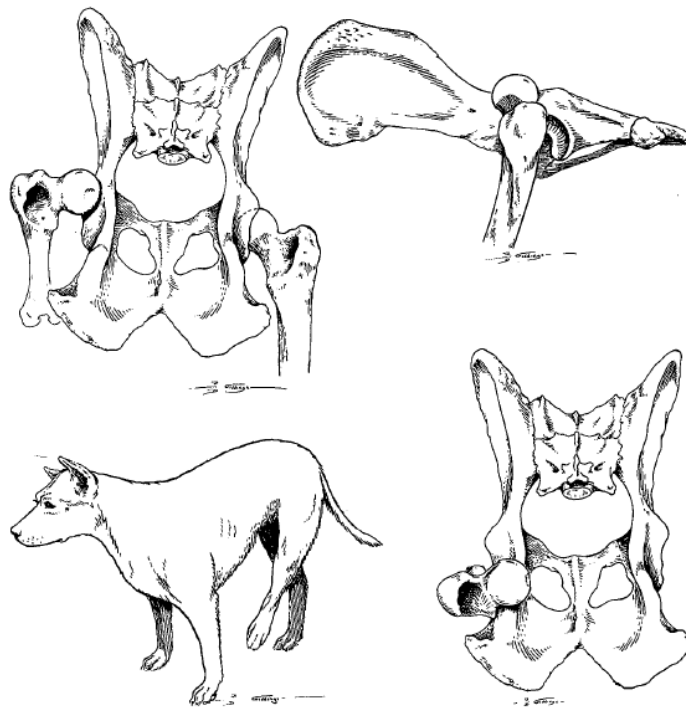


Figure 4: Top left – craniodorsal luxation, dorsal view; Top right – craniodorsal luxation, lateral view; Bottom left – typical stance of a dogs with a craniodorsal luxation. The leg is eternally rotated and adducted; Bottom right – caudodorsal luxation, dorsal view (3)

Caudo-ventral displacements, associated with the fracture of the head of the femur, are far less common than the cranio-dorsal luxation, and result in the femoral head lodged within the obturator foramen. Caudo-ventral luxation, as shown in Figure 5, results in the limb abducted, with the stifle rotated internally. Central dislocations of the femur are really fractures of the acetabulum that allow the femoral head to protrude into the pelvis lumen.

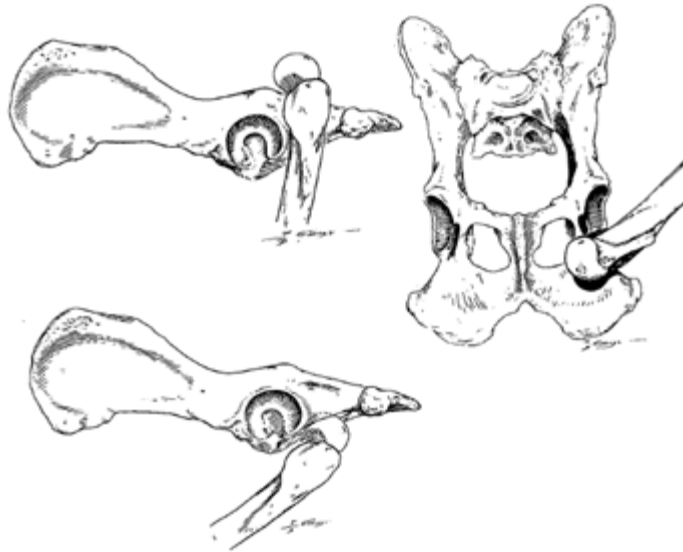


Figure 5: Top left – caudodorsal luxation, lateral view; Top right – ventral luxation, ventral view; Bottom left – ventral luxation, lateral view (3)

Damage in association with luxation is not confined to the joint capsule itself. Luxations are typically complex injuries with several injuries, including muscular, neurovascular, ligament damage, as well as bone fracture. If the other primary stabilizers of the hip, joint capsule and acetabulum have been damaged beyond primary repair, surgical methods for their correction must be explored.

Basic veterinary diagnosis begins with the comparison of damaged and healthy limbs. A lack of symmetry can be noted between the tuber ischii and greater trochanter on the affected side compared with the normal limb. With cranio-dorsal displacement, the greater trochanter is dorsal to an imaginary line drawn from the crest of the ilium to the tuber ischii and the distance between the tuber ischii and greater trochanter is greater than in the normal limb. With a ventro-caudal luxation, the greater trochanter is displaced ventrally and the space between the tuber ischii and the greater trochanter may be narrowed.

Confirmation of hip luxation is completed with ventro-dorsal and lateral radiographs. Radiographs should be evaluated before deciding which method of repair will be chosen as evidence of avulsion of the fovea capitis, associated hip joint fractures, and degenerative changes.

If the dog is hit by a car from behind, the animal starts to fall toward the hip and the rear leg moves into adduction precipitating luxation. It is believed that the center of gravity of the dog

moves lateral to the hip joint and as the hip moves toward the ground, the long lever arm of the adducted femoral shaft draws the femoral head out of the acetabulum as far as the joint capsule will allow (8). When the greater trochanter strikes the ground, the force is transmitted through the femoral neck to the head, pushing the head of the femur over the dorsal rim of the acetabulum, shearing the joint capsule and the round ligament. Cranio-dorsal luxation can also result from the rear legs being forced to the ground ventrally, with the weight bearing leg already extended. In this case, the hip and knee both flex. The knee withstands the impact of the ground before the hip can, resulting in the pelvis moving in a ventral and external rotation. If the force of the trauma exceeds the allowable force of the round ligament and the joint capsule ruptures, the tension of the surrounding muscles results in luxation (8).

3.3 Treatment

The repair of coxofemoral luxation must reduce the joint to its correct anatomical position and enable its full range of motion. Depending on the severity of the trauma, non-invasive procedures (closed reduction) or invasive surgical techniques (open reduction) can be performed to treat the luxated joint (6).

3.3.1 Closed Reduction

A closed reduction, as shown in Figure 6, is a non-invasive procedure that manipulates the surrounding muscle and ligaments to reduce the luxated joint (3). In order to relax the pelvic muscles and reduce pain, general anesthesia is administered to the patient prior to the procedure. For a craniodorsal luxation, the patient is placed in the lateral recumbent position; the affected limb is externally rotated while pressure is simultaneously applied to the greater trochanter. The femoral head is maneuvered until it is set in the craniodorsal rim of the acetabulum (9). For large breed dogs, a rope can be wrapped around the groin to serve as countertraction. Reduction is confirmed when a “pop” sound can be heard indicating the femur has been placed back in the correct anatomical position. For a less common ventral luxation, the femur is maneuvered distally and laterally to reduce the joint (3).

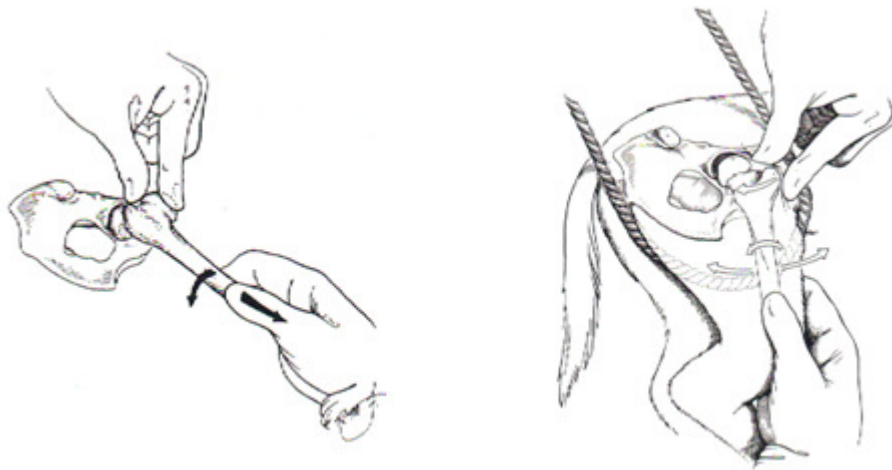


Figure 6: Closed Reduction Procedure (3)

The closed reduction procedure is generally completed with a success rate of 35-50% when the patient is treated within 72 hours of trauma. Immediate treatment is critical because the surrounding muscle and soft tissue begin to atrophy and block clear access to the acetabulum when the ligament is detached (3). If patients suffer hip dysplasia or other forms of degenerative joint diseases, relaxation is common. The recovery period following a closed reduction surgery is generally 7-10 days during which the affected leg is supported in an Ehmer sling (6). Although relaxation is more common in dogs that have undergone a closed reduction surgery, the relative cost of a closed reduction is much less than that of an open reduction surgery. Additionally, it has been shown that a failed closed reduction procedure does not affect the success rate of an open reduction (3). For these reasons, closed reduction is often the first treatment option, and if relaxation occurs, an open reduction surgery is attempted (10).

3.3.2 Open Reduction

An open reduction is an invasive surgical procedure that can be executed either by extra-articular or intra-articular means. The surgery is performed to reduce the coxofemoral joint and provide stability for 3-4 weeks thereafter (3). Success rates of open reduction surgeries are generally 85-90%, and thus, although invasive, are often pursued as treatment options (11).

Extra-articular methods of open reduction surgery involve the replacement of the surrounding stabilizers of the joint in order to allow contiguous biological tissue to heal and maintain the reduction. This usually includes repair of the coxofemoral joint capsule or muscle

attachments. Such procedures include a transposition of the greater trochanter and Devita (ischiolial) pinning which places a pin across the rim of the acetabulum to prevent the femur from pulling away and out of the joint.

In comparison, intra-articular methods directly reconstruct the round ligament located at the head of the femur. Numerous methods that involve a stabilizing pin or rod are common intra-articular techniques. Such methods include the femoral head and neck ostectomy, transacetabular pinning, and toggle pin and suture combination. One particular procedure has not been proven to be superior to another (6). The toggle pin procedure, in particular, has been developed by various companies due to its success.

3.3.3 Toggle Pin Procedure

The toggle pin procedure is a successful method that replaces the round ligament with a non-absorbable suture material anchored by a toggle rod. In preparation for the procedure, general anesthesia is administered to the patient and the affected leg is shaved. The invasive surgery requires an incision of approximately 8 cm. In order to access the coxofemoral joint, a caudal dorsal approach is preferred by some, as the joint is often luxated in this direction. To access the torn ligament, the femur must be externally rotated at a 45° angle. Any remaining ligament or tissue is then removed from the joint to create a clear path to the acetabulum. A hole (of varying sizes depending on the dog and toggle rod being used) is drilled through the femoral head at the original insertion point of the round ligament. An aiming guide, as seen in Figure 7, is used to center the drill bit in the fovea of the femoral head in order to achieve this accuracy.

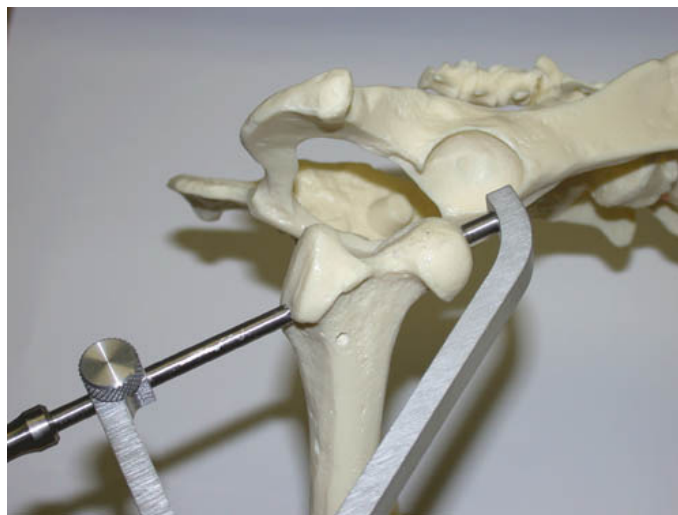


Figure 7: Securos aiming guide centering drill bit (13)

Once the hole has been drilled, the femur is rotated back into the joint capsule. The leg is placed in the normal standing position in order to correctly align the fovea in the acetabulum and ensure full range of motion will result. The hole that was drilled through the femoral neck is then continued through to the medial wall of the acetabulum as shown in Figure 8.



Figure 8: Drilling hole through femur and acetabulum (13)

The femur is once again rotated away from the joint in order to insert the toggle rod through the acetabular wall. The suture is threaded through the toggle rod, and then the rod is placed in an insertion tool. The insertion tool is used to push the rod through to the medial wall of the acetabulum. The suture material is pulled back through the hole in the femoral head (Figure 9) such that the toggle rod acts as an anchor securing the suture to the acetabular wall.

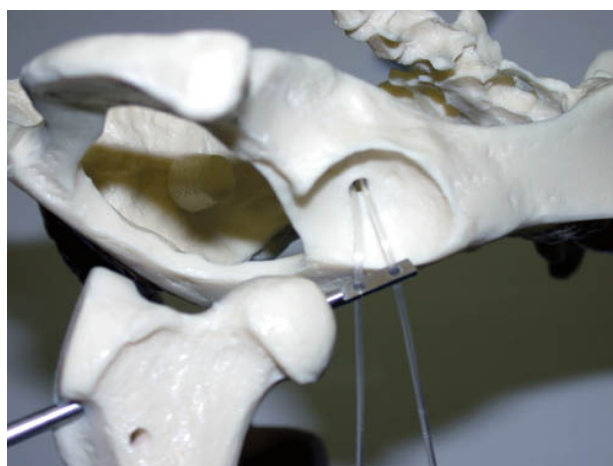


Figure 9: Inserter pulls suture material through holes (13)

A second hole is drilled perpendicular to the first, through the lateral femoral cortex, and is 2-3 mm below the greater trochanter. Each end of the suture material is pulled in opposing directions through this hole. The suture is then wrapped around the lateral side of the femur and secured with one primary crimp clamp and two secondary crimp clamps. The finished procedure, as seen in Figure 10, is completed the procedure in approximately one hour (excluding preparation time).

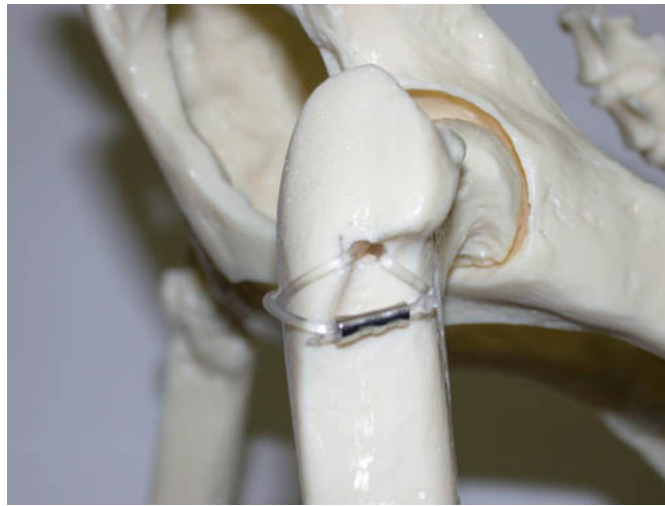


Figure 10: Crimp clamp secures suture material (13)

Postoperative care for the toggle pin procedure includes limiting the patient to minimal activity and prescribing NSAIDS to reduce pain and soreness. An Ehmer sling is used to support the joint while surrounding tissue heals. Patients must remain relatively inactive for 2-3 weeks, and gradually increase activity in order to allow suture material to be integrated into physiological surroundings and biological tissue to be re-incorporated into the joint capsule (3). Anti-inflammatory drugs such as Carprofen can be prescribed to reduce pain and discomfort.

3.3.4 Future Development

Veterinary medicine is developing rapidly as the percentage of pets in American households' increases along with the respective ages of these animals. For this reasons, it is crucial that veterinary medicine be continually improved, both to enhance and prolong the life of animals. Our project intends to adapt the current toggle pin procedure in order to both improve the procedure's overall success and ease of use. Our specific aims, which will be discussed in

greater detail in the next chapter, include the design and testing of an improved toggle rod and suture combination, as well as the development of new and improved surgical instrumentation.

4 Project Approach

4.1 Initial Client Statement

Developing technology in the field of veterinary medicine demands an effective procedure to treat coxofemoral luxation. The relatively high occurrence of hip luxation in dogs and the willingness of pet owners to subsidize the necessary treatment drive the need for the development of a simpler procedure. Current methods require a large incision and the implantation of a device that is difficult to maneuver. Current treatments yield relatively good results, but leave significant room for improvement. The toggle pin procedure in particular requires significant skill to perform and has some failure due to suture breakage. It is for this reason that our client, Securos, a leading veterinary orthopedic company, approached us to develop the instrumentation necessary to introduce an implant to correct coxofemoral luxation using a less invasive technique.

4.2 Objectives

Through our research and discussions with veterinarians across the country, we identified our main objectives. A pairwise comparison chart was used to determine the relative importance of each of our objectives; this chart can be found in Appendix B. After we ranked the objectives as a group, we compared our results to those of our client, Harry Wotton. We found a direct correlation between the importance of our proposed objectives and that of our client.

The three most important objectives of our project are the functionality of our device, the procedure be minimally invasive, and both the device and procedure be safe. The device must be functional such that it stabilizes the coxofemoral joint and allows contiguous biological tissue to re-grow into the cavity. A device that does not function is not practical and cannot be marketed to the user. The procedure we develop must be minimally invasive, as this will be an improvement over any other existing procedures. Through discussions with our client, minimal invasiveness was defined as an increased speed and ease of the procedure, which would decrease the trauma to the patient. These factors were deemed more necessary than decreasing the length of the incision during surgery. Finally, the device and procedure must be safe for both the user and the patient. Without this, our device and technique cannot be incorporated into the market.

In addition, we found that the device must provide longevity of correction, the procedure must be repeatable, and both the device and procedure must be user friendly. Current implants last for three to four weeks, at which time biological tissue is reincorporated into the joint. Our

objective is that our device is durable enough to last for this period of time. It is also important that the procedure be repeatable. It must be a simple procedure in order to be performed easily and repeated by any practicing veterinarian. Finally, both the device and procedure must be user friendly such that the implant is simple to maneuver inside the joint cavity.

In addition to our main objectives, several sub-objectives were also ranked with a pairwise comparison chart. Sub-objectives for the *Functional* objective include correcting coxofemoral luxation and maintaining range of motion. Of these, correcting coxofemoral luxation is most important. The main goal of our device is to correct hip dislocation and restore the function of the round ligament. Thus, although maintaining range of motion is important, it will not be the primary focus of our device.

The most important sub-objective pertaining to *User Friendliness* is that the device be easy to use. In addition, shortening the procedure is of great importance. Current techniques last an hour skin to skin, and thus a sub-objective of our project is that the procedure not exceed this time. Simple to prepare and easy to manufacture are two other sub-objectives that we listed that must be taken into consideration.

It is through the evaluation of all of our objectives and sub-objectives that we have determined which aspects our design should focus on. These same objectives have been deemed important by our client, and thus the success of our project will rely on our achievement of each.

4.3 Functions

To achieve our objectives, it was necessary to identify our functions and means through the use of a functions-means tree (Appendix C). This chart is necessary to properly analyze the primary functions in the design and the means to which each of the functions correlate. When looking at the toggle pin procedure, the functions necessary for a successful surgery are alignment of the femoral head, debriding of the ligament, drilling of a hole, insertion of toggle rod, securing of suture, and the decrease of the stress concentration on the suture. These functions are important to replicate in any alternative designs. One of the most important of these functions is the decrease of the stress concentration on the suture as it is passed through the implant. This function is necessary to avoid re-luxation and to ensure the procedure is successful. Improvement in the reduction of suture breakage has the greatest ability to increase the success of the procedure. The means identified for improving this function are improving the mechanical properties of the suture and improving the mechanical properties of the toggle pin.

In addition, another function which would need further analysis is the alignment of the holes in the femur and acetabulum. It has been found that the proper alignment of the holes is necessary to produce successful results. Because this part of the procedure is quite difficult, it requires the user to have significant skill. Two of the means identified to decrease the skill needed for the procedure was the improvement of the aiming guide design and reduction of the need for hole alignment. These functions and means must be considered throughout the design phase.

4.4 Revised Client Statement

After speaking with the client, Harry Wotton, President/CEO of Securos, the initial client statement was revised to provide a detailed outline of the objectives, functions, and constraints of the project. The results of the design will include a more successful procedure and appropriate instrumentation to correct coxofemoral luxation in medium-sized adult dogs of otherwise good health, while maintaining flexibility and range of motion of the hip. The procedure must be simple to prepare and able to be performed by general veterinary practitioners. While remaining safe and repeatable, the procedure must also be completed within one hour (skin to skin). Following the procedure, the patient must have decreased lameness and restored mobility within one week. The instrumentation must be easy to manufacture at a low cost to the client, be biocompatible and durable. The surgical tools must be integrated into existing technology to therefore simplify the compatibility of this procedure. The development of the procedure and design of the instrumentation must be completed by April 2009.

4.5 Specific Aims – Project Specifications

With the completion of our revised client statement it was necessary to identify the methods by which we intend to accomplish our goals. These methods are our specific aims and are described below.

4.5.1 Improve Overall Success of Procedure

As described by Dr. Mike Kowaleski, an orthopedic surgeon at Tufts Cummings School of Veterinary Medicine, the procedure in its current state is 80% successful. Dr. Kowaleski, as well as the other veterinarians we interviewed, has found that the most common means of failure was the breaking of the suture at the interface of the toggle rod implant. It is the design team's intent

to make the procedure have a 95% success rate. Successful procedures in correcting coxofemoral luxation are typically measured within 16 days of implantation, when the suture and surrounding soft tissue have taken.

4.5.1.1 Design and Test New Toggle Rod and Suture Material Combination

The team was tasked with the design and mechanical testing of a new implant to replace the toggle rod in order to correct coxofemoral luxation in dogs. It has been discussed by professionals and design members alike, that the primary concern with implant failure is the interface between the sutures and stainless steel implant. It was necessary analyze the current toggle rod to identify the reasons for its failure including but not limited to: orientation of the implant, material selection and the limitation of stress concentration and shear loading.

4.5.2 Improve Ease of Procedure

4.5.2.1 Revise Aiming Guide

The aiming guide is a device used to ensure the hole drilled through the femoral head originates exactly where the round ligament was previously attached. One main limiting factor of the current aiming guide is it is difficult to use. It is a three part system that makes it difficult to properly hold the device in alignment while the surgeon is drilling the hole. The current design also does not provide enough clearance to accommodate larger sized femurs. In addition, the current tip of the aiming guide slips out of its position in the fovea, which reduces the accuracy of this device. With these limitations in mind, it was necessary to re-design the aiming guide with the ease of use as the most important criteria.

