CANINE STIFLE STABILIZATION SYSTEM

FOR A CIRCULAR TIBIAL TUBEROSITY ADVANCEMENT (CTTA) PROCEDURE

A Major Qualifying Project Report Submitted to the Faculty of WORCESTER POLYTECHNIC INSTITUTE



In partial fulfillment of the requirements for Degree of Bachelor of Science

Sponsoring Agency:



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Date of Submission: May 1, 2014

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CONTRIBUTIONS

All authors contributed equally to all aspects of the project and this report.

ACKNOWLEDGEMENTS

All authors would like to acknowledge Worcester Polytechnic Institute (WPI) and its Department of Biomedical Engineering along with the sponsoring agency, SECUROS Veterinary Orthopedics, for providing the funding and facilities necessary to complete the Major Qualifying Project. The team would like to sincerely thank advisors from SECUROS Veterinary Orthopedics, Andrew Kazanovicz, Olivia Doane, and David Anderson, and WPI advisor Professor Glenn Gaudette for their guidance throughout the project. Additionally, the team extends their thanks to veterinary orthopedic surgeons Dr. Chuck Walls, Dr. Fred Pike, and Dr. Kechia Davis (VCA South Shore Animal Hospital) for their valuable contributions and insight on current surgical procedures and techniques in addition to the animal hospital survey participants. The team also acknowledges Professor Ali Kiapour (of WPI), Adriana Hera (of WPI), and David Polito for their assistance with various software programs and Lisa Wall for maintaining the lab used by the team. Lastly, the team would like to thank the WPI Manufacturing Labs, Timothy Ellsworth, and Richard "Papa" Newell for their manufacturing assistance throughout the project.

ABSTRACT

The goal of this design project was to create an optimal bone plate and screw fixation system to stabilize the stifle joint for a circular tibial tuberosity advancement procedure to treat canine CCL rupture or instability. Six possible designs were modeled via CAD and various prototypes; preliminary evaluations were made and three designs were selected for manufacturing at a SECUROS facility. Manufactured prototypes were assembled on nine canine cadaver tibias and tested via tension in the patellar tendon utilizing an Instron machine and a custom designed and manufactured Instron jig to determine plate performance. Loading was applied cyclically at forces experienced in the canine stifle during walking and running. While none of the three designs met initial force requirements, the "Modified TTA" design displayed the lowest failure loads (average=477N) and the highest displacement of the osteotomy and the "Triangle" design showed the most traumatic failure in the bone. The "Modified TPLO" design exhibited the highest performance with failure loads above 1000N (average=1234N) and minimal osteotomy rotation and displacement.

Keywords—Stifle, cTTA (circular tibial tuberosity advancement), CCL (cranial cruciate ligament)

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EXECUTIVE SUMMARY

In canines, damage to the cranial cruciate ligament (CCL) is a common problem, and improved treatments for CCL instability hold high market potential. CCL deficiencies account for more than 90 percent of stifle problems in dogs over two years of age, and the number of cases has more than doubled in the past 30 years (Griffon, 2009). A healthy CCL provides stability and contributes to proper joint function. The CCL is the equivalent of the anterior cruciate ligament (ACL) in humans, which generally tears as a result of traumatic injury. However, the CCL in canines degrades differently. Due to several factors including tibial conformation, obesity, activity level, and age, the CCL experiences degeneration over time, which eventually leads to rupture of the ligament. Since the ligament cannot be repaired, other treatments exist to correct the issue and stabilize the joint. Osteotomy procedures are common treatments, where the joint anatomy is surgically modified to render the CCL unnecessary for stifle stabilization (Kim, Pozzi, Kowaleski, & Lewis, 2008). Two existing procedures include tibial plateau leveling osteotomy (TPLO) and tibial tuberosity advancement (TTA), however these procedures still involve complications. A relatively new treatment called circular tibial tuberosity advancement (cTTA) combines the theory of TTA with



Figure 0-1: Scan of cTTA radial cut

the radial cut of TPLO. The cTTA is performed by a circular osteotomy of the tibial tuberosity followed by a customized cranial rotation of the bone segment (Fig. 0-1).

The procedure realigns the patellar tendon perpendicular to the total joint force within the stifle, eliminating shear forces and unloading the CCL. Since this procedure is so new, customized bone plates do not currently exist specifically for cTTA. There is a significant gap in research on cTTA technique and the results it produces, creating a need for a specifically designed bone plate that is optimized for this procedure. (Rovesti, Katic, Dalpozzo, Dondi, & Dupre, 2013)

The objective of this project was to design and manufacture a bone plate that is optimized for a cTTA procedure to redistribute and support the various forces within the canine

stifle joint. The design was defined by five obtainable objectives: the plate must be biocompatible and safe for the canine and surgeon, strong and stable to support the affected stifle joint postoperative, easy to use for the surgeon, cost effective, and must reduce the recovery period for the canine. Specific functions were also developed and incorporated into a final client statement; main points of the statement are outlined below:

- 1. Specialty titanium or stainless steel bone plate
- 2. Total joint force perpendicular to the tibial plateau
- 3. Eliminate cranial tibial thrust
- 4. Withstand peak vertical forces
- 5. Prevent osteotomy displacement

After definition of the client statement and development of objectives, functions, and specifications, six initial design alternatives were developed and modeled in SolidWorks. Initial design evaluations incorporated client feedback via interviews with three veterinary surgeons, a phone survey of local

animal hospitals, and assembly of aluminum prototypes on Sawbone tibia models. From this preliminary analysis, three final design options were selected: the Modified TTA, Triangle, and Modified TPLO designs.

The three selected final plate options were adjusted to conform to industry standards and redesigned based on results of preliminary evaluations and surgeon and engineer feedback. Prototypes were produced at a SECUROS facility and the designs were tested via finite element analysis and mechanical testing. The finite element model (Fig. 0-2) was loaded according to a joint force analysis of the canine stifle during maximum loading conditions and revealed increased stress concentrations at the screw holes. It was also noted that higher stresses were seen in the Modified TTA plate, which was thinner than the other designs.



