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A Novel Design to Canine and Feline Bone Healing Using External Fixation

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A NOVEL DESIGN TO CANINE AND FELINE BONE HEALING USING EXTERNAL FIXATION

A Major Qualifying Report
Submitted to the Faculty
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In partial fulfillment of the requirements for the
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By

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Abstract

With the constantly growing pet industry, veterinary technologies are rapidly evolving. The rising cost of veterinary procedures has resulted in pet owners resorting to methods such as amputation as a more cost effective solution to severe bone problems. Circular external fixation devices provide stabilization and improved bone healing for cats and dogs through the use of a minimally invasive procedure. This novel circular external fixation device provides an easy to use, radiolucent, safe, and economical design. The new ring design enables veterinarians to have more variability in the placement of the stabilization wires. The new clamp design has fewer parts and can be used with existing standard industry wires and pins. The use of magnets in this innovative design eliminates a large portion of the complex tooling required for assembly and disassembly of the external fixation device. The new design was tested using an Instron to ensure that its mechanical properties were superior to the existing device. This design was tested to sustain a load of 584.5N, which exceeds the amount of force produced by a 50 pound canine.

Chapter 1: Introduction

Pets such as dogs and cats are found in approximately 63 percent of the households in the United States (1). These United States households account for 78 million dogs and 86 million cats (2). The number of households with pets has also grown over the years. As pets continue to be important members of households throughout the United States, owners are more likely to go to extreme lengths to take care of their pets.

As the number of pets in United States households grows, it is common for pet owners to spend increased amounts of money on their animals. Between 2009 and 2011, the total veterinary expenses increased from 11 billion dollars to 13 billion dollars (3). With the increase in veterinary spending, devices such as external fixators are used more frequently. External fixation devices are currently used by specialty surgeons to fix complex fractures, lengthen bones, and realign bones.

Currently, the use of external fixation devices is restricted to specialty surgeons because of the complexity of the procedure and the cost. The current external fixation device on the market contains many parts that are challenging to assemble and time consuming to sort during surgery. In addition, the current device is expensive and the procedure associated with the device only adds to these costs. Many pet owners cannot afford such a costly procedure, and instead, choose a less effective method of treatment. For instance, amputation is often a more cost effective alternative.

The goal of this project was to create a circular external fixation device that is easier for veterinarians to use, contains fewer parts, and is more economical for pet owners. The device incorporates both circular rings and clamps to provide maximum stability for the healing bone. To make the device simpler, our device contains fewer parts and more pre-assembled components to cut down on the surgery time and reduce the amount of work for the veterinarians. The device is also more economical to appeal to a larger group of consumers. The device is easier to use so more veterinarians can perform this procedure.

In order to design an effective circular ring external fixation device, the group used the expertise of Securos, a veterinary orthopedic company, as well as feedback from various veterinarians who currently perform this procedure. Securos has created many orthopedic devices to improve the field of veterinary medicine. With their input and the feedback from veterinarians, this device has an innovative design that meets the needs of veterinarians, as well as dogs and cats with complex bone injuries.

Chapter 2: Background

In order to create an innovative design, it is important to understand the anatomy of cats and dogs, common injuries, treatments options, and specifically, external fixators.

2.1 Anatomy of Cats and Dogs

The skeletal structures of dogs and cats are very similar. Despite their differences in size, dogs and cats commonly experience the same types of injuries, specifically limb injuries. The skeletal structure of the dog is shown in Figure 1. The locations and names of each bone are nearly identical in dogs and cats. The skeletal structure of the cat is shown in Figure 2.

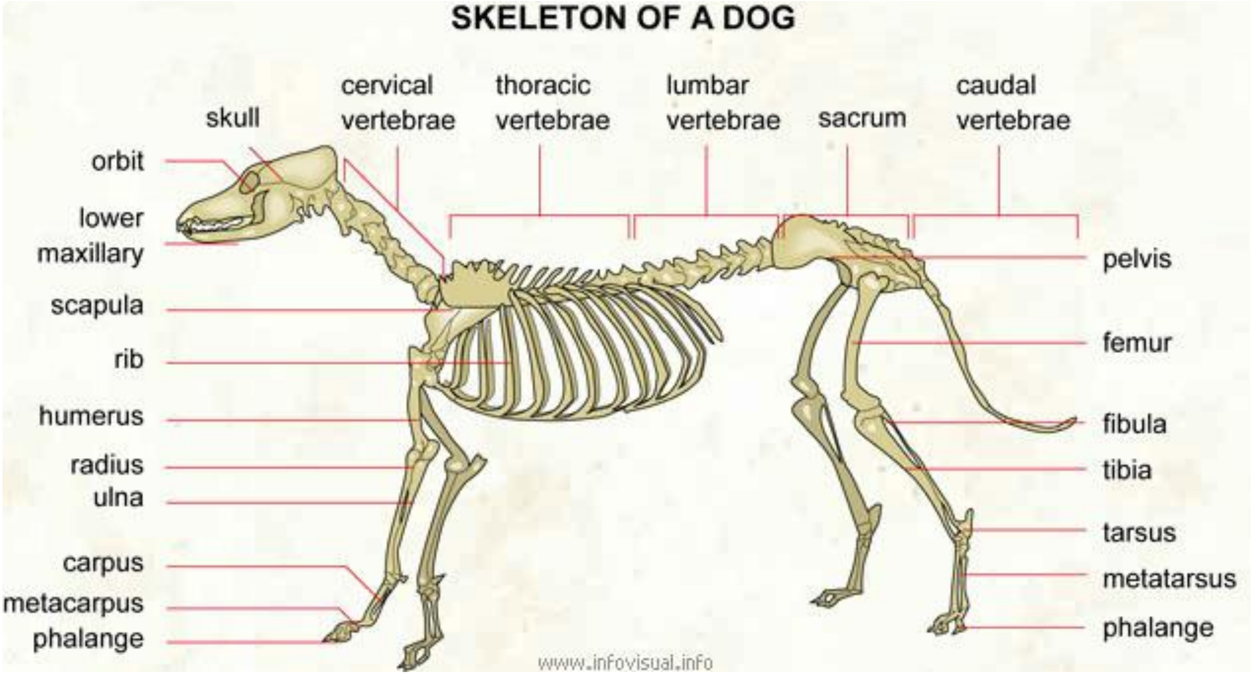

Figure 1: Skeletal Structure of the Dog (5)

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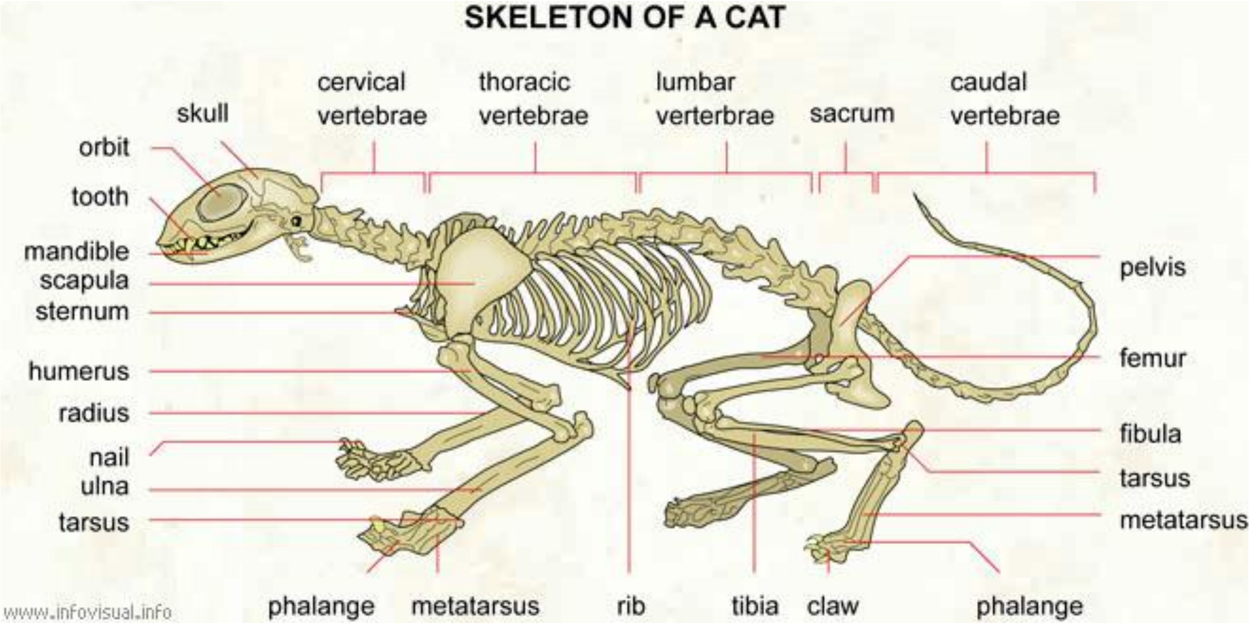
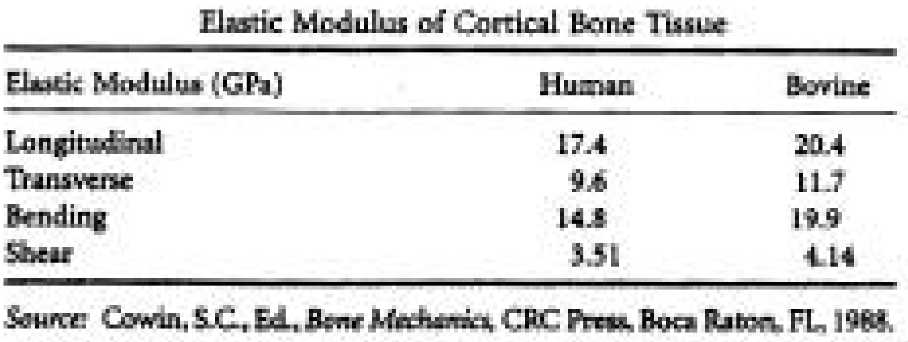


Figure 2: Skeleton of the Cat (6)

2.1.1 Cortical vs. Cancellous Bone

Cortical bone is commonly known as compact bone and is characterized as a dense shell like structure that generally forms around cancellous bone. It makes up nearly 80 percent of the skeleton and has a bony matrix that is filled with inorganic salts and organic substances with small spaces throughout. These small spaces are usually occupied by osteocytes. Cortical bone is especially prominent in the long bones of the arms and legs (10). Figure 3 displays the elastic modulus of cortical bone tissue.



Elastic Modulus of Cortical Bone Tissue

Elastic Modulus (GPa)	Human	Bovine
Longitudinal	17.4	20.4
Transverse	9.6	11.7
Bending	14.8	19.9
Shear	3.51	4.14

Source: Cowin, S.C., Ed., *Bone Mechanics*, CRC Press, Boca Raton, FL, 1988.

Figure 3: Elastic Modulus of Cortical Bone Tissue (8)

Cancellous bone is commonly known as trabecular bone or spongy bone and is characterized as a porous, light bone. The bone looks like a honeycomb or sponge in that it has many spaces throughout the structure. These spaces are usually filled with marrow. Cancellous bones account for approximately 20 percent of the skeleton and provide good mechanical properties, such as sufficient structural support and flexibility. Overall, cancellous bone undergoes larger decreases in mechanical properties than cortical bone (7).

2.1.2 Bones Found in Dogs and Cats

The femur is the thigh bone that connects the hip to the knee. It is the longest bone in the body and contains a cylindrical body with two expanded extremities. The femur head connects to the femur neck to make up part of the hip joint. The body of the femur has a caudal surface with medial and lateral lips. The distal extremity of the femur works with the fibula and tibia to make up the knee joint (4).

The tibia is the shin or leg bone and is wider than the distal part of the femur. There are two flat condyles that create this articulation with the femur. The body of the tibia is cylindrical in the middle, but the proximal end is triangular. The distal end is a quadrilateral and contains the tibial cochlea and medial malleolus (4).

The radius and the ulna are the two bones that make up the forearm. The ulna’s proximal end is medial to the radius, while the ulna’s distal end is lateral to the radius. The radius is shorter than the ulna and its head works with the humerus. The body of the radius contains both cranial and caudal surfaces. The cranial surface is fairly smooth, while the caudal surface is more rough and concave. The distal end of the radius is known as the trochlea. The trochlea has a concave shape and contains the ulnar notch and the styloid process (4).

The ulna makes up the caudal part of the forearm. The shape of the ulna is unique in that the distal end is smaller than the proximal end. The proximal end of the radius connects to the humerus at the trochlear notch and the radius at the radial notch. This joint is known as the elbow. The body of the ulna is divided into three sides. The ulnar tuberosity is the medial surface of the bone toward the proximal end. The interosseous border is the rough area that makes up the middle third of the bone. The distal extremity is known as the styloid process, which works with the ulnar, radius, and carpal bones (4).

The humerus is located in the arm of the dog and is actively involved in the shoulder and elbow joint. The head of the humerus comes into contact with the scapula, which forms the ball-and-socket shoulder joint. It also leads to the lesser tubercle followed by the greater tubercle. The greater tubercle is located on the craniolateral part of the proximal extremity, and in most breeds its summit is higher than the head of the humerus. The lesser tubercle is located on the medial side of the proximal extremity and is smaller and lower than the greater tubercle. The neck of the humerus connects the head and the tubercles and allows them to better interact with the body. The cranial surface of the humerus bone is the site of the attachment of branchiocephalicus and sections of the pectorals. The crest of the greater tubercle is the site of insertion of the pectorals and cleidobrachialis. The lateral surface of the humerus forms the deltoid tuberosity, the site of the deltoideus insertion. The body of the humerus contains the brachialis groove which is found on the lateral side and spirals around the bone. The body also contains a caudal surface that is smooth and continues into the deep olecranon fossa. The distal end of the humerus is called the humeral condyle and contains the trochlea and capitulum (4).

2.2 Common Injuries

Similarly to humans, dogs commonly break bones as a result of an accident. Getting hit by a car, falling, and repetitive activity are common causes of broken bones and fractures in dogs. Approximately 1.2 million dogs are killed each year as a result of being hit by a car in the United States (3). Dogs of different sizes and different breeds often experience varied fracture types and the causes of these fractures vary as well. For example, small dogs commonly fall from their owner's hands, while large dogs do not experience these risks. In addition, large dogs are more likely to fracture bones as a result of overuse from activities such as running, while most small dogs do not face these same concerns. Similarly, fractures in cats often result from being hit by a car or falling. For feral cats, they can experience injuries from other animals and predators as well. Approximately 5.4 million cats are killed every year due to being hit by cars (3). Indoor and outdoor cats have very different risks associated with injuries, specifically broken bones.

2.2.1 Fractures in Bones

In dogs and cats, femur fractures make up 45 percent of long bone fractures according to a study in small animal practices (1). The femur is the heaviest bone in the dog skeleton and contains a smooth head and an enlarged head (4). The femur is longer than the humerus, but shorter than the ulna and tibia (4). The enlarged head is positioned at the top of the hip joint to prevent dislocation and provide maximum movement (4).

In addition, 75 percent of long bone fractures happen in the hind legs of the dog (1). The second most common long bone fracture in dogs is the tibia, followed by the radius and ulna. It is common for dogs to fracture both the radius and ulna in traumatic accidents such as car accidents or falls. Humeral fractures make up approximately 10 percent of all limb fractures in dogs and cats (2).

Fractures in long bones are classified by several categories. They are classified first by their degree of damage, then by the site of the fracture, and finally by any complications that may have occurred. By using these three categories, and the names of bones, doctors and veterinarians can accurately describe any fracture in any bone in the body (32).

2.2.2.1 Degree of Damage to Bone

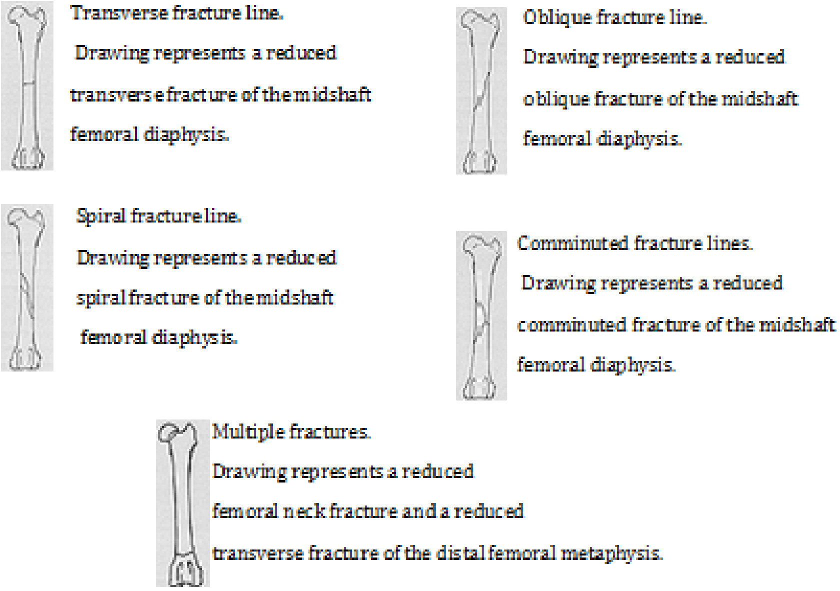
The first category used to classify a bone fracture is the degree of damage of the fracture to the bone. If the degree of damage done to the bone is large and the bone breaks all the way through, then the fracture is considered "complete." If the degree of damage done to the bone is less and the bone only cracks on one side, then the fracture is considered "incomplete." (33)

2.2.2.2 Incomplete Fracture

Incomplete fractures are categorized further depending on the nature of the fracture. Some of these fracture types include greenstick fractures, or fissure cracks. Greenstick fractures typically occur on younger animals that still have relatively soft bones. Fissure cracks occur when a direct impact results in a single fracture or multiple small fractures in one side of a bone (33).

2.2.2.3 Complete Fracture

Complete fractures are further categorized depending on the number of fracture lines. Complete fractures can be multiple fractures or single fractures. Multiple fractures occur when the bone is broken into three pieces or more. They are also categorized according to the shape of the fracture line. Complete fractures can be classified as transverse, spiral, oblique, or comminuted as seen in Figure 4. Transverse fractures occur directly across the cross section of the bone. Spiral fractures, as their name suggests, spirals around the bone. Oblique fractures occur at an angle to the cross section of the bone. Comminuted fractures occur when there are multiple fracture lines that intersect (32).



Transverse fracture line.
Drawing represents a reduced transverse fracture of the midshaft femoral diaphysis.

Oblique fracture line.
Drawing represents a reduced oblique fracture of the midshaft femoral diaphysis.

Spiral fracture line.
Drawing represents a reduced spiral fracture of the midshaft femoral diaphysis.

Comminuted fracture lines.
Drawing represents a reduced comminuted fracture of the midshaft femoral diaphysis.

Multiple fractures.
Drawing represents a reduced femoral neck fracture and a reduced transverse fracture of the distal femoral metaphysis.

Figure 4: Assorted Bone Fractures (32)

2.2.3 Location of Fracture

The second category used to classify bone fractures is the location of the fracture. Fractures are classified as epiphyseal, diaphyseal, metaphyseal. There are three main types of fractures in dogs. In immature dogs, physeal fractures are commonly seen (2). These fractures occur as a result of the physeal cartilage being softer than the surrounding bone and other tissues before the puppies are fully developed. Another type of fracture is known as a condylar fracture, which occurs in young dogs and adult dogs, but most commonly in puppies between three and five months of age. This type of fracture is generally caused a trauma or fall. The most common type of fracture is known as the diaphyseal fracture, which results from a major trauma. The diaphyseal fracture makes up approximately 50 percent of all canine limb fractures. In addition, this type of limb fracture is sometimes treated by using an external fixation device (2).

When determining the location of the fracture, the diaphysis of a long bone is also broken into thirds. When classifying a fracture that occurs in the diaphysis of the bone, the fracture is said to have occurred in the proximal third (closest to the core of the body) the middle third, or the distal third (farthest from the core of the body) (33).

2.2.3.1 Condylar Fracture

Condylar fractures are fractures that occur in the condoyle of the bone. The condyle, as seen in Figure 5, is the end section of the bone that is involved in the joint. This section of the bone contains the metaphysis, the physics and the epiphysis. Condylar fractures are typically classified as medial or lateral depending on the direction of the fracture. Medial fractures run in the medial plane, and lateral fractures run in the lateral plane. These fractures can be single fractures if the bone breaks into two pieces, or multiple fractures if the bone breaks into three or more pieces. If both condyles separate from the shaft of the bone then the fracture is considered to be a supracondylar fracture. If the condyles separate from each other and the shaft of the bone then it is considered to be a supracondylar/ intercondylar fracture. These fractures can also be classified further by describing the shape of the fracture lines. They are commonly called "V, Y, or T" fractures (32).

FIG. 11-10 Condylar fractures. (*A*) Lateral humeral condyle fracture. (*B*) Intercondylar and supracondylar fractures of the distal humerus (a "T" fracture). (*C*) Intercondylar and supracondylar fractures of the distal humerus (a "Y" fracture).