4.5.2.2 Development of Suture Sheath

The alignment of the holes drilled through the acetabulum and the femoral head are critical to the success of the procedure. It has been noted that accurate alignment is difficult to achieve and often the suture is left rubbing against exposed sections of the bone cortex. This rubbing frequently leads to suture breakage, well before the joint capsule has enough time to heal. The development of a suture sheath, similar to the design of a screw anchor, is intended to protect the suture as it passes through the femoral head. With the insertion of this device in the femoral head, a smooth surface for which the suture can rest is provided, regardless of exact hole alignment. This accomplishes both the overall success of the procedure by increasing the life of

the suture, as well as increasing the ease of the procedure, by decreasing the need for absolute alignment of the drilled holes.

4.6 Assumptions

In order to simplify the design of a system to correct coxofemoral luxation, the following assumptions must be considered:

Although there is no breed, age or sex of dog susceptible to coxofemoral luxation, for the intent of this project it will be assumed that the subject in question will be a healthy and active dog, ranging from two to eight years in age and of medium size. The subject must not have any preceding medical history especially relating to bone structure or the hip specifically. Dogs with hip dysplasia or re-occurring luxation should not be considered.

Simple coxofemoral luxation should be assumed as the diagnosis of all subjects. Specifically the luxation will be assumed to be cranio-dorsal in nature, which accounts for 90% of all luxations in dogs. The luxation must be limited to one leg to further simplify any complications. Although most luxations result from traumatic incidences (60% auto accidents), it must be assumed that no other injuries resulted. In this design, damage associated with luxation will be limited to the joint capsule and not include any other concurrent injuries (acetabular fracture, femoral head fracture, muscular, neurovascular and surrounding ligament damage). The means of luxation must be assumed to be complete a rupture of the round ligament, inducing complete luxation, as sub-luxation will not be investigated.

In accordance with our choice of material, and biocompatibility, titanium will be used for any implantable devices, assuming that titanium does not precipitate infections or a foreign body response. It will be assumed that any implant used will allow for stress distribution, eliminating the possibility of stress concentration and failure. If a suture material is to be used, the material will be assumed to be orthofiber polyblend, providing both strength and flexibility, until further testing procedures are established.

5 Design

5.1 Needs, Analysis & Specifications

Although the current toggle pinning procedure has achieved good success, there are elements to both the procedure and the instrumentation that need improvement. Modifications to the instrumentation and implant will make for an easier procedure and yield a greater success rate. Through discussions with our client, Harry Wotton of Securos, as well as interviews with orthopedic veterinary surgeons and general practitioners, several limitations of the current system were identified. This led to a further recognition of the specific needs of our project, which includes the development of a new aiming guide, toggle rod, insertion tool, and a method to ensure that the drilled holes in the acetabulum and femur are correctly aligned. We decided to focus the design of these devices for the purpose of making the procedure more applicable to general practitioners, or those who may not have the expertise and surgical skill of an orthopedic surgeon.

5.1.1 Simplified Procedure

Initial discussions with Dr. Kowaleski, of Tufts veterinary hospital, led us to the pursuance of a new surgical approach in order to develop a more “minimally invasive” procedure. However, after speaking with Dr. Seponoski, and other general practitioners (Appendix D), it was clear that the development of a new approach would not simplify the toggle pinning procedure. The proposed ventral approach was more difficult than expected due to the complexity of surrounding vasculature. In addition, discussions with our client indicated that the importance of this project lay in the simplification of the system in order for the technique to be adopted by general practitioners. Therefore the focus of this project was geared towards the design and improvement of the surgical devices that will simplify and increase the rate of success of the toggle pinning procedure.

5.1.2 Implant Modification

One of the main limitations of the current toggle rod is the sharp edges that the suture rests upon causing wear and eventual failure. Due to this severe limitation, the design of a new implant was necessary. The device was required to retain the same level of mechanical properties as the toggle rod including the resistance to deformation due to the high tensile forces

that are associated with normal movement of the hind leg. The orientation of the new implant also needed to be aligned along the horizontal axis of the acetabular wall. This orientation provides the best stability, adding to the overall strength of the device. In addition the implant needed to be inserted through the acetabular wall, and therefore its width could not be wider than the drilled hole. A 3.2 or 4.0 mm drill bit is used in the existing technique, thus our designs had to be developed accordingly. Finally, the new implant needed to increase the radius of curvature that the suture rests upon, decreasing the stress concentration found at the suture-implant interface. Ultimately, the new implant needed to eliminate these limitations in order to increase the overall success rate of the procedure.

5.1.3 Insertion Tool Modification

The new implant was designed to be inserted through the acetabular wall and thus required an insertion tool. This tool accommodated the final implant design. There were, however, essential criteria that had to be addressed for the device to function. The insertion tool was required to grasp the implant, transport it through the drilled hole in the acetabulum, and release the implant once inserted through to the medial wall. Additionally, the device needed to be ergonomic and easy to use for the surgeon. These criteria were necessary for the final device to function most effectively and integrate into existing technology.

5.1.4 Suture Sheath

Although suture breakage at the implant interface is one of the main causes of failure, the suture is also susceptible to break where it contacts the rough edges of the bone. It has been established that the holes in both the femur and the acetabulum must be exactly aligned in order for the suture to pass through both bones at a 180° angle. If the holes are not aligned, the suture will pass through the femur at an alternative angle, which will cause it to rub against the sharp edges of the bone. This wear will also cause eventual failure of the suture. It is for this reason that a second implant was designed to prevent the suture from breaking at this point. A hollow implant, inserted through the hole in the femoral head, would also reduce the need for perfect alignment of the holes. If the suture was consistently resting on a smooth surface, it would lessen the likelihood of breaking at the suture-bone interface. The development of this device would increase the ease of the procedure thereby reducing the surgical skill required to perform

it, and allowing more general practitioners to adopt this technique. Specifications for such an implant would include: biocompatibility with bone, a smooth surface on which the suture would rest, anchoring capabilities in the bone, and ease of implantation.

5.1.5 Aiming Guide

One of the most significant limitations of the toggle pinning procedure is the aiming guide. Through testimonials from surgeons, as well as through discussions with our client, it was identified that the current aiming guide does not provide enough clearance for larger femurs. The angle of the main body does not allow for the aiming guide to be easily adjusted and therefore increases the difficulty of the procedure. Another limitation of this device is the design of the tip that serves to stabilize the aiming guide around the femur. Many users complain that the tip slips out of the fovea when the aiming guide is adjusted, therefore increasing the difficulty of the procedure. We sought to make several improvements to the aiming guide, in order to significantly improve the simplicity and ease of the surgical procedure. Special attention was given to the tip of the aiming guide to ensure its stability. Another improvement aimed to increase the adjustability of the aiming guide. The device needed to be simply maneuvered with one hand as well as adjustable to accommodate larger sized femurs. Finally, the most important specification for the aiming guide was the accurate alignment of the drill such that the hole drilled through the femoral head penetrated through the original insertion point of the round ligament. This specification had to be met for the device to serve its overall need.

5.2 Alternative Implant Designs

The implants discussed in this section were all designed to reduce the likelihood of failure through the incorporation of smooth edges and an increased surface area at the suture-implant interface. We predicted that the success rate of the implant would improve dramatically through the incorporation of these key features. Additionally, this section addresses the alternative aiming guide, insertion tool, and suture sheath designs that have been proposed.

5.2.1 Dome Plug

The “dome plug” consists of a tapered rod with a rounded top. This design features a hollow shaft and two holes drilled through the rounded top. The shaft has a constant 3mm

diameter, meant to fit through the hole drilled through the acetabulum with a standard 3.2 mm drill bit. At its widest, tapered end, the diameter is 6 mm, to ensure the implant does not fall back through the hole when tension is applied to it from the lateral side. This implant is meant to be inserted, by hand, through the hole in the medial wall of the acetabulum. Once inserted, it will rest flush with both sides of the bone. The suture is looped through the two holes at the top and continued through the shaft.

With this design, shown in Figure 11, the rounded dome and round-edge holes ensure that the suture rests on an entirely smooth surface. This will minimize the wear on the suture, which will ultimately decrease the rate of suture failure. Another advantage of this device is its tapered design which provides easy insertion and a secure fit.

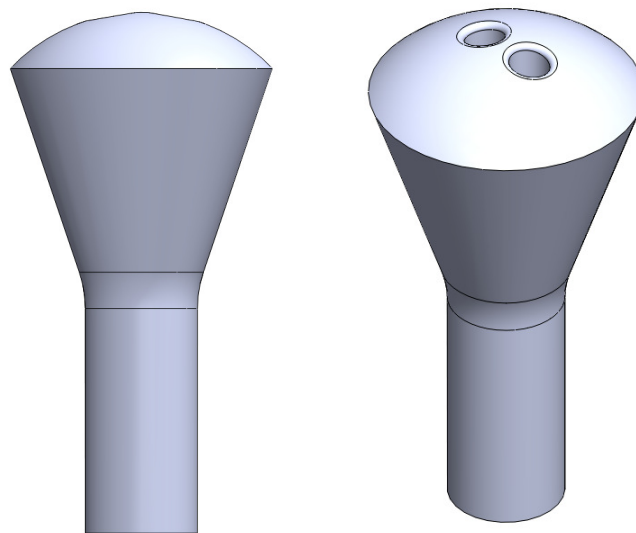


Figure 11: Dome Plug

One of the disadvantages of the domed plug is its manufacturability. The rounded edges of the holes are difficult to machine and the seam at the junction of the taper and shaft may be weak. The combined disadvantages outweighed the potential advantages of this design.

5.2.2 Button-and-Rod

The “button-and-rod” design, shown in Figure 12, consists of a hollow tapered rod shaped like the bell of a trumpet. On the inner wall of the implant, a groove is etched to hold a

rod placed inside the bell. The suture is threaded up through the bottom of the implant, looped around the 1.1 mm rod, and retrieved back through the bottom of the implant. The combination of the groove on the inner wall of the implant with the extreme tensile load applied to the rod will allow it to remain in place post-implantation. This implant is meant to be inserted, by hand, through a hole in the acetabulum and will rest flush with both sides of the wall.

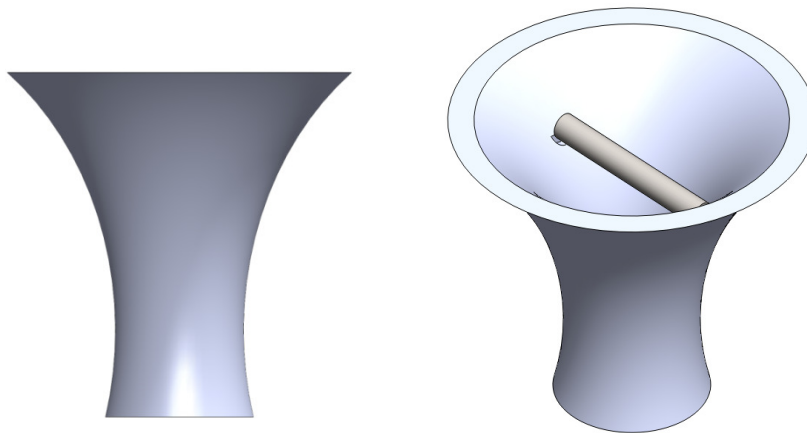


Figure 12: Button and Rod

By inserting this device through the medial wall of the acetabulum, the button and rod design takes advantage of the minimally invasive aspect of the ventral surgical approach. The button-and-rod design can protect the suture as it is passed through the acetabular wall such that it avoids contact with sharp bone. In addition, the implant ensures that the suture will consistently be resting on a smooth surface.

One of the disadvantages of the button-and-rod is the manufacturability and assembly of its two components. This may increase costs as well as decrease the ease of procedure. In addition, the implant must be inserted through the acetabular wall without interfering with the movement of the femoral head and therefore, the length of the implant must be carefully controlled. These limitations provided enough evidence to eliminate the button-and-rod from our design matrix.

5.2.3 Button-and-Tapered Rod

The button-and-tapered rod design is similar to the button-and-rod design, with one minor difference. Rather than consisting of a standard rod, this design utilizes a tapered rod

placed across the bell of the implant as shown in Figure 13. A side view of this rod appears as a bow-tie, thinner in the middle and wider at both ends. At its center, the rod is 1.1 mm in diameter to ensure it can withstand high loads. The ends of the rod are approximately twice as wide as the middle for support.

The button-and-tapered rod design is advantageous because it ensures that the suture does not travel or catch on the ends of the rod as the leg moves. It also can be easily press fit into the acetabulum using a ventral approach. However, a rod with such a small diameter may be more difficult to manufacture than a straight rod of the same magnitude. Also, the main body of the device is so small that the bell shape will be difficult to achieve through various machining mechanisms.

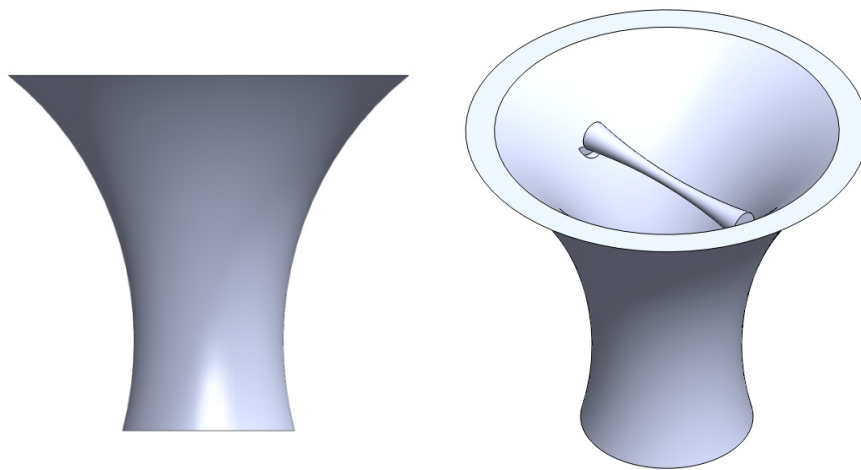


Figure 13: Button and Tapered Rod

5.2.4 Rod and Shelf

The rod and shelf device was designed as two separate parts to be assembled before distributed to the customer. The first component consists of an ellipse shaped disc with two flat faces to ensure the device will rest flush with the medial side of the acetabular wall. A grooved shelf is milled along the inner wall to allow for a cylindrical rod to rest upon. The rod is inserted along the major axis of the ellipse, where it is knowingly too short to be locked in place. The rod is rotated along the grooved shelf until it is press fit. The suture material is threaded such that it wraps around the cylinder. The implant is shown in Figure 14.

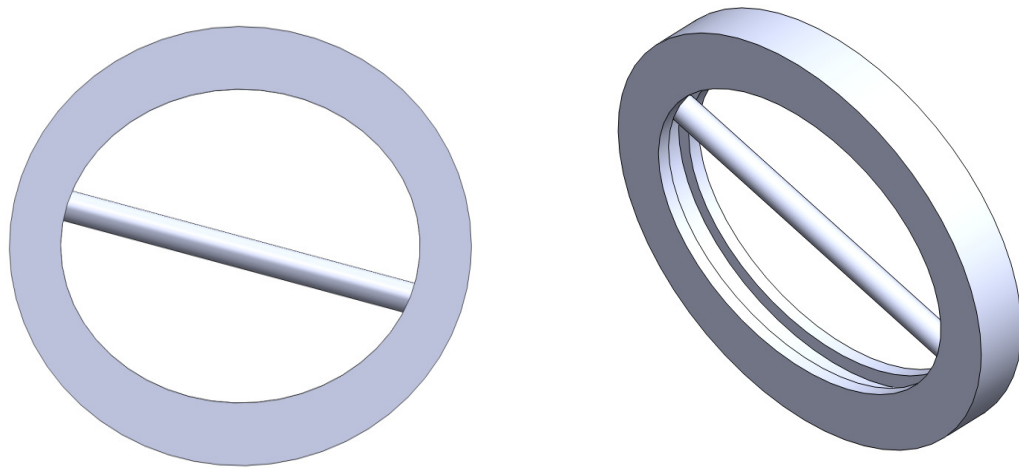


Figure 14: CAD design of Rod and Shelf

The rod and shelf is advantageous because it produces a strong implant that can evenly distribute and support the force resulting from the suture material. It is also simple to assemble as the rod need only be rotated along a guided shelf. Furthermore, the smooth surfaces lessen the stress concentration on the suture in order to prevent breakage.

A major drawback of the rod and shelf design; however, is its manufacturability. The grooved shelf is very difficult to manufacture due to its small magnitude. Additionally, the use of a press fit may not provide a suitable locking mechanism for the rod to remain in place during dynamic conditions.

5.2.5 Button

The button is the simplest design that still meets the objectives and functions required by this project. The button is an easily inserted piece that could be held tightly in place against the medial acetabular wall. Two holes drilled through the face of the button feature rounded edges to prevent suture breakage. The suture is threaded through the two holes and pulled through the acetabulum. The button has a diameter slightly larger than the drilled hole to ensure it does not get pulled through the acetabular hole. The button is shown in Figure 15.

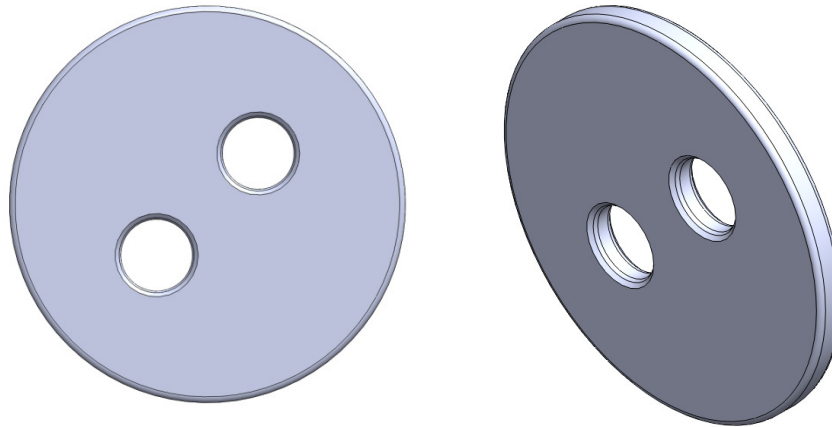


Figure 15: Button design

The advantage to the button design is its simplicity. The button is mechanically sound, and similar designs for implants placed elsewhere in a canine have already proven successful. A device such as this can be manufactured efficiently and effectively. The strength of the button is also advantageous, as it is crafted from a single solid piece.

The disadvantage of the button design lies solely in its insertion. Whereas the button is ideal for accommodation of the suture, its dimensions make it difficult for insertion through the acetabular wall. Access to the medial side of the acetabulum is necessary for this design to prevail.

5.2.6 Bow Tie

The bow tie is another simple design that will reduce the occurrence of suture breakage. The bow tie consists of a curved cylinder with an outer diameter slightly less than that of the hole drilled in the acetabulum as shown in Figure 16. The suture is looped around the cylinder such that it is contact with the smooth surface. Two angled flaps exist at the edge of the curved section in order to distribute the load resulting from the force applied to the suture material. The flaps are flattened in a press, thus simplifying the manufacturability of the part.

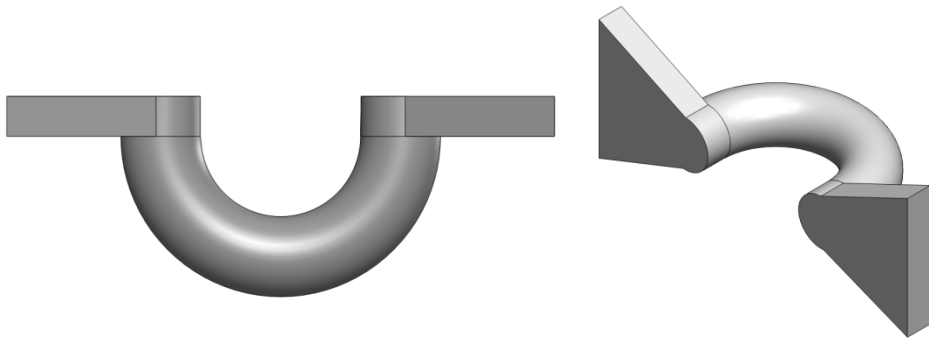


Figure 16: Bow Tie Design

The greatest advantage of the button design is its ease of manufacturability. A cylinder can be easily formed, then pressed to produce the flaps. The rounded edges are an improvement over the sharp edges that exist on the current toggle rod while the flaps provide the same mechanical stability.

The major drawback to the bow tie design is the difficulty that will exist in correctly placing and stabilizing the implant once inserted. Such a small piece is difficult to grasp, and thus an effective means is necessary to hold the implant in place. Additionally, it may be difficult to wrap suture material around the bow tie as it will be imbedded in the drilled hole, thereby decreasing suture clearance. There is also potential for the suture to rub against the surrounding bone, thus resulting in suture breakage and ultimately failure.

5.2.7 Lock

The lock design was created to incorporate key features of previous designs into a single device. The device consists of a circular base and a cross bar for the suture to rest on. The circular base was developed to ensure proper distribution of stress along the medial wall of the acetabulum. This design includes two grooved slots such that the rod can be “locked” into place. The mechanism does not rely upon a force directed from the medial to the lateral side to hold it in place, but would lock itself in place, and never need to be adjusted. Ideally the cross sectional bar has the capability to be removed and replaced if complications were to occur and the suture was damaged. This design can be seen in Figure 17.

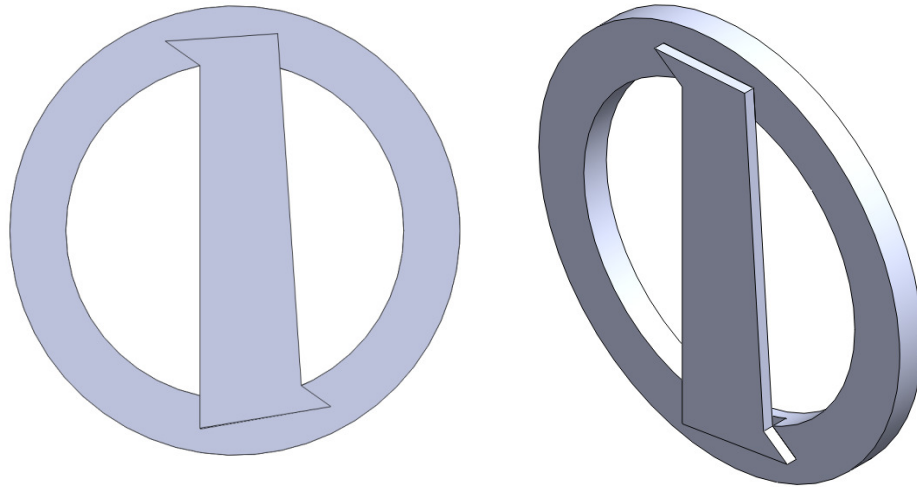


Figure 17- Lock Mechanism Design (Front View and Isometric View)

The lock design is advantageous because it is simple and serves the need of the implant. The locking mechanism ensures the rod will not come loose once implanted while the circular body evenly distributes the forces of the leg. After careful consideration and conversations with manufacturing experts, however, it was decided that the lock would be too difficult to construct. The elaborate locking mechanism appeared to be ideal in terms of its functionality, however impractical in its application. Another difficulty with this design is its incorporation of a two piece system. In order to successfully manufacture an implantable product, it should consist of minimal parts and be constructed with the current technology. Lastly, the rounded edges of the cross bar would be difficult to achieve on such a small part. These limitations ultimately eliminated the lock mechanism from the design matrix.