Figure 0-2: Finite element models of Modified TTA, Triangle, and Modified TPLO plate designs where red represents highest von Mises stress and blue represents lowest von Mises stress

Mechanical testing provided data on each plate's performance under loading specific to the gait of the canine. Axial loading tension tests were conducted on the final design selections using the

Instron 5544 machine. A custom Instron attachment and jig were designed and manufactured (Fig. 0-3). Each bone was held at a 60-degree angle for anatomical accuracy, with the patellar tendon held vertically. Nine canine cadaver tibias were cut to specifications of the cTTA procedure and three samples were plated with each design using surgical tools and the manufactured prototypes of the three final designs provided by SECUROS. Tension was applied to the patellar tendon at a magnitude of 530N at a rate of 800 N/minute for 40 cycles to mimic average stifle forces during walking. Additional testing was done to simulate running forces, with 1420N applied at a rate of 1700N/minute for 40 cycles, or until failure. Displacement of the tuberosity and points of failure were analyzed.

Results of mechanical testing revealed information about system performance. The Modified TTA plate samples reached system failure at 512N, 452N, and 466N (average=477N). Triangle plate



Figure 0-3: Jig developed for Instron testing

samples failed at 757N, 398N, and 1015N (average=723N). Modified TPLO plate samples all successfully completed 40 low force cycles, then failed during high force cycling at 1421N, 1143N, and 1137N (average=1234N). All failure occurred in the tuberosity at or along the screw fixation points. While Modified TPLO plates resulted in very little displacement, Modified TTA samples exhibited the largest displacement of the tuberosity. The Triangle samples yielded the most traumatic failure, displaying detachment of nearly the entire osteotomy (Fig. 0-4).



Figure 0-4: a) Modified TPLO plate during walking force cyclic loading b) Modified TTA plate before (left photo) and during (right photo) walking force cyclic loading c) Triangle sample failure

From the data, the Modified TPLO plate exhibited the best performance of the three designs. The Triangle plate provided ease of use when assembling and some mechanical strength under loading, but was difficult to contour to the bone's anatomy due to the plate shape and thickness. The TTA plate performed well under the walking loads, but could not hold under higher loading. With the Triangle and Modified TTA designs, problems originated with high stress concentrations due to screw placement in the tuberosity portion. The results obtained are not statistically significant due to small sample size, but do provide evidence for plate performance.

There were several limitations to this study. Testing was under strict time constraints, which limited the amount of samples tested. The time necessary to clean bones and prepare tests was considerable, so preservation by freezing was required. The freezing and thawing of the bones likely had a negative effect on bone properties. Samples varied in size due to availability; ideally, similarly sized bones would have been used for all tests. Additionally, necessary tools and experience using them were limited, primarily with performing the osteotomy to the tuberosity, which had the potential to make a significant difference in the results.

It can be concluded that the Modified TPLO plate design performed most satisfactorily. There is room for significant improvement in all three designs. Alterations and improvements on the designs based on the observations found in this study hold the potential for vastly improving performance. For future work, it is recommended that the plates be redesigned and the testing repeated using all proper surgical tools and techniques. It is also suggested that the number of test samples be increased to yield statistically significant results and that samples of consistent size and properties be used.

1 INTRODUCTION

Veterinary medicine is an industry that has gained significant momentum in the past several years. Pets have become an integral part of families in many societies, and the options for medical treatment of animals are rapidly expanding in order to provide high quality veterinary care. As technology progresses in the medical field, an increasing number of treatments are being modified and optimized for use in animals. In this way, advances in the field of veterinary medicine continually allow for improved treatment capabilities. (Kazanovicz, 6 Sept. 2013)

In canines, damage to the cranial cruciate ligament (CCL) is common. This ligament is located in the knee joint of the hind leg, called the stifle. When functioning normally, the CCL provides support to the stifle by connecting the distal end of the femur to the proximal end of the tibia and contributing to functional movement of the joint (Canapp, 2007). Several factors can contribute to the damage of the CCL. While injuries to the anterior cruciate ligament (ACL) in humans usually happen as a result of a sudden, traumatic force, the canine equivalent CCL injuries most frequently occur gradually over a period of time. Instability and tears can be caused by aging, obesity, or heavy activity. Also, some dog breeds are more prone to CCL injuries than others due to varying tibial conformations and joint angles. Once the CCL is torn, the ligament cannot heal on its own, and unless it is properly stabilized, the injury will eventually lead to a full rupture. CCL injuries are very painful and disruptive to the dog's regular activities; proper treatment is required to maintain the dog's quality of life. (Kazanovicz, 6 Sept. 2013)

The most common treatments of CCL injuries are surgical. Non-surgical methods including external orthotic braces, physical therapy, and activity restriction exist but are not extremely successful (Canapp, 2007). Activity restriction and therapy are very difficult to enforce in a canine patient, while braces are disruptive to normal movement and only temporarily treat the problem. Surgical methods are more practical treatment options for this application (Kazanovicz, 6 Sept. 2013). Although current surgical procedures are successful in unloading the CCL and stabilizing the joint, they still involve complications. Recently, a new surgical procedure was developed to address the drawbacks of the previous surgical techniques. This method, called circular tibial tuberosity advancement (cTTA), allows for faster bone healing, a less disruptive recovery, and more precise angle readjustment than the other procedures in existence (Rovesti et al., 2013). However, since cTTA is a relatively new development in the field, there is limited research and the procedure still needs to be refined. Specifically, there is no specialized bone fixation plate designed for cTTA procedures; bone plates must instead be borrowed from other procedures, even though these plates are not ideal for cTTA. This project focuses on designing a bone fixation plate system optimized for the cTTA procedure.