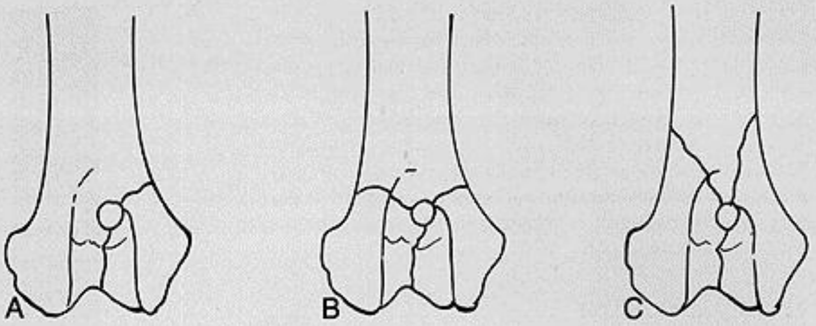


Figure 5: Condylar fracture (32)

2.2.4 Complications Associated with Fracture

Fractures can also be classified based on the complications associated with it. These fractures are known as simple, compound or complicated fractures. The best-case scenario for a fracture is to be a simple fracture because these involve only the bone, with little damage to the surrounding tissue. These are relatively simple to fix compared to compound fractures and complicated fractures. Compound fractures occur when a bone fractures and penetrates the skin. This fracture is more complicated to fix because it involves the fractured bone along with damaged soft tissue surrounding the bone. The worst kind of fracture, however, is the complicated fracture. These fractures occur when the fracture causes some other problem in the body, such as a pinched or torn nerve, a punctured vein or artery, or a pierced body cavity or joint (33).

2.2.5 Forces that Result in Fracture

Fractures in bones are caused by a single force or multiple forces acting on the bone, until the bone reaches a point where it begins to suffer damage. Different forces often result in different types of fractures in the bone. There are two main categories of forces that result in fractures: extrinsic forces and intrinsic forces. Extrinsic forces are forces coming from outside the body and act on the bone inside the body. Intrinsic forces are forces from inside the body acting on bones inside the body (32).

2.2.5.1 Extrinsic Forces

Extrinsic forces are broken down into two main categories: direct violence and indirect violence. Direct violence results in a fracture that occurs at the site of impact and often ends in multiple fractures at the fracture site. Indirect violence means that the force of the impact is transferred throughout the bone, resulting in a fracture in a weak part, or the “wet link,” of the bone away from the site of impact. Direct forces include bending, torsional, compressional, and sheering forces. These forces often result in different types of fractures. For example, bending typically cause greenstick fractures, whereas torsional forces often result in spiral fractures (32).

2.2.5.2 Intrinsic Forces

Intrinsic forces are forces that are produced from within the body. Sometimes these forces can be too great for the bones in the animal. These forces are broken down into two main categories: fractures due to muscular action and pathological fractures. A fracture due to muscular action occurs when a muscle in the body flexes too hard and fractures the bone at the site of the contraction. This is more typical with younger animals that still have weak bones. These are either caused by normal muscle contractions or violent muscle spasms. Pathologic fractures are ones that result from deformities. If an animal has a malformed bone, then the forces on that bone are not being absorbed in the intended manner. In cases like this, a small force, such as the force generated by walking, could be enough to fracture the malformed bone, or bones surrounding it (32).

2.3 Available Treatments

There are a variety of procedures and techniques that can be performed to treat the numerous injuries associated with bone fracture in cats and dogs. These treatments are based on multiple factors, and often depend on the size, breed, and age of the animal. Specifically for age, veterinarians take into consideration how old a patient is to determine its overall capability to heal. Research has shown that younger dogs heal both more effectively and efficiently in comparison to older dogs. While taking these factors into consideration, veterinarians have determined and implemented healing solutions that are patient specific. Not only are the physical characteristics of the animal taken into consideration, but the specific features of the injury also play an important role into the specifications of the healing method. As described below, the most common treatments of small animal limb fractures are broken into two categories: closed reduction and open reduction.

2.3.1 Closed Reduction

Closed reduction is defined as any treatment that does not involve surgery (11). This includes the procedures of splinting, providing slings, and casting. There are many advantages to this type of treatment, as the risks for infection are very small, and there is minimal to no invasion. Unfortunately, these procedures can only be performed in certain cases, depending on the type and location of the injury.

2.3.1.1 Cast

Casting is a very old technique. Commonly used in many general practice facilities, the use of casts provides stabilization and healing support for simple fractures that do not require surgery. To apply a cast correctly, three people must be involved in the overall procedure; two people hold the limb in place, while the other applies the padding and plaster to create the cast (12). While the leg is held in place by the two technicians, adhesive tape stirrups are applied for extra support (Figure 6). Most commonly, in the case of a lower limb fracture, the stirrups are placed on the dorsal and palmar surfaces or the plantar surfaces of the foot to reduce compression between the phalanges (12). This compression is created by the animal applying weight to the limb of interest.

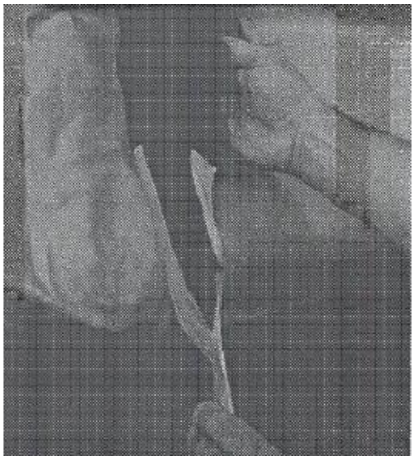


Figure 6: Application of cast stirrups (12)

After the stabilizing stirrups are applied, reduction can be completed. It is not necessary for this step to be completed at this point, but it has been found that different doctors prefer different methods. If the reduction is not completed at this point, it can be finalized after the padding material is applied (12). To apply the padding, bony protrusions are identified, and a thin layer of lining is used to cover these sections. This layer of padding is applied to protect these protrusions from pressure and friction, to avoid complications during later stages within the healing process. Research has identified that the best stabilization results from the use of minimal amounts of padding (12). Padding can be applied in multiple layers consisting of various materials. The first layer is comprised of an orthopedic stockinette and the second layer is comprised of a synthetic, hydrophobic cast padding (Figure 7).

Figure 7: Application of padding layers (12)

After the application of the padding, a dry tape (casting tape) is applied to the limb (Figure 8). This acts as a form of plaster and provides strength and stability to the cast (12). The application of the casting tape is a very delicate process, as the technician must be careful not to apply it too tight or create folds that could affect blood circulation during the healing process. The only section of the animal's leg that can be exposed to tightly wound tape is the proximal limb. This portion of the leg is not at high risk for blood circulation disruption, and by binding the tape tightly at this location, the cast can be secured (12).

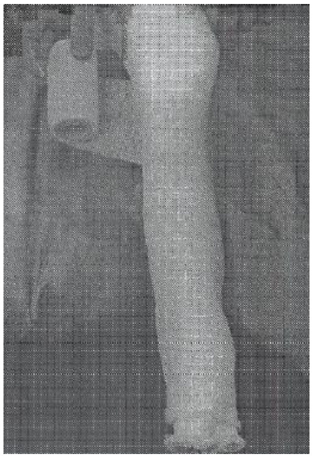


Figure 8: Application of Casting Tape (12)

The above mentioned procedure for applying a cast can be used in a variety of cases. These casts are very successful in simple radial and ulnar fractures or tibia and fibular fractures. In the case of a complex fracture, such as a compound radial/ulnar fracture, casting is considered to be unacceptable (13). It results in a high rate of non-healing and often leads to more problems, such as minor infections and non-union, as the bone begins to set in a non-uniform configuration.

Figure 9: Final application of cast (12)

2.3.1.2 Splint

Splints are often incorporated with the use of casts. The application of a splint to stabilize a limb is referred to as coaptation, and it can be achieved by using a lateral splint or a modified Thomas splint as seen in Figure 10 (14). Research shows that splints are often very effective for stabilizing and assisting in the healing process of diaphyseal fractures (14). In addition to stabilizing the fractured bone, splints are used to immobilize joints that are both proximal (stifle) and distal (tarsus) to the fracture site. While restraining these joints, it is also important for the splint to retain the proximal and distal portions of the limb in a normal angle of flexion. This helps to support the animal while in a standing position. This immobilization of joints can be hard to achieve through certain situations, specifically in the case of short legged or muscular breeds of dogs and cats (14).

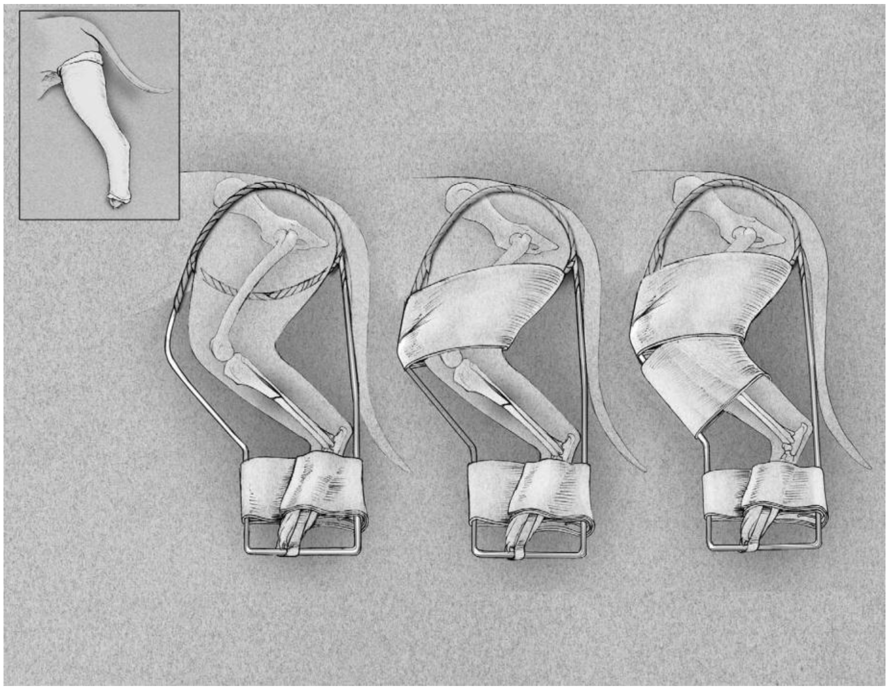


Figure 10: Cylinder cast with a modified Thomas Splint (14)

2.3.2 Open Reduction

Open reduction refers to all treatments that require surgical invasion (11). This type of treatment is used to fix fractures that are fundamentally unstable or fractures that failed to heal under closed reduction methods (15).

2.3.2.1 Steel Plates, and Screws

Plates and screws are commonly used to reduce and stabilize compound fractures, specifically radial or ulnar fractures (13). This treatment requires little care after surgery and tends to have a successful outcome. The use of plates and screws can also encourage elastic motion at the fracture site, which allows bone fragments to be pushed back in place, thereby promoting better alignment and healing (16). When a rigid fixation is used (plate and screw fixation) and normal loading conditions are applied, the fractured bone can move in small sections, micrometers at a time, and begin to go back into place (16). Through this minimal, but constant movement, circulation can be quickly restored, promoting proper and healthy blood supply to the bone.

By using a plate to stabilize the bone, the bone is able to maintain the amount of strength it had before the injury, whereas without a plate, the bone takes approximately eight weeks to regain its strength (Figure 11) (13). Unfortunately, the strength provided by the plate has a negative effect on the underlying bone, as it promotes cancellization of the cortical bone underneath the plate (16). This cancellous bone is a result of either stress created by the plate, a sudden change of blood supply to the bone (from the surgery), or a combination of both of these situations. With this in mind, the pre-injury strength of the bone is often not obtained until approximately two years after the plate has been put in place. Often times, this strength is not achieved until the plate has been removed and normal stresses have been applied on a daily basis (16).

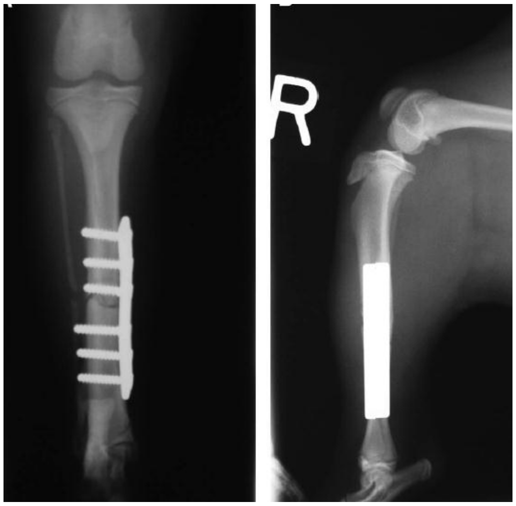


Figure 11: X-Ray showing plate and screw fixation stability (13)

Plates and screws also must be applied to encourage coaptation, the drawing together of tissue and bones. To achieve this, surgeons accurately reposition the bone and apply functional bracing, gravity alignment and early stage pressure on the bone (16). In addition to coaptation, the principal of compression is used to assist the healing process. When the plates and screws are surgically implanted, surgeons use hardware and other basic techniques to apply compression to the bone surface to give the fracture site stability (16). While the fracture site is under compression, surgeons will also apply forces to the fracture site to counteract the forces working to displace it. To properly achieve effective neutralization, a minimum of eight cortices of screw fixation through the plate are required on either side (16). If these screws are not properly fixed, they may begin to loosen and eventually pull out.

Additionally, stabilization through plates and screws must include a proper tension band system to resist bending of the fixation device. The plate acts as the tension band and provides rigid and strong support (16). Due to only having the plate on one side of the bone, the plate must be placed on the convex side of the bone to compensate for the greatest amount of tension (16). In the case of a radial fracture, the plate can be either placed on the inner portion (medial) of the bone (Figure 12) or the top portion (dorsal) of the bone (13).

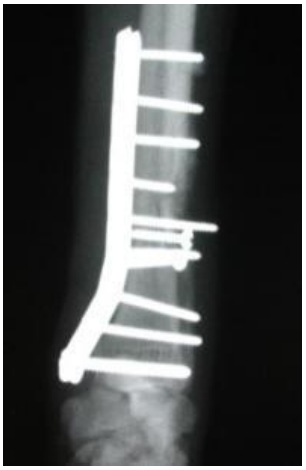


Figure 12: Radiograph of Radial Fracture with Plate and Screws (13)

To determine where the plate and screws should be located, surgeons must not only take into consideration the plane of greatest tension, but they must also consider the type and location of the fracture. For example, in the case of the distal humerus diaphysis fracture, many surgeons apply screws through the posterior section of the arm, positioning them between the triceps (16). For comminuted fractures that cannot be treated with a cast, a technique known as bridged plating can be used. If fractures are larger or more complex, such as spiral fractures, lag-screw fixation should be used initially, and then followed up by the use of a rigid plate (16). These techniques allow for proper alignment of the healed bone, and maximal strength and stabilization (Figure 13).

Figure 13: X-Ray showing healed bone with use of plate and screw fixation (16)

Unfortunately, there is a major risk involved with using plates and screws directly placed into the bone. Infection often occurs, in the form of staff infection, arthritis, or skin/bone infection. Surgeons often prescribe antibiotics when performing a surgery involving internal fixation to try to prevent infection (16). In the case of small animals, these antibiotics do not always prevent infection due to reasons like owners forgetting to give the patient the medication or the rejection of the medication by the patient.

2.3.2.2 Pins

An older technique that is often used to repair fractures is the use of a steel pin placed in the marrow cavity of the bone. This is often referred to as internal fixation. Using a pin in this manner serves to hold the fracture together, but unfortunately it is not used often due to its high rate of non-healing[13].

One type of pin is the Steinmann bone pin and it is often used to repair tibial fractures. This type of pin is an intramedullary bone pin and should be positioned in a normograde style to avoid interference with other delicate parts of the bone. These parts of the bone, specific to the tibia, include the synovial cavity, cranial cruciate ligament, patella, patellar ligament, and the femoral condyle (16). After the leg is stabilized and positioned, usually with the assistance of a technician, the pin is implanted near the medial surface between the cranial surface and the medial condyle. It is important that the pin is inserted at a slight angle to avoid damaging specific muscles and to provide the greatest amount of stability (16).

After the pin is initially inserted into the bone, the surgeon manually drives the pin the rest of the way. Using manual force, the pin is positioned to allow for a slight bend to follow the natural conformation of the bone (16). In some cases, as seen in Figure 14, two pins are placed in a cross-like pattern through the bone to increase overall stability and to help the bone heal with the proper alignment with regards to ligaments and muscles located around the fracture site.

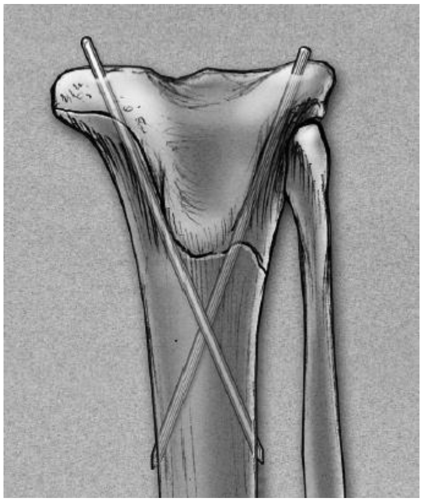


Figure 14: Cross pins used for a proximal tibia fracture (14)

2.3.2.4 External Fixators

External fixators are devices that are used to stabilize and align fractured bones or reconstruct deformed or damaged bones and joints (17, 18). These fixators consist of pins (Schanz screws and

Steinman pins) and wires (Kirschner wires and olive wires). The pins and wires are connected by a variety of clamps to external fixation rods, which are typically made of stainless steel or carbon fiber (23).

2.4 External Fixation Technology

There are three main types of external fixators: standard pin fixator, also known as a planar external fixator (Figure 15), ring external fixator (Figure 16), and hybrid external fixator (Figure 17).

Figure 15: X-ray of Standard Uniplanar External Fixator (23)

Figure 16: X-ray of External Ring Fixator (23)

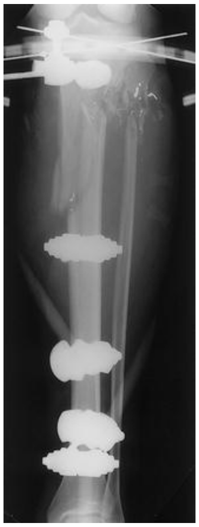


Figure 17: X-ray of Hybrid External Fixator (23)

There are many external fixators for humans already on the market. However, there are a limited number of devices designed specifically for dogs and cats. Due to the lack of options in the veterinary sphere, it is important to look at the technology behind the different human external fixation devices to develop an improved device for animals.

2.4.1 Planar External Fixators

Planar external fixators consist of pins that pass through one (unilateral) or both (bilateral) sides of a bone. These pins are located in the same plane and are connected to clamps and rods for support (20). These fixators are typically used for long bone fractures and "stabilization of complex distal radius fractures (23)."

2.4.1.1 The Hoffmann II External Fixation System

Based off the design created by Swiss doctor, Raoul Hoffman in 1938, Stryker created the Hoffman II External Fixation System for humans. This system consists of a series of carbon, aluminum, or stainless steel pins to hold fractures in place. It is typically used for the treatment of unstable fractures or in fractures where there has been skin or muscle damage (18). This system is known for its ease-of-use, versatility, and patient comfort (19). Its versatility enables surgeons to create an "unlimited number of frame configurations," allowing it to be used for temporary fracture fixation for tibia, femur, pelvis, and humerus fractures (19). See Figure 18 for examples of different frame configurations.

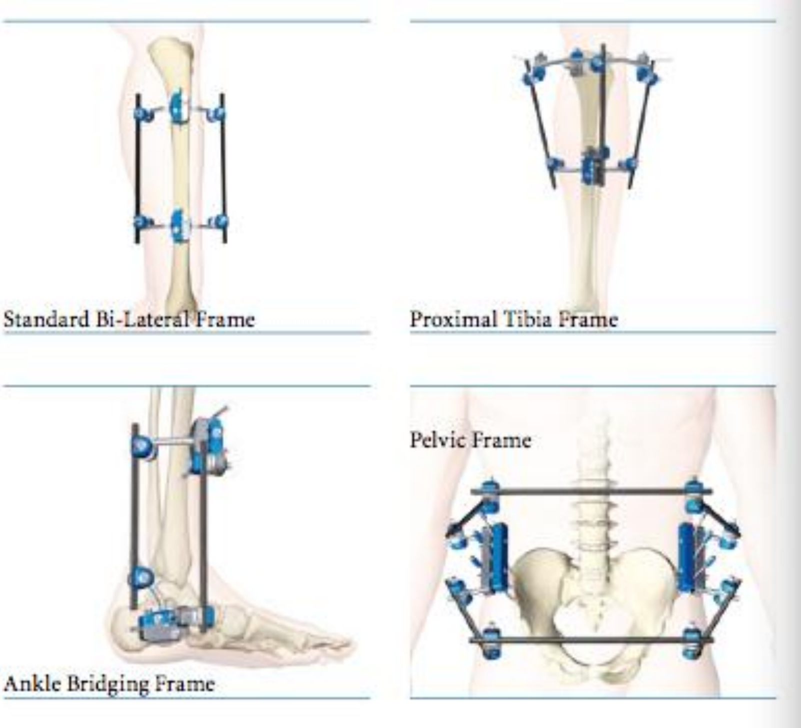


Figure 18: Possible Hoffmann II External Fixator Frame Configurations (19)

This device can be used with four-different types of pins, depending on the surgery and treatment. Stryker created a self-drilling pin, blunt pin, cancellous pin, and transfixing plan. Pre-drilling is only necessary when using the blunt pin (19). Not having to pre-drill the bone allows for more secure pins.