5.2.8 Crimp Theta

The crimp theta design is a two piece system consisting of a central cross bar and a circular base as shown in Figure 18. A rod is placed along the outer edge which sits distal from the side in contact with the medial wall of the acetabulum. This rod is securely crimped around the outside edge of a circular device for support. The suture is threaded around the central cross bar and pulled through the acetabulum.

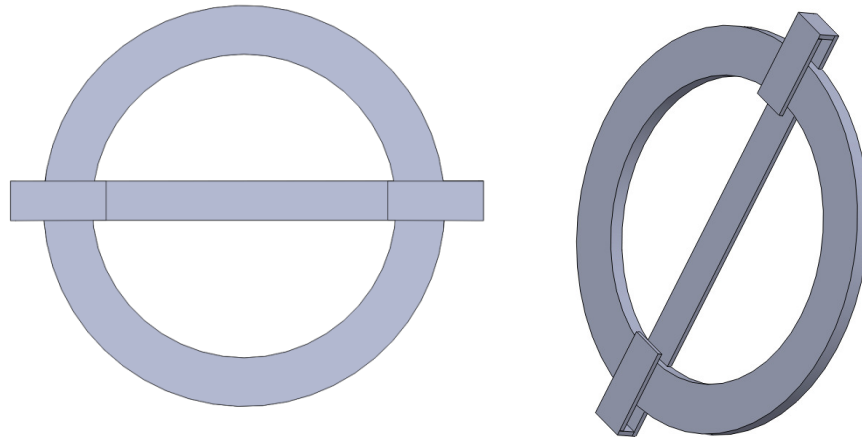


Figure 18- Crimp Theta Design (Front view and Isometric View)

Similarly to the lock mechanism, the crimp theta is advantageous because it is a simple design that will provide sufficient stability for the injured joint. However, it is again limited by its manufacturability. The crimping process may result in fracture of the central cross bar due to its decreased thickness and increased stress concentration. Although the simplified process of crimping is already integrated into the procedure this might account for additional steps easily avoided by other designs.

5.2.9 Theta Round

From our previous design criteria, it has been established that a circular base is best for stress distribution along the acetabular wall, and that a rounded surface is required for the suture to rest upon. The “theta round” design incorporates a flat sided circular device which rests against the medial wall of acetabulum and a horizontal cross bar which is rounded to prevent suture breakage. The circular base functions similar to a washer in that it provides a surface barrier between the suture attachment and the acetabular wall placement. The circular base diameter, at smallest 3.2 mm, ensures that the implant will not slip through the acetabular wall. This design is shown in Figure 19.

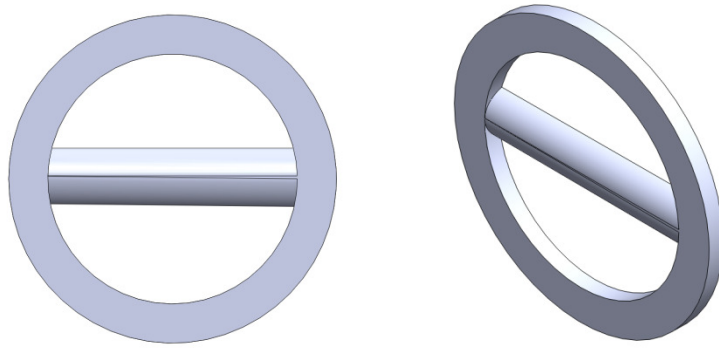


Figure 19- Theta Round Design (Front view and Isometric view)

Ideally the theta round device is manufactured as one piece. The piece is intended to be inserted ventrally along the medial wall of the acetabulum, whereas lateral insertion through the acetabulum would not need to be considered. The design is disadvantageous because the cross bar of the “theta-round” design is difficult to manufacture based on its small arcing radius.

5.2.10 Crimp

With all the previous designs hinged on a new ventral approach, it was necessary to further analyze the toggle rod itself and develop new implants that could be used with the craniolateral approach. The conceptual idea for the crimp design stemmed from a basic name tag holder. The implant is u-shaped and similar in size to the current toggle rod as shown in Figure 20.

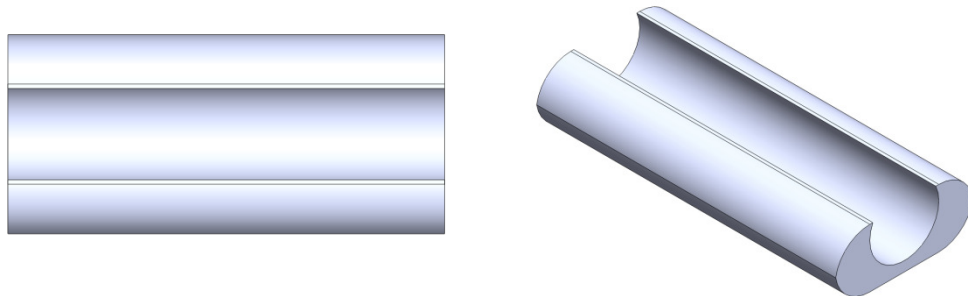


Figure 20: Crimp Design - Isometric View

The implant uses the existing crimping technology to secure the suture in the device. The suture rests half way in the implant and then extends upward perpendicular to the length of the device. The implant is crimped around the portion holding the suture such that when the suture is pulled, the device aligns itself perpendicular to the anchoring material. The implant is

designed to be pre-crimped with suture prior to insertion through the hole drilled during the craniolateral approach. The rod automatically orients itself perpendicular to the direction of insertion after passing through the acetabular wall due to the forces exerted on it by the suture.

Though this design is simple and easy to manufacture, the potentially detrimental effects of crimping the suture are unknown. There is concern that the additional stress on the suture (due to crimping) may lead to early suture breakage. In addition, it is unknown if the crimp will provide enough force to tightly secure the suture in place. This limiting factor was significant enough to prevent further investigation into this design.

5.2.11 Long Theta

The long theta design was devised as another implant to be used in the craniolateral approach. The implant is composed of a single continuous circular rod bent in the shape of a theta as shown in Figure 21. The completely circular shape eliminates the sharp edges found on the current toggle rod. The circular design also helps in distributing the overall load of the system. The suture is threaded around the central cross bar which serves as a completely smooth surface upon which the suture can rest. The long theta is inserted into the hole drilled in the femur using an insertion tool. Once passed through the acetabular hole, the implant aligns itself parallel to the acetabular to anchor the suture.

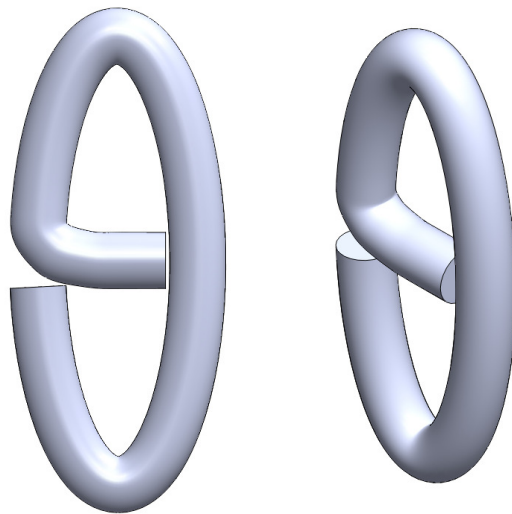


Figure 21: Long Theta

A key advantage of this design is that the suture does not come into contact with any sharp edges; one of the main causes for suture breakage. In addition, the design provides an effective distribution of load throughout the system. The design is also very easy to manufacture with minimal waste by simply bending wire into the desired shape. One of the main disadvantages of the design is the crossbar. This feature is very thin and its ability to withstand the forces in the hip without breaking is unknown.

5.3 Alternative Designs for Insertion Tool

With the design of a new implant, it became necessary to develop the necessary instrumentation to insert the device into the joint capsule. An insertion tool currently exists to implant the toggle rod through the acetabular wall, and thus modifications to this device were the primary focus of the alternative insertion tool designs.

5.3.1 Shovel Inserter

The Shovel design is similar to the current insertion tool used with the Toggle Rod. The design consists of a plunger-like device that pushes the implant through the acetabulum. The inserter has a “shovel” shaped end which the implant can be pressed securely into. The suture is guided along the outside of the device and held in place with two rubber o-rings. A plunging mechanism fits inside the hollow inserter such that it can push the implant through the drilled holes and be released from the insertion tool altogether. The design can be seen below in Figure 22.

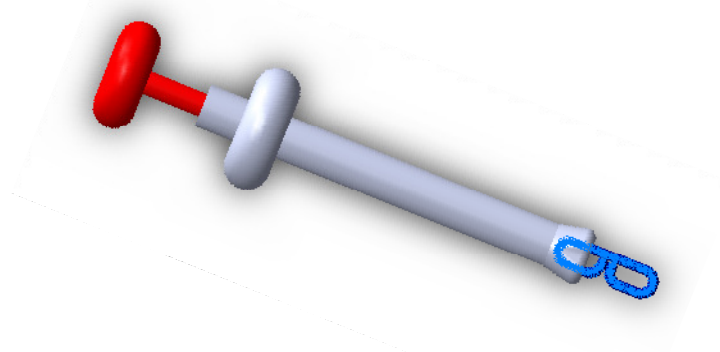


Figure 22: Shovel Inserter

The advantages of this design include its simplicity and ease of use. The inserter can be held and activated with a single hand. Additionally, it effectively pushes the implant through the acetabular wall such that it can be correctly aligned.

5.3.2 Scissor Inserter

The Scissor Insertion tool is modeled after surgical hemostats that are thin enough to place the implant through the drilled hole in the acetabulum. The ends of the scissors are ridged such that they can effectively grip the implant. A hook exists at the pivot to guide the suture away from the sharp edges of the scissors. This design can be seen in Figure 23 below.

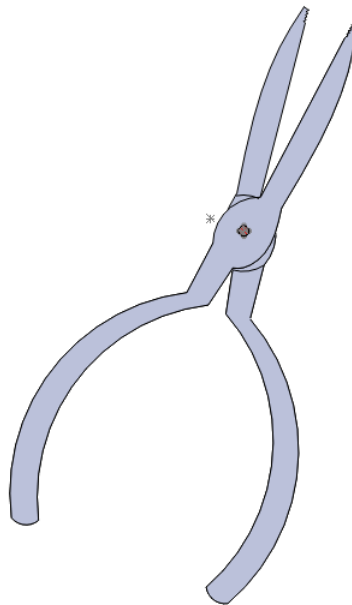


Figure 23: Scissor Inserter

The most significant advantage to the scissor design is its ease of use. The scissor insertion tool is designed to imitate common surgical tools that already exist, and thus provides simple integration into the existing technology. The scissors can also be used with a single hand, further simplifying their use. A concern, however, is that the scissors will be difficult to manufacture with ends small enough to fit through the drilled hole.

5.3.3 Plunger Inserter

The Plunger design is a device that completely encases the implant as it is inserted through the acetabular wall. The pre-threaded implant is snugly fit into the end of the device and when ready for use, the plunger is pressed tight against the lateral side of the acetabular wall. A marker along the outer edge of the plunger is used to indicate the alignment of the drilled hole with the end of the implant. A syringe-like device is then pressed to insert the implant through the acetabular wall. The plunger is shown in Figure 24.

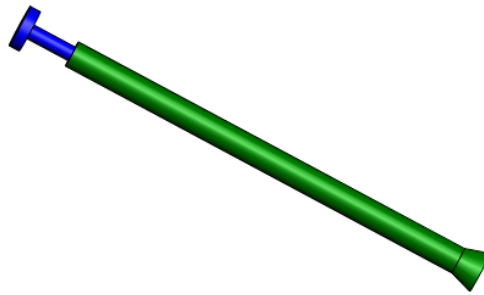


Figure 24: Plunger Inserter

This design is advantageous because it protects the suture during insertion. The plunger can also be easily stabilized, as the edges rest flush against the acetabular wall. The primary disadvantage is the accuracy that is required to align the holes blindly. The outer casing does not allow the implant to be seen when it is inserted, and thus the plunger must be exactly aligned with the drilled hole to ensure that the implant will fit through it.

5.4 Alternative Designs for Suture Sheath

The suture sheath designs were inspired by screw anchors that are inserted into a concrete wall prior to drilling a screw into a surface. The sheath reduces the accuracy necessary when drilling the hole through the femoral head because it provides a greater surface area for the suture to rest on. As a result, the hole will not need to be exactly aligned with the hole in the acetabular wall. Additionally, the smooth surface will reduce the friction between the suture and bone that can cause fraying and eventual suture failure.

The “grooved sheath” features four vertical grooves that are equidistant from one other. The inner diameter is filleted at the top of the device such that the suture can rest on a curved, smooth surface. The sheath is press fit into a pilot hole on the femoral head where the round ligament had been previously attached. The slots allow the sheath to be pushed downward into the bone, yet prevent it from coming loose and slipping out of the femoral head. Figure 25 below shows this design.

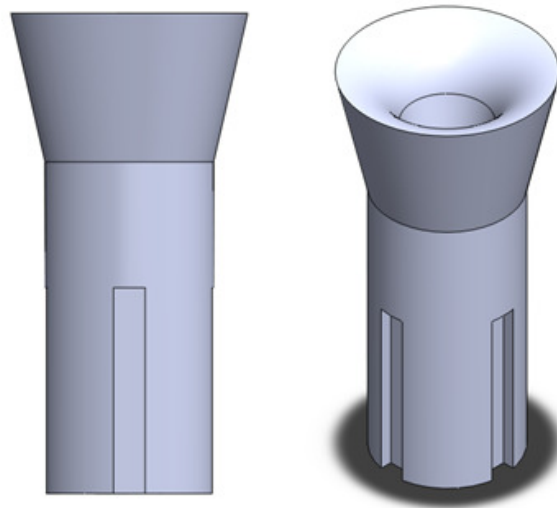


Figure 25: Grooved Sheath design

While the grooved sheath provides a smooth interface for the suture to rest on, insertion of the device may become difficult. A counter sunk hole would be necessary to insert the sheath, however with two different diameters at the top and bottom, the implant may be difficult to secure. Also, the manufacturability of this design will be somewhat expensive due to the intricate design features.

This “tiger” sheath is a ratchet like design that consists of four sets of sharp teeth aligned vertically along the outer surface of the device. Similar to the grooves in the previous design, these teeth will allow the device to be press fit downward, yet remain in place once implanted. The teeth are slanted downward such that they can easily slide along the bone. When pushed upward, the teeth will lodge the device in place. The tiger sheath also has a constant diameter with an inner filleted wall. Please refer to Figure 26 below.

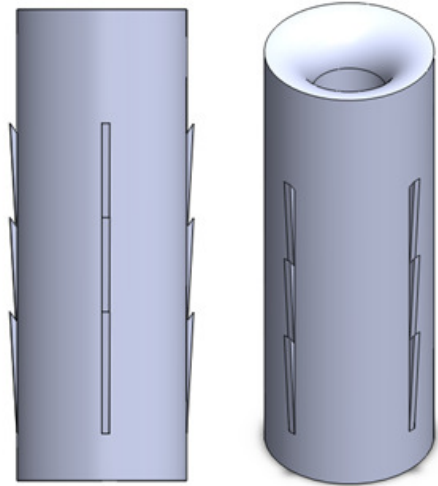


Figure 26: Isometric (Left) and Top (Right) views of Tiger Sheath

The most significant advantage to this design is the constant outer diameter. The part is a basic straight cylinder; therefore the implantation and insertion are simpler than that required for the previous design. The consistency in the overall shape simplifies the design and reduces the cost of production for the client. This design could be improved, if the teeth were re-designed to make them more manufacturable.

The tiger sheath evolved into a “bubble” design that features smooth, rounded ridges. In addition, each ridge has an increasingly larger diameter to ensure the sheath is pressed tight into place. This concept was adopted from the method in which a femoral stem of an artificial hip implant is inserted. The bubble design is tapered at the insertion tip and has an increasing diameter to create the tightest fit possible. As in the previous tiger design, the diameter is constant throughout the part and the inner surface where the suture rests is filleted. CAD models of the part can be seen below in Figure 27.

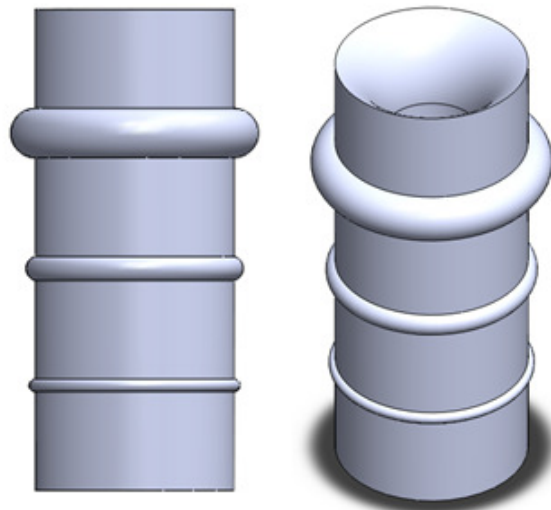


Figure 27: Front and isometric views of Bubble Sheath

The greatest advantage to this design is its rounded ridges. They provide a smooth surface to contact the bone and decrease any trauma caused to the femoral head when inserted. Additionally, the increasing ridge size is expected to ease implantation while creating a tight fit at the implant-bone interface. Lastly, the filleted top should prevent suture breakage as it is a smooth resting surface. The main disadvantage to this design is the ease of insertion. It is critical that the sheath rest flush with the femoral head, and due to the location of the top ridge, this may be difficult to achieve with the proposed insertion method. Additionally, manufacturing of rounded ridges requires more time and money than other designs, and thus is not ideal.

The final sheath design optimized all previous designs to create the best combination of functionality and manufacturability. The “shark fin” design has ridges with an increasing diameter, similar to the bubble design. The final and largest ridge is flush with the top of the part, and the inner diameter is filleted. As in most other designs, the overall inner diameter is constant. The shark fin can be seen in Figure 28.

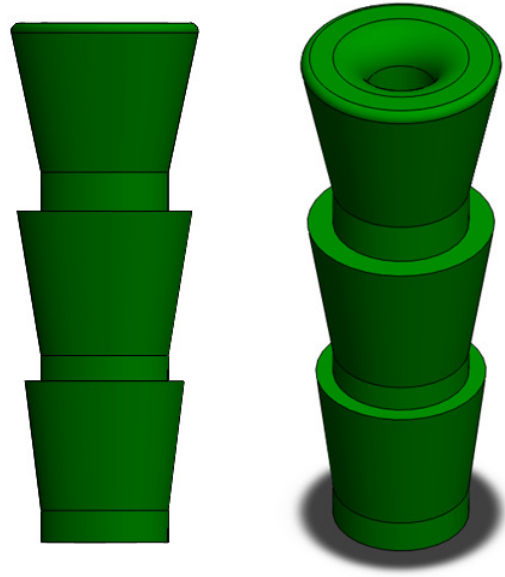


Figure 28: CAD models of Shark Fin

The biggest advantage of this design is its ease of use and functionality. The part is easily manufactured and simply inserted. The smooth inner diameter again protects the suture and the placement of the largest ridge along the top of the overall part will allow the sheath to rest flush with the bone. The increasing size of the ridges will ensure the part is snug in the fovea and will not come loose. This final design achieves the goal to reduce the accuracy necessary in aligning the drilled holes (through the femoral head and acetabular wall) while it also protects the suture to reduce breakage.

5.5 Alternative Designs for Aiming Guide

The alternative aiming guide designs aimed to improve the features of the current device that make it difficult to use. All of the designs maintain the functionality of the device by including a tip that is inserted in the fovea of the femoral head and a drill sleeve that guides and steadies the drill during its operation. Drawings of the final design can be found in Appendix K.

5.5.1 Threaded Drill Sleeve

The first re-designed aiming guide, shown in Figure 29, focuses on improving the ease of use for the surgeon. The shape of the body is similar to that of the current aiming guide, however the end that secures the tip has been lengthened in order to accommodate larger femurs. The tip has also been lengthened and sharpened in order to ensure it stays in place once inserted in the fovea. The main difference in this design compared to the existing device is the drill sleeve. Both the outer surface of the drill sleeve and the hole in the body of the aiming guide are threaded. Once the tip is placed in the hole of the fovea, the surgeon can effectively screw the drill sleeve inward until it is tight against the lateral side of the femur. This mechanism will allow the surgeon to drill the hole accurately and once complete, unscrew the drill sleeve to release the aiming guide from the bone.

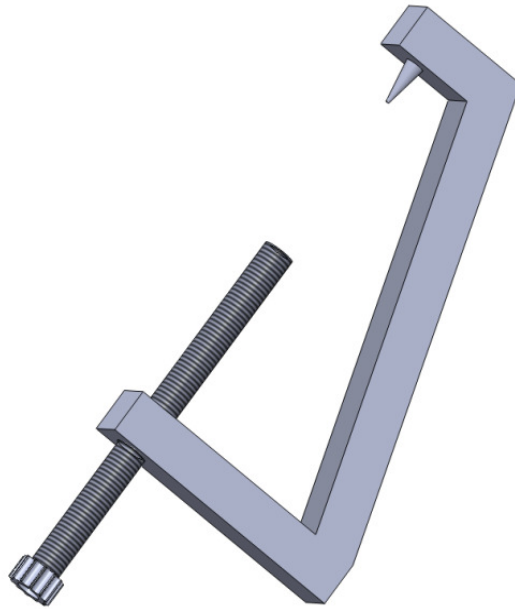


Figure 29: Threaded drill sleeve

This design greatly increases the ease of use for the surgeon. The drill sleeve has been simplified such that it can be operated with a single hand and tightened along the acetabular wall. This entire mechanism requires only two hands, and will ensure that the aiming guide is secured accurately during drilling. The sharper tip will prevent the aiming guide from slipping out of the fovea, and the lengthened end will ensure the aiming guide will have enough clearance for larger sized femurs. One limitation of this design is the lack of a locking mechanism to maintain the

tight fit between the drill sleeve and the femoral head. As a result, the threads along the drill sleeve must match those on the inner wall of the hole drilled in the aiming guide. This will require very small tolerances that will in turn increase manufacturing costs.