2 LITERATURE REVIEW

2.1 SIGNIFICANCE OF CCL DISEASE

Canine cranial cruciate ligament disease is a significant problem, and improved treatments for CCL instability hold high market potential. In 2003 alone, 1.3 billion dollars were spent by dog owners in the United States to surgically treat CCL issues. This number continues to grow as more procedures are created and refined. This disease has such a large economic impact because canine CCL problems are extremely prevalent in the veterinary world and the number of cases has more than doubled in the past 30 years (Griffon, 2009). CCL issues account for more than 90 percent of stifle problems in dogs over 2 years of age and the problem is often recurring, as 50 percent of dogs with CCL issues will develop this problem in both knees (Kazanovicz, 6 Sept. 2013). The high cost of surgeries also exemplifies the significance of this problem in canines. In 2003, 1.7 million dollars were spent on surgeries completed by the American College of Veterinary Surgeons, while 1.02 billion dollars were spent by the American Veterinary Medical Association (Kazanovicz, 6 Sept. 2013; Wilke, Robinson, Evans, Rothschild, & Conzemius, 2005). There is clearly a significant market and demand for these procedures to treat CCL deficiencies. In addition, the surgical procedures currently used to treat CCL issues have a complication rate of 28-59 percent, indicating the need for development of new technology to provide more, and potentially better, treatment options (Griffon, 2009).

2.2 CANINE STIFLE ANATOMY

The cranial cruciate ligament is located in the knee joint of the hind limb, or the stifle, of canines. Canine stifle anatomy and joint forces play a large role in understanding cranial cruciate ligament disease and the resulting stifle instability.

2.2.1 Cranial Cruciate Ligament

The cranial cruciate ligament provides support to the stifle joint by connecting the distal end of the femur to the proximal end of the tibia and contributes to functional movement of the joint. The CCL is similar to the anterior cruciate ligament (ACL) in humans; however, problems with the CCL occur very differently in dogs. While ACL tears in humans are often traumatic injuries, the type of tear in canines is often gradual and occurs over years. A comparison between a normal and torn canine cranial cruciate ligament is shown in Fig. 2-1. (Kazanovicz, 6 Sept. 2013)



Figure 2-1: Canine Cranial Cruciate Ligament (Normal vs. Ruptured) ("Cranial Cruciate Ligament Rupture," 2009)

2.2.2 Joint Forces

To understand the different treatments for CCL insufficiencies in canines, it is important to first understand the forces present in the canine stifle. The canine stifle joint is dependent on the total joint compressive force, the cranial tibial thrust, the counterforce of the cruciate ligament and the force of the quadriceps muscles. CCL treatments often depend mainly on the effects of cranial tibial thrust, but it is still necessary to take into account other existing forces. Figure 2-2 depicts a free body diagram of these stifle forces.



Figure 2-2: Forces Present within a Canine Stifle (ECVS, 2011)

The joint forces are applied differently during different phases of the gait of the canine. Joint forces are at a peak during the stance phase of the gait, while these forces drop to zero in the swing phase (Kim et al., 2008). This is an important factor to consider for bone plate design, specifically in determining joint loading. The plate used for fixation in a CCL surgery needs to support the forces within the stifle at stance phase, but also must account for the heightened forces when a dog runs or jumps. One study analyzed the ground reaction forces of canine gait on both force plates and instrumented treadmills in nine adult dogs of varying breeds and found that the peak vertical ground reaction force in the hind limb averaged at 61.58% body weight (BW) on the force plate and 51.87% BW on treadmill at a walking pace (Drüen, Böddeker, Nolte, & Wefstaedt, 2010). Another study tested the peak vertical forces experienced by galloping dogs. This study looked at six adult dogs of varying breeds and measured peak vertical force in the hind limb via a force plate after running along a 20-meter runway. The mean velocity of the galloping dogs was $9.2 \pm .3 \text{ m/s}$, measured with laser sensors positioned along the runway. The peak vertical force in the lead hind limb was the highest measured force, averaging at 1.64(BW) for 116 trials. Additional results from the study are shown below in Table 2-1. (Walter & Carrier, 2006)

	Lead fore	Trail fore	Lead hind	Trail hind
Contact time (ms)	74.5±4.6*	70.8±5.0*	71.5±3.2	74.3±4.0
Forces (BW)				
Mean vertical	1.25±0.07	1.31±0.08	0.99±0.07*	0.94±0.07*
Peak vertical	2.12±0.10	2.23±0.13	1.64±0.11*	1.47±0.09*
Peak accelerating	$0.44 \pm 0.04^{\dagger}$	$0.49 \pm 0.04^{\dagger}$	$0.46 \pm 0.07^{\dagger}$	$0.38 \pm 0.05^{\dagger}$
Peak decelerating	-1.02 ± 0.10	-1.00 ± 0.11	-0.62 ± 0.05	-0.57±0.03
Peak lateral	0.22±0.04	0.20±0.04	0.12±0.03	0.16±0.03
Peak medial	-0.11±0.03	-0.11±0.04	-0.12 ± 0.03	-0.11±0.04
Impulses (BW ms)				
Vertical [‡]	91.7±3.0	91.8±4.0	70.0±4.2	68.6±3.8
Accelerating	$10.8 \pm 0.90^{\dagger}$	12.3±0.75 [†]	13.0±2.22*	10.7±1.85*
Decelerating [‡]	-11.0±0.43*	-9.80±0.79*	-5.41 ± 0.70	-5.43 ± 0.78
Lateral	3.81±0.80	3.88±1.17	1.87 ± 0.83	4.36±1.23
Medial	-1.2 ± 0.44	-1.77±0.90	-1.37±1.24	-2.18±1.49

Table 2-1: Contact Times and Ground Reaction Forces (Walter & Carrier, 2006)

Significant difference between leading and trailing limbs with *P < 0.05, $^{\dagger}P < 0.01$. ‡ indicates a significant difference between total forelimb and total hindlimb impulses (P < 0.01). BW, body weights.

A simplified analysis of the forces present in the canine stifle joint is shown in Fig. 2-3 below. This analysis focuses on three main forces.