Stryker also developed tools, like the stabilization/reduction wrench, to aid in tightening different clamps and couplings during surgery without affecting the patient's fracture site (19). Additionally, Stryker has an organized storage case for all the tools needed for surgery.

2.4.1.2 Unilateral Fixator

The Unilateral Fixator, created by Biomet Vision, is used for applications similar to the Hoffmann II frame, but can also be used for human limb lengthening and the correction of bone or joint deformity (18, 25). The frame is made of carbon fiber to keep the device lightweight and radiolucent. It has a unique central body design and is modular, allowing for the creation of different frame configurations that can be used for a variety of needs (see Figure 19).

Figure 19: Unilateral Fixator Standard Frame Configuration (25)

Biomet Vision's system is very distinct from others on the market due to its serrated locking connectors and universal application. The serrated locking connectors "provide a mechanical locking mechanism with up to 120 degrees of articulation in any plane" and the universal application allows it to be used on the right or left side of the body (25). This system also has a variable ankle fixator component, which allows for increased flexibility of the joint for the patient (Figure 20) (25).

Figure 20: Unilateral Fixator Ankle Component (25)

Additionally, this frame is shipped to surgeons pre-assembled, but can easily be adjusted to accommodate a specific length (25).

2.4.2 Ring External Fixators

Ring fixators consist of thin wires under tension, which attach to circular or semicircular rings. This concept was created by Russian surgeon Ilizarov for limb-lengthening procedures, but is now used for more medical applications, such as deformity correction, non-unions, and bone gaps (23, 24).

2.4.2.1 Ilizarov Frame

The Ilizarov Frame is the most commonly used human circular fixator (20). The frame is made of stainless steel or carbon fiber rings, and is attached to the bone by K-wires, olive wires, and pins for bone fixation (see Figure 21) (18,20). Kirschner wires, also known as K-wires, are thin, rigid wires used to hold bone fragments in place (21). Olive wires are used for bone transport and are named for the olive shape located at the end of the wire (22, 20). This is a versatile frame and can be used for limb lengthening or reconstruction (18).

Figure 21: Ilizarov External Fixator (27)

For limb lengthening procedures, this device is adjusted four times a day. The tension in the wires pulls the ends of the bone apart and the body then fills in this space with new bone with its natural healing process (26). Many of the Ilizarov frames can be adjusted with a dial that turns with a "click." Other frames are adjusted by using a wrench to move specific nuts a quarter turn (26).

2.4.3 Hybrid External Fixators

Hybrid external fixators consist of partial rings, pins, and wires (20). It is a combination of ring and planar fixators. This type of fixator is most commonly used to treat proximal and distal tibial fractures near the joint. These are typically made up of a ¾ ring that is attached to the bone by K-wires. The ring is attached to a unilateral rod that is connected to the distal bone shaft by Schanz screws (23).

2.4.3.1 TenXor

The TenXor (Figure 22) is made of carbon fiber rings, thereby making it lightweight and radiolucent. The device is made to allow surgeons to insert wires free hand before connecting them to the ring. The entire device is based on a spring-loaded, snap-fit mechanism that improves ease of use and flexibility, making it usable for surgeons of all skill levels (28).

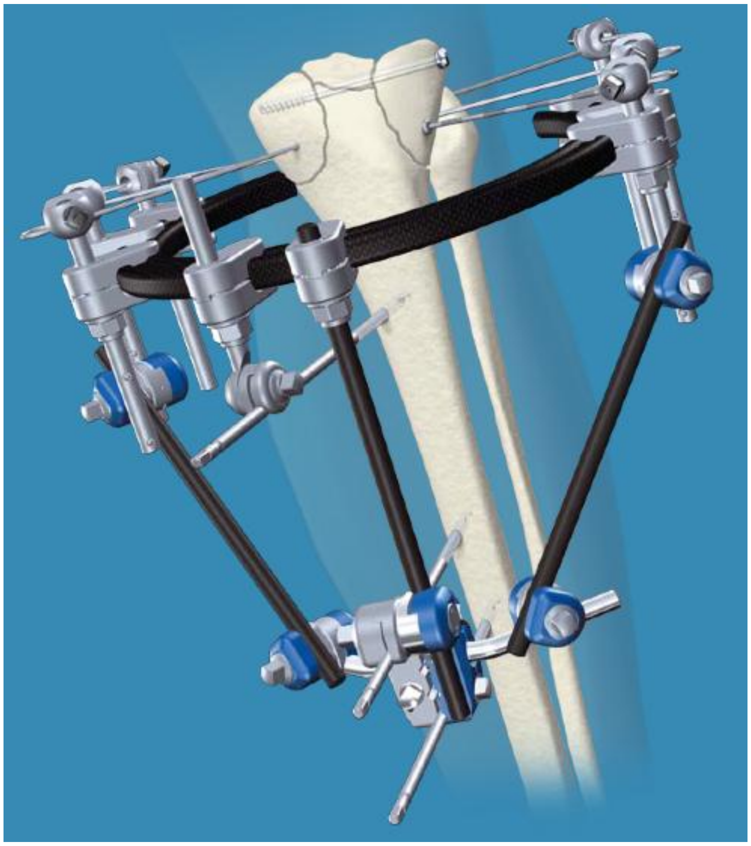


Figure 22: TenXor Hybrid External Fixator (29)

Only four major components make up this device, making it more accessible to hospitals. Since Stryker also manufactures this, it can be used with Stryker's Hoffmann II external fixation system mentioned above; the tools for each device are compatible (29). The frame is easy to build because it "clicks" together and the ring clamps can be positioned inside or outside the ring. The rings clamps can also slide around the ring for positioning. This "clicking" together, also known as a "snap fit," makes pre-assembly unnecessary. Each component has "direct positioning access to the ring construction" and can be added or removed with one motion (29).

2.4.3.2 IMEX

After looking at the human systems, it is important to see how these compare to the only existing hybrid external fixator for dogs—the IMEX SK Fixator (Figure 23).

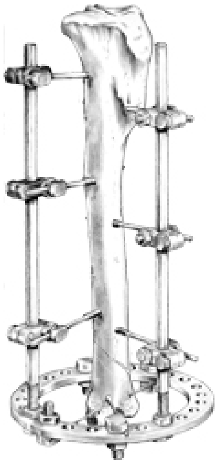


Figure 23: IMEX SK Hybrid External Skeleton Fixator (30)

The IMEX hybrid external fixator consists of a single ring with fine wires attached to a frame of rods. This design is best for treating small fracture fragments and growth deformities (30). This design is also compatible with IMEX's circular external fixator, which was produced to be structurally sound, affordable, and easy to use to treat fractures and limb deformities (31). Like the Ilizarov fixator, it needs to be adjusted daily (31).

Chapter 3: Project Approach

3.1 Initial Client Statement

There is currently only one veterinary hybrid external fixation device on the market. This device has several limitations that need to be improved upon. For instance, it currently uses stainless steel and aluminum, which are often too heavy for small dogs and cats. In addition, these materials are not radiolucent, which poses a problem when veterinarians need to see the progress of the healing on an x-ray. Another limitation is the restrictiveness of the ring structure. The current ring structure has various holes throughout the ring, but with various sized animals and numerous types of fractures, the holes cannot always accommodate the versatile uses of this device. Our client, Securos, a leading veterinary orthopedic company, has instructed us to design a circular ring fixation device with the ability to treat multiple orthopedic defects.

3.2 Objectives

After completing background research and discussing this project with contacts from Securos and an on campus advisor, the team devised a list of objectives and sub-objectives. This list of main objectives included “Safe,” “Effective,” “Useful,” and “Economical.” For each objective, the team discussed how to define and describe these objectives in detail, specifically when presented to the client.

Following brief discussion, the team determined that the objective of “Safe” was to be defined as creating a device that was safe for the veterinary surgeon and technicians performing the surgery, as well as for the patient (dog or cat), and the patient’s owner. The team felt that there should be no risk or harm to the parties involved.

The objective of “Economical” was defined as developing a cost-effective product that is affordable by a wide range of consumers. In order to make the device more cost effective, the product needs to be more affordable for the veterinarians as well as for the pet owner. To reduce the cost of the device, the new product will contain fewer parts to decrease manufacturing expenses. By using fewer parts, the new device will reduce surgery time and therefore reduce the cost of the procedure for the pet owner.

The group decided that in order to be “Effective,” the device must properly stabilize the limb of interest and allow the bone to properly heal without any complications. The device must be rigid enough to provide stability throughout the entire healing process. However, this device must allow for minor bone movement as healing takes place in order to encourage bone growth.

The last main objective was “Useful.” This objective was defined as creating a device that would allow the user to perform the respective surgery in an easier and more efficient manner. As a main goal of the project, the team felt that this objective would allow the device to be more versatile and innovative, incorporating new functions and ideas into its overall uses.

The team used pairwise comparison charts to prioritize these objectives by order of importance. It was noted that all of the objectives were important, even if it was ranked the lowest. The team completed one pairwise comparison chart (PCC) (Figure 24), and had the design team at Securos complete another PCC (Figure 25), to allow for the comparison of the results. To ensure that all of the charts were filled in similarly, the team created a guide to represent the priorities of each objective numerically.

The guide is displayed below.

Table 1: Guide for Pairwise Comparison Chart

Number	Description
1	Objective in row is more important than the objective listed in the column
0	Objective in the row is less important than the objective in the column
0.5	Objective in the row is equally important than the objective in the column

Objectives	Safe	Economical	Effective	Usefulness	Total Points
Safe	X	1	0	0	**1**
Economical	0	X	0	0	**0**
Effective	1	1	X	1	**3**
Useful	1	1	0	X	**2**

Figure 24: Pairwise Comparison Chart Created by the Team

Objectives	Safe	Economical	Effective	Usefulness	Total Points
Safe	X	1	1	1	**3**
Economical	0	X	0	0	**0**
Effective	0	1	X	1	**2**
Useful	0	1	0	X	**1**

Figure 25: Pairwise Comparison Chart Created by Securos

By using this ranking system, the team was able to total the points in each row to determine which objective ranked the highest in terms of importance.

After review of the pairwise comparison charts, and following discussions with Securos, the team determined which objectives were the most important with regard to the project. Since Securos ranked the objectives differently, the team prioritized the objectives to best meet the client's needs. Securos ranked the objectives in the following order, 1. Safe, 2. Effective, 3. Useful, 4. Economical. The team's ranking was slightly different and had "Effective" ranked above "Safe". From this observation, the team decided that these two objectives were both important, but safety should be considered the most important objective, as the client ranked it the highest.

From this initial review and ranking of the main objectives, the team focused on the sub-objectives, specifically for the objectives “Safe” and “Effective.” As mentioned above, the “Safe” objective included aspects such as avoiding harm to the patient, operating room safety, and surgeon and technician safety. From this definition, the team created sub objectives that provided more detail for goals to ensure safety of the final device. These sub-objectives, which can be seen in the objectives tree (Figure 1), included “safe for patients,” “safe for surgeons,” and “safe for owners.” From these sub-objectives, second level sub-objectives were developed including “avoid infection,” “avoid muscle damage,” and “avoid soft tissue damage,” under “safe for patients.”

For the objective of “Effective,” the team determined that the sub-objectives must include “durability,” “high strength,” “lightweight,” “high stability,” “simple user interface,” “radiolucent,” and “versatility.” Branching off from “durability,” a detailed description of “multiple uses” was added. The team depicted this sub-objective as allowing the device to be reusable and used on different patients after a sterile cleaning was performed. From the sub-objective of “versatility,” the team branched off with goals of “used for both cats and dogs” and “multiple frame configurations.” Both of these sub-objectives allowed the team to focus on creating a device that could meet a variety of needs.

The team also created sub-objectives for the other two main objectives, “Useful,” and “Economical.” Due to these objectives ranking lower than the other objectives on the pairwise comparison charts, the team felt that sub-objectives were necessary, but they would not result in the main goals of the project. For “Useful,” the sub-objectives were defined as “expedite healing” and “adjustable.” Lastly, the team brainstormed ideas for detailed goals to branch off of “Economical.” These included “reproducible” and “reduce surgery time.” By creating a device that was able to be reproduced, the team felt that money could be saved and ultimately, the device could be produced at a lower cost, allowing a wider range of consumers to purchase it.

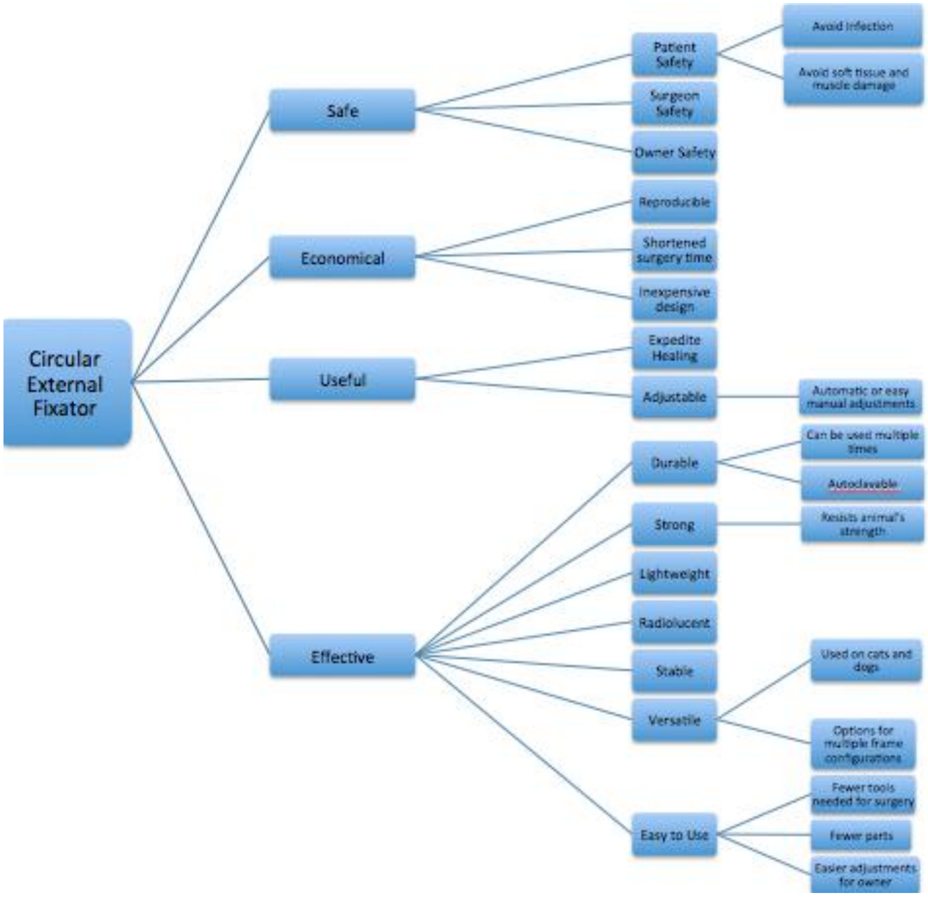


Figure 26: Objectives Tree

3.3 Constraints

Following analysis of the objectives by both the team and the client, a list of constraints was generated to assist in defining the overall design space. These constraints were defined to allow the team to create a device that could optimize all objectives, but still keep in mind the overall and realistic scope of the project. Below, each constraint is described in detail and an explanation is given on how it relates to this project.

The device must successfully heal a variety of fracture types on a large range of dogs and cats. This means that the device must be highly variable with a wide variety of parts that can be used on any cat or dog. The components of the device should easily assemble into any shape and size that the veterinarian deems necessary.

All parts of the device that go into the animal's body must be biocompatible. To ensure the safety of the animal, extensive research must be done to choose a biocompatible material that will safely stay in the animal's body for an extended period of time. In previous cases that used the external fixation device, infection has been seen as a common problem. To avoid infection and other complications, the device needs to be easily disinfected and avoid contamination.

The weight of the device must be low relative to the weight of the dog or cat to allow the animal to be mobile while the device is in place. The weight of the device is variable depending on the number of parts and the size of the parts. The number and size of the parts depends on the fracture size, and site, and the size of the animal suffering from the fracture.

Time is a constraint for this project. The deadline for this project is April 29th, which is WPI's Project Presentation Day. Different tools will be used to ensure that this deadline is met. The team developed a Gantt Chart, Linear Responsibility Chart, and a Work Breakdown Structure to ensure on time completion of this project. These can be found in Appendix B.

Money is a constraint for this project. Each group member has a budget of 150 dollars from the school to go toward research and development of this product. With four group members, the team collectively has 600 dollars to spend on this project. Any additional funds required for the completion of this project will be provided by Securos or by the team members themselves.

3.4 Functions-Means Chart

A function-means chart was designed to graphically represent the primary and secondary functions of the device. The team used this tool to expand their design space, and to enable themselves to associate design requirements with a means of accomplishment. The left column represents the basic functions of the circular ring fixator. The columns to the right display possible means by which the functions can be accomplished. From observing this function-means chart, methods have been clarified for achieving various functions pertaining to the circular ring fixator.

	Means/Feature			
Function	1	2	3	4
Adjust to different sizes	Multiple holes in ring component	Slide-able ring (fit inside itself to make different radii)	Removable attachments for the ring component	Two half ring components with holes in different locations to allow for creation of various radii
Maximize stability	Use multiple ring components (each at varying heights)	Use of a strong material		
Stabilize fractures	Increase the numbers of pins	Integrate wires under tension with rigid pins	Use only wires under tension, no pins	Use only pins, no wires under tension

Correct angular limb deformities	Use rigid linear rods all around the limb, connected by three ring components	Use multiple ring components connected by two linear rods	Use a linear guide that is in the shape of the limb (similar to a hard cast)	
Stabilize joints	Use linear rods connected at joints by hinges	Circular ring above and below joints, linear rods connected by hinges	Circular ring above and below joints, connected by hinges	
Support tendon repair	Biocampatible material	Use of only external components, no pins or wires		

Figure 27: Function-Means Chart

3.5 Revised Client Statement

After discussions with the client, Securos, the team revised the initial client statement to include more detail with regard to the objectives, constraints, and functions of the device. The goal of the project is to design a circular ring fixation device with the ability to treat multiple orthopedic problems in dogs and cats of various sizes. The device must be easily adaptable to fit animals ranging from 4 pounds to 180 pounds, include implant grade materials in the body and as much radiolucent material as possible, provide stability for the fracture while allowing gradual movement throughout the allotted time period, and consider safety of the animal and simplicity of the surgical procedure. Additionally, the procedure must be simple enough for one veterinarian to complete on his or her own. The device must contain fewer parts than the existing system while providing improved strength and durability.

3.6 Specific Aims- Methods for Completing Project Goals

After completing the revised client statement and conducting various interviews with our client, it was determined that the methods to complete our overall project goals must be identified. By mapping out these methods, our aims for the project became clear, not only for our team, but for our client, Securos, as well.

3.6.1 Improve Overall Stability of Circular Ring External Fixator

From research and analysis conducted by engineers working at Securos, it has been observed that the overall stability of existing circular ring external fixators has room for improvement. The use of hybrid frames and the integration of circular ring models with linear rods have been shown to increase stability, but there are still limitations. By interviewing veterinarians and specialized surgeons, the team determined how to integrate various frame shapes and different types of materials to create a device that can withhold animal strength while still stabilizing the limb of interest.

3.6.1.1 Integration of Various Materials in Fixator Frame

By integrating different materials into the overall design of the fixator frame, the team analyzed and tested various strength properties to determine which set of materials worked the best with one another. Research has been conducted to determine various strength properties, but a main challenge the team faced was finding a lightweight material that provides strength and stability. Since the device is used on small animals, such as cats, it is important that it be lightweight. While stabilizing healing limb fractures, the external fixator is used to help allow the animal to regain motion and mobility. If the external fixator is too heavy, the animal will be unable to lift the limb of interest, preventing a successful healing process.

3.6.1.2 Redesign of Fixator Frame

Research has been conducted to determine the strengths and weaknesses of various frame shapes and configurations found within existing fixators. Circular ring frames have been compared with linear rod frames, and both of these frames have been analyzed against the hybrid frame, an integration of the two above mentioned frames. The team has been tasked with designing a new type of frame that can maximize the stability of the fixator, while still providing appropriate healing assistance to the specific limb. Using various mechanical properties and analyzing the stress and strain created by frames incorporating different angles, the team determined which configuration of circular rings and rods would create the most stable and effective device.