5.5.2 Wrench Mechanism

The second aiming guide design, shown in Figure 30, also focuses on the ease of use for the surgeon. The top of the aiming guide was lengthened in order to accommodate larger femurs, and additionally the tip was lengthened and sharpened in order to ensure it stays in place once inserted in the fovea. In this design, the drill sleeve is first set in place and the body of the aiming guide is then adjusted to tighten the device around the bone. The body can be made in two pieces, with a threaded screw-like device joining the two parts. Much like a common wrench, the threaded piece would be rotated in one direction to tighten the aiming guide. The surgeon would then unscrew the threaded piece to release the aiming guide after completion of drilling.

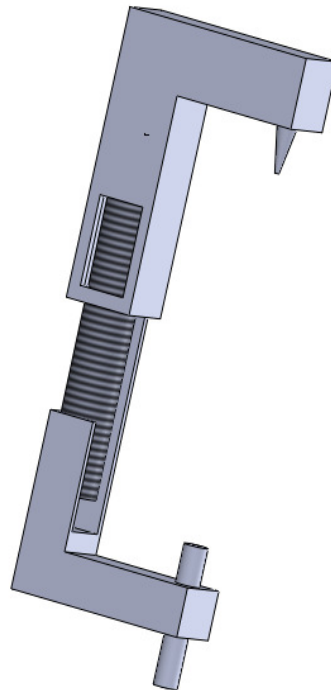


Figure 30: Wrench mechanism

This design greatly improves the ease of use of the aiming guide. It only requires two hands, and the surgeon can easily maneuver the wrench mechanism while holding the aiming guide in place. In addition, the lengthened body can accommodate larger femurs in various sized dogs. While this design has improved the ease of use from the existing aiming guide, the device may be difficult to manufacture. It also lacks ergonomic considerations, and thus may be uncomfortable for the user.

5.5.3 Scissor Mechanism

The scissor mechanism, shown in Figure 31, explores a vastly different approach to guiding the drill. This design mimics surgical scissors that are prevalent in many surgical procedures. The tip is located on one “blade” of the scissors, while the drill sleeve is located on the other. The device can be held as normal scissors are grasped. The scissoring mechanism clamps the aiming guide in place, and it can be locked by squeezing until the locking mechanism is activated. This design will allow surgeons to use only one hand, thus increasing the ease of use. The scissors would also allow the surgeon to externally fixate the aiming guide, which could make the procedure more minimally invasive.

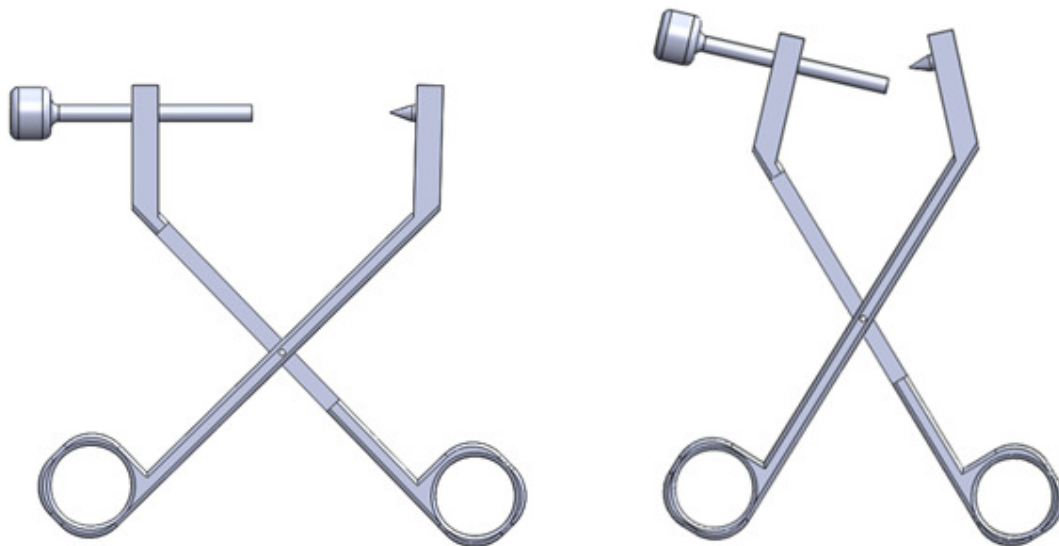


Figure 31: Scissor design (a) correct alignment

(b) incorrect alignment

Although there are several advantages to this design, there was one obvious disadvantage. As is shown in Figure 31, when the scissors are closed, the drill sleeve and the tip of the aiming guide are no longer aligned. As this is essential to the functionality of the aiming guide, this specific design will not work correctly.

5.6 Modeling

5.6.1 3-D Rapid Prototyping

Three dimensional printing provided the design team the opportunity to perform preliminary functionality tests on product designs using models made of acrylonitrile butadiene styrene, ABS, plastic. These models are tough enough to be used as working parts and the low cost of the products is a key incentive for its use. Models typically cost \$3 per square inch and can be built within a few hours.

During the 3-D printing process, the virtual design from the computer aided design software (SolidWorks) is converted into cross sections of the model in order to build the piece layer by layer (14). The CAD file first must be converted into an STL file. The STL file approximates the shape of the part using triangular facets, with smaller facets producing a higher quality surface. Several layers of liquid and powder are combined to form the model. The time length of production is based on the size and complexity of the model (15).

The use of 3-D printing has many advantages including the rapid time frame in which a part is made (usually less than 24 hours) as well as the low cost. This production method is limited, however, by the dimensions of the designed part. Sharp angles and steep contours make prototyping especially difficult. In addition, the wall thickness must be greater than 0.06" in order for the part to be printed. As a result of these size limitations, the parts we built ranged from 1 to 3 times larger than the actual part dimensions. The theta, double theta, bowtie and crimp implants were all manufactured with this rapid prototyping technology, in addition to the final aiming guide, insertion tool and sheath designs.

The rapid prototyping process bridges the gap between the initial stages of development and design, and the first steps towards manufacturing. The process results in a reduction of time to market, better understanding of the design and the ability to communicate the design with the client. Specifically during the development of our project, the plastic parts allowed us to refine the designs and present them to our client Securos. They also provided functional tools for us to

test on model bones. Ultimately the use of the plastic models was essential to make final design decisions for all parts of the system.

5.6.2 Finite Element Modeling

Finite Element modeling was critical during the design process to determine where the highest stress concentration on the toggle rod, and thus the suture, results when a force is applied. A program within SolidWorks, COSMOSXpress is a modeling tool designed to determine how a part will perform under specific conditions. This program was used to model our implant to ensure it would be strong enough to withstand the force of the suture. For a 3D, solid model, a 10 node tetrahedron shaped element was used (16). Caution must be taken when using tetrahedral elements as models for thin-walled structure for if the size to thickness ratio is not proportional, the structural behavior could be much too stiff in bending. Additionally, linear tetrahedral elements should not be used to model parts with sharp edges because they will be inaccurate. Extra shape functions or the enhanced strain formulation should be activated for bending dominated problems. The volume was meshed according to the COSMOSXpress software. It was critical that this was done correctly, as poor meshing can lead to inaccurate results, slow performance, and convergence issues (18). The structural system was then modeled by a set of finite elements interconnected at points referred to as nodes. Nodes were placed at the vertexes and in the element faces. The volume mesh was then redefined to incorporate additional elements in specific areas. Both the toggle and final implant were re-meshed at the point of suture attachment- the horizontal cross bar section (17) . Material properties, proper restraints and load characteristics were also identified.

The program mathematically solves equilibrium equations for each element based on boundary conditions and engineering materials assumptions. Assumptions considered during linear static analysis included: 1) the response was directly proportional to the applied loads and was linear, 2) loads were static and applied gradually at a slow rate, 3) the material properties were isotropic and thus uniform in every direction. COSMOSXpress solves the model by calculating the displacement of the mesh nodes, then solving for the resulting stresses. The von Mises stress is a scalar quantity that simplifies interpreting results to predict failure and factor-of-safety (FOS). These values were used in the final analysis of the implant to confirm that it was a superior design to the existing toggle rod.

Our final implant design was modeled with a load corresponding to the forces of the suture pulling on the central cross sectional bar. Loads of one suture diameter along the cross bar were applied in the z-direction. Structural deformation and failure properties were determined under conditions of linear elastic isometric loading. Similar tests were conducted on the toggle rod in order for comparisons and analysis to be made.

5.7 Decisions

To effectively analyze our designs, it was necessary to develop a design matrix. This matrix helped to properly quantify the advantages and disadvantages of each of our designs. Through the design matrix, we identified variables such as manufacturability, cross-arm strength, cost, ease of use, functionality, distribution of load, and suture compatibility to consider for each design. The ability of each design to fulfill the above requirements was then compared. In addition, we presented all of our designs to our client, Harry Wotton, and gathered his input on the manufacturability and functionality of each. Through both of these analyses, we were able to identify the three chief implant designs that warranted further analysis. These three designs included the bow tie, the crimp, and the long theta.

To further develop these three designs, we identified the most significant disadvantage of each. The bow tie was the most difficult to manufacture while the crimp had sharp edges that could foster suture breakage. The greatest concern with the long theta design was the structural integrity of the cross-bar, as it would need to support the suture and resulting forces from the leg. Through discussions with the client and additional brainstorming sessions, we devised a solution to the major limitation of the long theta: we modified the shape such that both ends were bent inward to create a cross bar with twice the diameter of the original design (as shown in Figure 32). This design modification eliminated the main concern of implant deformation and allowed us to choose the long theta as our final preliminary design.

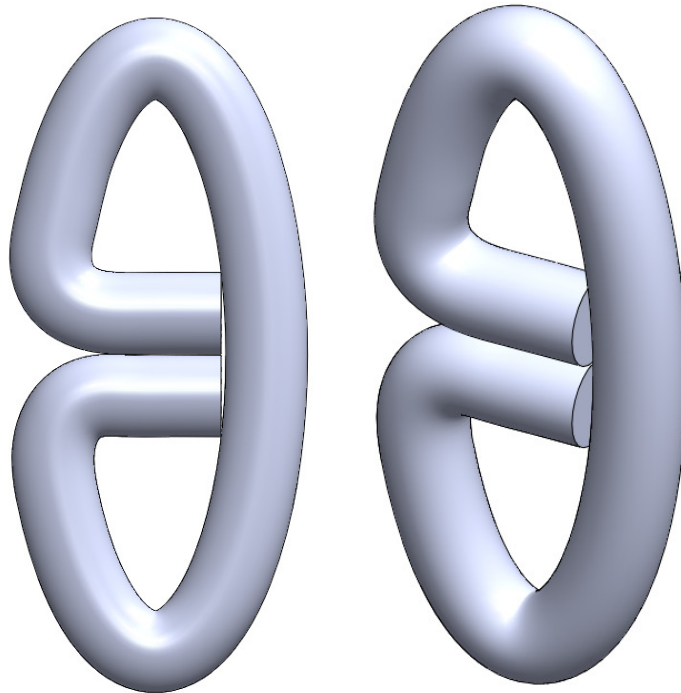


Figure 32: Long Double Theta

5.8 Optimization

The optimization of our designs included the selection of the appropriate surgical approach with which our device would be used in addition to the materials that would best serve the client. It was crucial during the optimization process to evaluate the current methods and materials, and make comparisons to potential novel approaches and design ideas. The designs were chosen in order to meet the defined aims and specifications of our project.

5.8.1 Approach

The surgical approach to correct coxofemoral luxation with the toggle pin procedure must enable access to debride the round ligament, drill the femoral head, and insert an implant into the acetabulum. Various approaches exist, some more invasive than others, and thus research as well as first hand insight from general practitioners and orthopedic surgeons was necessary to

optimize the best approach. An investigation of the ventral, caudal, and craniolateral approaches was done in order to formulate our designs.

The ventral approach was first investigated as a novel approach to the Toggle Pinning procedure. It is a technique that has not been performed previously and initially posed a simpler method to access the luxated joint. By placing the canine on its back, the joint capsule can be easily seen in the medial approach. The incision provides clear access to the round ligament and acetabular cavity. This approach could potentially ease the process to debride the ligament and enhance visualization of the fovea. The most significant advantage, however, is access to the medial wall of the acetabulum. We thought the ventral approach would allow the surgeon to place the implant on the medial wall of the acetabulum directly by retracting the surrounding muscle. This access would eliminate the need to create a small implant and insertion device to blindly place the implant along the medial wall from a lateral approach.

Through research and interviews, we learned that there were numerous drawbacks to the ventral approach that would significantly complicate the procedure. First, the femoral artery and sciatic nerve are both located in close proximity to the ventral side of the coxofemoral joint, and if sliced, could cause fatal complications for the patient. Thus, the incision must be extremely precise. Additionally, the incision from a ventral approach will sever the muscle belly of the adductor muscles. This will in turn cause excessive bleeding and obscure visualization of the joint capsule. Lastly and perhaps most importantly, access to the medial wall of the acetabulum will be very complicated. Too many muscles will need to be retracted and drilling through the acetabular wall will be much too difficult through this approach. These considerable limitations, in addition to the required adoption of a new surgical approach, led us away from developing a ventral approach.

The second researched approach was the caudal approach. This is an uncommon approach used by Dr. Flynn, an original inventor of the Toggle Rod. The caudal technique accesses the coxofemoral joint through the back side of the dog. An 8cm incision is required, and the resulting visualization of the joint is very clear. The most common luxation dislocates the hip away from this view, and thus the round ligament is easily accessible from this approach.

A disadvantage of the caudal approach is the requirement of a second incision along the femur in order to crimp the suture. Any time a second incision is necessary, the potential for infection and complication of the surgery are increased. A more significant drawback, however,

is that this approach is very uncommon, and most surgeons are unwilling to change their technique unless the success rate of the procedure is significantly enhanced, or the overall procedure is greatly simplified.

The final approach we examined is the most commonly used by all surgeons; the craniolateral approach. This technique requires an 8cm incision (the same length as that used in the caudal approach) extending from the pelvic crest down along the lateral side of the femoral shaft. This technique requires the femur to be externally rotated in order to allow access to the coxofemoral joint cavity. An aiming device is used to drill through the femoral head and an insertion tool is required to pass the toggle rod through the acetabular hole.

The greatest problem associated with this approach is the invasiveness of the procedure. A clear passageway is not available to reach the joint capsule and thus numerous muscles and tissues must be retracted in order to reach the acetabulum. Additionally, the femoral head must be rotated externally in order to achieve sufficient visualization of the cavity. Another common difficulty associated with the craniolateral approach is accurate drilling through the femoral head. It is critical that the holes drilled through the femoral head and acetabulum be exactly aligned, thus precise drilling is required.

After discussions with orthopedic surgeons and general practitioners, we concluded that the best surgical approach to use in conjunction with our newly designed devices would be the craniolateral approach. Although obtaining access to the coxofemoral joint is a more laborious process than reaching it caudally or ventrally, it is the most commonly used approach that already yields good success rates. Thus, the design modifications that we had created would be easily integrated into the existing technology. Additionally, this conventional approach is relatively simple and thus most appealing to those with little experience performing the procedure.

5.8.2 Materials

5.8.2.1 Implant

Two materials were chosen to optimize the design of a new implant. These materials constituted the implant itself as well as the suture used to stabilize the joint. Current materials have advantages and disadvantages that were assessed before a final decision was made.

The current toggle rod is made of 316L stainless steel. This material has a low carbon content which diminishes chromium depletion and corrosion. Corrosion most often occurs when there is not enough oxide on the surface layer and usually occurs in crevices and sharp corners. The nickel content in stainless steel provides the mechanical strength of the material such that the toggle rod rarely fractures (20). The 316L grade stainless steel is also relatively inexpensive, and thus it is a suitable material to be used for the toggle rod.

In addition to stainless steel, titanium was considered as a material to be used in the manufacture of each device. Titanium is biocompatible and corrosion resistant; however it has a high coefficient of friction and is susceptible to wear due to shear stress (20). This could cause potential problems if the implant were to shear against the acetabular wall, and eventually lead to fracture. Beyond this material, few others were investigated because the client expressed his content with either 316L stainless steel or titanium.

Titanium was chosen as the final material to be used for each device that directly contacts bone. It is easily manufacturable and will have sufficient strength for its function. Titanium is relatively inexpensive, and can be used for each device. By choosing a material that can be used for each part of the system, we have reduced the overall cost to the client as well as eased the manufacturing process.

5.8.2.2 Suture

Two potential suture materials were investigated; the current monofilament nylon suture and a new generation polyblend, OrthoFiber. Nylon monofilament suture material is currently used because it has been found to have reasonable tensile strength. A manufacturer of numerous grades of nylon monofilament, Deme Tech, claims that the non-adsorbable suture material is advantageous because it has a low coefficient of friction. This allows it to pass through biological tissue relatively easily. Furthermore, the company claims the suture has low reactivity and good elasticity (21). Nylon monofilament is a synthetic material and thus does not degrade over time.

OrthoFiber is a braided polyblend material, with a strong polyester core. It yields 5% elongation and has a low melting temperature of approximately 300°F. OrthoFiber is resistant to most acids and alkalis, in addition to being resilient to aging and abrasion. These properties make it an ideal suture material to be used in combination with our new implant as it will provide sufficient strength and resistance to corrosion.

After a thorough investigation of the two materials, OrthoFiber was chosen as the optimal suture. Its superior mechanical and wear properties make it an ideal material to stabilize the coxofemoral joint. Although it is more expensive, it can potentially eliminate the most common failure of the procedure; suture breakage.

5.9 Preliminary Data

Preliminary experiments were conducted to confirm the occurrence of suture breakage at the point of contact with the existing toggle rod. It was critical for us to determine if we would encounter the same type of suture failure when using the OrthoFiber that currently exists with the nylon monofilament material.

Previous research has been conducted by Kurt Schulz et al. to confirm the breakage of nylon monofilament material at the point of highest stress concentration (22). The research team performed both monotonic and cyclic tests to determine the failure of the toggle rod as well as suture material. During toggle rod testing, the device rested on an aluminum plate and was threaded with a twisted steel wire. The ends of the wire were submerged in polymethylmethacrylate (PMMA) within a ribbed clamp. Tensile loading tests were then conducted to determine the failure of the rod in comparison to an earlier device termed a toggle pin. For suture testing, a single strand of suture material was pulled between two clamps, with its ends hardened in PMMA. Cyclic testing of the suture material was performed in a similar manner, however the toggle rod was threaded with suture at the top clamp while the bottom clamp was ribbed and held the PMMA coated suture ends (22).

Results from the toggle pin and rod tests showed that the toggle rod was 1.3-2.8 times as strong as the toggle pin (22). These results confirm the advantageous performance of the toggle rod that has been reported from various surgeons. Monotonic tests of the suture material were difficult to analyze, as the test set-up induced error. All of the suture failures occurred within 2mm of the top or bottom clamp, suggesting that the clamps produced a stress concentration that caused the suture to fail prematurely (22). During cyclic tests, however, all suture breakage occurred at the suture-toggle rod interface. The nylon monofilament material failed at a strength of 14-89 times less than the braided polyester, a material similar to OrthoFiber.

Our own experimentation has yielded similar results; OrthoFiber suture fails at the point of contact with the toggle rod. Thus, we have confirmed the need to re-design the toggle rod

such that a smooth surface rests in contact with the suture. In order to obtain relevant data, we have also created our own test set-up to eliminate early failure. The test report can be found in Appendix F, and it explains our efforts to eliminate suture breakage at or near the clamps as well as the results from our preliminary experiments. Through these series of tests, we have successfully confirmed that failure of OrthoFiber will occur at the point of contact with the implant.

6 Methods

6.1 Suture Tensile Testing

Suture plays a critical role in the correction of coxofemoral luxation, as it serves to replace the function of the round ligament. Veterinarians across the nation have stated that a successful procedure is marked by the life of the suture; if the suture is able to maintain its structural integrity for a period of fourteen days, the joint capsule is able to fully recover. In the existing toggle rod and monofilament suture combination, suture breakage occurs at the suture-implant interface. As previously discussed, we decided to replace the nylon monofilament suture with OrthoFiber based on its superior mechanical properties. To confirm that suture breakage still occurred at the sharp edges of the toggle rod (using the new suture material), we performed uniaxial tensile tests.

An Instron machine was used to pull the suture material at a consistent rate of 5mm/min. The suture was first pulled in isolation to determine its full load capacity. The ends of the material were each wrapped around a metal cylinder to prevent the suture from breaking at the grips. The suture was then threaded through the toggle rod, and pulled at the same rate to determine the load and location at which the suture failed. The free ends of the suture were once again wrapped around a metal cylinder. The results from these tests proved that suture failure is due to the design flaws of the toggle rod, and not the properties of the suture material.

Following the completion of the final implant design, similar uniaxial tensile tests were performed to determine if a reduction in suture breakage was achieved. The tests were repeated and data was collected. The load capacity and location of suture failure were analyzed and compared to the data collected from previous tests (both the isolated suture and suture-toggle rod combination).

6.2 Implant Manufacturing

In order to create the Double Theta implant, we have designed a fixture that mimics a stapler to guide the wire into the correct shape. The part consists of two blocks that when clamped together, will form the implant. The wire must first be notched such that it's shape appears similar to that of an unused staple. The top block contains a slot in which the bent wire can be secured. See Figure 33 below.

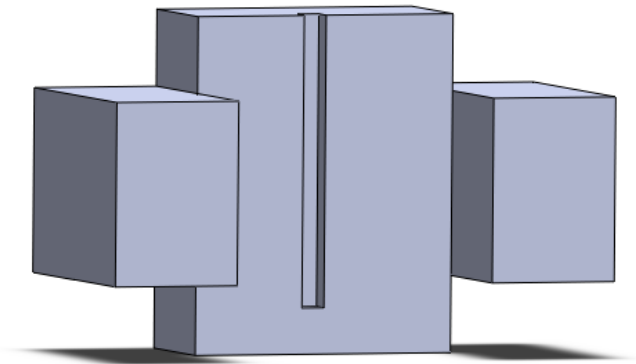


Figure 33: CAD parts of the described top block

The bottom block has been custom designed to model the exact shape of the implant. The blocks fit together like a puzzle such that when they are closed, the wire will form the double theta. After the blocks have been clamped together, the implant is removed a laser weld can be used to secure the ends. Please see Figure 34 below of the bottom block.

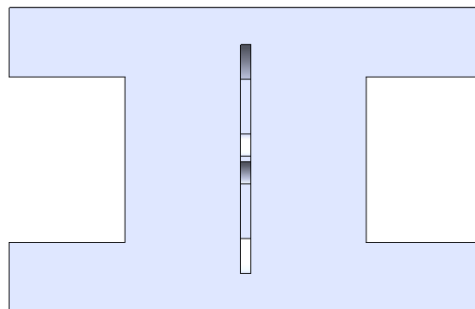


Figure 34: Bottom part of die set

The advantages to the fixture design are its repeatability and ease of use. The device guides the wire to form the same, correct shape each time it is used. In addition, the fixture can be manually operated in a similar way to a standard stapler. The whole assembly can be seen in Figure 35.