Figure 2-3: Joint Force Free Body Diagram (Peck & Marcellin-Little, 2013)

Typically, the moment arm "a" in Fig. 2-3 is about three times the length of moment arm "b", so the patellar tendon force is equal to about three times the ground reaction force (Equation 1).

$$PT = 3 * GRF \tag{1}$$

Using the free body diagram (Fig. 2-3) and assuming that the patellar tendon force acts at about 30 degrees to the vertical ground reaction force, the joint force can be calculated in terms of body weight (Equation 2):

$$JF_{x} = \frac{a}{b} * GRF * \sin(30) = .75(BW)$$

$$JF_{y} = GRF + \frac{a}{b} * GRF * \cos(30) = 1.8(BW)$$

$$JF = \sqrt{JF_{x}^{2} + JF_{y}^{2}} = 1.95(BW)$$
(2)

Along with these three main forces, the loading of the CCL is important to consider. Mid-stance, the CCL reaches a total tensile force of 0.12(BW) and is loaded throughout roughly the first 80 percent of the canine's stance. This is very high compared to the caudal cruciate ligament, which is loaded to a maximum of only 0.02(BW) at the end of the stance phase. (Peck & Marcellin-Little, 2013)

When the CCL begins to degrade it is impossible to repair and will inevitably rupture. However, the bone anatomy can be modified to render the CCL unnecessary for stifle stabilization. To keep the CCL unloaded and unnecessary for normal joint movement, a 90 degree angle must be maintained between the tibial plateau and the total joint force. (Kim et al., 2008)

2.2.3 Variability in Canine Breeds

In comparison with other mammal species, canine anatomy contains a large degree of diversity and variability. Anatomical differences range drastically between breeds and variously sized canines, making veterinary orthopedic devices difficult to design. In the case of cranial cruciate ligament deficiency, the anatomy of a canine makes treatment more difficult and recovery less effective. There are limited sizing options for canine orthopedic implants because the devices are not designed for each individual canine. The conformation of the tibia has the greatest effect on CCL deficiency and the need for surgery. Unlike the human tibia, the tibia of a canine is oriented at an angle. This orientation affects the forces present within the stifle and CCL, often causing degradation of this important ligament; the majority of CCL injuries are caused by wear rather than traumatic injuries. Figure 2-4 compares the tibia of a Golden Labrador to the tibia of a Greyhound. The figure clearly shows a difference in tibial conformation between the two breeds, and this is typical of many dog breeds. The angle where the tibia meets the femur is very different in each image. The anatomy of the canine stifle greatly influences the likelihood of developing CCL issues; Labrador Retrievers are prone to CCL ruptures while Greyhounds are less often affected. In addition, treatment method and success of the procedure for CCL injuries is affected by the anatomy of the stifle. (Kazanovicz, 6 Sept. 2013)



Figure 2-4: Comparison of Tibia Conformations in Golden Labrador and Greyhound (Kevin Benjamino, 2012)

2.2.4 Canine Bone Properties

The specific mechanical properties of canine bones must be taken into account when considering the forces that would result from an orthopedic device such as a bone plate. The elastic modulus of canine cancellous bone is approximately 11 GPa (Pressel et al., 2005). As with human bones, the tensile and compressive strengths of canine bones vary depending upon the bone's location in the body and the loads to which the bone is regularly subjected.

2.3 CAUSES OF CCL DISEASE

In simple terms, the canine stifle is a joint in which all components must function together, or failure will occur. This failure of the joint leads to hind limb lameness, pain, and stifle dysfunction in affected canines. There is no definite cause of cruciate disease; instead there are a variety of biological and biomechanical factors that contribute to CCL failure in canines. Main biologic components include inflammation, degradation, degeneration of the joint over time, impaired synthesis and turnover of extracellular matrix, necrosis, and apoptosis. Biomechanical components include muscle weakness and dysfunction, misalignment, conformational changes in the joint (and varying tibia conformations between breeds), altered kinematics, and misaligned joint contacts and pressures. In most cases of CCL deficiency, degeneration of the CCL ligament over time is a major contributing factor. Only a small percentage of reported canine CCL ruptures were the result of a traumatic event or injury, indicating that biologic components may be a greater causal factor. Other biological causes include tissue composition abnormalities. (Cook, 2009)

When considering biomechanical components of the stifle joint, tibia conformation, specifically the proximal tibial tuberosity conformation, is the fundamental element leading to abnormal stifle biomechanics. However, many studies analyzing different tibia conformations and their relation to CCL disease have resulted in contradicting data and have provided no proof of a significant risk factor. In addition to poor conformation of the tibia itself, poor pelvic conformations can lead to misalignment of joints throughout the hind limbs, essentially causing the same issue and potentially accelerating degeneration of the CCL. Other possible risk factors are neuromuscular problems including "microklutz" syndrome where muscle degradation leads to painful cartilage damage, joint incongruity, and changes in joint contact and pressure over time. (Cook, 2009)

The dog's lifestyle can also affect its risk for CCL disease; these factors include activity level, nutrition, and repeated traumatic stifle injuries (Cook, 2009). Dogs suffering from arthritis are also at a higher risk of developing CCL issues (Griffon, 2009). Typically, full CCL rupture occurs in older dogs around seven to ten years of age (Jerram & Walker, 2003).

Lastly, genetics can also be a determining factor in possible causes of CCL disease; inherited metabolic disorders and breed disposition can contribute to development of the disease. Breed disposition is important because different dog breeds have different sizes, weights, and body types. Hormonal changes, such as spaying or neutering, metabolic changes affecting fat and vitamin content and metabolism, and release of degrading enzymes can also affect ligament and joint health, including the CCL. (Cook, 2009)

Causal factors and breed disposition are important to consider in the treatment of CCL rupture because there is such a wide spectrum of causal factors, risk factors, disease progression rates, disease mechanisms, disease severity, and patient types and requirements. Due to these extensive ranges, clinical applications must be considered. It is important to offer a variety of treatment types that are able to "best treat" different cases and circumstances of the disease while still maintaining consistency between surgical tools and techniques to facilitate ease of use for surgeons. Different treatment options should specifically address the causal issues, distinguishing biomechanical failure and biological failure and catering towards the more pertinent failure (Cook, 2009). A simple and effective system optimized for cTTA procedures will provide an additional treatment option for canines suffering from CCL deficiencies.