3.6.2 Increase the Versatility of the Circular Ring External Fixator

Through discussions with the Securos engineering team, it has been noted that with the current circular ring external fixators available, the number of limitations on each model is very high. Most models can only be used on a specific sized patient (small cat or large canine), requiring veterinarians to purchase multiple devices so that they can perform the appropriate surgery for various species (both dogs and cats), ranging in size from 4 to 180 pounds. It has also been observed that each device can only perform a limited number of functions. External fixators can be used for numerous applications, including limb lengthening and straightening, fracture healing and support, as well as limb deformity correction. Unfortunately, the current devices are often designed to only fix one of these problems, making it very difficult for veterinarians to choose which device is not only the most appropriate for their patients, but which is also the most cost-effective and efficient for use in their practice.

3.6.2.1 Integrate Existing Components into a Single Device

To create a device that has the ability to complete multiple tasks for various applications, the team was asked to design an external fixator that integrated numerous components into one device to allow for maximal function. Analyzing existing parts and ideas, the team has researched the benefits of creating a device that can be adjusted while in use to maximize its performance. It has been discussed by veterinarians and engineers that by combining these various ideas it will be possible to create a more feasible and cost-effective device. Components that may be combined, and have been discussed, are circular rings with adjustable clamps, rotating clamps to allow for various wire angles, and the integration of linear fixators with circular fixators.

3.6.2.2 Create a Universal Clamp

The team has gathered a large amount of information pertaining to the clamps that are currently used in the external fixator designs. Through discussions with the client as well as with veterinary surgeons, it has been noted that the clamps used to hold the wires, pins, rods, and rings in place have a large need for improvement. These clamps are very small, and are comprised of a variety of parts, making it hard for the surgeons to assemble the device during surgery. The team has put focus on creating a new clamp that can be pre-assembled as well as universal, to allow the surgeon to easily attach it to the device. Currently, as mentioned above, there are different clamps that perform four different functions. By creating a clamp that can perform all of these functions alone, the team was able to simplify the surgery, making it more efficient, and easier to use for the client.

Chapter 4: Design Alternatives

4.1 Needs Analysis

Although the current veterinary circular external fixation design has been, and is still being used by the majority of veterinary surgeons, there are numerous limitations associated with the device. From the lack of universal use and simplicity, to appropriate and easy to use tooling, veterinarians have expressed the need for improvement of the current device. After discussions with veterinary surgeons, Dr. Jim Easley of Townsend Veterinary Hospital, Dr. Matthew Barnhart of MedVet in Ohio, Dr. Josh Jackson of San Diego Veterinary Specialty Hospital, and Dr. Michael Kowaleski of Tufts Veterinary School, it was determined that there is a strong need for a pre-assembled device and simpler parts.

All four of these veterinarians touched on the idea of creating a new clamp for the system that eliminated assembly involving small parts, such as screws and bolts, which are commonly used to assemble the current clamps. It was noted that while in surgery, it is very difficult to handle the small parts associated with the clamp. The design would appeal to a larger variety of veterinary surgeons if it were more user-friendly, universal, and easier for in-surgery assembly.

Improving the design of the ring would make a simpler clamp more effective. The current ring is made of stainless steel and consists of several holes. While this design provides good stability, it does not allow for the necessary angle changes needed in certain procedures. In addition, the use of stainless steel causes the device to be radiopaque, which creates a problem for veterinarians when assessing the healing process. By focusing on these specific needs and recommended improvements, the team proposed four alternative designs to make this device easier to use and encourage increased efficiency of the overall surgical procedures associated with this device. Below, the device is broken into three main components: the ring, the clamp and the overarching material. The team performed an evaluation on each section of the device with regards to objectives and functions of the project, to assist in choosing a final design of the device.

Table 2: Types of Ring

	I-Beam	Flat	Holes	Tube	Olympic Torch
Ease of Use (5)	4	5	1	1	4
Manufacturability (2)	1	2	2	0	1
Testing Requirements (3)	2	3	2	1	3
Safety (5)	5	4	3	1	4
Functionality (5)	4	5	2	2	4
Weight (4)	3	2	4	1	3

Durability (4)	4	3	2	1	4
Reusability (2)	2	2	2	1	2
Prototype Time (2)	1	2	2	1	1
Stability (4)	4	3	2	1	3
Cost (3)	2	2	3	1	3
Total	32	33	25	11	32

Table 3: Types of Clamp

	Lego	**Modified Lego**	**Suitcase**	**3 Part**	**Magnetic**
Ease of Use (5)	5	5	4	3	5
Manufacturability (2)	1	0	2	0	2
Testing Requirements (3)	1	2	3	3	2
Safety (5)	2	3	5	4	3
Functionality (5)	1	2	4	4	4
Weight (4)	4	3	3	1	3
Durability (4)	2	2	3	4	3
Reusability (2)	2	2	2	1	2
Prototype Time (2)	1	1	2	0	2
Stability (4)	1	2	3	4	3
Cost (3)	2	1	3	2	3
Total	22	22	34	26	32

Table 4: Types of Material

	Carbon Fiber	Stainless Steel	Ultem	Titanium
Manufacturability (5)	3	5	4	4
Testing Requirements (3)	2	3	1	1
Radiolucency (5)	5	0	5	0
Safety (5)	3	4	5	5
Biocompatibility (4)	2	3	4	4
Weight (4)	3	1	4	2
Durability (4)	3	4	2	4
Reusability (2)	1	2	1	2
Stability (4)	3	4	3	4
Cost (3)	2	3	1	2
Total	27	28	30	28

4.2 Functions

The clamps in external fixators are used to hold the different components of the device together. There are three different types of clamps used to do this. The first of these are the ring to rod clamps, which are responsible for attaching the rod(s) to the ring structure. Next is the ring to wire clamp. This clamp is used to clasp the wires that pass through the bone. These wires need to be versatile because they play a crucial role in healing fractures. This means that these clamps must be adjustable so that veterinarians are not restricted in where they can position the wires. These can be adjusted by height and angle. Finally, the third type of clamp is the rod to pin clamp, which is designed to grip the shafts of the pins used to stabilize large bone fractures.

The ring structure is commonly used in fixators to provide increased structural support and stability. By fully surrounded the bone, rings create 360 degrees of support for the healing limb. In addition, the ring is used to stabilize wires that pass through the bone. In a severe fracture, wires are commonly used to hold the bone fragments together. These wire clamps need to be versatile so that they can be placed at any point around the bone. The ring structure allows for this versatility of the wires as the clamps are adjustable to account for the passing wires. While it is important for the ring to be supportive, it should not interfere with limb movement or provide harm to the animal at any time. The ring structure should be only slightly larger than the animal's limb.

4.3 Conceptual Designs

The team brainstormed many ideas for fulfilling their client's needs. The project was broken into two main components to ease the overall design process. The concepts for a specific ring design as well as a specific clamp design that could be universal to work with all existing parts of the IMEX device were created by the team and then put together to propose various design alternatives.

4.3.1 Simplified Clamp

As mentioned above, there are three types of clamps used in a fixator: a ring to rod clamp, ring to wire clamp, and rod to pin clamp. All of these clamps play an integral role in the success of an external fixator because they are the parts responsible for holding the device together. As a result, it is important that they be easy to use, safe, and functional. However, the current clamp designs are difficult to use due to the number of small parts. These small parts are challenging to handle when attempting to assemble or disassemble the clamp during surgery.

Additionally, the current clamps are made of stainless steel. While there are many positive mechanical properties in stainless steel, it is heavy and not radiolucent. Veterinarians also occasionally fasten the clamps too tightly so that they make slight deformations to the parts they are holding together. Although these are small deformations, these can lead to part failure or hinder the structural integrity of the fixator after multiple uses.

By simplifying the clamps so that they have a fewer number of parts, assembly time will greatly be reduced, which will also reduce the surgery time. Creating clamps based off of a modified "stud-and-tube coupling system" (36) used in LEGO® manufacturing or a briefcase type clasp, will lessen, or possibly eliminate, the need for screws in the clamps. Furthermore, using a radiolucent material, such as carbon fiber or a medical grade plastic, rather than stainless steel, will allow veterinarians to see all aspects of the healing process in x-rays. Also, these materials are much lighter than stainless steel, which will enable the dog or cat to move more easily with the device.

4.3.2 Redesign of Ring

The current ring design for veterinary applications is not sufficient enough to satisfy all functions of the circular fixation device. The current ring is made of stainless steel. While stainless steel is strong and durable, it is radiopaque. It is common for veterinary surgeons to use x-rays to assess the progress throughout the duration of the healing process. With these large stainless steel rings, it is often hard for veterinarians to assess the healing of the bones. By using a radiolucent material, such as carbon fiber, veterinarians will be able to assess the healing. Carbon fiber rings tend to be less strong than stainless steel rings, but altering the ring design will improve this gap (37). The team proposed that the carbon fiber ring will be a solid ring with an I-beam shape to provide maximum stability or an Olympic torch ring with specific raised areas for the clamps. This design alteration will also allow for the snap-fit clamps to work effectively. The I-beam ring and the Olympic torch ring both provide for more variability in the wires and pins. Many veterinarians expressed that sometimes the holes in the stainless steel rings do not align with the wires and pins. By using an I-beam ring or an Olympic torch ring, the problems associated with the lack of alignment will be eliminated.

4.4 Preliminary/Alternative Designs

For both the ring and the clamp, several designs were created to compare the parts based on how they met each function (see Tables 1 and 2). The various designs were generated in SolidWorks and are described below.

4.4.1 Alternative Designs for Rings

Five ring designs were created by the team to fulfill the greatest number of functions. The team considered the strength, low weight, and versatility of the ring in all designs. Based on evaluations and input from experts, a final decision on one of the proposed designs, or a combination of multiple designs could be made.

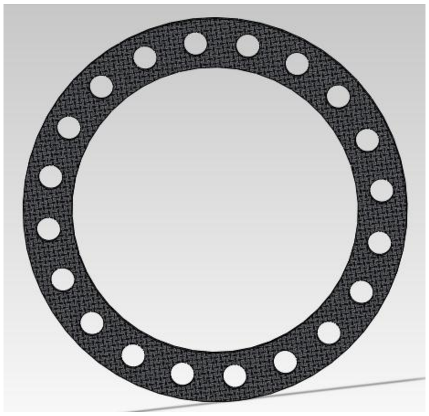


Figure 28: Carbon Fiber Ring with Holes

The first design proposed by the team was a full circular ring made of carbon fiber. Holes were placed equal distances apart from one another around the entire ring, similarly to the rings used in the IMEX device. The ring was 10mm in cross sectional thickness, and had an inner diameter of 100mm and an outer diameter of 140mm.

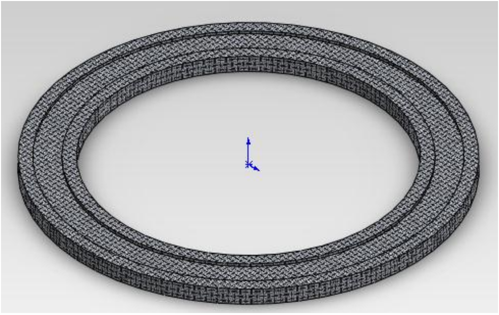


Figure 29: I-Beam Ring

The second design proposed by the team was also a full ring made out of carbon fiber. Instead of having holes all around the ring, the team felt that a ring with a solid construct would make it stronger and more durable when used with all of the other parts of the device. This design had a cross sectional shape of an I-beam, which created a groove in the center portion of the ring's width. The outer cross sectional thickness was designed to be 5mm and the inner cross sectional thickness (located in the groove) was 2.5mm. Similarly to the carbon fiber ring with holes, this ring was also 84mm in inner diameter and 114mm in outer diameter.

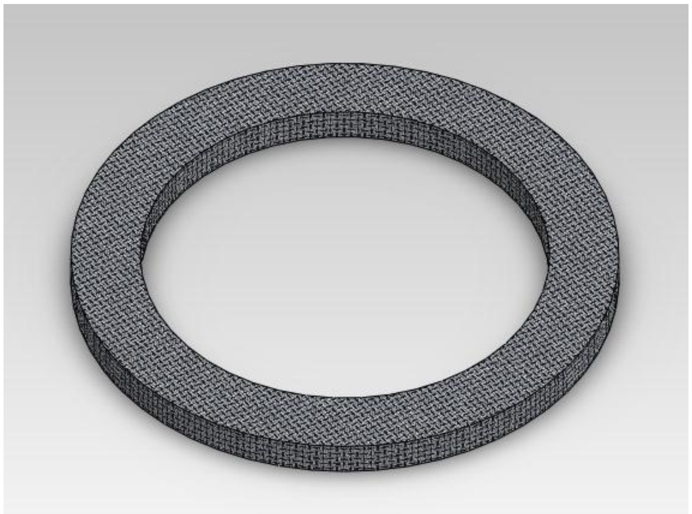


Figure 30: Carbon Fiber Flat Ring

The third design was a design that stemmed from the second design, the carbon fiber I-beam ring. This design was proposed as a more universal design, as the team felt a wider range of clamps could be used with it. Having a flat surface, this ring design could be easier to manufacture and could easily be adapted to any clamp design proposed by the team (see below). The outer cross sectional thickness of this design was 5mm and like the first two designs, this ring had an inner diameter of 84mm and an outer diameter of 114mm.

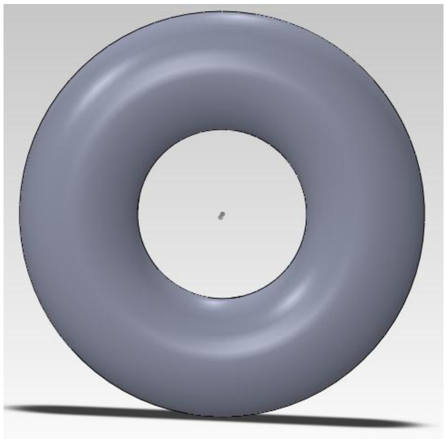


Figure 31: Carbon Fiber Full Tubular Ring

The fourth design that the team proposed consisted of a carbon fiber tubular ring. The reasoning behind creating a ring that had a circular cross -section, was to create a solid structure that had a greater amount of strength and could withstand a greater amount of compression produced by the clamps that it would need to interact with. The inner diameter of the ring was 100mm and the outer diameter of the ring was 140mm. The cross sectional diameter of the ring was 20mm.

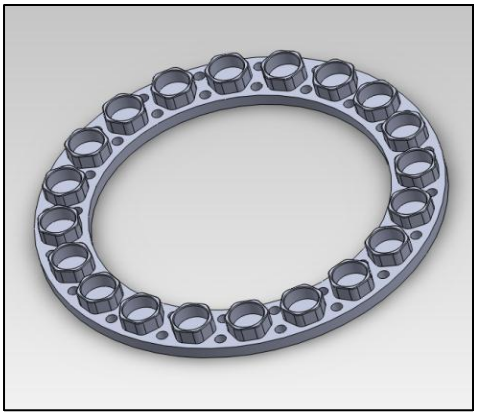


Figure 32: Olympic Torch Ring

The fifth design that the team proposed worked directly with the 6-sided polygon shape of the proposed clamps described below. This ring had an inner diameter of 100mm and an outer diameter of 140mm and was proposed to be manufactured out of carbon fiber. Hexagonal raised areas were placed all around the top of the ring, to allow for a snap fit of the clamps into specified locations. This would provide for a stable construct, and would eliminate the need for multi-screw clamps, which would be needed to attach to the existing ring.

4.4.2 Alternative Designs for Clamps

The team generated seven design alternatives for the ring to rod clamp, since this clamp is used as the basis for all other clamp designs. The rod to wire and rod to pin clamp was a slightly modified version of the ring to wire clamp.

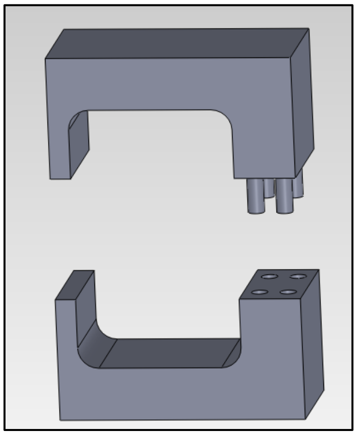


Figure 33: "LEGO®" Based Clamp Exploded Assembly

The first alternative clamp utilizes the "snap-fit" concept that LEGOs ® are based off of. In this design, there are two separate units that snap together around the clamp. The upper component has plastic tubes that snap into the holes in the lower component. This design does not use any small parts, such as screws, nuts, or bolts. It also allows the clamp to be used on the inside or outside portion of the ring.

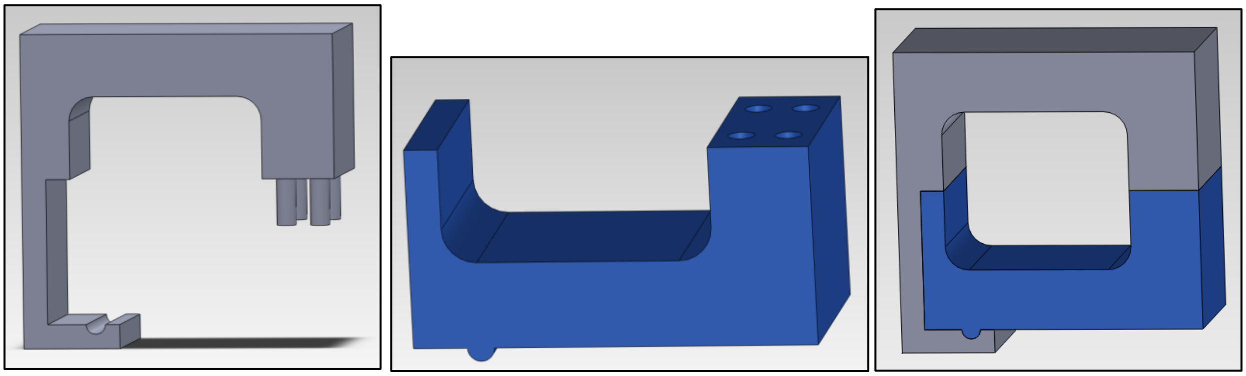


Figure 34: Modified "LEGO®" Based Clamp; Separate Components and Assembly

The second alternative clamp also uses the LEGO ® design, but has an additional connecting mechanism to ensure that the two components of the clamp do not separate while the fixator is in use. Similar to the first alternative design, the upper component has plastic tubes that snap into the holes in the lower component. Additionally, the bottom component has a small plastic hook to be used as a locking mechanism. The plastic hook on the top component hooks into this piece, also connecting the two parts. This design is similar to the connecting devices on remote controls—where the lid of the battery chamber locks into the overall remote. This clamp can also be used on the inside or outside of the ring.

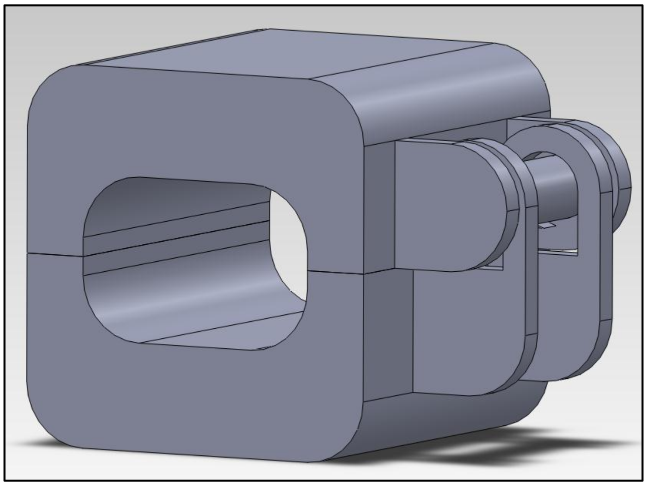


Figure 35: Hinged "Briefcase" Clasp Clamp

The third alternative clamp design utilizes a similar clip design as seen on briefcases and ski boots. This clamp can be used on the inside or outside portion of the ring and does not use screws or other small parts. The piece is advantageous because even though it does not use screws, it can be adjusted to ensure a tight, secure fit. It also prevents any partial deformations resulting from tightening the clamp components too tightly because there are set levels of adjustments. This clamp is hinged on one side to reduce the number of parts and make it easier to use for veterinarians during surgery. Also, since the clamp is secured using a clasp, it is much easier for veterinarians to disassemble the fixator when it is time to remove the device; no special tooling is required.

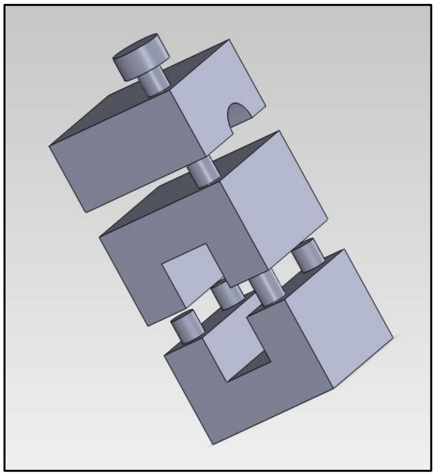


Figure 36: Three Piece "LEGO®" and Screw Clamp (Ring to Rod)

The fourth alternative clamp design is based off of the LEGO ® concept and the current IMEX clamp design. The three components of this design snap together like LEGOs in order to facilitate assembly during surgery. After the parts are assembled and the surgery is complete, the veterinarian can tighten the different clamps with a screw. The screw is threaded through the three components, thereby ensuring that the clamp is secure and structurally sound for as long as the device is worn.