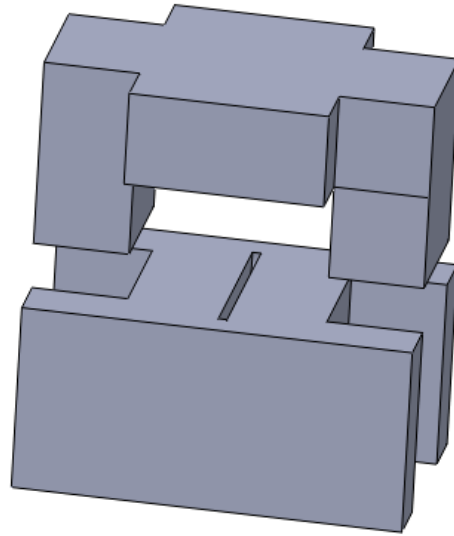


Figure 35: Die Set Assembly

6.3 Finite Element Analysis

Finite element analysis was completed in order to determine the location of the largest stress concentration found on the implants, and thus the point where this load is transferred to the suture. The COSMOS application preconditions the material properties, and limits conditions of the load scenario as desired by the user. During the finite element analysis of both the toggle rod and double theta implant, the material was specified as 304 L Stainless steel and the structural material was set to linear elastic with isotropic properties. The elastic modulus was set to 193 GPa and the Poisson's ratio was defined as 0.28. The face of each that contacts the acetabular wall was set as the only restraint. The load was distributed over five faces in both the toggle rod and the double theta design. In order to properly distribute the load, the number of faces was accounted for. Twenty pounds was applied to each of the five faces in order to reach the total sum of 100 lbs, which mimics the load of the suture as it pulls on the implant.

It has been previously discussed that the deformation of the toggle rod is extremely unlikely, yet a strong stress concentration results at the suture-implant interface. The location of the stress concentration on the toggle rod can be seen in Figure 36 below. We have previously described that the location of this stress concentration occurs in the same location on the suture material.

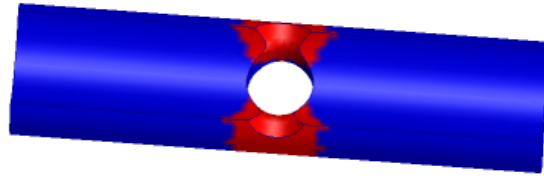


Figure 36- Stress Concentration located on the Toggle Rod

During finite element analysis of the double theta implant, we found that the stress concentration results along the middle crossbars. These crossbars, reinforced by a lateral weld, will withstand the necessary load conditions, far exceeding the strength of the suture material. The analysis confirms that the double theta implant will withstand comparable loads however yield a significantly less stress concentration at the suture-implant interface when compared to the toggle rod-suture combination. The lower stress concentration found on the crossbar of the double theta design, confirms that we have developed an implant that will decrease the likelihood of suture breakage. The location of the stress concentration experienced by the suture can be seen in Figure 37 below.

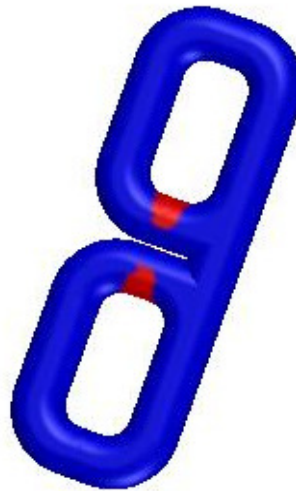


Figure 37- Stress Concentration located on the Double Theta

7 Results

7.1 Suture Tensile Testing

In order to test the effect the toggle rod has on suture breakage, the ultimate yield strength of the suture was first determined using uniaxial tensile testing. The suture was then wrapped through the toggle rod and the same test was performed. Finally, the suture was wrapped through the new double theta implant and the load data was collected and analyzed.

7.1.1 Suture

The suture was pulled by an Instron tensile test machine at a rate of 5 mm/min until failure. Six random samples of the OrthoFiber suture were pulled in order to have a sufficiently large testing group. The load was measured in Newtons and compared to the extension of the suture. The load was then converted to pounds, and the resulting data can be seen below in Figure 38.

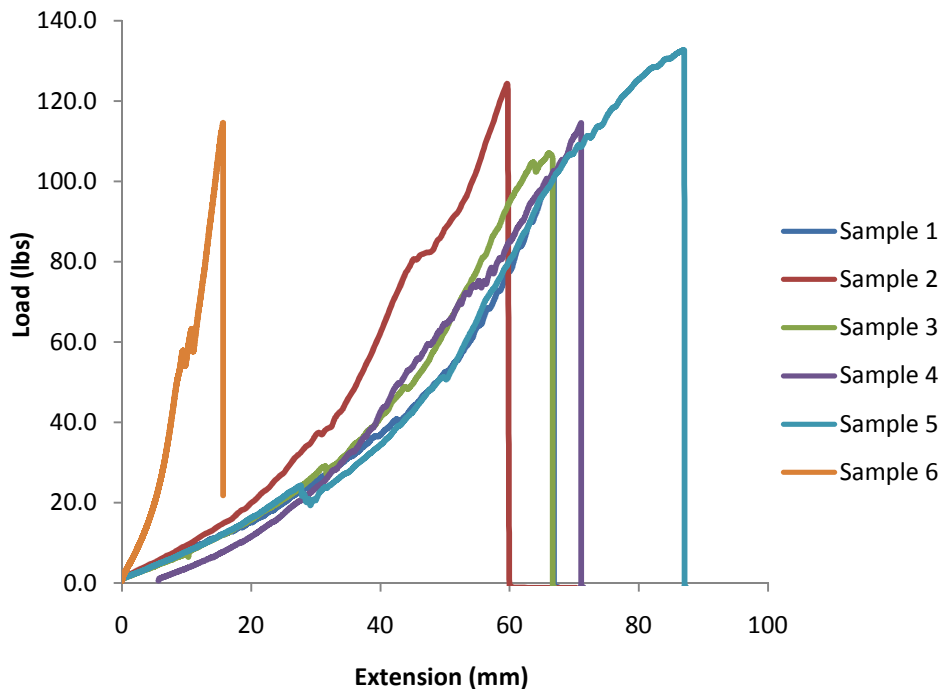


Figure 38: Suture Tensile Testing - Load vs. Extension graph

After six samples were tested, the data showed that the suture's ultimate yield strength averaged 116.2 ± 11.1 lbs, with the maximum strength at failure equaling 132.7 lbs. The suture

elongated significantly, with the average extension reaching 63.2mm, and a maximum extension of 87.3mm. Incidentally, the sample with the largest extension also had the highest yield strength at failure. Sample six was pulled at a rate of 5 mm/sec, which explains why it resulted in a shorter extension. However, its yield strength at failure was 115.0lbs, which indicates that the rate at which the suture is pulled may not affect the ultimate yield strength of the suture. The suture failed at a consistent location between the support cylinders, avoiding failure at the grips. More testing at alternative rates would be required to validate this conclusion.

7.1.2 Toggle-Suture Interface

The suture was threaded through the toggle rod and pulled by an Instron tensile test machine at rate of 5 mm/min until failure. Five random samples of the OrthoFiber suture and toggle rod combination were pulled in order to have a sufficiently large testing group. The load was measured in Newtons and compared to the extension of the suture. The load was converted to pounds, and the resulting data can be seen below in Figure 39.

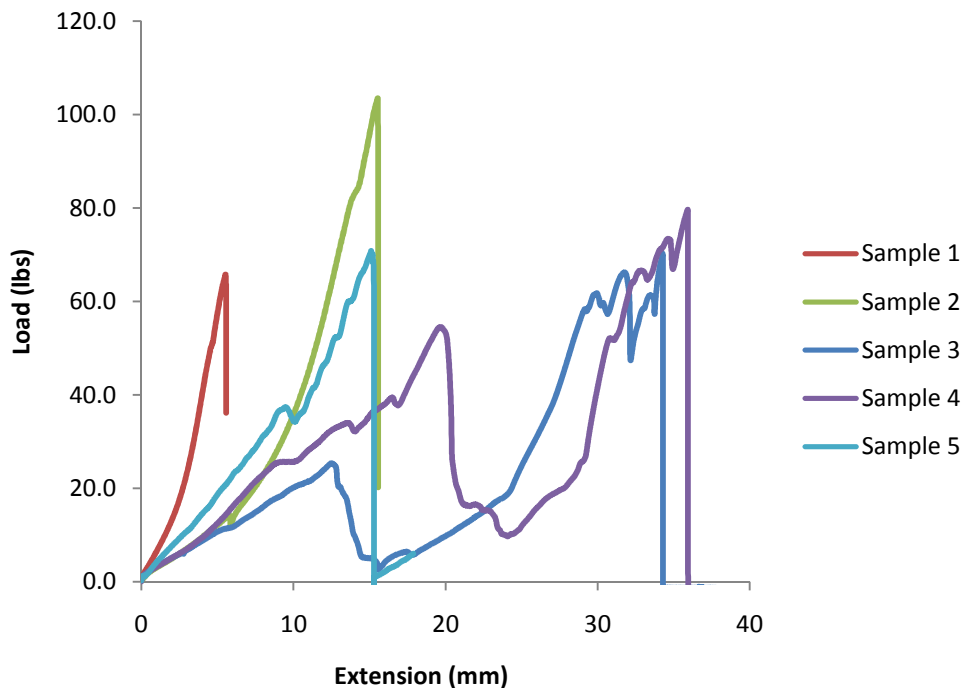


Figure 39: Toggle Rod-Suture Interface Tensile Testing - Load vs. Extension graph

After five samples were pulled, the data showed that the suture's ultimate yield strength averaged 71.6 ± 15.1 lbs, with the maximum strength at failure equaling 79.7 lbs. The suture wrapped through the toggle rod had a much lower extension than the isolated suture, with an average extension of 24.4 mm, and a maximum extension reaching 37.8 mm. These results show that the suture fails at 61.8% of its actual load capacity when threaded through the toggle rod. Each suture failed at the interface with the toggle rod. This point of failure is located along the sharp edges of the toggle rod, as well as and where the stress concentration is the highest. Samples three and four yielded uncharacteristic results due to an insufficient test set-up. During the course of the testing, the knot slipped through the fixture, which resulted in a rapid load decrease. This occurred after ~ 25 pounds for sample three and at 60 pounds for sample four. After this slip, the slack was tightened again and the final yield strength was measured at the failure of the suture. This slip did not affect the accuracy of the results; the two samples failed within the average range of the other samples.

7.1.3 Double Theta-Suture Interface

The suture was looped through a hand-made double theta prototype and pulled by an Instron tensile test machine at rate of 5 mm/min until failure. Seven random samples of the OrthoFiber suture and double theta combination were pulled in order to have a sufficiently large testing group. The load was measured in Newtons and compared to the extension of the suture. The load was converted to pounds, and the resulting data can be seen below in Figure 40.

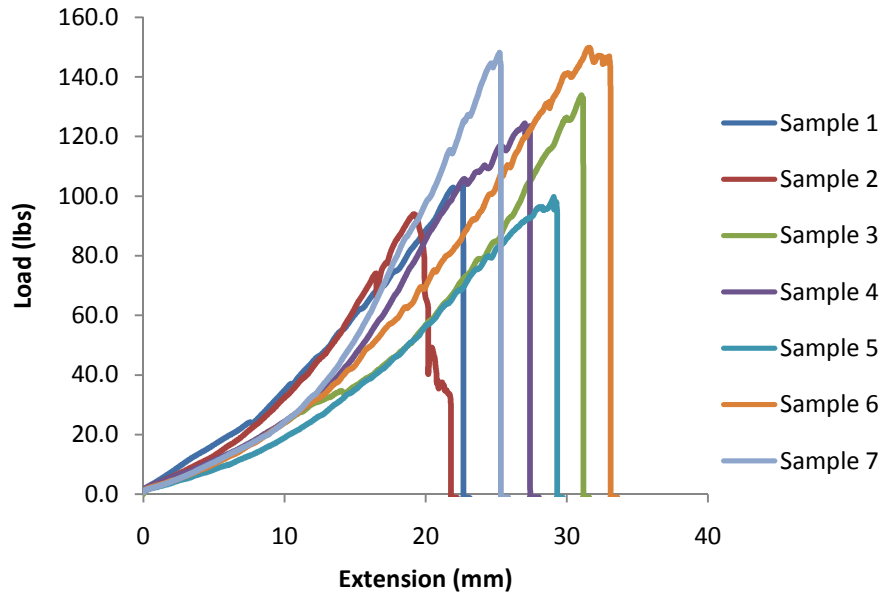


Figure 40: Double Theta-Suture Interface Tensile Testing - Load vs. Extension graph

After seven samples were pulled, the data showed that the suture’s ultimate yield strength averaged 111.4 ± 23.0 lbs, with a maximum strength at failure reaching 128.6lbs. While this shows that the suture failed due to a load less than its full capacity, the yield strength of the suture passed through the double theta is comparable and in fact extremely close to that of the isolated suture. The suture wrapped through the double-theta extended an average of 27.7mm, with a maximum extension of 33.6 mm. Although the suture failed at the implant interface, the data shows that the yield strength of the suture when looped through the double-theta implant was nearly equal to that of the isolated suture. The double-theta implant showed very little deformation at the suture-implant interface indicating the new design has sufficient strength.

7.2 Implant

The final design of the double theta implant features completely rounded edges and an increased surface area for the suture to rest on. The radius of curvature for the suture path has been doubled in the new design as compared to the toggle rod. The implant can be made from a single piece of 0.045” titanium wire that is bent into the appropriate shape. A laser weld is used to secure the ends in place such that they do not deform when the suture is wrapped around them. A 4mm hole drilled through the acetabular wall is sufficient to fit the 3.8mm wide implant.

The new double theta implant incorporates all of our design criteria and is easily manufacturable. It can be made from stock material and simply welded. After speaking with manufacturing companies, standard wire bending techniques can be used to achieve the final shape within the specified tolerances. The CAD part can be viewed below in Figure 41.

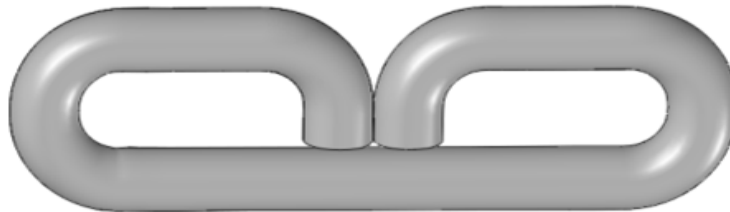


Figure 41: Final Double Theta implant design

7.3 Insertion Tool

The insertion tool was modeled according to an existing device marketed by Securos. After discussions with our client, it was determined that the current device functions well and thus needed little modification. We altered the existing insertion tool to accommodate the new implant, and made several ergonomic changes to enhance the comfort of the device for the user. The device features two grooves at one end in which the double theta fits snugly. A notch at the same end serves to guide the suture along the length of the device while two rubber o-rings can be used to secure the suture in place. The contoured grips are comfortable and provide stability for the user. The plunger is pushed to insert the implant through the acetabular wall such that it rests parallel with the bone. The final product will be manufactured out of titanium because the device contacts a biological surface. This material will also be used to make the other components within our system and thus will reduce the total manufacturing cost for the client. The CAD model can be seen below in Figure 42.

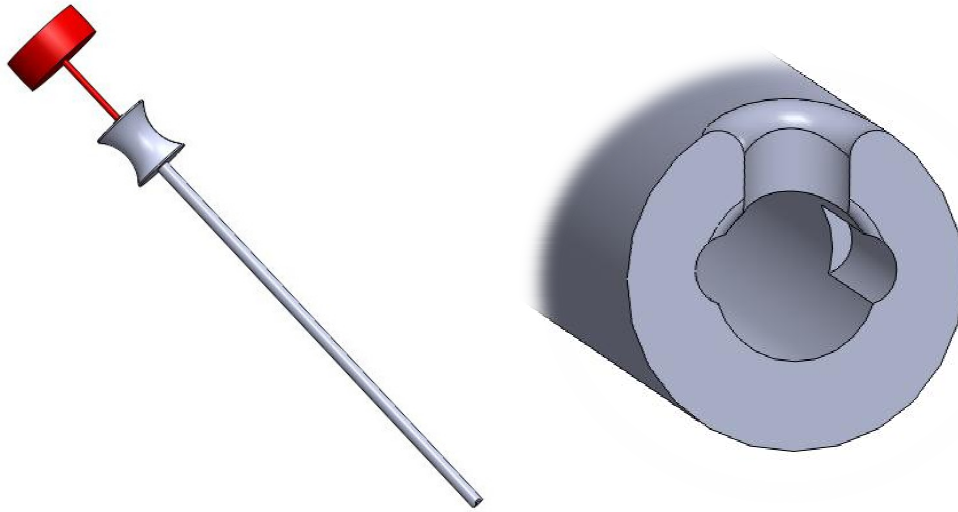


Figure 42: Final Insertion Tool (left); enlarged view of tip (right)

7.4 Aiming Guide

Several modifications were made to the original aiming guide to improve its ease of use. First, the overall shape was changed to enhance functionality; it was lengthened to accommodate larger sized femurs and reduced from three interfacing parts to two. The new aiming guide utilizes a ratcheting mechanism such that when a grooved drill sleeve slides upward against spring tempered metal, it locks into place. To release the drill sleeve, the grooves are rotated away from the body of the device. This reduction of the number of interfacing parts has improved the overall ease of use. Another modification made to the aiming guide was the design of a new tip to enhance the stability of the device in the femoral head. The existing tip can easily slip out of the fovea which requires the user to re-align the aiming guide prior to drilling the hole. Thus, we re-designed the tip as a piece of hollow tubing with sharp teeth that can secure the aiming guide while the hole is drilled through the femur. More functional than the current tip, the new tip can be made from the same tubing used for the drill sleeve, thus making manufacturing of the device more cost effective for the client. Finally, we have adopted the aiming guide to incorporate a more ergonomic shape such that it is more comfortable for the user.

The body of the aiming guide will be made of aluminum whereas the drill sleeve will be made of titanium. Standard hole sizes were incorporated into the design to accommodate stock

tubing (to be used for the drill sleeve). Rapid and functional prototypes were built to demonstrate a proof of concept. The design was optimized through discussions with the client as well as manufacturing companies, and can be seen below in Figure 43.

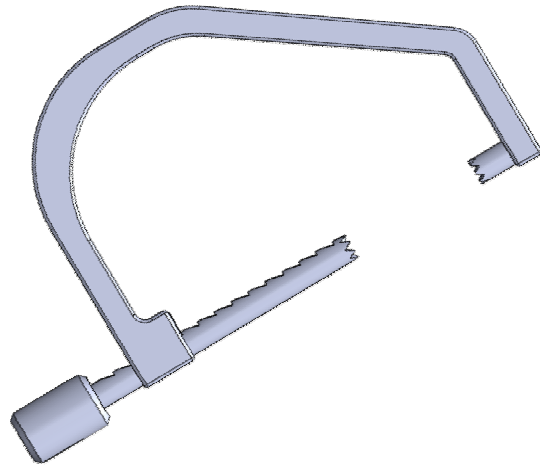


Figure 43: Final aiming guide design

7.5 Suture Sheath

The suture sheath mimics an anchoring device currently distributed by Securos. Our device is novel in that we have incorporated it into our system to protect the suture from the sharp edges of the bone and reduce the necessary accuracy during drilling. The suture sheath features a constant inner diameter with a decreasing outer diameter. The inner wall is filleted such that the suture is always resting on a smooth metal surface. The outer surface is ridged to increase the overall surface area of the device, thereby increasing bone-implant contact. This will ensure that the device can be tightly press fit within the femoral head. The device will be made of titanium as it will provide sufficient strength and biocompatibility. The final design can be seen below in Figure 44.

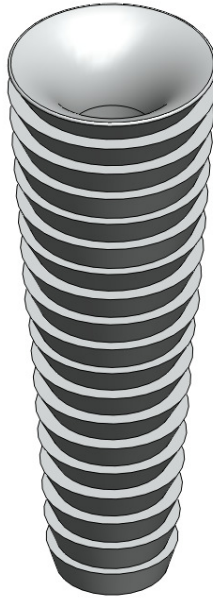


Figure 44: Final design of suture sheath

Each of the designs for the insertion tool, aiming guide, and suture sheath have been finalized through critical analysis and in depth discussions with the client. Modifications may still be necessary as the designs are optimized further for manufacturability and marketability.

8 Discussion

8.1 Implant

The design of a new implant to correct coxofemoral luxation was the original client statement, and thus was the focus of our project. The optimization of a device that improved the overall success of the corrective technique as well as improved the ease of procedure was our goal throughout the design process. Through the completion of conceptual, preliminary, and detailed design, as well as uniaxial tensile testing and the generation of rapid prototypes, the double theta design was optimized. Results from the testing proved that the double theta will be more successful in reducing suture breakage, thus improving the overall success of the procedure. Additionally, the implant can be made from a single wire and as a result will be inexpensive to manufacture. These advantages have made the double theta a more functional and cost effective means of correcting hip dislocation in canines.

8.1.1 Suture testing

The results from the suture testing showed that Orthofiber is a sufficiently strong material to secure the femur in the acetabular cup. It is critical that the suture be able to withstand the weight of the leg in addition to any forces that may result from sudden movements. During testing, each strand of suture failed due to necking, and broke at the center of the set up. These results can be deemed accurate because the suture did not break at the grips of the Instron machine, the most common source of error in tensile tests.

When the suture was threaded through toggle rod and pulled uniaxially, its ultimate tensile strength was significantly reduced. The test set up was designed to simulate the forces that act on the implant in vivo, and results confirmed that suture breakage occurs due to the sharp edges and large stress concentration at the interface. As predicted, each sample failed at the suture-implant interface and validated the need for a re-designed implant.

The double theta implant was constructed from a single piece of wire that was bent and soldered at its ends. Suture testing with this new implant showed great improvements over the suture and toggle rod testing. The ultimate tensile strength of the suture was 30% greater when wrapped through the double theta as compared to the strength of the suture when wrapped through the toggle rod. This increase was a result of the smooth resting surface and rounded edges of the implant. Additionally, the increased surface area that the suture rests on reduces the stress concentration, allowing the material to withstand a greater load. Thus these results confirm the superior design of the double theta implant and predict its ability to improve the overall success of the procedure.

8.1.2 Comparison of Toggle Rod and Double Theta

The re-design of the toggle rod was necessary to achieve the overall goals of the project. Table 1 below summarizes the features of each of the implants.