2.3.1 Failure of the Stifle

CCL disease, which eventually leads to CCL rupture in all cases, causes stifle failure through joint instability. This disease can cause pathologic issues such as tissue inflammation, synovitis, osteoarthritis, and meniscal injury. The most prevalent and painful issue associated with CCL rupture, however, is altered stifle kinematics that cause sliding of the joint, or "cranial tibial thrust". This shear force occurs when the CCL is no longer intact to constrain the force along with the pull of the hamstring muscles on the proximal tibia. Cranial tibial thrust is illustrated in Fig. 2-5.



Figure 2-5: Normal canine stifle vs. a stifle with CCL rupture. The ruptured knee experiences cranial tibial thrust, where the tibial tuberosity thrusts forward when pressure is applied to the joint. ("Ruptured Anterior Cruciate Ligament (ACL)," 2013)

The magnitude of the cranial tibial thrust in affected dogs is determined by the external ground reaction forces, internal muscular forces, and the slope of the tibial plateau. When the magnitude of

the cranial tibial thrust exceeds the tensile strength of the CCL, degradation or rupture of the CCL occurs. The difference between CCL degradation and full rupture of the CCL is determined by the age and health of the canine. A healthy CCL will experience degradation; a CCL that has already experienced significant degradation will fully rupture. (Canapp, 2007)

2.4 CURRENT TREATMENT OPTIONS

There are several treatment methods for CCL deficiencies in canines. Most of the treatment options involve altering the anatomy of the tibia, more specifically, the angle of the tibial plateau. The most common procedures performed are the tibial tuberosity advancement (TTA) and the tibial plateau leveling osteotomy (TPLO). There is currently a procedure emerging into the veterinary world that combines the theory of TTA and the technique of TPLO. This procedure is called circular tibial tuberosity advancement (cTTA). (Kazanovicz, 6 Sept. 2013)

2.4.1 TPLO

The tibial plateau leveling osteotomy procedure involves a radial osteotomy of the proximal tibia and a rotation of the proximal segment to adjust the slope of the tibial plateau. A bi-radial saw is used to make the crescent shaped cut and a custom jig is used to maintain the alignment of the bone during the procedure for accurate rotation of the bone segment. This procedure provides dynamic stability to both the cranial and caudal ligaments of the stifle. The TPLO procedure eliminates cranial tibial thrust at a tibial plateau angle of 6.5 degrees. At this angle, the loads initially on the cranial ligament are transferred to the caudal ligament. The rotation of the bone aligns the total joint force with the angle of the tibial plateau. The TPLO procedure is illustrated in Fig. 2-6.



Figure 2-6: Tibial Plateau Leveling Osteotomy (Kim et al., 2008)

TPLO is the most commonly performed surgery for fixing CCL injuries in canines. Surgeons are very familiar with this procedure and the associated tools. TPLO maintains the original tibial tuberosity and patellofemoral joint. Very precise angles can be achieved due to the radial cut, allowing for specific customization for each patient. This procedure also results in sufficient bone-on-bone contact, which allows for enhanced and faster bone healing post-operatively. However, the bone is cut on the load bearing portion of the tibia, which can lead to significant pain for the canine during the healing process. The procedure, though common, is also technically difficult and is associated with torsional deformities due to imprecise positioning after the cut. Additional problems with TPLO include angular and rotational deformities, implant failure, patellar tendonitis, meniscal tears,

infection, recurrent lameness, and tibial tuberosity fractures. There is also increased loading on the caudal pole of the meniscus which can have further complications. Additionally, 26 to 34 percent of TPLO procedures result in one or more of these complications. (Kim et al., 2008)

2.4.2 TTA

Tibial tuberosity advancement is a surgical procedure that involves a longitudinal cut along the tibial tuberosity. Once the cut has been made, a spacer cage is placed at the proximal end of the osteotomy and a bone plate is fixated on the medial aspect of the tibia. Bone graft is usually placed in the space to accelerate bone union post-operative. The procedure stabilizes the deficient limb without any leveling of the tibial plateau. The objective of the procedure is to align the patellar tendon so that it is perpendicular to the total joint forces within the stifle joint. This alignment eliminates any shear forces present and also unloads the CCL. In stance phase, the angle between the patellar tendon and plateau is about 105 degrees. Reducing this angle by tibial tuberosity advancement sufficiently stabilizes stifle. This procedure is illustrated in Fig. 2-7.



Figure 2-7: Tibial Tuberosity Advancement (Kim et al., 2008)

The tibial tuberosity advancement procedure preserves the natural tibial plateau, is a minimally invasive procedure, is technically less demanding and requires a short operation time of about twenty minutes. The procedure is effective in eliminating cranial tibial thrust and stabilizing the stifle joint. However, TTA has several disadvantages as well. The spacer cage required for the procedure only comes in four sizes (3, 6, 9, 12mm). This size limitation is not ideal for the vast differences in canine anatomy. There is also a high rate of meniscal injuries and the potential for iatrogenic patellar luxation. The TTA procedure has also caused problems with implant failure, tibial tuberosity fracture and caudal cruciate ligament injuries due to excess advancement. (Kim et al., 2008)

2.4.3 cTTA

The Circular Tibial Tuberosity Advancement procedure is relatively new to the veterinary world. The procedure combines TPLO radial cut technique and TTA theory of joint force alignment. Specifically, cTTA is performed by a circular osteotomy of the tibial tuberosity followed by a cranial rotation of the bone segment. This procedure is illustrated in Fig. 2-8.