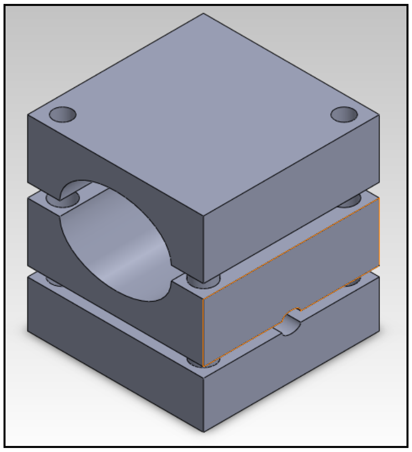


Figure 37: Three Piece "LEGO®" and Screw Clamp (Rod to Wire)

The fifth alternative clamp design is based off of the fourth alternative clamp design. This design allows a rod to be connected to a wire. In addition to the LEGO® concept, this clamp design includes two screws to provide more stability and less rotation.

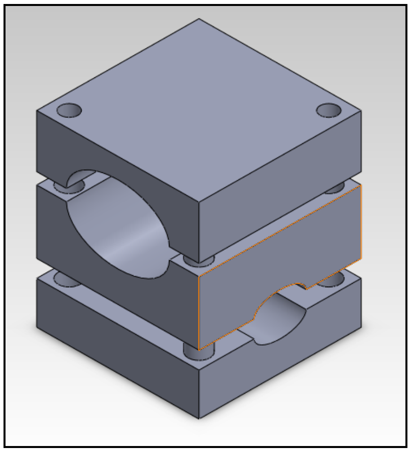


Figure 38: Three Piece "LEGO®" and Screw Clamp (Rod to Pin)

The sixth alternative clamp design is based off the fourth alternative clamp design. This design allows a rod to be connected to a pin. In addition to the LEGO® concept, this clamp design includes two screws to provide more stability and less rotation.

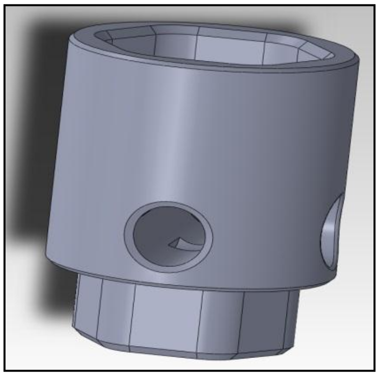


Figure 39: Magnetic Clamp

The seventh alternative clamp design consists of a six sided polygon shape that allows for rotation at 60 degrees intervals while in the ring. It is designed to form a "snap fit" within the Olympic torch ring and can also be used with the I-beam ring. A total of two rare earth magnets, each with a pulling force of five and a half pounds, are used in this clamp. The magnets allow the clamp to be attached to other clamps with magnets as well as fit into the ring.

4.5 Feasibility Study/Experiments

Circular external fixators are very complex devices with many parts that can be used for different applications. One model that the team looked at, the IMEX fixator, has been in development for over 20 years and has had many different parts developed for it. Since the team was unable to redevelop each part used on an external skeletal fixation device due to time limitations, the team decided to concentrate on the two parts of the fixator that needed the most improvement. These are parts used on every circular external fixation device.

The first part that the team concentrated on redesigning was the ring. This part is currently made out of stainless steel, making x-rays difficult to read for surgeons because stainless steel is not radiolucent. The clamp is the second part of the device the team concentrated on. There are three necessary clamps to develop, but the team used the same concept to develop all of the clamps. Additionally, the team determined it was unnecessary to redesign several parts, such as half pins connecting rods, and olive and k-wires, used in current circular external fixation devices, because they are an industry wide standard. As a result, the team designed the clamps and ring around these parameters.

In order to test the ring and clamp designs, the team first used finite element modeling. By using this, each part was tested in a computer-aided design (CAD) program, such as SolidWorks. By generating the CAD designs, the team was able to determine which designs had the best mechanical properties before prototyping. Once the finite element modeling was used, specific designs were chosen for rapid prototyping, which allowed for better visualization of the parts and a more thorough understanding of how each part fit together. After the parts were manufactured in their final prototype material, further testing using the Instron was used to test tension and compression. These tests better compared the alternative designs and further tested the parts to ensure their compatibility.

4.6 Modeling

The team utilized numerous types of modeling to perform preliminary and basic tests on their design. Ranging from virtual stress analysis, to enlarged plastic parts, different methods allowed the team to eliminate various designs and potential materials that had been proposed for final use.

4.6.1 Finite Element Modeling

Finite Element modeling was used as a crucial source for determining which designs and materials would succeed in the team's overall design of the device. Determining structures of both the ring and the clamp relied heavily on these virtual tests performed within SolidWorks, using a program called SimulationXpress. This program is a tool that allows for a variety of tests to be performed on different parts of the design that were created in SolidWorks. It allowed the team to look at each part individually to determine how it would perform under specific environments and conditions. Specifically, SimulationXpress provided the team with the ability to perform basic stress analysis tests on each part to calculate displacements, strains, and stresses specific to materials used, fixtures and loads. Using linear static analysis, these calculations are made, and can give a report as to how each part will react, and when it will fail.

More specifically, the SimulationXpress program uses the Finite Element Method, which partitions the part of interest into several small pieces comprised of basic shapes called elements. Each element in the part is made up of nodes, common points in the structures. Analysis of these nodes provides the program with specific calculated values for each element under a variety of conditions. The nodes are described by their motion relative to the X, Y, and Z directions, which is commonly referred to as degrees of freedom (DOF). Equations are formulated to combine the values of the elements and their connecting elements, and are used for comparisons of known material properties, fixtures, and loads. These equations are then arranged into a set of concurrent algebraic equations, and the displacements in the X, Y, and Z directions at each node are found. These displacements allow the program to calculate the strains in many directions, which are then used to calculate stresses.

SimulationXpress was used to model and test the team's ring design to ensure that it was strong enough to withstand the forces of the clamps and rods attached to it, as well as the forces created by the patient. Specific force and load values were obtained from previous studies and various articles, and were within this program to create a realistic environment for the device.

This program was also used to determine which clamp design was the most appropriate and effective for the overall design. Forces were applied using this program to ensure that the clamp would withstand the loads created by the connecting wires, pins and rods, as well as undergo minimal wear. Due to the many functions of the clamp, it was important for the team to determine which design and material would be the most effective before creating an actual prototype.

4.6.2 Rapid Prototyping

Preliminary functionality tests were performed on proposed designs through the use of three-dimensional printing. These designs were printed into three dimensional models made of acrylonitrile butadiene styrene, ABS, plastic, via 3-D rapid prototyping. The models produced from this process are strong enough to work with other parts of the design to model a working device, enabling the team to easily visualize which designs are the most feasible to fulfill their client's needs and functions. The rapid prototyping procedure is an inexpensive and relatively quick process, allowing the team to create multiple parts while staying well within their budget and time constraints.

Virtual designs were created in SolidWorks, a computer aided design (CAD) software, and were then converted into cross sections of the model, which allowed the part to be built layer by layer (35). To create the 3-D model from the computer drawing, the file must be converted into an STL file. This type of file uses triangular facets, with smaller facets to produce a higher quality surface to approximate the shape of the model. When this file conversion is complete, the rapid prototyping machine uses layers of combined liquid and powder to build the model.

The advantages of this modeling process allowed the team to save both time and money, but there were some significant limitations that the team had to take into consideration. Due to the rapid nature of this production method, the dimensions of the model were very limited. No sharp edges or steep contours can be designed using this method, and the wall thickness of each part must be greater than 0.06". Due to the team's small parts, the parts created in this 3-D process were enlarged to be between one and three times larger than the actual part.

The team used this production method as a link between their initial proposed, conceptual designs and the manufacturing of their final prototype. The low cost, plastic models of the proposed designs allowed the team to physically visualize the parts and gain a better understanding of how they would work with one another in the overall assembled device. In addition, the 3-D rapid prototyping models provided the team with physical objects to present to their client, Securos, and various veterinary surgeons, to help communicate their ideas and thoughts with regards to the parts of the device.

4.6.3 First Order Prototype

The team felt that after completing basic tests using Finite Element Method modeling and Rapid Prototyping, a cheap and very rough model could be created using scrap material from the WPI BME Lab in Higgins Laboratory, as well as from the WPI Washburn Machining Shop. By creating a one to one scaled model of their design, the team was able to visualize the interactions of each part, perform basic tests to determine how the assembled device would react to different situations, and determine how it would interact with the existing parts that many veterinarians already owned. Using materials such as stainless steel and aluminum, the team machined their main components of the device and integrated them with the existing pieces such as the rods, wires, and pins. This then gave them the opportunity to make adjustments and modifications to their design. Due to the use of scrap and basic materials, the team was able to save money and create a model that could be used to show their progress and ideas to their client.

4.7 Final Preliminary Design

From preliminary models of the alternative designs described above, the team combined various aspects from each design to create a final preliminary design that would be used for testing. The characteristics of this design were determined through discussions with the client as well as numerous team discussions regarding which specific aspects would result in the most successful device.

4.7.1 Ring Design

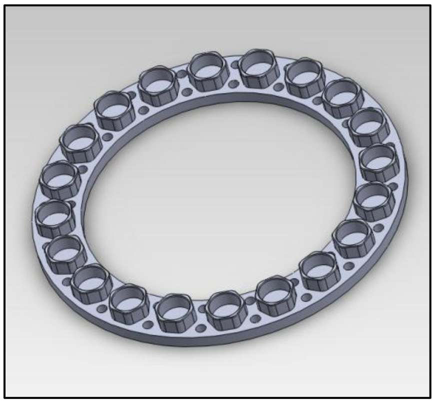


Figure 40: Final Ring Design

The ring design that the team decided would be the best fit for their final design was the ring containing six sided polygon protrusions all around the ring, also known as the “Olympic torch” ring. The clamps fit snugly onto these polygon holders and are secured through the use of magnets. The ring has an outer diameter of 114mm and an inner diameter of 84mm, and is machined out of aluminum.

4.7.2 Clamp Designs

The clamps created for this design consist of a ring to wire clamp, and a rod to pin clamp. These clamps satisfy all functions of the final device, allowing all parts of the device to be connected while producing a stable and strong structure.

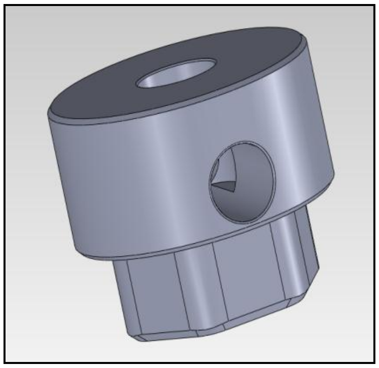


Figure 41: Ring to Wire Clamp

The ring to wire clamp is made of aluminum and consists of a six sided polygon. This polygon allows for rotation at 60 degree intervals of the wire with respect to the ring, allowing it to conform to any orientation needed. The clamp is held together by neodymium rare earth magnets with a five and half pound pulling force, creating a secure fit, and minimizing any unwanted rotation of the wire. Magnets are placed within the clamp as well as in the protrusions on the ring to allow for a secure and stable connection between the two parts.

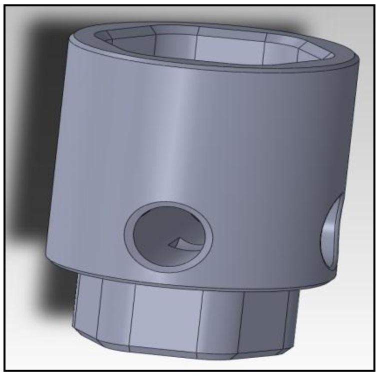


Figure 42: Rod to Pin Clamp

The rod to pin clamp is made of stainless steel and consists of a six sided polygon, similar to the ring to wire clamp. This clamp is held together by neodymium rare earth magnets with a five and half pound pulling force, and is attached to height adjusters (Figure 44) to allow the pin to be inserted at any height on the bone.

4.7.3 Supporting Part Designs

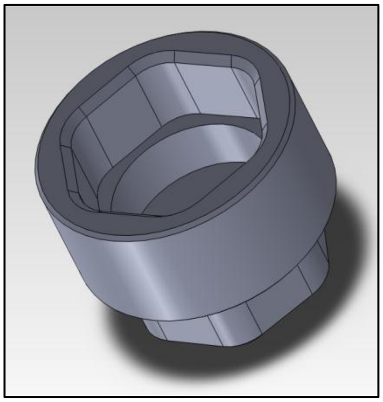


Figure 43: Height Adjusters

The height adjusters assume the same shape as the clamps and are held together by magnets. These pieces are used to adjust the height of the wires with respect to the ring, to allow for optimal positioning when placed within the bone of the animal. They also are used in place of the rod that is currently used to hold two rings together. By stacking the height adjusters on top of one another, a stable and strong rod is formed that is able to hold two rings together. The height adjusters are also machined out of aluminum.

4.8 Mechanical Testing

The team determined that the use of mechanical testing procedures would be a key component of their modeling and testing portion of the design process. By testing their device under simulated forces produced by the animal wearing the device, they would be able to conclude if it was acceptable to be used in veterinary practice.

4.8.1 Machines Used for Testing

The Instron is a machine commonly used for testing the mechanical properties of materials. This machine can be used to test tension, compression, fatigue, torsion, hardness, and flexure. The Instron was used to test tension and compression of the ring as well as torsion and fatigue strength. The use of new materials, such as carbon fiber, makes it imperative to test these materials and compare their mechanical properties to current ring materials. In addition, the mechanical properties of the clamp designs are evaluated through compression and tension tests. The team used the Instron in WPI's Goddard Hall to test the various ring and clamp designs. Based on these results, further testing may be done using the MTS.

The MTS is a device used for material, fatigue, tensile, and simulation testing. Once the clamp and ring are assembled, it will be beneficial to test the assembly using motion simulation because the device must account for the walking motion of a dog or a cat. In addition, these devices are commonly worn for four to eight weeks and the testing should represent at least eight weeks of wear. The team will use the MTS in WPI Goddard Lab to test the assembly of the clamp and ring designs. With these results, the group will be able to choose the superior design.

4.8.2 Testing Using ASTM Standards

In order to verify the design of each part and the entire assembly, the American Society for Testing and Materials (ASTM) standards were used. The ASTM F1541-02 (2011) specifically pertains to external fixation devices. The ASTM standards were used to compare the mechanical properties of the existing device parts to those of the newly designed device parts using standard testing procedures. These standards provided verification for the new design of the ring, clamp, and the entire assembly.

The ring design was tested using section A3 of the ASTM F1541-02 standards. The section A3 addresses in plane compressive properties. The ring was tested by applying a compressive load quasistatically for 30 seconds until failure. A quasistatic load implies that the load is applied at 4 points equidistantly around the ring. The compressive load was used to compare the compressive strength of the carbon fiber ring compared to that of the stainless steel ring. In addition, the compressive strength was affected by the lack of holes in the new carbon fiber ring design.

The clamp designs were verified using sections A2 and A4 of the ASTM F1541-02 standards. The section A2 deals with the test methods for the connectors. This technique was used to test the torsional loading strength of the clamp. In addition, section A4 was used to test the joints of the clamp. This method determined the stiffness and durability of the clamps and calculated the stiffness and failure loading. This technique measured loads in the X, Y, and Z directions and allowed for the XY plotting of load versus deformation. This testing was especially important because it tested the clamps while they were attached to the ring, rod, or wire.

Once the ring and the clamp were tested using the ASTM standards, further testing was done on the sub-assemblies. The sub-assemblies used ASTM F1541-02 section A6. Section A6 outlines both force loading testing as well as moment loading testing. In terms of force loading, the sub-assembly was tested for axial loading, medial-lateral shear force, and anterior-posterior shear force. In addition, the sub-assembly was tested in torsion, medial-lateral bending, and anterior-posterior bending. These tests ensured that the ring and clamp could withstand the mechanical properties needed to be part of an external fixation device on a dog or a cat.

Lastly, the various assemblies were tested using ASTM F1541-02 section A7. These tests were used to determine the stiffness, strength, and repetitive loading performance characteristics of the assemblies. This testing was performed while the external fixator is on a bone or a material that imitates the mechanical properties of bone. In addition, these tests determined the force and moment loading of the various assemblies to determine the strongest and most stable assembly.

4.8.3 Testing Details

After research and discussions with the client, the team determined that the device must pass specific mechanical testing procedures in order to be considered successful. Protocols were written for all testing procedures pertaining to the clamps and the rings based off of previously documented studies and discussions with Securos as seen in Appendix F.

4.8.3.1 Tensile Testing of Magnets

The team also tested the strength of the rare earth magnets used in the clamps and the height adjusters to determine if they were strong enough to withstand forces produced by the patient while the device was in use. Using the Instron mechanical testing machine, two height adjusters were stacked on top of one another and were connected with a total of four magnets, two in each adjuster. The stacked adjusters were placed in the grips in the machine, one in the top grip and one in the bottom grip (Figure 47).

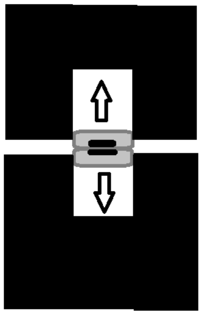


Figure 44: Tensile Test Set-up of Magnets

Applying a constant load rate of 70N per minute, the adjusters and magnets were pulled away from one another, until separation occurred. This test was repeated a total of four times, and the team identified success as any load sustained over 222.95 Newtons. This value was calculated from an average dog weight of 50 pounds, with all weight applied on a single limb (Appendix G).

4.8.3.2 Compression Testing of Full Construct

The Instron mechanical testing machine was also used to test the strength of the fully assembled prototype. Both the I-beam ring and Olympic Torch ring designs were tested with the magnetic clamps, connected to a saw bone via two wires. The wires were inserted into one end of the bone at a 90 degree angle to one another to simulate a strong healing structure of a complex fracture. These wires were then attached to the device via the ring to wire clamps as seen in Figure 46.

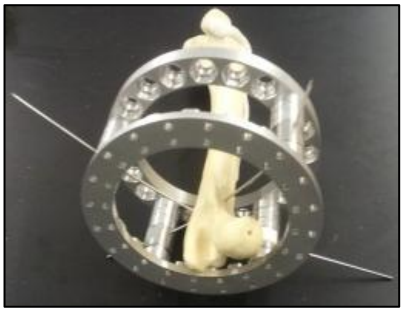


Figure 45: Fully Assembled Prototype

Height adjusters were stacked on top of the clamps and functioned as a stabilizing rod to connect the two rings. This full assembly was placed in the Instron machine, placing the end of the bone without the wires between the bottom grips of the machine. A custom aluminum piece with a flat bottom was placed in the top grips of the machine, and was used to apply a compressive load to the entire top surface area of the bone (Figure 47). The group programmed the machine to apply a constant compressive load rate of 70 Newtons per minute to the construct. This load was applied until failure, which was defined as deformation or disassembly of any part of the device. Any load greater than 222.95 Newtons sustained by the device was considered successful, as 222.95 Newtons was the calculated force produced by a 50-pound dog (Appendix G).

Figure 46: Testing Setup of Full Construct

4.9 Preliminary Data

The final design included the newly developed parts that were manufactured and tested. The team machined the clamps in the machine shop with stainless steel and manufactured the ring of the device with aluminum. Each design was manufactured several times so that the parts could be tested to failure to determine the maximum ultimate yield strengths. The device will be highly marketable as it provides increased stability to the forces exerted on a dog or cat limb.

4.9.1 Ring

The ring was tested in axial compression as well as in tension using loads of both 75 Newtons and 125 Newtons until failure to determine the maximum load allowable. The ring was also tested in compressive loading with the force of an average dog (~50 pounds), 222.95 Newtons, distributed amongst two rings (125 Newtons per ring), to determine if the ring would crack or deform in any unpredictable ways.

4.9.2 Clamp

The clamps underwent several performance tests using an Instron machine. The Instron applied forces in the x, y, and z planes in various amounts ranging from 75 Newtons to 125 Newtons to observe any cracks or imperfections in the rod or ring caused by the force of the clamp. These forces were also applied to the clamp until failure along the rod or ring to determine the maximum force of the clamp.

4.9.3 Assembly

The ring was assembled with four clamps that were attached to two K-wires. These K-wires were assembled similarly to how they would be when used on a dog or cat. The K-wires were inserted into a simulated cortical bone from Saw Bones. A force of 250 Newtons was applied at the top of the bone to simulate the loading that would occur if a dog were walking.

Chapter 5: Design Verification

5.1 Tensile Testing of Magnets

To test the strength of the magnets used in the height adjusters and the clamps, the ultimate yield strength of a set of four magnets (two in each clamp) was determined using uniaxial tensile testing. Two height adjusters, each containing two magnets, were stacked on top of each other and were positioned between the grips of the Instron machine. One height adjuster was placed in each grip, and the tensile load was applied at a rate of 70 Newtons per minute until failure. Four magnet samples were randomly selected for testing in order to have a sufficiently large testing group. The load was compared to the extension of the height adjuster. The results from the tensile testing of the magnets are displayed in Figure 48.