Table 1: Comparison of Toggle Rod to Double Theta

Toggle Rod	Double Theta
Sharp edges	Smooth edges
Small surface area for suture to rest upon	Larger surface area for suture to rest upon
Manufactured from a sheet of material	Manufactured from a single wire

Requires machining of hole	Requires a laser and tack weld
Made of 316L Stainless Steel	Made of Titanium
Inexpensive to manufacture	Inexpensive to manufacture

As previously mentioned, the rounded edges of the double theta implant make it a much more desirable choice for surgeons to use to correct coxofemoral luxation. The smooth surface greatly reduces the likelihood of the suture material failing at the interface. In addition, the greater surface area increases the curvature of the suture, and consequently reduces the stress concentration at the suture-implant interface. These changes in the design make the double theta implant more functional than the current toggle rod.

Manufacturability was another critical element of the design of the double theta. Although the new implant and suture combination can withstand a greater load capacity than the toggle and suture combination, the double theta is not practical if it cannot be manufactured. In addition, the manufacturing costs must remain reasonable in order for the client to market and sell the device. The consideration of these criteria enabled us to optimize the design.

The existing toggle rod is extruded from a sheet of metal, and a hole is drilled through the center of each implant. In an effort to minimize the processing as well as reduce the time to manufacture, our design uses a single piece of wire. It is intended that the wire be shaped then laser welded to secure the ends. This is more efficient and requires less machining than that necessary to produce the toggle rod. In addition, the double theta implant can be made of titanium instead of 316L stainless steel. This material is biocompatible and has a very good strength to weight ratio: it is as strong as stainless steel, yet up to 45% lighter (23). Titanium is also easy and inexpensive to manufacture, thus is a suitable material to be used for the new implant design.

8.1.3 Assumptions

During the design of the double theta, several assumptions were made to simplify the problem. First, it was assumed that the strength of a solder is comparable to that of a laser weld. During testing, each sample was soldered instead of laser welded due to our limited manufacturing capabilities. Observations of each sample following the uniaxial tensile testing showed that the double theta implant did not deform, and thus the solder was strong enough for

the implant to retain its shape. A weld is generally stronger than a solder, and thus this assumption should not impact any conclusions regarding the overall strength of the implant. Second, it was assumed that the wire used to create the double theta implant could be bent into the correct shape. After speaking to several manufacturing companies, small diameter wire bending is a common technique and could be used to manufacture the double theta. However, alternative methods may be more efficient and less expensive to the client. Lastly, it was assumed that the simplest way to thread the suture material through the implant would be to wrap it once. However, there may be alternative means of wrapping the suture that can further reduce the stress concentration. One such method may include wrapping the suture in a *figure eight* configuration. Other wrapping techniques were not tested, and thus the conventional means, wrapping the suture once, was assumed to yield the greatest results.

8.1.4 Limitations

Throughout any design process, there are various limitations that must be acknowledged in order to correctly interpret the results. During the design of the double theta implant, several limitations were identified. First, although the part and its exact dimensions were detailed in a CAD drawing, the tested samples were not dimensioned within specific tolerances. Due to our limited manufacturing capabilities, the double theta implant was bent manually using stainless steel wire. In addition, each sample was soldered instead of laser welded, as was recommended to the client. These manufacturing limitations must be considered when analyzing the testing results. We believe that the uniaxial tensile testing results of accurately dimensioned prototype implants would not yield significantly better results when compared to those of our handmade prototypes. In addition, a laser weld should physically be stronger than a solder, and thus the results could potentially be better. A second limitation was the use of material. We recommended the final implant be made of titanium for numerous reasons discussed previously, however all tested samples were made of stainless steel. The limited availability of material did not allow us to test with the desired metal, and thus may have altered the final results. Lastly, the final design was unable to be tested in vivo. With strict animal research laws, it is very difficult to test new medical products under biological conditions. The amount of time required to complete the project limited us in performing any further tests. These constraints must eventually be overcome before the implant can be mass produced and brought to market.

Although we faced several limitations during the design of the new implant, the final product has helped us achieve our project goals. The testing results show that the implant will improve the overall success of the procedure to correct coxofemoral luxation. The rounded edges and increased surface area function to reduce suture breakage; the most common problem associated with failure of the procedure. Additionally, the low manufacturing cost of the device makes it desirable to both the client and the end user.

8.2 Insertion Tool

The design of an insertion tool was critical to achieve the second goal of our project; to improve the ease of the procedure. The insertion tool is necessary to correctly place the implant along the medial wall of the acetabulum. There are few problems with the existing insertion tool and thus only simple modifications were made to alter it to accommodate the double theta implant.

8.2.1 Function

As previously mentioned, the new insertion tool mimics the existing device. It consists of a plunging mechanism that is used to push the double theta implant through the acetabular wall. Functionality and ergonomics were two key components of the design. The insertion tool should be held at the grips with a single hand in order to keep the body of the device tight against the acetabular wall. The other hand should be used to plunge the implant through the hole in the acetabulum. Once the implant is through the hole, the suture can be toggled to correctly align it along the medial wall. It is essential that the device be operated with two hands in order to prevent the implant from falling into the joint cavity.

The main body of the insertion tool should be manufactured from titanium. The metal can be easily processed and will not corrode. The plunger can be made from aluminum, an even simpler material to manufacture. The biocompatibility of aluminum is much less than that of titanium, however the plunger should not come in contact with any biological surface, and thus biocompatibility is irrelevant. Lastly, aluminum is a much less expensive material than titanium and can be easily colored if this is desired by the client. These material selections optimize the design as well as the cost, and thus have been chosen for the final design.

8.2.2 Comparison of New Insertion Tool to Existing Device

The main advantage of the new insertion tool is its ergonomic grip. The rounded grip simplifies the device and makes it easier for the user to understand how the mechanism should function. The large plunging top is also comfortable to push and makes the device easier to use. The current device does not incorporate these ergonomic features and can also be uncomfortable to the user. Thus the new insertion tool will more desirable to veterinary practitioners and orthopedic surgeons alike.

8.2.3 Assumptions

While the insertion tool was not built from metal, it was assumed that the final product will function similarly to the rapid prototype. The plastic model easily plunges the implant, and thus the same dimensions and tolerances were included in the recommendations for the manufacturing of a metal prototype. In addition, it was assumed that o-rings can be used in the same manner as they are currently used with the existing insertion tool. They effectively hold the suture in place and should be able to function similarly with the new design. Lastly, it was assumed that the two grooves will provide a snug fit sufficient to hold the implant in place. The insertion tool must effectively hold the implant while it is plunged through the acetabular wall and release it following insertion. Grooves were assumed to serve this purpose and provide enough stabilization for the implant to be held in place until its release.

8.2.4 Limitations

We faced several limitations during the design of the new insertion tool. First, a working prototype was unable to be built due to a lack of time and materials. Therefore, a complete analysis of the functionality of the tool in conjunction with the implant could not be conducted. Second, the tool was not tested during a live procedure. This is the ultimate test and setting that can be used to determine if the insertion tool will function as well as have improved ease of use. Although these limitations may not have allowed us to make the final design decisions, we were able to generate a detailed CAD drawing to submit to the client for review. His enhanced access to various resources will enable him to generate an optimized prototype before the device is mass produced.

In conclusion, the final design for the insertion tool has achieved our goal of improving the ease of procedure. We were able to devise a new device that is simple, yet entirely

functional. A key aspect for the design of this device was acknowledging that the current device has few problems, and thus by designing a similar tool, we were integrating our system into existing technology. There is relatively no learning curve associated with the use of this device, and thus it is an ideal tool for the client to market to the users because they will already know how to use it.

8.3 Aiming Guide

In addition to the development of an implant-specific insertion tool, certain modifications were made to the current aiming guide to improve its ease of use. The aiming guide ensures that the hole drilled through the femur originates exactly where the round ligament was previously attached. With our modifications, the aiming guide is easier to use without detracting from its overall function.

8.3.1 Function

The aiming guide must function to firmly tighten around the femoral head and guide the drill through the original insertion point of the round ligament. The drill sleeve must lock into place while the hole is drilled, and then easily release after drilling has been completed. This must be done while the aiming guide is held in the correct alignment. In addition, the tip of the aiming guide must be designed in such a way that it does not slip once it is set in place. All of these functional requirements were essential and incorporated into the newly designed aiming guide.

8.3.2 Comparison of Aiming Guide to Existing Device

The alterations to the current aiming guide have made the device easier to use for the surgeon. In addition, due to improvements made to the tip of the device, it can now ensure accuracy without great skill. The existing aiming guide has three parts: a body, a drill sleeve, and a set screw. These three parts are difficult to maneuver while holding the system steady and guaranteeing accuracy of the drilled holes. Our modified device has reduced the number of interfacing parts to two and allows the surgeon to use the device with one hand while drilling with the other.

Our second modification to the aiming guide was the lengthening of the body in order to increase the clearance. This alteration makes the new aiming guide more universal, as it can now

be used with a larger variety of femur sizes. Surgeons will be more willing to buy an aiming guide that can be used on a greater patient population. The increased clearance makes the device easier to use as well as cost effective for our client.

Finally, drastic alterations were made to the tip of the aiming guide. Instead of the sharp pointed tip featured on the current device, the drill sleeve tubing is now used for the tip. The cylindrical tube has sharpened teeth at the end to lock securely into the bone. These teeth provide a no-slip grip of the aiming guide at the point of contact with the bone. Lastly, the improved ease of use of the aiming guide allows a less skilled surgeon to accurately drill the hole through the femoral head.

8.3.3 Assumptions

In the development of our new aiming guide, several assumptions were made. We created a preliminary prototype in order to demonstrate our proof of concept. This prototype functions correctly, therefore we are assuming that a mass-produced aiming guide would work in a similar manner. In addition, the ratcheting mechanism is much the same as in other devices that utilize ratcheting technology, and thus it is assumed that it will work in our application. Finally, it was assumed that based on the aiming guide's improved ease of use, our design would be preferred by surgeons over the existing tool.

8.3.4 Limitations

Due to the time and resource limitations, our prototype was never able to be tested during an actual procedure. Although it is assumed that our device would work, thorough testing and analysis would have to be conducted in order to confirm the functionality of our new device.

In conclusion, the new design for the aiming guide has increased the ease of use for surgeons. The ratcheting mechanism ensures the drill sleeve can be easily set in place against the bone, and will be locked into place until the surgeon releases it. The tip will have a firm grip on the bone and will not slip from the desired location. Finally, the increased clearance makes our new device more universal, as it can now be used for a wide variety of femurs.

8.4 Suture Sheath

Suture breakage is one of the main causes of failure during the toggle pinning procedure. During the investigation of this surgery, we found that suture breakage occurs not only at the

suture-implant interface, but also where it comes into contact with the bone. The suture is prone to contacting the sharp edges bone if the holes drilled through the femoral head and acetabulum are not exactly aligned. When this occurs, the suture frays and breaks before the joint has completely healed. To decrease the bone-suture contact, we developed a novel device that protects the suture as it passes through the hole in the femur. We call this device the suture sheath.

8.4.1 Function

The suture sheath protects the suture from coming into contact with the bone by providing a smooth metal surface for the material to rest on. This decrease in bone-suture contact will lead to a reduction of suture breakage. The design of this device contributes to the achievement of our first goal, which is to improve the overall success of the procedure. The suture sheath also helps to achieve our second goal, the improvement of the ease of procedure. Because the suture sheath has a large radius of curvature for the suture to rest on, as well as ensuring the suture never comes in contact with the bone, the development of this device has decreased the need for absolute accuracy of the drilled holes. The exact alignment of the holes was one of the most difficult parts of the current surgery; as such, the decrease in need for alignment will significantly increase the ease of procedure.

8.4.2 Assumptions

Our limited manufacturing capabilities prevented us from creating a suture sheath prototype out of titanium. Thus we created a plastic, 3-D rapid prototype instead. This model was printed at the actual size and dimensions of the design, and was used as the basis for our conclusions. We assumed that a suture sheath properly made from titanium would function similarly to that of the rapid prototype. In addition, we also assumed that the suture sheath would be able to be tapped into the hole in the femoral head until it is flush with the bone. Without an actual bone or a titanium prototype, this could not be tested.

8.4.3 Limitations

The main limitations to this device were our restricted manufacturing capabilities and our inability to test our device in a live system. We were only able to create a rapid prototype of the suture sheath. The lack of a biological system also prevented us from fully testing our new

device. While we assumed that the implementation of this device would decrease suture breakage, we were unable to confirm this through testing.

8.5 Economic Impact of θ De-Lux System

As was previously discussed, veterinary expenditures have been gradually increasing over the past 20 years. Pet owners are willing to spend more money than ever before in an effort to extend their pets' lifetime, and thus the continual production of life sustaining implants is critical to serve the market demand. Specifically, implants to treat hip dislocation in canines are critical as the hip joint is one of the most commonly luxated joints. The existing toggle pin does not meet all the functional requirements necessary to guarantee a success rate of greater than 90%, as its sharp edges commonly cause suture breakage. The toggle can however, be manufactured at very little cost to the client. The design team was faced with the task of improving the overall success rate of the toggle pinning procedure while maintaining the low cost to the client. The final double theta implant, in conjunction with the aiming guide, insertion tool and suture sheath fulfill the design criteria as well as meet the needs of the client.

The double theta implant was designed to reduce the large stress concentration that results on the suture material. Rounded edges were the simplest way to reduce the concentration and could be achieved through the use of a single titanium wire bent into the appropriate shape. Titanium wire is inexpensive and easily shaped such that the cost to the client is minimal. The suture sheath and insertion tool will also be made of titanium, as the use of a common material will ultimately reduce the manufacturing costs. Lastly, the main body of the aiming guide can be made of aluminum; a weaker material, however sufficiently strong for our application. In addition to the material selection, the use of common hole sizes and drill bits will allow for the lowest possible manufacturing costs. All of these factors combined have optimized each design while incorporating economic considerations.

8.6 Environmental Impact

At first glance, there are no obvious environmental impacts of the new θ De-Lux system. In reality, the improvements made to the system have created a new, greener procedure for treating coxofemoral luxation. While using similar amounts of natural resources and manmade materials, the new design is believed to be significantly more successful. In turn, less follow up

surgeries will need to be performed conserving a multitude of resources. In addition, the concentration on ease of use has made it so more veterinarians are able to perform the procedure leading to a decrease in the travel necessary to access proper treatment. This decrease in travel not only conserves natural resources but also reduces the production of green houses gases. Through these two examples, it is obvious that the creation of the θ De-Lux system will have an overall positive impact on the environment.

8.7 Societal Influence

Once the θ De-Lux system is brought to market, it will have a significant societal influence. The simple procedure will be highly attractive to general veterinary practitioners, as they will become more willing to perform the once deemed “highly technical” surgery. Additionally, the simplification of the instrumentation will be appealing to the orthopedic surgeons who currently use the toggle pinning technique, as it will reduce the necessary accuracy and overall length of procedure. As consumers, pet owners will be attracted to the new θ De-Lux system because it is a less traumatic solution to correct coxofemoral luxation in canines. These combined effects on the user and consumer make the θ De-Lux system a highly desirable solution to repair ruptured ligaments within the dislocated hip of canine patients.

8.8 Political Ramifications

With far less political ramifications than current buzz words such as “stem cell research”, the new θ De-Lux system to correct coxofemoral luxation will be met with opposition from the typical political and ethical foundations. People for the Ethical Treatment of Animals (PETA), the largest animal rights organization in the world, is dedicated to defending the rights of all animals. Although supportive of the advancement of veterinary technology and the increased life and wellness of animals, PETA specifically examines protocols during the experimental and research stages of product development. Through public education, PETA aims to ensure that humane guidelines are followed when using animals for experimentation and testing. In order to eliminate any adversity with PETA and similar organizations, it is important to follow basic experimental protocols and ensure animal testing is held to a minimum.

8.9 Ethical Concern

It is in the nature of our project that ethics are constantly considered. The two ultimate goals of this project were to increase the overall success of the procedure and to increase the ease of procedure for the surgeons. Because the implant used in the current procedure often causes the suture to break before the hip can heal itself, a second surgery is sometimes necessary to correct the coxofemoral luxation in the canine patient. Every surgery can be equated to trauma to the dog; by increasing the rate of success of the procedure, our project is decreasing the amount of trauma that a dog faces. If no secondary surgery is needed, the dog is spared an unnecessary ordeal.

8.10 Health and Safety

During the development of our new implant and instrumentation, the health and safety concerns were always considered in terms of wellness and survival of the canine. Analysis of the procedure provided opportunities to both limit the trauma experienced by the canine as well as improve the success of the correction, limiting additional surgeries to a minimum. As previously defined by this project, the term “minimally invasive”, came to mean “less traumatic” to the canine patient.

Whereas the health of the canine is the main focus during any surgical procedure, it was also imperative to consider the health and safety of the operating physician during the design process. A pair-wise comparison chart was used to identify the most important objectives when considering the priorities of our designs. In each comparison, safety was found to be the most important. When handling animals at any point in the surgical procedure, special precautions must be made. In accordance with the Occupational Safety and Health Administration (OSHA) guidelines for veterinarians, particular attention must be paid to any instance in which a disease may be transmittable from human to animal or the reverse. Additionally, procedure specific training sessions as well as descriptive product manuals should also be provided to the user such that he or she fully understands how to perform the surgery safely. These precautions are necessary in order for the health and safety of the animal and surgeon to be properly maintained.

8.11 Manufacturability

All of our alternative designs were created to incorporate the ease of manufacturability. Made of a single titanium wire, the double theta implant can be simply bent into the appropriate

shape, with the ends laser welded to the body for increased stability. The suture sheath can be milled from a solid piece of titanium. The hole would be drilled and the ridges cut into the body. The filleted inner hole may be slightly difficult to attain the proper radius of curvature, but once the machine is calibrated for the production of this part, it should be easily mass-produced. The insertion tool and aiming guide will be manufactured in much the same way that they are currently made. Due to the minor manufacturing modifications, Securos should be able to easily integrate the production of these parts into its mass production system. The cost to manufacture specific components to the system can be viewed in Appendix N.

8.12 Sustainability

The θ De-Lux system is truly a sustainable method of treating coxofemoral luxation. Not only does this procedure provide a successful correction with a minimal amount of materials, but it also has become significantly more successful and sustainable than the current procedures. The simplifying of this procedure has also increased its sustainability by decreasing the skill necessary to complete. This decrease significantly increases the number of veterinary practitioners that will be able to complete the procedure, which furthers its sustainability. Finally, and most importantly, these improvements were made without increasing the overall cost of the procedure. A perfect procedure can become unsustainable if its price increases so much that no one can afford it. This system has remained equally as affordable as the current toggle pinning procedure making it an overall sustainable method.

9 Final Design Validation

Validation is a key factor if our novel medical device system is to become adopted in veterinary practice. The Food and Drug Administration, although somewhat lenient in terms of the veterinary market, defines validation as the “confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use can be consistently fulfilled” (1). The validation process allows a manufacturer to establish a high degree of confidence that all units will meet safety and production requirements. Validation should not be confined to in-process inspection as the testing of the finished product is equally important. Destructive testing may be required to prove that the manufacturing process is adequate, and that variations that may occur in the product will not impact its safety or effectiveness. (2)

Securos has an extensive validation process that involves continued mechanical testing to demonstrate significance as well as a clinical trial to evaluate the product’s use. Additional testing should be conducted in a simulated biological environment as well as examination *in vivo*. Harry Wotton has high expectations for his products, often exceeding standards applicable to the human market in order to ensure his product’s success. Additional validation protocol should incorporate supplemental materials in order to train veterinary practitioners with the new © De-Lux System.

10 Conclusions

In concluding this project, we have developed a new system for our client to manufacture and bring to market in a thriving veterinary industry. We have addressed the key limitations with the existing toggle pin technology and designed a new system that we believe will improve the overall success of the procedure as well as be easier to perform for general practitioners and orthopedic surgeons alike.

10.1 Double Theta Implant

The double theta implant is a device that is used to anchor the femoral head within the acetabular cup of an injured coxofemoral joint. Suture material is wrapped through the implant in order to replace the round ligament and maintain the stability of the joint until the surrounding tissue has healed. The device we have designed can be manufactured from a single piece of wire that is bent into the appropriate shape. This design for manufacturability has optimized the device for our client, as he will be able to manufacture it at a low cost.

The double theta implant has resolved the most common problem associated with the toggle pin procedure; suture breakage. The former implant placed a large stress concentration on the suture due to a very small radius of curvature. Furthermore, the existing toggle pin has sharp edges that enhance the likelihood of suture breakage at the implant-suture interface. The double theta implant has addressed the problem of suture breakage by decreasing the stress concentration on the suture material. The radius of the suture path has been doubled and the implant surface is entirely smooth.

The key features of our device have addressed suture breakage at the implant-suture interface and we believe will help improve the overall success of the procedure. The results from suture testing have shown that the suture material can withstand 30% more load when wrapped through the double theta than when wrapped through the toggle pin. These results confirm the reduction in stress concentration and therefore have resolved the most common complication with the toggle pin procedure.

10.2 Insertion Tool

Instrumentation to effectively insert the implant became necessary with the design of the double theta. The new insertion tool is made of titanium and can easily be used. Two slots at the

tip hold the implant, while the grooved notch guides the suture along the outer length of the tool. An ergonomic grip makes the tool easy to grasp with one hand while the other can be used to push the plunging mechanism. This means of inserting the implant is similar to the existing technology such that the current technique can be utilized by the user. This eases the integration of our implant system into the current corrective procedures.

The integration of our system into existing technology was critical to make it marketable. Few limitations were identified with the existing insertion tool, and thus we made minor modifications to it in order to accommodate the design of our implant. This approach allowed us to simplify the overall system as well as achieve our second goal of improving the ease of the procedure. The device effectively inserts the implant through the acetabular wall and will require the user to obtain little to no additional knowledge regarding how to use it.

10.3 Suture Sheath

The suture sheath is a novel device that was designed to protect the suture as it passes through the holes in the femur and the acetabulum. The suture sheath has a filleted inner diameter, which utilizes a smooth, rounded surface on which the suture rests. This device also features many ridges and a decreasing outer diameter that ensures a tight press-fit into the fovea of the femoral head. Made of titanium to decrease the likelihood of an immune response, our suture sheath effectively decreases suture breakage as well as decreasing the need for exact alignment of the drilled holes in the bones.

We believe that the development of this device will improve the overall success of the procedure because it will decrease the premature suture breakage that occurs in the current procedure. Not only will it increase the success of the surgery, but we believe the use of this device will also greatly increase the ease of the procedure, as the surgeon will no longer need to exactly align the holes between the femur and the acetabulum. The incorporation of this device into our system is simple, and can easily be adopted by the end user.