Figure 2-8: Circular Tibial Tuberosity Advancement (Rovesti et al., 2013)

The rotation can range from 0-30 degrees based on the size of the tibia and anatomy of the specific patient. The cut bone is fixated by a bone plate. Currently, bone fixation is done using a plate from the TTA procedure. Since the cTTA procedure is so new, specialized tools have not yet been developed. There is a significant gap in information about this procedure and the results it produces. (Rovesti et al., 2013)

Advantages of this procedure include bone-on-bone contact, a continuous degree of correction without spacer cages, and contact with tibial tuberosity and tibial metaphysis. This technique eliminates the gap seen in the TTA procedure and the need for a bone graft. Bone-on-bone contact produces better healing in a shorter time period and, since the bone is cut through the lesser load bearing portion of the tibia, the joint forces from the body have a limited effect on the healing process. However, the lack of research and practice with cTTA is a major disadvantage to this procedure. Custom cTTA materials have not yet been developed, resulting in less effective results and recovery compared to TTA and TPLO. Once cTTA gains more popularity in veterinary medicine, research and developments will increase along with its success rate. Until then, more tests and design innovations must be completed to provide the specialized materials needed for this procedure. (Rovesti et al., 2013)

2.5 EXISTING BONE FIXATION PLATE DESIGNS

2.5.1 TPLO Plate

Each of the surgical procedures discussed above utilizes its own combination of plates, parts, and screws as fixation for the cut bone. Due to the circular cut used in TPLO, the priority of the plate is to maintain this cut's angle of rotation. Examples of TPLO plates can be seen in Fig. 2-9. For this plate, the distal end of the plate is fixed to the tibial body. The proximal end, however, is fixed to a segment of the tibial plateau that was cut to hold the rotation in place. While the distal end and the intermediate portion are straight, the proximal end is angled medially and has a curvature to fit the contour of the tibial plateau (Fig. 2-9 b).



Figure 2-9: a) SECUROS stainless steel TPLO plate; b) US Patent 2007/0233106 A1 TPLO plate (T. Horan, Scholl, & Touhalisky, 2007)

Additionally, the screw holes in the proximal end are angled inward to direct the path of the screws toward each other (Fig. 2-10). These angles accommodate for the circular shape of the cut. (T. Horan et al., 2007)



Figure 2-10: Angled screw insertion in TPLO plate (T. Horan et al., 2007)

2.5.2 TTA Plate

In the TTA procedure, the bone plate used fixates the advanced tibial tuberosity by anchoring it to the tibial body (Fig. 2-11a). The distal end of the plate is fixed to the tibial body, while the proximal end is attached to the tuberosity advancement. These ends of the plate are arranged in a way that optimally supports the desired position of the bone advancement. The part of the plate between the locations of fixation, known as the intermediate portion, is shaped so the proximal end is cranial to the distal end, because the tuberosity is advanced cranially. This shape ensures that the plate is tilted enough to maintain the advanced angel from the surgery (T. J. Horan, Buck, & Bordeaux, 2012). Two examples of plates used for TTA procedures are shown in Fig. 2-11a and b.

Since TTA advances the tibial tuberosity to adjust the joint force, the force of the patellar tendon naturally pulls the bone advancement back towards the tibial body. Because of the nature of the cut and advancement, there is not enough bone-on-bone contact to prevent the tuberosity from being pulled back to its original position, so a spacer (labeled as 38 in Fig. 2-11a) is used to maintain the gap between the tuberosity and the tibial body. This spacer is a cage formation (Fig. 2-11c) that is

slightly angled to match the shape of the bone gap. Like the bone plate, it is fixed medially to both the tibial tuberosity and the tibial body. (T. J. Horan et al., 2012)



Figure 2-11: : a) Setup of TTA devices; b) SECUROS XGen TTA plate; c) SECUROS stainless steel TTA cage (T. J. Horan et al., 2012; "SECUROS Orthopedic Resource Guide,")

2.6 SCREW SYSTEMS

For orthopedic devices, various methods of fixation can be used. Occasionally pins or nails will be used to fix implants to the bone, but screws are the most frequently used fixation device. There are two common screw systems that can be used for bone fixation plates.

2.6.1 Conventional Screw System

The first type of screw technology is known as the conventional plate system. In this system, only the cylinder of the screw is threaded, which anchors the system to the bone. When the screw is inserted it compresses the plate to the surface of the bone, providing the stability of the system. The conventional screw system is popular for implants because it is very easy to manufacture due to screw standardization and simplicity of the screw holes. This system does have a number of disadvantages, however. Since the plate lays flush against the bone, it must be contoured to exactly match the shape of the bone to which it is fixed, which can be quite difficult to accomplish. If the fit is not perfect, the fixation will cause stresses on the parts of the bone that are in more direct contact with the plate. An inexact fit also introduces the potential for screw loosening over time, which can lead to an inflammatory response, infection, and/or device failure. In addition, the direct contact between the plate and the bone necessary to secure this system disrupts the cortical blood supply to bone tissue beneath the plate, leading to oxygen deficiency and bone resorption (Herford & Ellis,

1998). Another aspect of the conventional screw system is the use of both circular and elliptical screw holes. Circular standard holes are made to match the diameter of the screw. Some conventional screw systems also utilize elliptical compression screw holes. These specifically shaped screw holes allow for customization during implantation, because orientation of the screw in the hole during implantation affects the compression of the plate to the bone. An illustration of this effect is shown in Fig. 2-12. (Lorich, 2007)



Figure 2-12: Compression screw holes (Lorich, 2007)

2.6.2 Locking Screw System

The second screw technology for plate fixation is the locking plate system. These screws also have a threaded cylinder to anchor the system to the bone, but the stability of the system itself results from fixation of the head of the screw to the plate's screw holes. This fixation can be achieved in a number of ways that varies between designs. One method involves threading both the head of the screw and the screw hole; when the screw is inserted the head fits securely to the hole (Fig. 2-13).