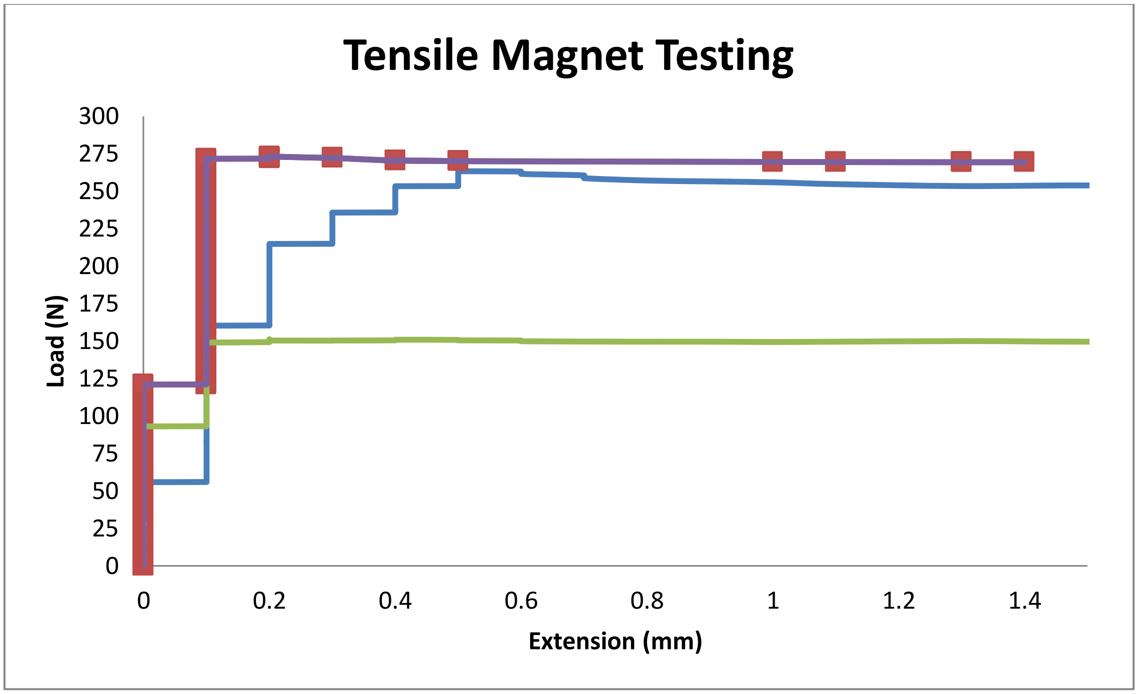


Figure 47: Magnet Tensile Testing- Load vs. Extension graph

After four samples were tested, the results showed that the ultimate yield strength of the magnets averaged 238.45 ± 59.5 Newtons, with the maximum failure strength measuring 269.5 Newtons. The fourth sample failed at a significantly lower load than the other three samples due to the height adjusters slipping out of the Instron grips. By eliminating this outlier, the average ultimate yield strength of the magnets was 268.127 ± 4.4 Newtons. There was no significant elongation observed between the two height adjusters or the between the magnets prior to failure. All samples failed in a similar manner, pulling apart at the location where the two height adjusters were connected by a simple "snap-fit" design.

5.2 Compression Testing of Full Construct

To test the strength and stability of the fully assembled prototype, the ultimate yield strength of the device while attached to the bone via wires was determined using uniaxial compression tests. Two separate tests were conducted, one for each ring design (I-beam and Olympic Torch), and four samples for each design were tested. All tests used ring to wire clamps to hold the bone in place and used height adjusters to connect both rings. One end of the bone was placed into the bottom grips of the Instron machine, and a small, flat aluminum piece was placed in the top grips to apply an evenly distributed compressive load to the bone. A compressive load was applied at a rate of 70 Newtons per minute until failure. A total of seven samples were tested, three on the Olympic Torch design, and four on the I-Beam design. An eighth test was also conducted solely on the saw bone used in all other tests to determine the strength of the bone without any external fixation. The load of all samples was compared to the extension of the device, and the results are displayed below. Figure 49 shows the results for the Olympic Torch ring, and Figure 50 shows the results for the I-beam ring.

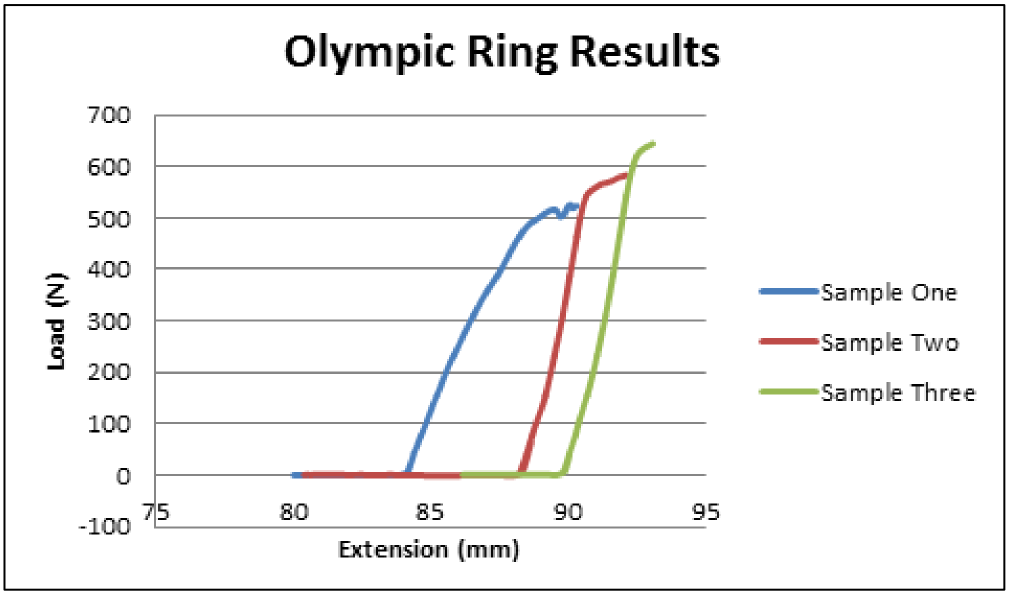


Figure 48: Olympic Torch Ring Compression Test Results

The results showed that the average ultimate yield strength of the three Olympic Torch ring samples was 584.5 ± 59.1 Newtons, with the maximum failure strength occurring at 644.4 Newtons. All samples failed as a result of the wires within the bone bending, forcing the bone to slightly move, and slip from the bottom grip. The holes in the bone at the locations of the wires were noted to become elongated as the compression load was applied. At failure, all components of the device were still intact, and zero deformations or notable damage was observed on any parts of the device. The Saw bone, which was used in all testing samples, failed at a load of 323.9 Newtons, indicating that the Olympic Torch design was significantly stronger than the bone. All samples were noted as successful, as they surpassed the load of 222.95 Newtons, the success rate calculated from the weight of an average sized canine.

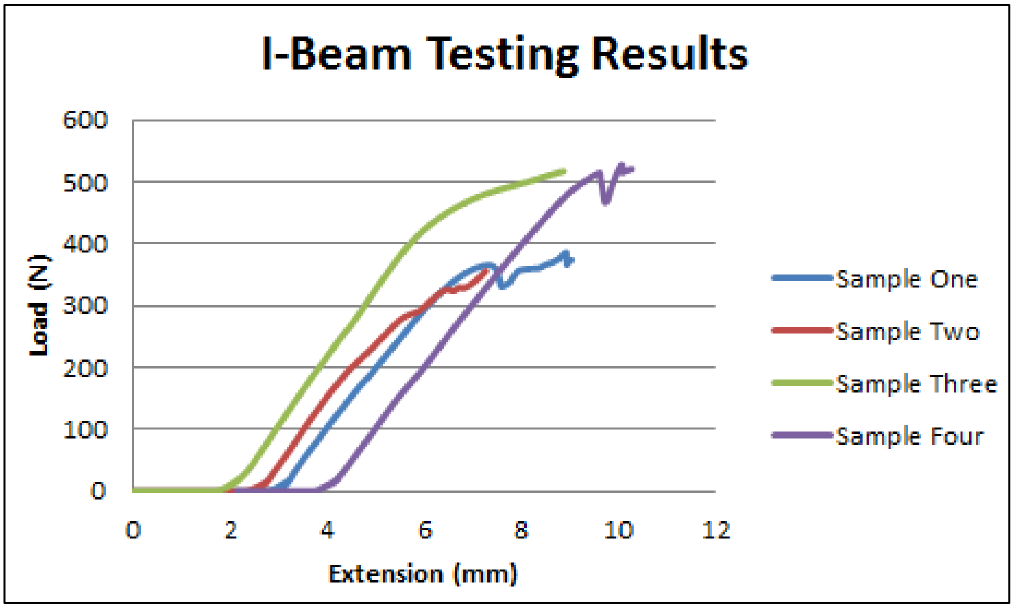


Figure 49: I-Beam Ring Compression Test Results

The average ultimate yield strength of the four I-Beam ring samples was 446.6 ± 88.3 Newtons. The maximum strength withstood was 527.4 Newtons, and all samples were observed to have slight deformation at failure. The construct was observed to stay intact, but the ring to wire clamps were pulled inward as the load was increased and were forced out of the inner groove of the ring. All samples surpassed the success rate of 222.95 Newtons, as well as the failure load of the individual bone.

Chapter 6: Discussion

6.1 Analysis of Results

The testing results of both the magnets and the full constructs provided the group with evidence that their device was successful and could be used to satisfy the client's need. After a detailed analysis of all parts, objectives, and goals of the project were complete, the group was able to determine the overall effectiveness and functionality of their device while pinpointing both strengths and weaknesses in the design.

6.1.1 Magnets

The results from the magnet tests showed that the magnets used in the clamps and height adjusters are strong enough to support the overall structure of the external fixator, as well as the force produced by the weight of the dog. Using an average dog weight of 50 pounds, it was calculated that the maximum amount of force produced by a dog (as a result of its body weight) is 222.95 Newtons. After an analysis of a dog's gait cycle, it was noted that all weight can be placed on a single limb at any given time. Due to the external fixation device being applied to a single paw, it must withstand the force produced by the dog's total body weight. The first three magnet samples withstood forces that were considered successful, as they all did not fail until they surpassed the 222.95 Newton mark. The fourth magnet sample failed due to the magnets slipping in the Instron during testing.

These results proved that the magnets provide the needed stability and strength to create an effective fixator. These also proved that the magnets alone are enough to keep the fixator together, thereby eliminating the need for extra assembly tooling and reducing the overall cost of the fixator. The cost of the fixator is further reduced since the magnets can be reused and if they need to be replaced, are only $0.54 a piece.

The use of magnets instead of screws, nuts and bolts, is a very novel idea, and can be greatly expanded on to improve a variety of veterinary and medical devices.

6.1.2 Ring

Two ring designs were tested in compression and both were observed to tolerate a load that was greater than that of a 50-pound dog. They both withstood a greater load than that withstood by a single bone, indicating that they were stronger, and able to stabilize a fractured bone while it was healing. The I-Beam structure failed on average at loads slightly smaller than those sustained by the Olympic Torch design, but many factors could have attributed to this. The inner groove in the I-Beam structure was manufactured to be the same width as the largest diameter of the hexagonal shape on the bottom side of the clamps and height adjusters, resulting in a very tight fit. During testing, it was observed that the ring to wire clamps did not entirely fit into the I-beam ring, causing them to move back and forth as the compressive load was applied to the bone and wires. These clamps were not secured into a specific section of the ring, allowing for the magnetic forces within each clamp to attract one another, pulling them towards each other, deforming the overall structure. The Olympic Torch ring was able to provide the construct with a stable and strong structure, but it was observed that the fixed clamp locations limited the positioning of the wires. It was hard to thread the wires through the bone so that they would be positioned in the exact location of the hole in another clamp. The wires became strained and needed to be bent in order to fit into both clamps on either side of the bone. In comparison with the existing ring, the Olympic Torch design was able to improve upon the amount of variability for the placement of the wire, as the clamp could be rotated in six different directions, due to the hexagonal shape. The group noted that a combination of these two designs would be an ideal solution for this device, providing both variability and stability to the clamps and height adjusters.

6.1.3 Clamps

The clamps, which were the main focus of this project, passed all testing requirements and satisfied the needs of the client, meeting all specifications stated in the client statement. They were able to withstand the force produced by an average sized dog without deforming or breaking, and they only require two parts to be assembled, as opposed to the existing clamps which require multiple small parts. The incorporation of magnets within the clamps eliminated the need for extra tooling and multiple screws. As discussed in the magnet testing results, the magnets were strong enough to withstand forces applied while the device was in use, providing evidence that they allow the clamps and height adjusters to be more effective and simpler to use. One of the main concerns presented by the veterinarians was that there were many small parts required to assemble each clamp and that it was easy to lose these during surgery. The use of magnets and only one screw helps to eliminate this problem and provides the surgeon with an easy to assemble, easy to hold clamp. The magnets allow the clamps to quickly be placed within the ring, and allow for a tight and secure fit that requires minimal adjustment and manual tightening.

6.2 Limitations

As with all medical devices, limitations are present in the team's final design. As a result of the use of new materials that have not been used in this application before, areas of the circular ring external fixator have a few apparent limitations.

The size of the different parts of the fixator created several manufacturing issues. The team was not able to create several of the small parts they designed due to the limited machining capabilities at WPI's Washburn Machining Shop. For instance, the team wanted to create clamps with a small groove for pins or wires. However, the material used and length of the cut in the design made it impossible to use any of the available machines. Several workers in the shop suggested that the use of an electrical discharge machine, or EDM, would be the best way to create the small holes and cuts in the team's clamp design. Due to limited finances and time, the EDM option was not a feasible solution. The team adjusted the clamp design to fit the machining capabilities on the WPI campus in order to create a final working prototype.

After creating the base ring for the Olympic Torch design with a press-fit construct for the magnets, the team realized that there was no way to adjust the magnets if one was put in incorrectly. As a result, the receiving ring for this design was created with holes where the magnets are placed, so that the magnets could easily be put in or taken out if adjustments needed to be made. The team recommends that all future manufacturing of the base and receiving Olympic Torch ring have these holes to remove this limitation.

In terms of function, the overall stability of the team's device is limited due to the new design of the rod-less configuration. By using height adjusters stacked on top of one another, the ease of use will be increased, but there is a chance that this will not be as strong as a solid aluminum rod. The use of magnets also poses a risk of breaking of the device, as these magnets do have a chance of coming apart during the time that the device is being used.

Additionally, there may be situational limitations of the device due to the magnetic components. For instance, further testing needs to occur to ensure that the magnets do not negatively affect nearby electronic devices, such as computers or cell phones. While the device has been proven to be effective, the team does not want it to ruin any devices that the pet owner may own or any electronic medical devices in a veterinarian's office. Furthermore, the team wants to prove that the magnets present would not have any impact on a pet owner or veterinarian with a pacemaker.

6.3 Real World Applications

The team also analyzed the effects that their final design would have on various aspects of society, such as its economic impact, environmental impact, societal impact and a variety of other concerns that could be related with the device.

6.3.1 Economic Impact

The team's final device is projected to be significantly cheaper than the existing IMEX device, as the total number of parts has been decreased, and the number of required tools is less. As discussed previously, veterinary costs and willingness to spend more on veterinary medicine has increased over the past 20 years. For pet owners who encounter the need for a circular ring external fixator, the overall cost of the device and the procedure is very expensive, and frequently out of the owner's price range. This results in animals requiring this surgery not being able to receive the proper treatment, receiving alternative treatments instead. With the team's device costing less, a larger portion of pet owners will be able to afford the overall treatment, while still staying within budget. The device will also be compatible with existing parts from other fixation devices. The wires and pins will be industry standard to enable veterinarians to continue using these parts with the new device. Due to the team's device integrating the use of low-cost magnets, the manufacturing costs of the device are very small. All client needs were incorporated into the team's design, which in turn produced an optimal design that incorporated economic considerations. Enabling more consumers to purchase a circular ring external fixator would help to boost the veterinary medicine economy.

6.3.2 Environmental Impact

After discussions amongst the team and with Securos, it was determined that the device produced some significant impacts on the environment. Overall, due to the use of less material, and an increase in the amount of natural resources used within the materials, the device encourages a greener surgical procedure. A smaller number of follow up surgeries will be required, eliminating the amount of material and biological waste that is commonly accumulated during these procedures. In addition, the device is sustainable in that veterinarians do not have to buy all new parts. The veterinarians can reuse the wires and pins from previous devices and eliminate unnecessary environmental waste. Overall, the team's device will have a positive impact on the environment, eliminating the amount of harmful waste often associated with the external fixator surgical procedure.

6.3.3 Societal Influence

After the manufacturing process and the initial release of the team's device to the market, a significant impact on the society will be noted. As discussed in the economic benefits section, the team's device will be able to be purchased by a wider range of people. Not only will the device be attractive to private practice, specialized veterinarian surgeons, but due to the simplicity of the external fixation surgery encouraged by the team's device, veterinarians who are not as familiar with external fixation will begin to take interest in the device as well as the specific surgical procedure. Ordinary pet owners will be more likely to afford this device and provide their pet with an appropriate treatment plan, that may not have been an option for them before the team's device was developed.

6.3.4 Political Ramifications

In terms of the global market, the team's device can potentially have a large impact. People all over the world have pets, and these pets are all susceptible to problems requiring circular ring external fixators. This device can easily be shipped to any part of the world, and the requirements for assembly are very simple, making it easy for a veterinarian from any country to use the device. Due to the cost of the device being much less than the existing device as stated above, it will also be more affordable for people from other countries. It is the team's hope that this device will make external fixation for small animals more accessible all over the world.

6.3.5 Ethical Concern

The team's device will allow for a larger range of people to provide the proper treatment to their pets in the case of a serious fracture or limb deformity. Giving pet owners the peace of mind knowing that treatment for a serious injury will be available at an affordable price will result in the overall happiness of the owners. Without the team's device being introduced to the market, the only device available for this type of treatment was very expensive and limited. This resulted in the dissatisfaction of pet owners due to the lack of treatment they could provide to their animals. The team's device hopes to solve this problem and increase the availability and affordability of the circular ring external fixator to increase the overall satisfaction and sense of security for everyday pet owners.

6.3.6 Health and Safety

Even though the team's device is intended for use on small animals and not people, it will pose to be safer for human use (surgeon use) than the existing IMEX device. With the use of magnets instead of screws and other small parts, the risk of loose objects dislodging from the device during assembly and disassembly is decreased. The magnets require a strong force to be removed, but eliminate the use of high torque produced by tools to remove the device from the animal. Without these tools, the risk of misuse and injury is greatly decreased, increasing the overall safety of all humans involved in the use of the team's device.

The health and safety of the patients was also a concern of the team. To ensure that no risk was posed to the animal during the use of the device, fewer parts were incorporated into the design and the overall stability of the device was increased. With the increase in the stability, the risk of the device falling off the animal while in use is decreased, and the potential malfunction of the device is significantly decreased. While eliminating these potential problems, the health and safety of the patient can be ensured.

6.3.7 Manufacturability

The final design was produced with the ease of manufacturability in mind. Through the use of stainless steel clamps and aluminum rings, CNC machines were used to convert CAD drawings into three-dimensional parts. The use of magnets to hold all pieces together instead of the use of screws eliminated a complex step in the overall manufacturing process. The team determined that mass production would become appropriate when 100 or more devices needed to be made at one time. In this case, CNC machines would still be used, but all assembly would be performed through a simple assembly line. This type of manufacturing can easily be accomplished by Securos through a low-cost and efficient process.

6.3.8 Sustainability

This design is a very sustainable solution to treating various injuries through the use of external fixation. Being able to reuse both the clamps and the rings through the simple use of sterilization allows this device to be used for a longer amount of time, saving both money and material. The team also designed the device to incorporate existing parts of the IMEX device. Many veterinarians who currently perform this procedure already have pins, wires, and rods in stock from the IMEX device. The team's device will allow these veterinarians to reuse these parts without having the burden of buying all new, specialized pieces. The cost of this device is still lower than the current device, making it affordable to more people, producing an overall sustainable method.

Chapter 7: Final Design and Validation

The validation process is an important aspect of the team's device to ensure that veterinarians will use it. By validating the new design, veterinarians will be more likely to buy this device, as it will provide them with improved safety, effectiveness, lower costs, and increased usability. While veterinary devices do not need to follow the Food and Drug Administration standards, Securos upholds an extensive validation process to ensure that their products are effective. To validate the new design of the circular external fixation device, more *in vivo* experiments should be performed to test the effects of magnets near biological tissues. In addition to further testing and clinical trials, training sessions should be arranged to teach veterinarians how to assemble and disassemble the device during surgery.

7.1 Safety

This novel design is easier to use than the existing device, and therefore should be safer for both pets and veterinarians. The use of magnets in the clamps eliminates most of the tooling and decreases the surgery time. For the veterinarians, the time consuming and frustrating aspects of the current device were the clamps and the tedious assembly and disassembly procedures. The use of magnets and decreased tooling will decrease the assembly and disassembly time and eliminate some of the frustration associated with the current device's small parts and tooling. To ensure safety for the pet and the pet owner, the device does not have any sharp edges. The device comes in a variety of sizes to ensure that it will fit properly on each specific patient. The clamps use a single screw, but the screw is secured in the stainless steel clamp and tightened using a screwdriver to avoid loose parts. The ring is strong and stable and stays close to the bone to reduce the risk of the pet getting caught on household items. Though the magnets in the clamps are strong, the force exerted by the magnets will not be dangerous to the pet or potential household items that the pet comes in contact with.