10.4 Aiming Guide

The new aiming guide is an altered version of the current aiming guide, which features modifications that will greatly improve the ease of use for the surgeons. The aiming guide is specific to our implant, which requires a 4 mm hole to be drilled in the acetabulum. As such, the new drill sleeve in the aiming guide accommodates a 4 mm drill bit. The drill sleeve has grooves

that pass along a piece of spring-tempered metal, which is attached to the body of the aiming guide. This acts like a ratcheting mechanism, where the drill sleeve slides forward along the ratchet, and cannot be retracted. The drill sleeve is locked into place when the drill is being used, and retains a tight fit due to the sharp teeth of the tip. When the surgeon has finished drilling, the mechanism is released by rotating the drill sleeve and pulling it free from the bone.

The final design of the modified aiming guide has incorporated our specific design criteria as well as addressed the limitations of the current device. The locking mechanism involves only the body and the drill sleeve, which eliminates the complication of three interfacing parts. The elongated body of the aiming guide was designed to accommodate all sized femurs, which promotes the universality of the device. In addition, the new tip with teeth will ensure that there will be much less tip slippage once it has been correctly placed in the fovea. Each of these modifications makes the new aiming guide much easier to use for the surgeon, and more universal to use with all canine patients.

Lastly, we have designed the aiming guide to incorporate ease of manufacturability. Standard drill bits can be used to drill the holes through the femur and acetabulum, while stock tubing can be used for the drill sleeve and tip. By constructing the device out of one material, we have also reduced the cost of manufacture for our client. These manufacturing considerations, in conjunction with the improved functionality and ease of use, make our final aiming guide design ideal for both the client and the end user.

11 Recommendations

Upon the completion of our project, we would like the Θ De-Lux system to be brought to market. We have compiled recommendations for our client, Securos, to use to effectively complete validation testing and optimization of each of the designs. If these recommendations are followed, the Θ De-Lux system should be successfully integrated into the existing technology and used to replace the existing instrumentation.

In order to provide complete validity of the new products, our client should by conduct clinical trials with the double theta implant. Studies should begin in canine cadavers, in which no other trauma to the hip has occurred. For these trials, hip dislocation can be induced and provide accurate results as to the immediate ease of the procedure. These same studies should evolve into later tests with living systems. During these tests, the ease of procedure as well as success of procedure can be evaluated, as the recovery of the test subjects can be monitored.

Final instrumentation modifications should be validated through collaboration with several veterinarians. As the end user, surgeons should be the most comfortable with the devices and should feel confident recommending our system to colleagues. Additionally, the ease of use and functionality of the instrumentation can most effectively be evaluated by orthopedic surgeons and veterinary practitioners, as they will be most impacted by each modified device.

The team has already developed a simple system to begin early stages of double theta implant production, but would like to see commencement of mass production of each of the system components. It is suggested that any component, specifically the implant and suture sheath, in direct contact with biological surfaces be made out of biocompatible Titanium. Any component or instrumentation not contacting a biological surface, including parts of the insertion tool and the aiming guide, should be made of aluminum for considerations of ease of manufacturability, cost effectiveness as well as the ability to color code the products.

As this system begins to collect the recognition of veterinarians nationwide, the commencement of a marketing and business plan for the Θ De-Lux system should be heavily pursued. As market approval becomes a reality, the development of a procedural manual and instructions for use (IFU) document should be written in order to integrate this new system into existing technology. By decreasing the learning curve for surgeons and general practitioners, the system will become more widely acceptable in the veterinary field. It is the intent that this new Θ De-Lux system become the gold standard for correction of coxofemoral luxation in canines.

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Appendix A: Glossary of Terms

Abduction – the movement of a part away from the median plane

Acetabulum – the socket of the hip, formed where the ilium, ischium and pubis meet

Adduction – the movement toward the median plane

Axis – the central line of the body or any of its parts

Caudal – toward or relatively near to the tail

Cranial – toward or relatively near to the head

Debride – Surgical excision of dead, devitalized, or contaminated tissue

Deep – relatively near to the center of the body or the center of a solid organ

Distal – away from the main mass or origin; in the appendages, the free end

Dorsal – toward or relatively near to the top of the head, back of the neck, trunk or tail

Dorsal plane – runs at a right angle to the median and transverse planes and divides the body or head into dorsal and ventral portions

Extension – the movement of one bone upon another is such that the angle formed at their joint increases: the limb reaches out or is extended; the digit is straightened. Extension beyond 180 degrees is overextension

Femur – thigh bone; largest bone in the body

Flexion – the movement of one bone in relation to another in such a manner that the angle formed at their joint is reduced: the limb is retracted or folded; the digit is bent; the back is arched

Fovea – small shallow fossa beginning near the middle of the head of the femur; gives attachment to the round ligament to the femoral head

Greater Trochanter – largest eminence of the proximal extremity; located directly lateral to the head of the femur

Ilium – largest and most cranial of the bones forming the hip; articulates with the sacrum

Ischium – the most caudal of the bones forming the hip

Lateral – away from or relatively farther from the median plane

Lesser Trochanter – a pyramidal projection at the proximal end of the medial side of the femur; serves as the insertion

Luxation – complete dislocation of a joint

Medial – toward or relatively near to the median plane

Median plane – divides the head, body or limb longitudinally into equal right and left halves

Os Coxae – hip bone; formed by the fusion of the ilium, ischium, pubis and acetabulum

Plane – a surface, real or imaginary, along which any two points can be connected by a straight line

Proximal – relatively near to the main mass or origin; in the appendages, the attached end

Rotation – the movement of a part around its long axis

Sagittal plane – passes through the head, body or limb parallel to the median plane

Superficial – relatively near to the surface of the body, or to the surface of a solid organ

Transverse plane – cuts across the head, body or limb at a right angle to its long axis or across the long axis of an organ or a part

Ventral – toward or relatively near to the underside of the head and body

Appendix B: Pairwise Comparison Chart

<i>Objective</i>	Safety	Inexpensive	Fuctional	User friendly	Minimally invasive	Repeatable	Longevity of correction	Integration into existing technology	Total	n+1	(n+1)/sum
Safety		1	0	1	1	1	1	1	6	7	0.194
Inexpensive	0		0	0	0	0	0	1	1	2	0.056
Fuctional	1	1		1	1	1	1	1	7	8	0.222
User friendly	0	1	0		0	0.5	0	1	2.5	3.5	0.097
Minimally invasive	0	1	0	1		1	1	1	5	6	0.167
Repeatable	0	1	0	0.5	0		0	1	2.5	3.5	0.097
Longevity of correction	0	1	0	1	0	1		1	4	5	0.139
Integration into existing technology	0	0	0	0	0	0	0		0	1	0.028
<i>Total</i>									36	1	

Functional

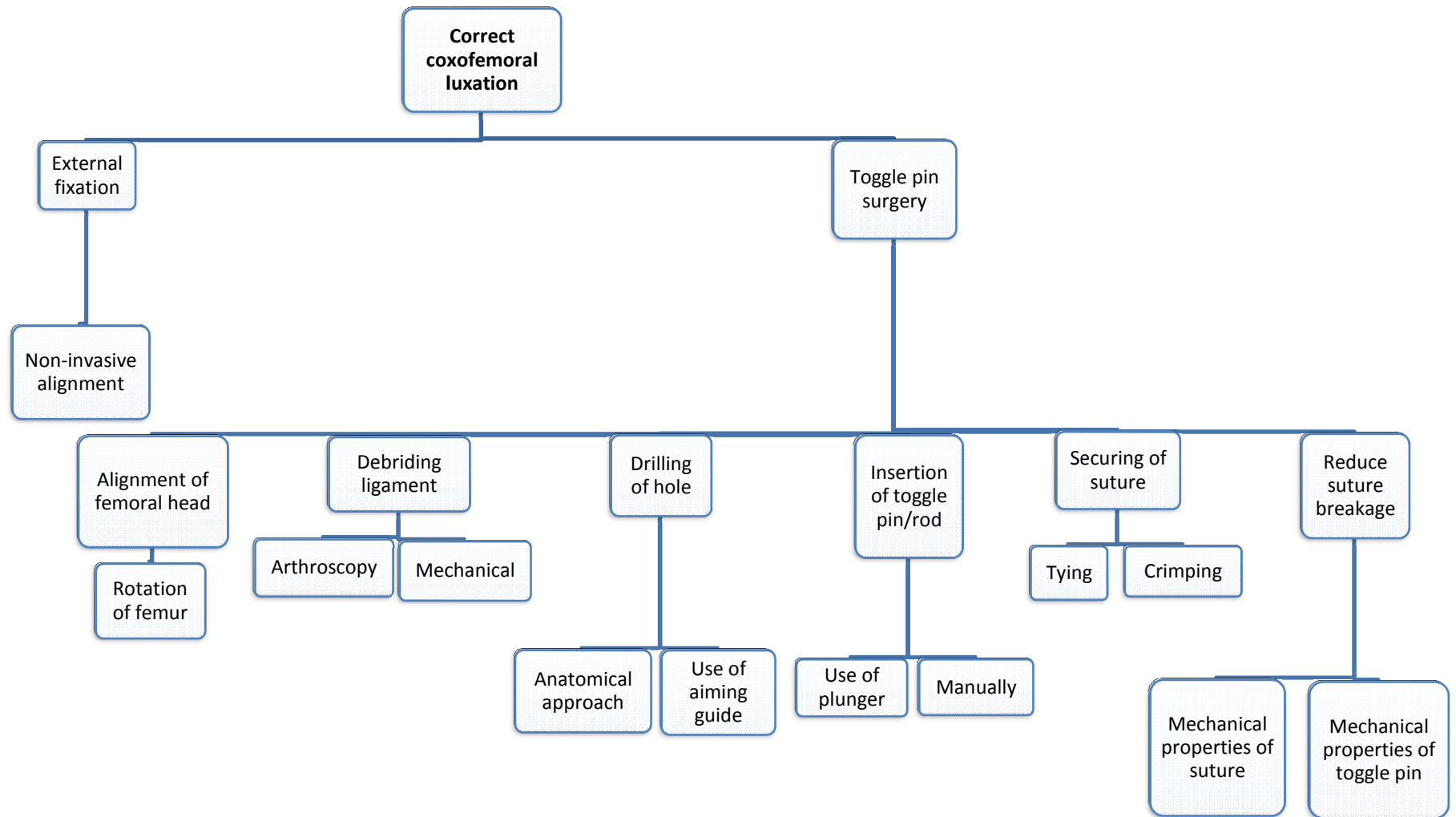
<i>Objective</i>	Coxofemoral Luxation	Maintain range of motion	Total	n+1	(n+1)/sum
Coxofemoral Luxation		1	1	2	0.667
Maintain range of motion	0		0	1	0.333
<i>Total</i>			3	1	

User friendly

<i>Objective</i>	Easy to use	Easy to manufacture	Simple to prepare	Short length of procedure	Total	n+1	(n+1)/sum
Easy to use		1	0.5	1	2.5	3.5	0.35
Easy to manufacture	0		0.5	0	0.5	1.5	0.15
Simple to prepare	0.5	0.5		0	1	2	0.2
Short length of procedure	0	1	1		2	3	0.3
<i>Total</i>					10	1	

In order to design a new device and procedure to correct coxofemoral luxation, it is crucial that the main objectives of the project be well defined. A pairwise comparison chart is a tool that can be used to prioritize objectives to determine which are most important. Each objective is listed along the first row and column, and then compared to all other objectives. The ranking is done by placing the number 0 in the corresponding cell if objective A is less important than Objective B, 0.5 if Objective A is equally as important as Objective B, or 1 if Objective A is more important than Objective B. The total score across each row is then summed, and an additional column Total ($n+1$) is calculated. Each $n+1$ column is then divided by the total score to determine the relative ranking of each objective.

Appendix C: Function Means Tree



Appendix D: Interview with Dr. Seponoski

**Interview – Dr. Seponoski, General Practitioner
Lakes Region Veterinary Hospital
November 26, 2008, 2:30pm**

1. What is your experience with correcting coxofemoral luxation in dogs?

As a general practitioner, I do not perform invasive, complex surgeries. I do simpler surgeries that involve removing material from the animal. I do not do the Toggle Pin procedure. I use the Femoral Head Ostectomy (FHO) because it is simple, easy, and has pretty good success. I remove the head of the femur and put the joint back in place.

2. Would you perform the Toggle Pin procedure if it were made simpler?

I would only do the Toggle Pin surgery if it were made much simpler. Without sufficient surgical training, the risk of drilling and getting the rod through the acetabulum is too great; Orthopedic Surgeons are the main doctors who do such levels of surgery.

3. We are looking at a different surgical approach to inserting an implant. Do you think it would be possible for us to directly insert an implant, through a ventral approach, into the medial wall of the acetabulum?

That seems like it would be a much more invasive procedure than the craniolateral approach. The way that most luxations occur, it would be difficult to access the joint and maneuver inside. Also, by making the incision along the ventral side of the joint, you would be cutting through the belly of the muscle. This would cause much more bleeding and injury to the muscle than through the lateral approach, which could actually increase healing time. It's already difficult to apply ice packs to a dog's hip post-surgery, and I don't think a dog would be willing to sit with an ice pack in its groin where the incision would be made. The location of the incision might prove difficult, because the sciatic nerve and femoral artery run along the hip joint.

4. If we were able to accurately make ventral incision, do you think there would be enough room along the medial wall of the acetabulum to place the pin?

In a medium sized dog, you could probably get two fingers back there to put an implant. It would be difficult to see though, and there is a lot of muscle that would need to be retracted.

5. Do you know of any other surgeons we could talk to for more information?

Yes, I would contact Dr. Clark. He is the Orthopedic Surgeon who does the Toggle Pin procedure for us. He works for Veterinary Surgery of New England and his email is vsne2004@aol.com. He works mainly in Dover but comes here to do surgeries when we need him.

Appendix E: Interview with Dr. Flynn

November 21st 2008

6pm EST – Call received

Dr. Michael F. Flynn DVM, Diplomate ACVS

Formerly of:

Mt. Hood Veterinary Specialists

Gresham, Oregon

(503)666-4711

Now with:

Cascade Veterinary Referral Center

11140 SW 68th Parkway

Tigard, OR 97223

(503)684-1800

Original Researcher of the Toggle Rod

Michael.Flynn3@att.net

Concerns with Lateral Approach

- Fighting muscle contraction

- Behind the luxated femoral head

- “Why is this approach still being taught”

Caudal Approach

- Moving less muscle

- Similar Incision length to lateral approach

- Ultimate Access

- Most Ideal Approach

Ventral Approach

- Very Invasive

- Impossible to reach medial cortex

Knowles Pin

- Often pulled into the joint, no standard break

- 4 different orientations, all differ in strength properties

Toggle Rod

- Toggle Rod will NOT break

Huge supporter of the toggle rod as per his expertise

The best ideas to improve the toggle rod will be those that are least likely to cut suture

Tensile properties not necessary- has only seen suture break at concentration with rod

Innovative Ideas

Improvement will be based on how round and smooth the eyelet can be

Suture failure- try braided Orthofiber as opposed to Nylon Suture

Polish/File edges of eyelet

Correct the acute angle of the Rod

Totally smooth in all directions

*Wear resistance at the eyelet causes break in suture, not tensile rubbing

*Improve Abrasive resistance of implant

Dr. Flynn was very interested in the fact that somebody was going to take his toggle pin to the next level...

Surgical Approach is not going to increase the successfulness of the procedure

Minimally invasive is not a top priority of his, he would much rather see increased compatibility between suture and implant

Willing to keep in contact for further developments or challenges

Appendix F: Interview with Dr. Ralphs

Notes from Conversation with Dr. S. Christopher Ralphs DVM MS

Diplomate American College of Veterinary Surgeons

Ocean State Veterinary Specialists

Discussion points concerning Toggle Pin Procedure and Distal Fracture Fixation Plate in collaboration with LFI Inc:

- Dr. Ralphs was familiar with Toggle Pin procedure and had completed a few
- Never attempted ventral approach, but was excited about hearing further
- Uses Lateral approach as gold standard
- Caudal approach – concerned with sciatic nerve and rotator cuff difficulties
- Agrees with use of orthofiber, material mimics properties of ligament
- Accurate drilling was his biggest concern with access to the femur
- Had never seen the “reverse drilling” from fovea to cortex
- Concerned with access to femoral head with reverse drilling
- Has faced difficulties with slippage in terms of aiming guide use
- Felt that removal of Pectineus, was a craze to correct hip dysplasia by relieving pressure in dogs in the 1980’s but had no worries as procedure has no harmful disadvantages to dog
- Concerned with blood vessels in pelvic region, but felt as if they could be held back during procedure
- Used to use homemade pins, typically failed prematurely
- Thought breakage of suture was caused by irritation at side of acetabular wall, not the junction with the rod
- Would like to see barrier to protect this area of the suture
- Wished to see rod that was expandable, grommet or eyelet that could be pushed through and would squeeze out on the other side.

Appendix G: Preliminary Testing Protocol

Tensile Testing of OrthoFiber Suture Material

Objective

To determine the point of fracture and fracture strength of OrthoFiber suture material when subjected to tensile loading through a Securos' Toggle Rod. The results from this test provide criteria for the design of a new implant for use in the correction of coxofemoral luxation.

Materials

OrthoFiber Suture Material

Securos Toggle Rod

Instron Tensile Test Machine/BlueHill 2 Software

¼" Female Flare with Gasket Adapter

Epoxy

Safety Glasses

Fiber Glass Shield

Medical Scissors

Caliper

Procedure

1. Cut strips of OrthoFiber suture material approximately 20cm in length
2. Thread Securos Toggle Rod with suture material
3. Wrap both ends of the suture material around a ¼" Female Flare with Gasket Adapter three times and pull tight.
4. Apply a single bead of Epoxy around the wrapped suture material and let set for 24 hours.

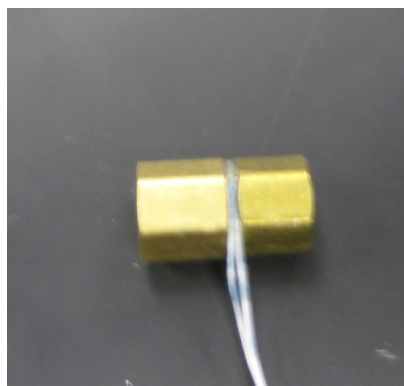


Figure 45: Suture material wrapped and epoxied

5. Log in to BlueHill 2 Software and then power on Instron to prepare samples for tensile testing.

6. Place Toggle rod along top of Instron grips, such that it is resting along the top surface of the grips and is perpendicular. Ensure the suture does not contact the grips. See Figure 46 below.



Figure 46: Test sample set-up

7. Place the ¼” Female Flare with Gasket Adapter in the bottom grips and tighten.
8. Adjust Instron grips such that 5N is pulling on the suture, then reset the gauge length to 0.
9. Measure the length and diameter of the suture material using the calipers (See Figure 47).

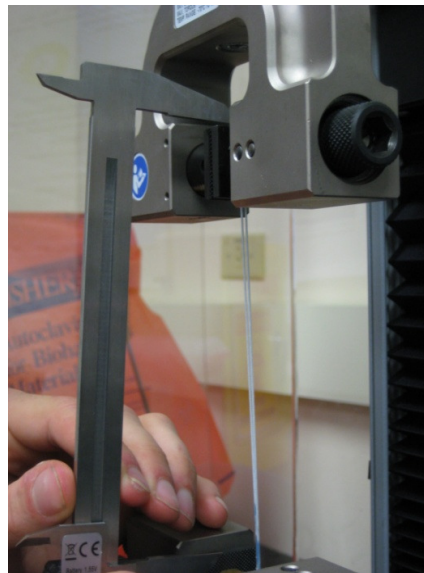


Figure 47: Measure length of suture with calipers

10. Place fiberglass shield around test set-up (See Figure 48)



Figure 48: Glass shield placed around test set-up

11. Run test and export all data.

Appendix H: Single Suture Strand Tensile Test

Objective

To determine the ultimate strength of a single strand of OrthoFiber and identify the location of suture breakage.

Materials

OrthoFiber Suture Material

Instron Tensile Test Machine/BlueHill 2 Software

2 3/8" CXC Copper Couplings

Safety Glasses

Fiber Glass Shield

Medical Scissors

Caliper

Procedure

1. Drill a 2.8mm hole through the center of 2 copper couplings.
2. Thread each end of 1 strand of suture material through the couplings and tie 4-5 knots.
3. Wrap each end of suture around the coupling 6-7 times as shown below in Figure 49.