7.2 Economical

While circular external fixators are not currently used by all veterinarians, by making it more affordable, it is expected that this device will become more popular among veterinarians. This novel design is adaptable to fix a variety of injuries in different sized dogs and cats. This procedure is less invasive than other bone fixation procedures as the majority of the parts are external. In addition, the currently used wires and pins are compatible with this device, enabling veterinarians to reuse existing parts. In terms of sterilization, the rings and clamps can be autoclaved and reused. While the clamps with the magnets cannot be autoclaved, veterinarians can either remove the magnets to autoclave the clamps or use alternative sterilization techniques. Since the clamps are entirely external, it would be acceptable to use sterilization techniques that do not require extreme heat. The use of magnets eliminates the need for multiple screw and extensive tooling. As a result, this procedure will be less time consuming for veterinarians and therefore less expensive for pet owners. By decreasing assembly and disassembly time, veterinarians can do this procedure more efficiently and therefore more economically.

7.3 Useful

This device is very useful to veterinarians because it will be able to treat both limb deformities and various fractures on all sizes of dogs and cats. This external fixator is highly adjustable in terms of the distance between rings and in terms of where the wires and pins can be attached to the bone providing more versatility. Because this device is easily adjustable, the veterinarians will be able to use the device for many types of fractures, limb-lengthening procedures, and fixing angular deformities of limbs.

7.4 Effective

This device is effective because it is lightweight, durable, and provides the support needed to assist in the healing of the patient’s limb. This device is also easy to use because it contains fewer parts than previous models of external fixators such as the IMEX. By having fewer types of parts, the veterinarian will be able to assemble the device easily and without a significant amount of training. If the ring is manufactured from carbon fiber, it will be even lighter and radiolucent. By making the ring out of carbon fiber, veterinarians will be able to track the progress of the healing limb with less interference on x-ray images of the limb.

Chapter 8: Conclusions and Recommendations

8.1 Conclusions

In finishing this project, the team developed an improved external fixation device, with newly designed clamps and rings, for their client, Securos. Limitations of the existing device were addressed and the needs of the client and user were fulfilled. The team believes that their device will allow veterinary surgeons to complete the external fixator assembly procedure in a more efficient and safer manner. It is their hope that this device will allow not only specialized surgeons to perform the procedure, but will allow general veterinary practitioners to perform it. By providing a wider range of surgeons with the tools and resources to perform this surgery, more felines and canines will have the chance to be properly treated.

8.1.1 Magnets

The use of rare earth magnets is a novel idea in the design of external fixation devices. In the group's design these magnets are used to hold the clamps and rings together while maintaining a stable structure. They are very affordable, approximating a cost of $0.54 per magnet, and are reusable, resulting in a sustainable solution for the client.

The magnets address the problem of too many small parts required for assembly and eliminate the need for extra tooling, such as screwdrivers and wrenches. The surgeon can use this technology to simply "snap" all parts containing magnets together and the magnetic force helps to pull the parts into place. From the testing results that the group obtained, it was observed that the magnets were more than capable of supporting the forces produced by dogs or cats. These results confirmed that the use of magnets instead of multi-part screws and bolts reduces the overall complexity of the device and still maintains the required strength and stability that the device needs in order to properly function.

8.1.2 Full Construct

A uniquely designed ring and clamp was needed to work with the specific shape of the rare earth magnets. Clamps and height adjusters were created with a circular indent on one side and a circular protrusion on the other side to accompany the magnets, allowing for a tight fit and stable construct. The group noted that without the use of screws and bolts, a "snap-fit" design would be necessary so that all parts could securely fit within one another. The Olympic torch ring that the group manufactured satisfied this need for a specialized fit, and allowed all parts to work with one another. The testing results provided evidence that this ring design created a stable structure that was stronger than a stand-alone bone and could sustain a load that was greater than what an average sized dog could produce. When integrated with the uniquely designed clamps, the hexagonal shape allowed for more variability than that allowed by the existing device. The clamps were able to be rotated to adjust to the location of the wires and pins threaded through the bone, and allowed the surgeon to place the wires at a variety of different angles. The height adjusters also worked well with the other parts, and created more variability in the specific location of the wires and pins in the bone with relation to the ring. The existing device only allowed for wires to be placed millimeters above the ring, whereas the team's device allows for the height of the wires and pins to be placed at any location between the two rings.

Additionally, the device is easier for the veterinarian to disassemble and is far less cumbersome and more aesthetically pleasing for the animal and pet owner.

Through the introduction of these new parts, existing wires and pins can still be used, which will save the surgeons money and time during future procedures. This device provides the client with an overall safe, effective, and economical design that can successfully be introduced to the rapidly growing veterinarian market.

8.2 Recommendations

While the new design of the circular external fixation device provides several improvements to the existing device, there are still several aspects of the device that could benefit from further advancements. Due to the time constraints and financial restrictions of this project, there were certain aspects of the project that were not explored to the fullest potential. With more time and funding, further testing could be done to improve this design and future machining techniques could make the device more marketable.

The unique magnet design creates a very tight seal on the clamps and height adjuster pieces. While this strength helps to keep the device stable, it would be beneficial to add a better grip to these pieces to allow veterinarians to easily separate the pieces during assembly and disassembly. The use of knurling, a diamond-shaped pattern cut or rolled onto the stainless steel parts would allow for easier gripping to pull the magnetic pieces apart.

Many of the veterinarians mentioned that the rings should be made of a radiolucent material to ensure that the bone healing could be assessed through x-rays. The current device uses stainless steel for the ring, but some of the human devices use carbon fiber. By using a material such as carbon fiber, the rings would be entirely radiolucent and lighter in weight. Further analysis should be conducted to determine exact manufacturing and material costs for bulk production.

Due to the time constraints, a full construct was only built and tested for a 50 pound dog. The team recommends further testing of constructs of all sizes to determine that the design is effective for dogs and cats of various weights.

Further testing of the device would be beneficial to determine how the device responds to torsional loading. Since the dog or cat wearing the device is still mobile, it is essential that the device can sustain the torsional loading exerted by the dog or cat. The torsional testing could be done using the MTS and the protocol in Appendix E. Further testing of this device would give more validity to this design and better ensure veterinarians that the device is safe and stable.

Further testing of how the magnets may affect electronic devices, such as computers or cell phones, may also be beneficial in order to answer any questions or concerns pet owner or veterinarians may have.

In addition, it would be beneficial to sell this device as a kit and create an organizational method to make it simpler for the veterinarians. Creating a toolbox like device to keep all of the parts together in an organized manner would ensure for less confusion during surgery. This organizational kit could also include number coding to color coding to allow for better clarity during surgery.

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Appendix A: Background Statistics and Further Information

Breed Distribution and predisposition for humeral fractures treated at NCSU between 1983 and 1995 (2)

Breed	Humeral Fractures	Hospital Population	Proportion of Dogs with Humeral Fractures
Brittany Spaniel	7	170	4.1%
Great Dane	7	387	1.9%
Cocker Spaniel	32	1,941	1.6%
Boston Terrier	6	371	1.6%
Beagle	5	392	1.3%
Chow-Chow	5	395	1.3%
Labrador Retriever	32	2,628	1.2%
Yorkshire Terrier	5	458	1.1%
German Shepherd Dog	14	1,388	1.0%
Rottweiler	5	696	0.72%
Mixed-Breed Dogs	49	7,425	0.66%
Golden Retriever	10	1,962	0.51%
Other Breeds	66	18,067	0.37%
Total	243	36,289	0.67%

Appendix B: Work Breakdown Structure

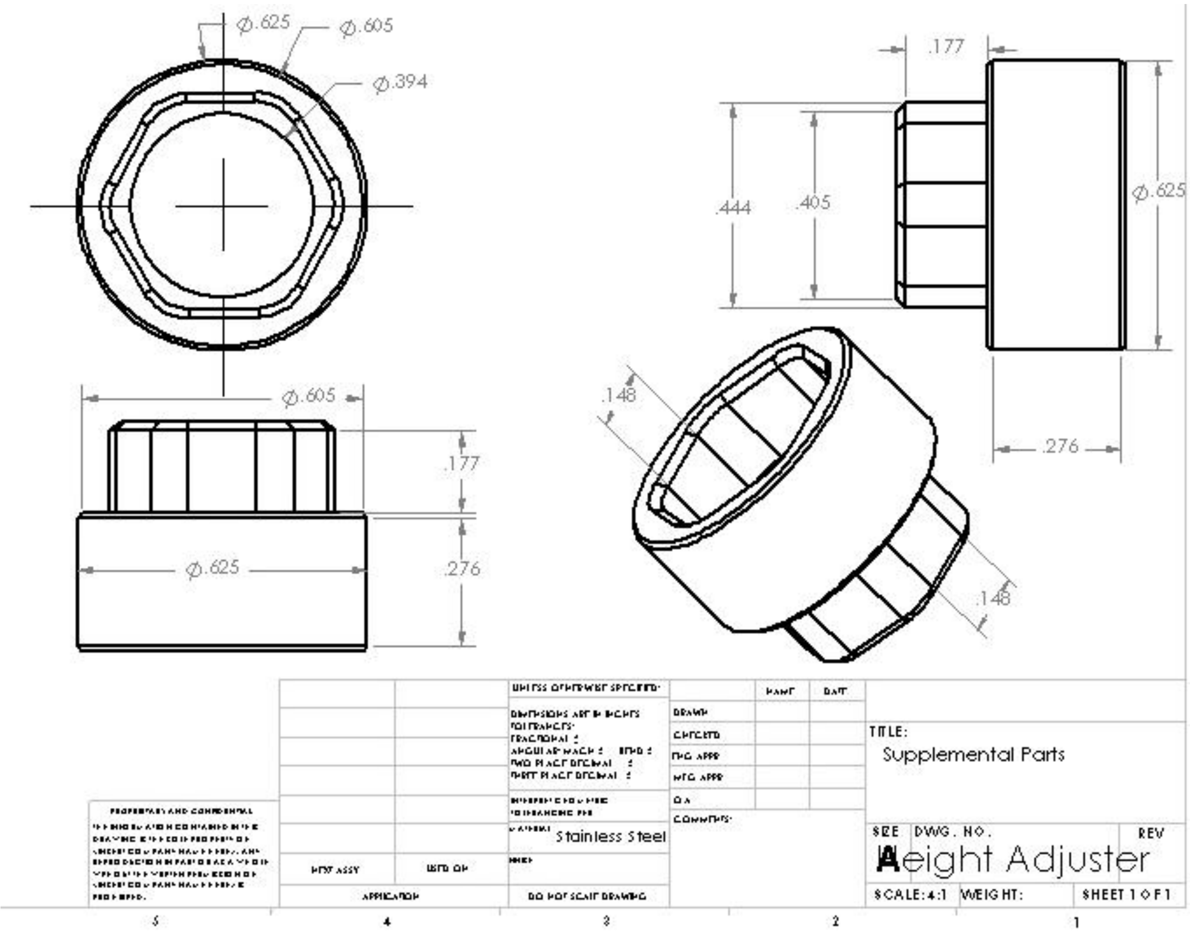
Work Breakdown Structure

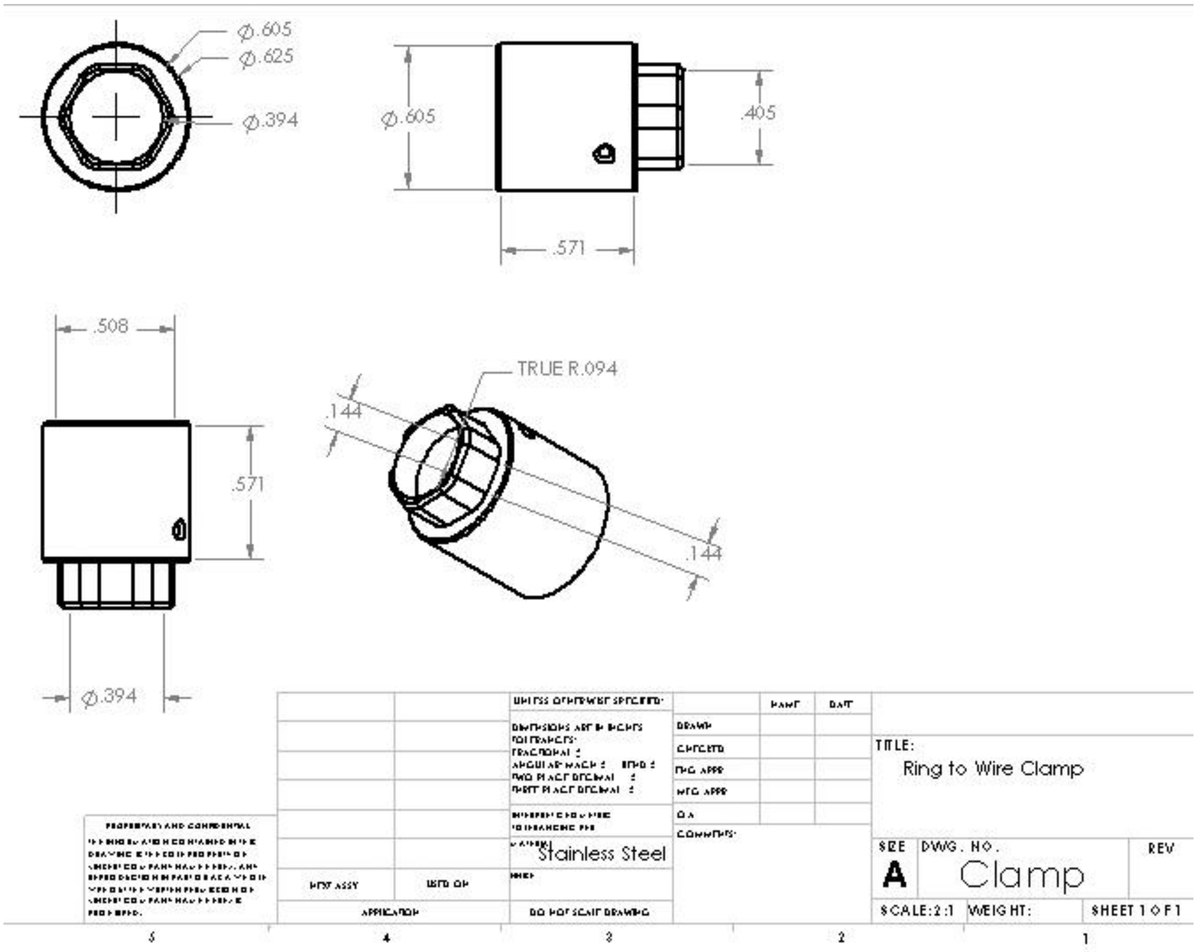
17 Establish Team Dynamics
1.1. Set up meeting times
  1.1.1. Set up two meetings per week with team
  1.1.2. Set up one meeting every other week with Securos
  1.1.3. Set up one meeting every other week with Gaudette
1.2. Generate schedule/organizer
  1.2.1. Create team website
  1.2.2. Create team calendar
  1.2.3. Create WBS
  1.2.4. Create Gantt chart for up to two weeks in advance
18 Identify client's needs
1.3. Conduct literature review
  1.3.1. Research articles pertaining to existing hybrid external fixators (IMEX)
  1.3.2. Research articles pertaining to circular frames and/or linear frames
  1.3.3. Conduct a patent search
  1.3.4. Read articles provided by Securos
1.4. Understand Client Statement
  1.4.1. Interview Securos (Meet with them at facility)
  1.4.2. Simplify statement into needs vs. wants
1.5. Generate objectives list
  1.5.1. Create objectives tree
  1.5.2. Create pairwise comparison chart
  1.5.3. Gain input from client and review objectives with them
  1.5.4. Refine objectives and finalize
1.6. Research and understand all other designs
  1.6.1. Interview veterinarians
  1.6.2. Interview Securos
  1.6.3. Interview IMEX
19 Generate conceptual design
1.7. Brainstorm design ideas
  1.7.1. Create list of design specifications
    1.7.1.1. Confirm specifications with Securos
  1.7.2. Brainstorm functions of design
    1.7.2.1. Brainstorm means to complete these functions

1.8. Begin to incorporate designs into CAD
    1.8.1. Research specific measurements of existing designs
    1.8.2. Begin to calculate animal-device interactions (strength, tension)
1.9. Reverse engineer products provided by Securos
1.10. Create a list of design alternatives
1.11. Analyze cost
    1.11.1. Research material costs
    1.11.2. Create tentative work schedule (approximate labor costs due to time)
    1.11.3. Solidify budget with Securos
20 Evaluate alternative designs
1.12. Prioritize functions
    1.12.1. Rank functions
        1.12.1.1. Determine which functions are essential to success of design
        1.12.1.2. Make a list of functions in order of importance
    1.12.2. Review ranking with Securos
1.13. Test designs
    1.13.1. Develop first order prototypes (rapid-prototyping)
        1.13.1.1. Procure specific materials
        1.13.1.2. Manufacture individual parts
        1.13.1.3. Assemble all parts
    1.13.2. Use prototype in simulation (place on saw-bones)
        1.13.2.1. Complete tension tests (simulate animal strength)
        1.13.2.2. Analyze and record functions
        1.13.2.3. Evaluate results from simulated test
1.14. Choose final design
    1.14.1. Select most successful design (meets objectives and requirements most successfully)
    1.14.2. Approve design with Securos
        1.14.2.1. Contact Securos
        1.14.2.2. Contact Veterinarians
21 Refine Final design
1.15. Finalize list of metrics and benchmarks
1.16. Finalize choice of materials (carbon fiber vs. aluminum)
    1.16.1. Assess the benefits and set backs of each material
1.17. Finalize specifications
    1.17.1. Analyze total cost
        1.17.1.1. Create an end financial report
        1.17.1.2. Review end budget with Securos

    1.17.2. Analyze the presentation of the design
        1.17.2.1. Document aesthetics
            1.17.2.1.1. Approve with Securos
22 Implement Final design
1.18. Procure required materials
    1.18.1. Talk with Securos to obtain appropriate materials
1.19. Assemble all parts to finish final design

Appendix C: Final Design Drawings

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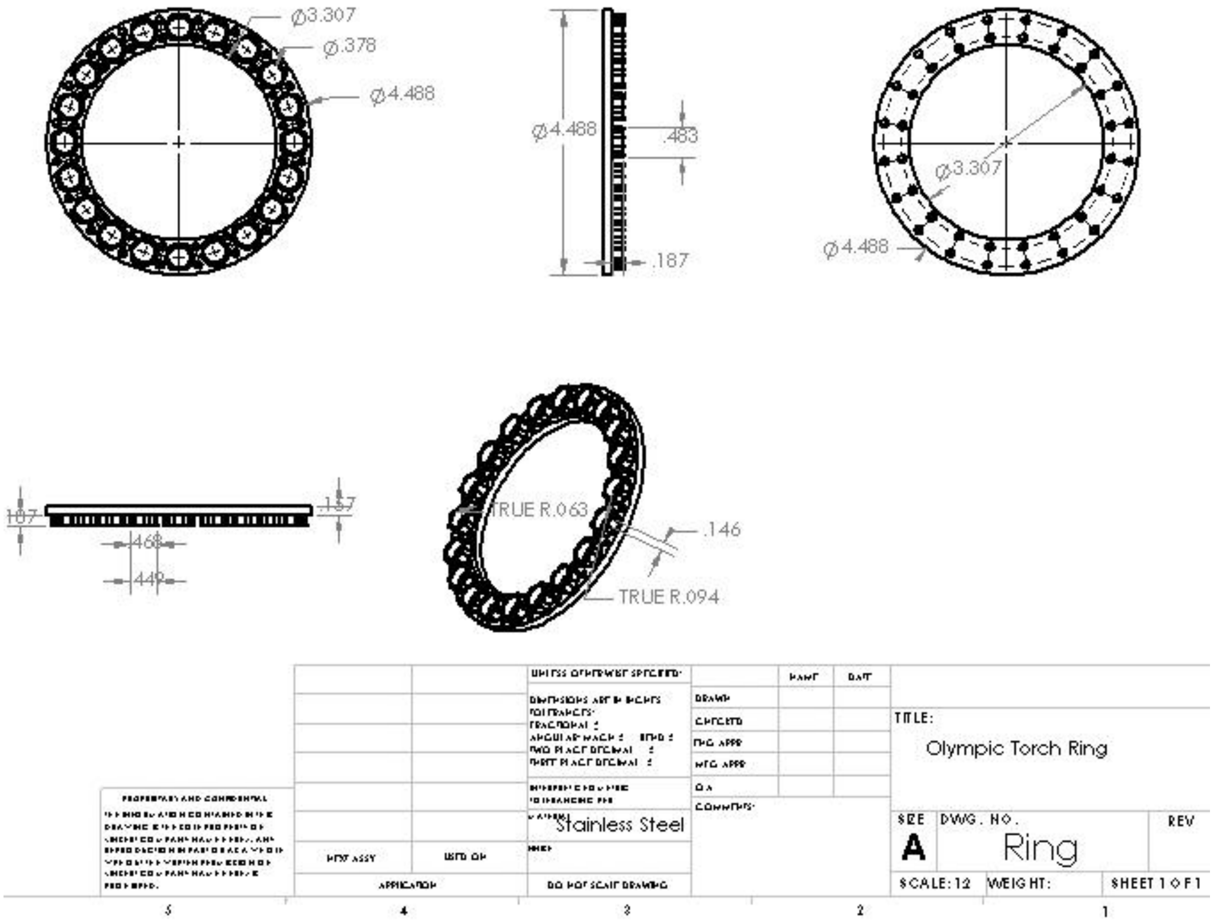
UNLESS OTHERWISE SPECIFIED:
DIMENSIONS ARE IN INCHES
TOLERANCES:
FRACTIONAL ±
ANGULAR: MACH ± BEND ±
TWO PLACE DECIMAL ±
THREE PLACE DECIMAL ±
INTERPRET GEOMETRIC
TOLERANCING PER:
MATERIAL
Stainless Steel
FINISH
NEXT ASSY
USED ON
APPLICATION
DO NOT SCALE DRAWING
NAME
DATE
DRAWN
CHECKED
ENG APPR.
MFG APPR.
Q.A.
COMMENTS:
PROPRIETARY AND CONFIDENTIAL
TITLE:
Ring to Wire Clamp
SIZE
A
DWG. NO.
Clamp
REV
SCALE: 2:1
WEIGHT:
SHEET 1 OF 1
5
4
3
2
1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NAME
DATE
DIMENSIONS ARE IN INCHES
TOLERANCES:
FRACTIONAL ±
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ENG APPR.
MFG APPR.
Q.A.
COMMENTS:
TITLE:
Olympic Torch Ring
MATERIAL
Stainless Steel
FINISH
NEXT ASSY
USED ON
APPLICATION
DO NOT SCALE DRAWING
PROPRIETARY AND CONFIDENTIAL
SIZE
A
DWG. NO.
Ring
REV
SCALE: 1:2
WEIGHT:
SHEET 1 OF 1
5
4
3
2
1

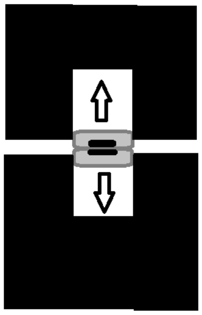
Appendix D: Magnet Tensile Test Protocol

Objective
To determine the ultimate strength of rare earth magnets with the five and half pound pulling force while used in conjunction with aluminum height adjusters.

Materials
4 neodymium rare earth magnets with the five and half pound pulling force
Instron Tensile Test Machine/BlueHill 2 Software
2 Aluminum Height Adjusters
Safety Glasses
Fiber Glass Shield
Caliper

Procedure

1. Set up Instron machine
   - Pre-set loading cell to 2500N
   - Place testing jig in proper location



Magnet Placement

2. Place magnets into height adjusters
   - Put two magnets in each height adjuster
   - Stack two height adjusters on top of one another
   - Place each height adjuster in a set of grips (one in the top grip, one in the bottom grip)

4. Turn on testing machine
   - Apply tensile force at a rate of 70N/min
   - Video record height adjuster separation
   - Measure deformation and separation
   - Collect data from the machine's displacement transducer and load cell at 50 points per second

- Transfer data to computer using data acquisition card

5. Repeat testing of each magnet set four times

Appendix E: Full Construct Compression Test Protocol

Objective

To determine the ultimate strength of the fully assembled external fixation construct.

Materials

2 Aluminum Olympic Torch Rings
2 Aluminum I-Beam Rings
Instron Tensile Test Machine/BlueHill 2 Software
20 Aluminum Height Adjusters
4 Stainless Steel Ring to Wire Clamps
2 Fixation Wires
1 Saw Bone
Safety Glasses
Fiber Glass Shield
Caliper

Procedure

1. Set up Instron machine
    - Pre-set loading cell to 2500N

Compression Test Setup

2. Place saw bone into bottom grips
    - Tighten clamp to desired position
3. Apply 10N (preload) to the mechanical jig

- Position jig directly over the bone

4. Turn on testing machine

    - Apply compressive force at a rate of 70N/min
    - Video record clamp movements
    - Measure deformation and disassembly of device
    - Collect data from the machine’s displacement transducer and load cell at 50 points per second
    - Transfer data to computer using data acquisition card

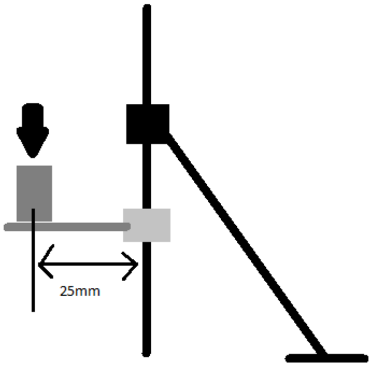
5. Repeat testing of each device four times

Appendix F: Future Mechanical Testing Protocols

Future Rod to Pin Clamp Testing

Using the Instron mechanical testing machine and information gathered from discussions with Securos as well as from various scientific articles, the team created a protocol (Appendix B) to test the strength of the rod to pin clamp. The loading cell was pre-set to 2500 Newtons and a custom testing jig was placed into the top grip of the Instron (Figure 42).

The rod to pin clamp was attached to a vertically positioned rod and the metal pin was horizontally attached to the other end of the pin. Using another rod and small metal connector, the team created a triangular base with respect to the rod attached to the clamp to ensure all testing materials were securely held in place (Figure 43).

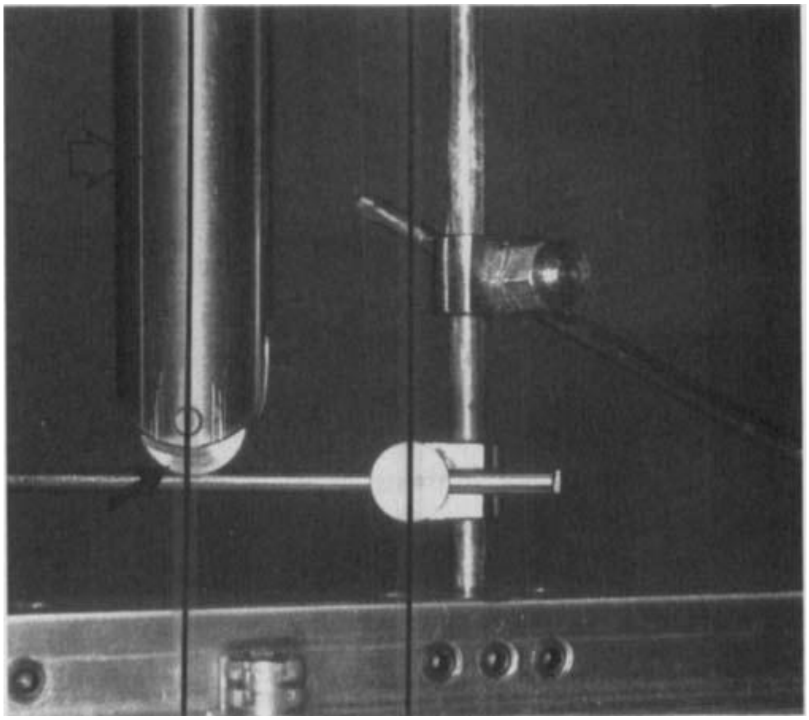


The clamp was tightened, and 10 Newtons was applied to the mechanical jig, which was placed exactly 25 millimeters away from the center of the clamp. The Instron was turned on and the team programmed the machine to apply a force at a rate of 0.1mm per second for a total of 4mm. Data from the machine's displacement transducer and load cell at 50 points per second was collected. This data was transferred to a computer using a data acquisition card. A stress-strain curve was obtained from these data and the total deformation of the clamp was also measured. Three clamps were tested in total, and for each clamp, three tests were conducted; one at 4.4Nm, one at 6.1Nm, and one at 7.8Nm of torque.

FUTURE ROD TO PIN CLAMP TESTING PROTOCOL

1. Set up Instron or MTS machine

- Pre-set loading cell to 2500N
- Place testing jig in proper location



Mechanical Testing Jig (39)

2. Place clamp around vertical aluminum rod and attach metal pin horizontally (rod and pin provided by Securos)

- Using another rod, create a triangular base connected to the aluminum rod to hold all components in place
- Tighten clamp to desired position

3. Apply 10N (preload) to the mechanical jig

- Position jig perpendicular to the pin, allowing it to rest on the pin
- Position jig 25mm away from center of clamp

4. Turn on testing machine

- Apply force at a rate of 0.1mm/second for a total of 4mm
- Video record clamp movements

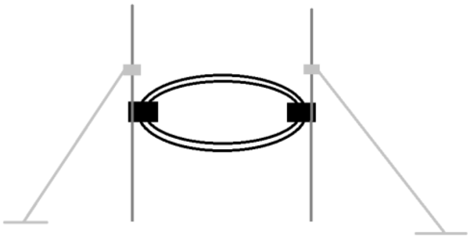
- Measure deformation and orientation change of clamp
- Collect data from the machine’s displacement transducer and load cell at 50 points per second
- Transfer data to computer using data acquisition card

5. Repeat testing of each clamp three times

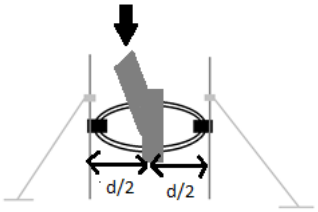
    - For each test, increase torque (4.4, 6.1, 7.8 Nm)

Future Rod to Ring Clamp Testing

The Instron mechanical testing machine was also used to test the strength of the rod to ring clamp (Appendix B). Using a set-up similar to that of the rod to pin clamp testing set-up, the loading cell was pre-set to 2500 Newtons and the testing jig was placed into the top grip of the machine (Figure 39). The clamp was attached to a vertically placed rod and the other end of the clamp was attached to the ring. To ensure that the ring was securely stabilized, a clamp and rod was placed on either side of the ring (Figure 44). For each vertical rod, another aluminum rod was attached at an angle to create a triangular base to create a stable reinforcement.



The mechanical jig was placed perpendicular to the ring, allowing it to rest on the ring with its surface area distributed evenly across the diameter of the ring. 10 Newtons of force was applied to the jig (Figure 45).



The Instron was turned on and a force at a rate of 0.1mm per second for a total of 4mm was applied. The deformation and orientation change of the clamp was observed and recorded. The machine's displacement transducer and load cell collected data at 50 points per second and this information was transferred to a computer via a data acquisition card. A stress-strain curve was produced and the strength of the clamp was determined. Three clamps were tested in total and each clamp was tested three times at various torques; 4.4Nm, 6.1Nm, and 7.8Nm.

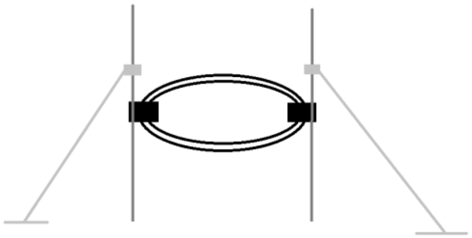
FUTURE ROD TO RING CLAMP TESTING PROTOCOL

1. Set up Instron or MTS machine

- Pre-set loading cell to 2500N
- Place testing jig in proper location

2. Place clamp around vertical aluminum rod and attach other end of clamp to the ring, one clamp and rod on each end of the ring (rod provided by Securos)

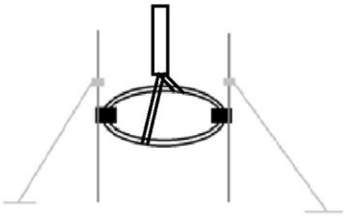
- Using another rod, create a triangular base connected to the aluminum rod to hold all components in place
- Tighten clamp to desired position



Set up of Ring and Rods

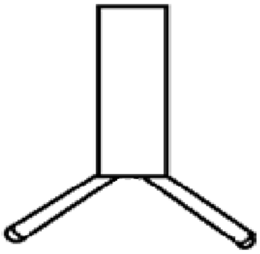
3. Apply 10N (preload) to the mechanical jig

- Position jig perpendicular to the ring, allowing it to rest on the ring (each leg evenly distributed)



Jig on ring

- Position jig 25mm away from center of clamp



Mechanical Jig for Ring to Rod clamp

4. Turn on testing machine

   - Apply force at a rate of 70N/min
   - Video record clamp movements
   - Measure deformation and orientation change of clamp
   - Collect data from the machine's displacement transducer and load cell at 50 points per second
   - Transfer data to computer using data acquisition card

5. Repeat testing of each clamp three times

   - For each test, increase torque (4.4, 6.1, 7.8 Nm)

Future Bending Testing of Ring

The MTS testing machine was used to determine the bending stiffness, bending strength and bending structural stiffness of the ring component of the team's device. With reference to the ASTM F1541-02 standard, as discussed above and information gathered through previous testing studies and discussions with Securos, the exact procedure for testing these mechanical properties was determined (Appendix B). Four rings were tested, each undergoing axial compression at a rate a 15 N per second, torsion at a rate of 375 Nm per second, bending at a rate of 1.2 N per second, and transverse bending (4 point bending) at a rate of 3 N per second. All tests for all rings underwent 3660 cycles at a frequency of 1 hertz to imitate the force produced by an average dog proportional to the ring size.

The sawbone, which was provided by Securos, was proximally mounted with the steel pot over the plateau of the sagittal and coronal planes. The ring was positioned around the sawbone with the half pins and wires inserted into the central location of the bone (Figure 46).

MTS Ring Testing Set-up (38)

Loads were applied at a distance of 100mm from the wire-bone interface and the rings were held rigidly through the distal fragment for axial loading. For torsional loading, the rings were held rigidly from the proximal fragment.

The chiller was turned on and the machine was turned onto low. After one minute, the MTS was turned to high and the teststar file was loaded onto the computer. The testware file was then opened and the load rollers were positioned onto the edge of the ring. The ring was then preloaded with a load of 10 Newtons. The force and extension values were zeroed on the control panel and a shield was placed in front of the machine for safety.

The testware program was executed and was run until plastic deformation was achieved. After the testing sample was complete, the ring was removed from the machine and the data was saved onto a flashdrive to be imported into Microsoft Excel, in order to plot a curve of all data collected.

FUTURE RING BENDING TESTING PROTOCOL

OBJECTIVE:

To compare the mechanical properties (bending stiffness, bending strength, and bending structural stiffness) of the new design of a circular external fixation device to the existing external fixation devices.

REFERENCE DOCUMENTS:

- The ASTM F1541-02 external fixation devices (2011)
- Ankle Fusion Stability: A Biomechanical Comparison of External Versus Internal Fixation (Hoover, 2011)
- Circular External Fixation Frames with Divergent Half Pins A Pilot Biomechanical Study (Lenarz, 2008)
- Stability of external circular fixation: a multi-variable biomechanical analysis (Bronson, 1998)
- Biomechanical comparison of five external wrist fixators (Chang, 2002)

TEST DETAILS:

Machine: MTS
File: 001000.tcc, 0001000.000
Type: Axial compression, Torsion, Bending
Rate: 200 N (varied based on dog size in proportion to ring size) at a frequency of 1 Hz for 3660 cycles
Axial Compression = 15N/s
Torsion = 375 Nmm/s
Bending = 1.2 N/s
Transverse Bending (4 point bending) = 3 N/s

TEST GROUPS:

1. Carbon fiber ring without holes and magnetic clamps (n=4)
2. Stainless steel ring with holes and IMEX clamps (n=4)

PROCEDURE:

1. Mount Sawbone proximally with the steel pot over the plateau of the sagittal and coronal planes with bolts to stabilize the pot
2. Pots should be parallel to each other and perpendicular to the mechanical axis of the Sawbone

3. Use a jig that holds the Sawbone in the same position within the steel pot distally and allow the metal to cool and solidify around the plafond
4. A mounting plate was used to position the Sawbone in the frame with the tensioned wires and half pins and a central location was chosen for better stability of the configuration
5. Loads were applied at a distance of 100mm from the wire-bone interface
6. Rings were held rigidly through the distal fragment for axial loading
7. For torsional loading, rings were held rigidly from the proximal fragment
8. Turn on chiller. It should run between 17-21 degrees F.
9. Turn machine on to LOW. After 1 minute, turn to HIGH.
10. Load teststar file from folder.
11. Load testware file from folder.
12. Jog load rollers down to the edge of sample. Preload the sample with 10 N.
13. Zero the force and extension values on the control panel.
14. Place shield in front of machine for safety.
15. Execute testware program (PROGRAM – EXECUTE – RUN).
16. Run program until plastic deformation is achieved.
17. After sample is finished, close the data file, manually move the load rollers upward, and remove the sample.
18. Repeat as necessary.

Appendix G: Force Calculations

Weight (lbs)	Weight (kg)	Total Force (N)	Force/4	Force/2
4	1.82	17.84	4.46	8.92
6	2.73	26.75	6.69	13.38
8	3.64	35.67	8.92	17.84
10	4.55	44.59	11.15	22.30
12	5.45	53.51	13.38	26.75
14	6.36	62.43	15.61	31.21
16	7.27	71.35	17.84	35.67
18	8.18	80.26	20.07	40.13
20	9.09	89.18	22.30	44.59
22	10.00	98.10	24.53	49.05
24	10.91	107.02	26.75	53.51
26	11.82	115.94	28.98	57.97
28	12.73	124.85	31.21	62.43
30	13.64	133.77	33.44	66.89
32	14.55	142.69	35.67	71.35
34	15.45	151.61	37.90	75.80
36	16.36	160.53	40.13	80.26
38	17.27	169.45	42.36	84.72
40	18.18	178.36	44.59	89.18
42	19.09	187.28	46.82	93.64
44	20.00	196.20	49.05	98.10
46	20.91	205.12	51.28	102.56
48	21.82	214.04	53.51	107.02
50	22.73	222.95	55.74	111.48
52	23.64	231.87	57.97	115.94
54	24.55	240.79	60.20	120.40
56	25.45	249.71	62.43	124.85
58	26.36	258.63	64.66	129.31
60	27.27	267.55	66.89	133.77
62	28.18	276.46	69.12	138.23
64	29.09	285.38	71.35	142.69
66	30.00	294.30	73.58	147.15
68	30.91	303.22	75.80	151.61
70	31.82	312.14	78.03	156.07
72	32.73	321.05	80.26	160.53
74	33.64	329.97	82.49	164.99
76	34.55	338.89	84.72	169.45
78	35.45	347.81	86.95	173.90
80	36.36	356.73	89.18	178.36

These forces refer to the amount of force a dog or cat could produce based on their body weight. These forces were calculated using the formula, Force=mass*acceleration (mass=weight of the animal, acceleration=9.81m/s)

Appendix H: Expense Report

Material	Cost	Quantity	Total Cost
Aluminum Sheet (2'x2') (Rings)	$141.00	1	$141.00
Stainless Steel Rod (2') (Clamps)	$30.00	1	$30.00
Aluminum Rod (1') (Height Adjusters)	$0.00 (Scrap)	4	$0.00
Drill Bits (Holes in Clamps)	$11.05	2	$22.10
Magnets	$0.54	130	$70.72
			$263.82

Appendix I: Glossary of Terms

Amputation- the intentional surgical removal of a limb or body part, it is performed to remove diseased tissue or relieve pain

Angular Limb Deformity- a lateral (outward) or medial (inward) deviation of a limb

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

Caudal-toward or relatively near to the tail

Complex fracture- a closed fracture in which the soft tissue surrounding the bone is severely damaged, damage to multiple bones, joints, ligaments and tendons; are often debilitating, and require personalized treatment plans

Compressive Load-a load (of a specified force) applied directly onto an object, pushing either down on the top, or up on the bottom

Cranial-toward or relatively near to the head

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, head or limb into dorsal and ventral portions

Femur-thigh bone, largest in the body

Fixation- act of fastening or holding in a fixed position

Instron Machine-a mechanical testing machine with the ability to apply both compressive and tensile loads to determine stress and strain relationships of an object

K-wire- a thin, rigid wire, also known as the Kirschner wire, used to hold bone fragments in place

Lateral-away from or relatively farther from the median plane

Medial-toward or relatively near to the median plane

Median Plane- divides the head, body or limb longitudinally into equal right and left halves

Minimally Invasive- surgical intervention involving the least possible physical trauma to the patient

Non-union fracture-a complete break of a bone resulting in two separate bone fragments

Olive wire- wire used for bone transport; named for the olive shape located at the end of the wire

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

Quasistatic- loading where inertial effects are negligible, equally distributed load at four locations

Rare earth magnet- strong permanent magnets made from alloys of rare earth elements; Neodymium rare earth magnets were used in this device

Rotation-the movement of a part around its long axis

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

Securos-manufacturer of veterinary orthopedics located in Fiskdale, Massachusetts

Tensile Load- a load (of a specified force) applied directly onto an object, pulling the object in the direction of its outer surfaces, away from the middle

Tibia- The inner and larger of the two bones of the lower human leg, extending from the knee to the ankle

Transverse plane- cutes 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