Figure 49: Suture wrapped around copper coupling

4. Place copper couplings perpendicular between Instron grips and tighten as shown in Figure 50.

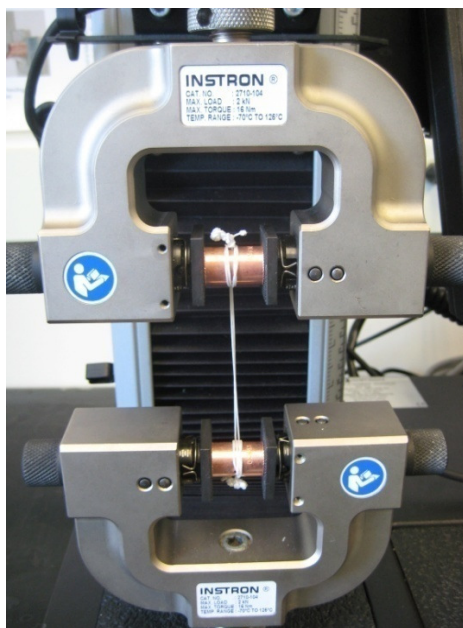
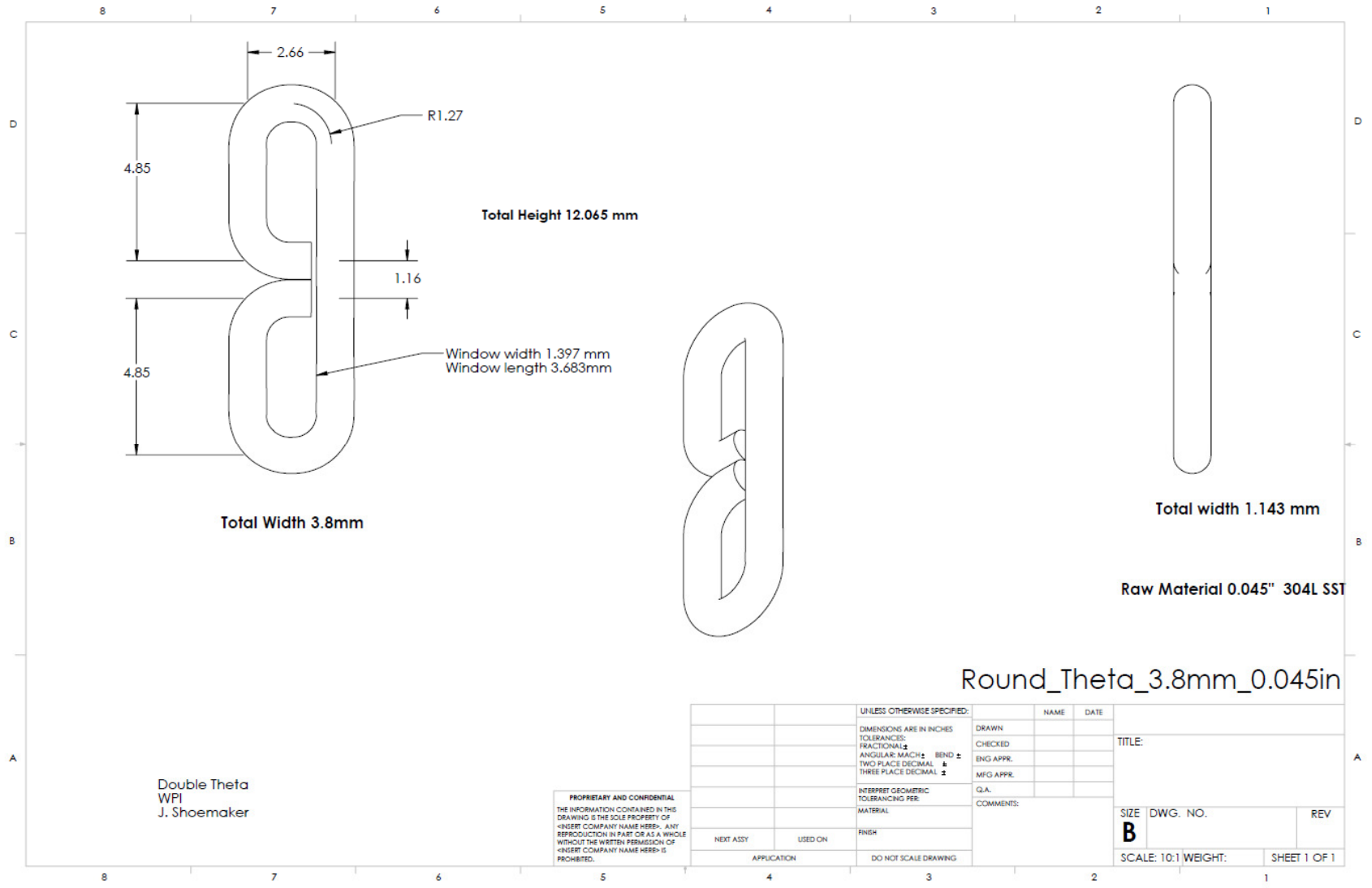


Figure 50: Test set-up

5. Apply 5N of force and reset gauge length on Instron.
6. Measure diameter and length of suture, then enter values into BlueHill Program. Set pull rate to 5 mm/min.
7. Place glass shield over testing unit and Start test.
8. After test has completed, export all data and remove sample from Instron.

Appendix I: Double Theta Drawing



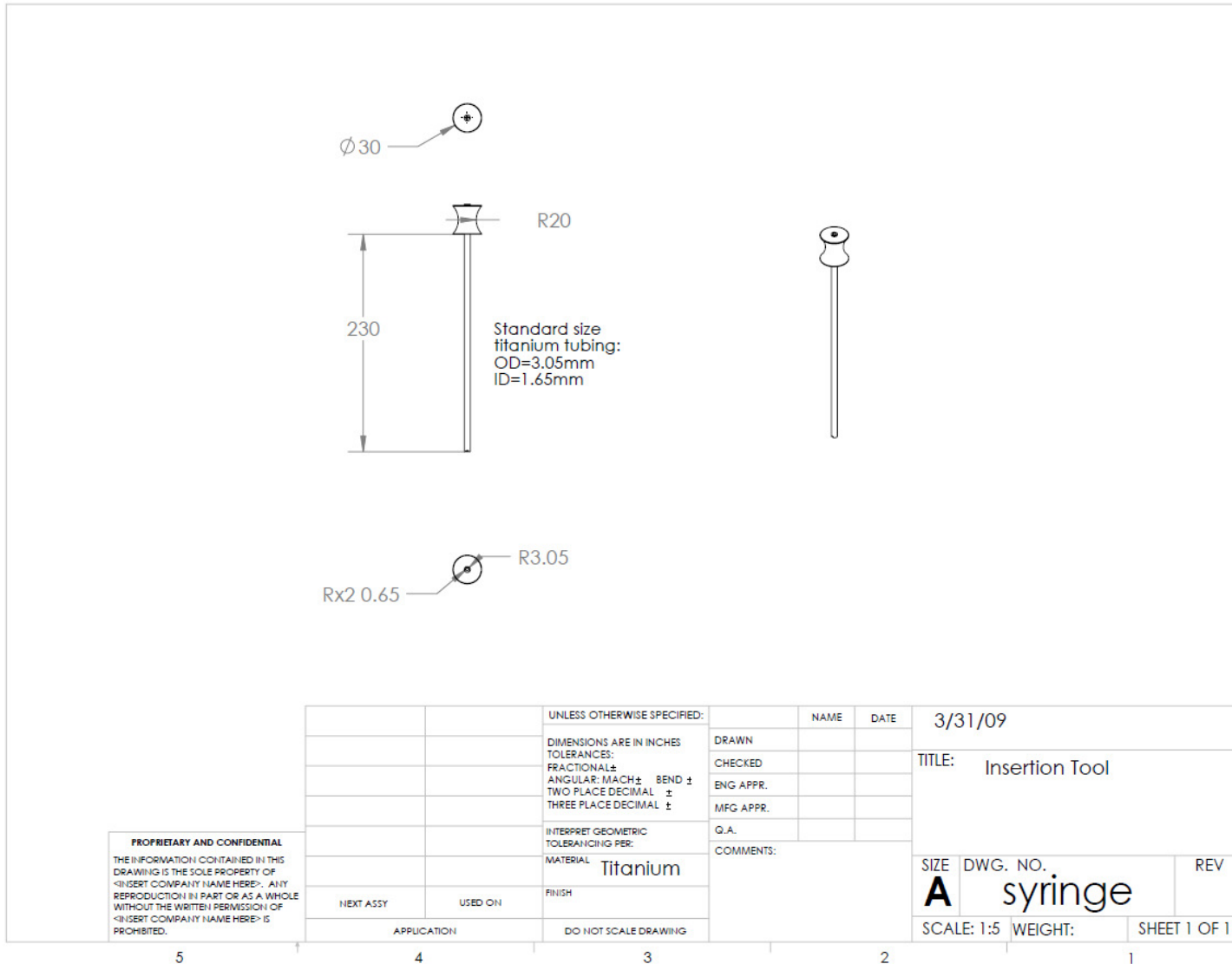
Double Theta
WPI
J. Shoemaker

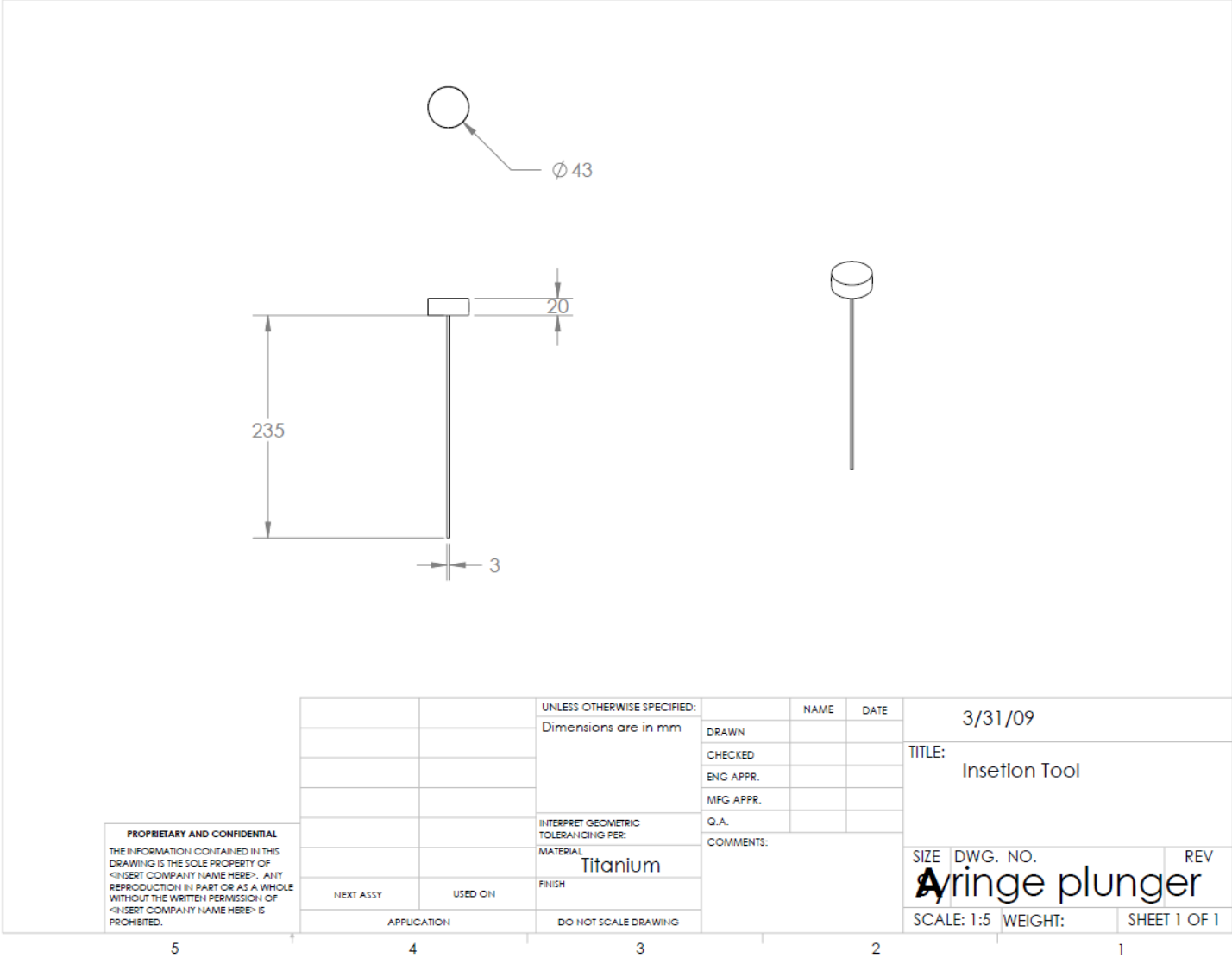
PROPRIETARY AND CONFIDENTIAL
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		UNLESS OTHERWISE SPECIFIED:		NAME	DATE
		DIMENSIONS ARE IN INCHES		DRAWN	
		TOLERANCES:		CHECKED	
		FRACTIONAL ±		ENG APPR.	
		ANGULAR MATCH ± BEND ±		MFG APPR.	
		TWO PLACE DECIMAL ±		G.A.	
		THREE PLACE DECIMAL ±		COMMENTS:	
		INTERPRET GEOMETRIC TOLERANCING PER:			
		MATERIAL:			
		FINISH:			
NEXT ASSY	USED ON				
APPLICATION		DO NOT SCALE DRAWING			
		TITLE:			
		SIZE	DWG. NO.	REV	
		B			
		SCALE: 10:1 WEIGHT:		SHEET 1 OF 1	

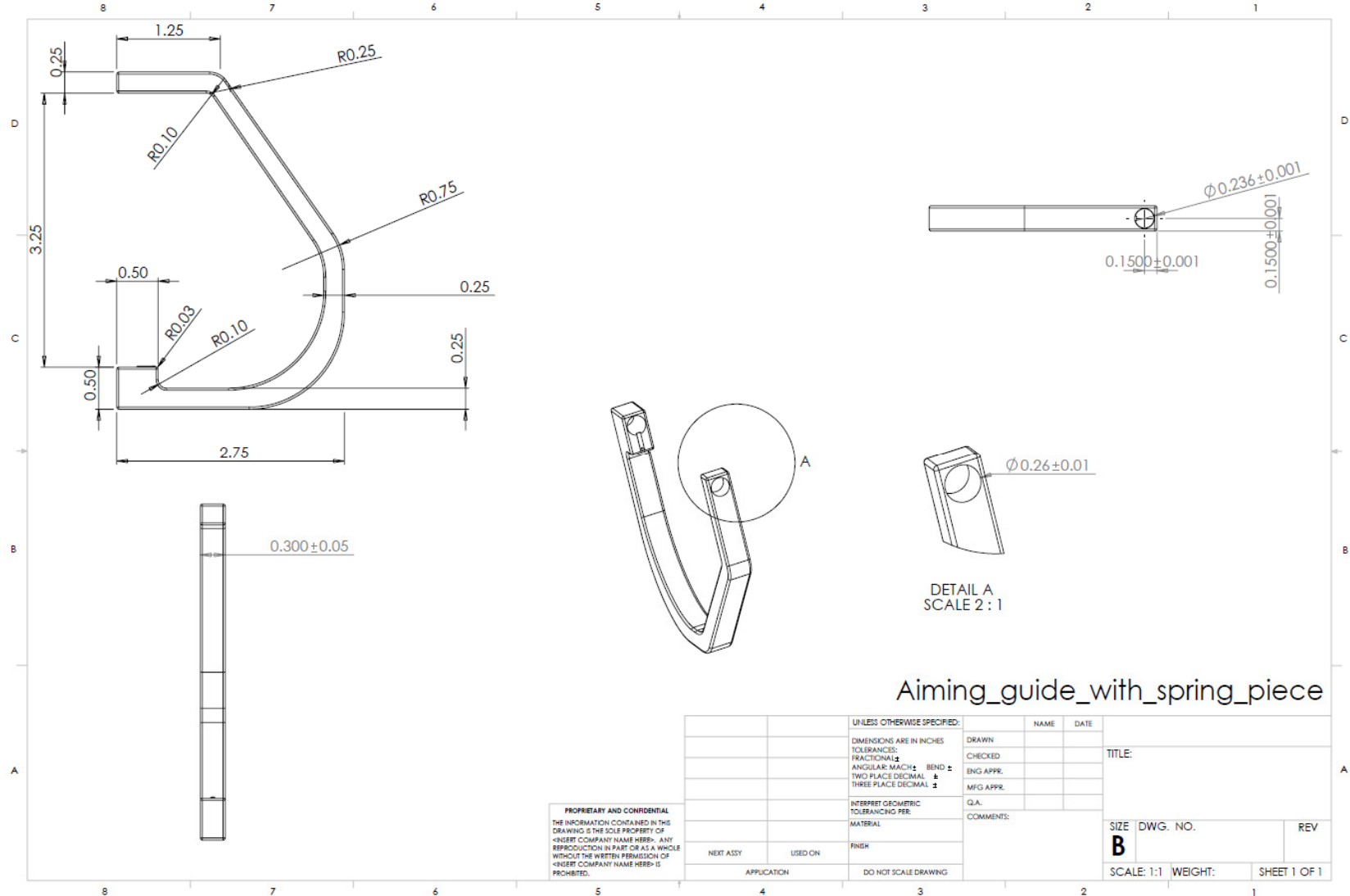
Round_Theta_3.8mm_0.045in

Appendix J: Insertion Tool Drawing





Appendix K: Aiming Guide Drawing

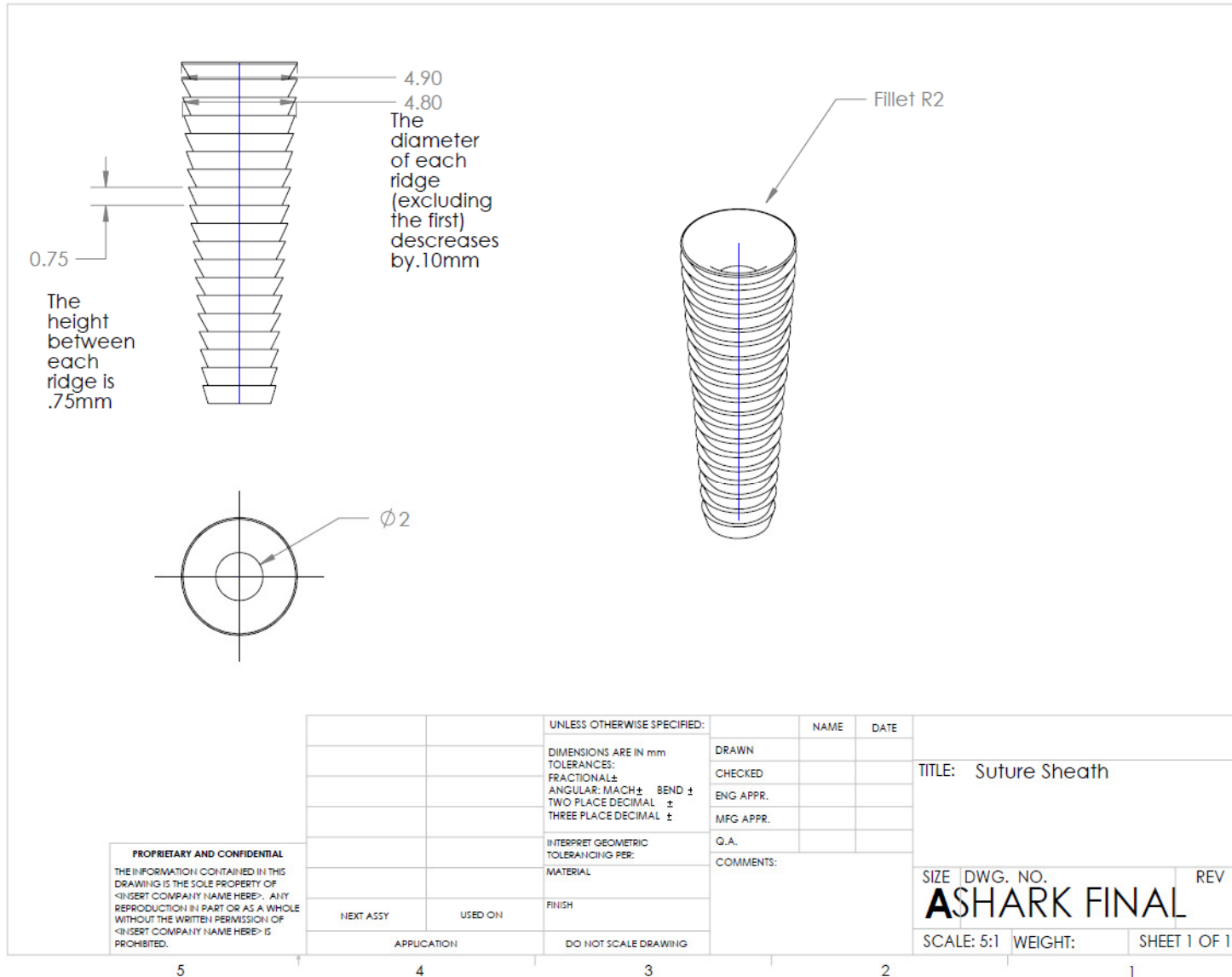


Aiming_guide_with_spring_piece

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		UNLESS OTHERWISE SPECIFIED:		NAME	DATE
		DIMENSIONS ARE IN INCHES		DRAWN	
		TOLERANCES:		CHECKED	
		FRACTIONAL ±		ENG APPR.	
		ANGULAR: MACH ± BEND ±		MFG APPR.	
		TWO PLACE DECIMAL ±		Q.A.	
		THREE PLACE DECIMAL ±		COMMENTS:	
		INTERPRET GEOMETRIC TOLERANCING PER:			
		MATERIAL:			
		FINISH:			
NEXT ASSY	USED ON	APPLICATION		DO NOT SCALE DRAWING	
			TITLE:		
SIZE		DWG. NO.		REV	
B					
SCALE: 1:1		WEIGHT:		SHEET 1 OF 1	

Appendix L: Suture Sheath Drawing



Appendix M: Expense Report

Toggle MQP Expense Report








Date	Store	Item	Price	Mileage(Round Trip)	Quantity	Subtotal	Tax	Shipping	Total	Bought By
1/21/2009	Home Depot	3/8" x 2" Black Nipple	\$ 0.89	---	4	\$ 3.56	\$0.18	---	\$ 3.74	Nick
1/15/2009	Lowe's	3/8" CXC Copper CO	\$ 0.67	---	4	\$ 2.68	\$0.13	---	\$ 2.81	Meg
12/7/2009	Lowe's	0.47 Oz Epoxy Instant	\$ 3.98	---	1	\$ 3.98	---	---	---	---
		1/4" x 1/4" Flare Component	\$ 1.96	---	4	\$ 7.84	\$0.59	---	\$ 12.41	Meg
11/30/2009	Lowe's	1/4" Flare Component	\$ 1.86	---	2	\$ 3.72	\$0.19	---	\$ 3.91	Meg
1/12/2009	Stony Brook	Parking	\$ 6.00	---	---	---	---	---	\$ 6.00	JD
	WPI MACHINE SHOP	Double Theta		---	3	*	---	---	*	Account
		Crimp		---	1	*	---	---	*	Account
		Insertion Tool		---	1	*	---	---	*	Account
		Drill Sleeve		---	1	*	---	---	*	Account
		Aiming Guide		---	1	*	---	---	*	Account
		Theta		---	1	*	---	---	*	Account
3/5/2009	Home Depot	Caulking Gun	\$10.97	---	1	\$10.97	\$0.55	---	\$11.52	JD
3/23/2009	Staples	Stapler	\$18.49	---	1	\$18.49	\$0.92	---	\$19.41	Meg
3/1/2009	Toys R Us	Nerf Gun	\$9.99	---	1	\$9.99	\$0.50	---	\$10.49	Meg
4/1/2009	Saw Bones	Canine Right Hemi Pelvis	\$18.25	---	2	\$36.50	---	---	---	---
		Canine Right Femur	\$24.50	---	2	\$49.00	*	\$16.00	\$101.50	JD
3/31/2009	McMaster-Carr	304 SS Tubing	\$9.91	---	3	\$29.73		\$5.00	\$34.73	JD
	Travel	---	---	---	---	---	---	---	---	---
1/13/2009		SUNY Stony Brook -WPI	\$0.55	427.66	1	\$235.21	---	---	\$235.21	JR
Multiple		Securos-WPI	\$0.55	46.54	3	\$139.62	---	---	\$139.62	Meg/Nick

Nick	\$50.28
Meg	\$142.11
JD	\$153.75
JR	\$235.21

\$154.00 per Member 4 Group Memebers

Machine Shop	Approx	\$32.00
Sub Total		\$581.35
YTD Total		\$613.35
Allowable Budget		\$616.00
Expected Reimburtment		\$581.35

Appendix N: Cost to Manufacture

Device	Securos		De-Lux	
Implant		\$3.85 (Qty. 250)		\$3-5.00 (Qty. 100)
Aiming Guide		\$75.00 (Qty. 100)		\$100.00 (Qty. 100)
Insertion Tool		\$25.00 (Qty. 100)		\$25.00 (Qty. 100)
Suture Sheath	N/A			7.00 (Qty. 500)