Figure 2-13: US Patent 2009/0222051 A1 locking screw system (Pengo, 2009)

This fixation can also be accomplished via a smooth inner screw hole surface, allowing the threaded head of the screw to carve its own matching thread in the screw hole as it is inserted (Fig. 2-14). This method provides flexibility in manufacturing because various screws can be used with this type of plate, eliminating the need to manufacture exactly matching threads on the screw head and on the plate. This method also allows for variation of screw insertion angle on a case-by-case basis without any additional manufacturing. (Herford & Ellis, 1998)



Figure 2-14: Synthes locking reconstruction bone plate (Herford & Ellis, 1998)

A third, less common locking plate system uses a hollow screw to fix the system to the bone and an additional smaller expansion screw to fix the hollow screw to the screw hole. When the expansion screw is inserted into the hollow screw, the flanges of the hollow screw are pushed outward and the lateral forces of the flanges against the screw hole stabilize the system (Figure 2-15). (Herford & Ellis, 1998)



Figure 2-15: Synthes titanium hollow screw and reconstruction plate system (Herford & Ellis, 1998)

Due to the more complex parts involved in the locking screw systems, manufacturing of this type of system is more costly and time-consuming than the conventional screw system. However, there are a number of advantages to using locking screws. This system is more stable than the conventional system, potentially requiring fewer screws to hold the plate in place. Another potential benefit is that screw loosening is unlikely, decreasing the chances of infection. Since the system itself is

stabilized by the locking of the screw head into the plate, contact between the plate and the bone is not required. This stability eliminates the need for exact contouring of the plate; since there can be a small gap between the plate and the bone, the plate contour only needs to be approximate. In addition, this gap prevents disruption of the cortical blood supply to the bone tissue beneath the plate. (Herford & Ellis, 1998)

2.7 MATERIALS

The fracture fixation plates that SECUROS currently manufactures are titanium and stainless steel. Both materials have been used in medical applications, particularly fracture fixations, for many years and are biocompatible. In addition, titanium and stainless steel implants have excellent resistance to corrosion *in vivo*; in titanium this is due to a titanium oxide film that forms on the surface of the implant. These materials generally last without adverse effects for the duration of the patient's life. Although both materials are suitable for internal fracture fixation devices there are slight differences to consider. Medical grade stainless steel, 316L, has a high elastic modulus of about 240 GPa and therefore a high strength. Titanium typically used in orthopedics, Ti-6Al-4V, has a slightly lower elastic modulus of about 100 GPa and is less dense than stainless steel (Shivkumar, 2013). Elastic modulus is important to consider in bone fixation devices due to stress shielding; to minimize stress shielding the elastic modulus of the fixation material should be as close to that of bone as possible (~20 GPa) (Nagels, Stokdijk, & Rozing, 2003). An Australian study was performed in 2010 by the Japanese Orthopaedic Association comparing the effectiveness of stainless steel and titanium hip implants in humans. According to the study results, the stainless steel implant generated 23 percent more stress than the titanium implant within the implanted femur. Reduced stress leads to less complications and better mechanical performance (Taheri, Blicblau, & Singh, 2011). It is also important to consider the effects of pre-bending and pre-twisting of these materials since material manipulations will be an important factor in the cTTA plate design. For both materials, pre-bending lowers the stiffness and strength and pre-twisting very slightly increases the stiffness of the material but also lowers the strength (Shivkumar, 2013).

3 PROJECT STRATEGY

3.1 PROJECT APPROACH

After reviewing the initial client statement, the project approach was better defined through the development of objectives, primary and secondary functions, and project and design constraints. The development of these project elements led to a more defined revised client statement.

3.2 INITIAL CLIENT STATEMENT

The initial client statement was derived by the group after consulting with both the representatives from SECUROS (Andrew Kazanovicz, Olivia Doane, and David Anderson) and the project advisor, Glenn Gaudette. The client statement is shown below.

Design a specialty bone plate optimized for a circular tibial tuberosity advancement procedure that ensures the CCL will not be loaded. Optimize the plate design with finite element analysis and computer aided design, create rapid prototypes, manufacture prototypes and utilize mechanical testing.

3.3 OBJECTIVES

To further define the scope of the project, general project objectives were developed. These general objectives outlined what should be achieved and focused on during the design of the bone plate including supporting walking, running, and jumping forces in the stifle joint, durably fixating the bone to maintain a 90 degree angle over time, accommodating for as many medium sized dog breeds as possible, and supporting loads immediately following surgery to allow for canine recovery conditions. Based on these general objectives, five key project objectives were developed and ranked in order of importance according to the team's goals for the project and feedback from advisors at SECUROS. Ranking was determined by using a pairwise comparison chart, seen below in Table 3-1.

	Strong and Stable	Reduce Recovery Period	Easy to Use	Cost Effective	Biocompatible and Safe	Total
Strong and Stable		1	1	1	0	3
Reduce Recovery Period	0		0	0	0	0
Easy to Use	0	1		1	0	2
Cost Effective	0	1	0		0	1
Biocompatible and Safe	1	1	1	1		4

Table 3-1: Objective Rankings by Pairwise Comparison Chart

Ranked design objectives determined from the pairwise comparison chart are:

- 1. Biocompatible and Safe
- 2. Strong and Stable
- 3. Easy to Use

- 4. Cost Effective
- 5. Reduce Recovery Period

In designing the device, biocompatibility and safety were a top priority. The Food and Drug Administration (FDA) only regulates veterinary device companies and the products they produce in extreme cases. Therefore it is the designer's responsibility to design and manufacture a device that is completely safe for the animal. The device must also be safe for the veterinary surgeon to use during the procedure. The strength and stability of the device was also at the top of the ranked objectives because of the large loading forces that are present in the stifle. The plate must support and appropriately distribute forces in the canine stifle in order to function properly. Ease of use for surgeons was also an important objective. The commercial success of the device depends heavily on this objective because more surgeons and animal hospitals will be willing to purchase and use the device if it is compatible with existing surgical equipment. Ease of use for surgeons will also allow for a relatively quick and simple procedure in comparison to current osteotomy procedures being used to treat this type of injury. Our lowest ranked objectives were cost effectiveness and reduced recovery period. Although these objectives are still important to consider, they fell outside of the central focus on the design of the bone fixation plate. The cTTA procedure itself will help control the design cost, because it utilizes the same radial bone saw used in a TPLO procedure. In addition, the design is made from the same materials and manufacturing processes as existing bone plates used in TPLO and TTA procedures, so the cost should be comparable. The cTTA procedure will also help reduce recovery time compared to TPLO and TTA procedures because cTTA incorporates bone-on-bone contact via radial cut on the non-load bearing portion of the tibia, which is conducive to bone healing and reduces the pain of recovery. Additionally, it is outside of the scope of the project to monitor a recovery period for this procedure using our device. Comparisons between existing procedures can be made, but it is not realistic to test the device long term given the timeline for the project.

3.4 FUNCTIONS

Specific functions for the device were also developed. Functions described how the device should perform.

- 1. Support average canine stifle forces. The maximum force on the CCL occurs during the stance phase of a normal gait, but the design should also account for increased loading from running and jumping. The design must also account for the distribution of forces between the front and hind limbs.
- 2. Maintain proper alignment of total joint force and tibial plateau by preventing osteotomy displacement.
- 3. Perform at peak operating condition for bone recovery period.
- 4. Strength of materials must support loading from body weight.

3.4.1 Specifications

Specifications helped examine the functions of the device in more detail and provide specific limits or ranges as a guideline for analysis and evaluation.

1. The plate must be able to support a certain range of stifle forces. On average, the canine stifle supports 74 percent of the canine's body weight. The range of maximum forces was

calculated between 33-56lbf based on a weight of 45-75lbs. However, owner noncompliance must be taken into account in the calculation. These forces are representative of a canine at the stance phase of the gait. However, if the dog runs or jumps during the recovery period, the forces will increase within the stifle. (Ballagas, Montgomery, Henderson, & Gillette, 2004)

- 2. The plate must maintain an angle of 90 (±5 degrees) between the tibial plateau and the total joint force (Ballagas et al., 2004).
- 3. The plate must remain in peak operating condition for 18 weeks post-operative (Ballagas et al., 2004).
- 4. The plate must be strong enough to support the following:
 - a. \sim 74% of body weight in clinically normal dogs
 - b. \sim 32% of body weight, preoperatively
 - c. ~64% of body weight, 4-12 months after procedure (Ballagas et al., 2004)

Specifications 3 and 4 are important to consider for the process of the project, however, are not within the scope of this study. These specifications could be evaluated with further testing.

3.5 CONSTRAINTS

Both design and project constraints were identified; design constraints are pertinent to the development of the specialty bone plate and screw system and project constraints are limitations to the general project method. Some general design constraints include the force distribution, plate size, plate compatibility with existing surgical tools, and the existence of stress shielding within the bone. For this project, designs were developed for medium sized dogs (45-75 pounds) because this size range represents those most affected by cranial cruciate ligament deficiencies. However, the design must be adapted for different sizes by direct scaling once it is produced for medium sized canines.

The plate must also be compatible with existing surgical tools and instruments. Compatibility is an important factor to consider to meet two of the main objectives, ease of use and cost effectiveness. Surgeon knowledge, cost of procedure, and frequency of use of the procedure must be taken into account. A surgeon generally prefers a procedure that is familiar to them and is best suited for the condition of the patient. The cTTA method is very new to veterinary surgery and has not been performed by many surgeons; utilizes existing surgical tools will produce a shorter learning period and a greater learning curve for the surgeons. This factor is also relevant to cost evaluation by eliminating the need for purchase of new surgical materials. If the tools and methods associated with the plate design are familiar to surgeons and new equipment is not necessary to perform the cTTA procedure, there will be an increased likelihood that this procedure is utilized more frequently until it becomes common practice.

The plate design is constrained to only two possible materials, stainless steel or titanium. Stress shielding is also a constraint to consider. Bone requires compressive forces in order to heal properly. However, if the strength of the plate material is much greater than the bone it is fixated to, the forces will be transferred through the plate, eliminating the compressive forces that the bone needs to heal. The given materials, titanium and stainless steel, have strengths ($\sim 250/\sim 100$ GPa, respectively) much greater than that of bone (~ 20 GPa), so stress shielding is important to consider (Shivkumar, 2013).

There are two essential project constraints for the team: the project must be completed by May 2014 with a budget of \$468. Other project constraints include a set material and manufacturing process by which the group must abide, bone model limitations, lack of literature on canine stifle procedures, and testing limitations due to the timeline constraint. Since prototype manufacturing was done though SECUROS, wait times of up to two months were considered while developing prototypes and design alternatives.

Since the FDA does not require pre-market approval veterinary devices, there are no limitations to testing on live animal subjects. However, in consideration of patient condition and safety, it would be unwise to test prototypes in living canines. The product designers, manufacturers, and distributers are responsible for ensuring production of safe and effective veterinary products ("How FDA Regulates Veterinary Devices," 2012). Thus, the testing is limited to Sawbone models and cadaver bones. Since bone models do not always provide accurate results, the product may not perform as intended in a living canine.

The veterinary world is a small but growing field. As a result, there is very little literature on development and testing procedures for canine devices, specifically involving the canine stifle joint. The lack of research limits the background knowledge available to develop the project approach and can lead to inaccurate assumptions.

Finally, another constraint is a lack of communication and feedback from the patient post-operative. In human medicine, solutions often come from a trial and error approach and a majority of the data is received from patient feedback. Canine patients provide limited feedback, and different testing methods for success are utilized to reform the design and provide a better final product. Additionally, since the project scope does not involve in vivo implantation, the plate performance is measured differently. The challenges provided by the given constraints will be overcome through technical, managerial and financial project approaches.

3.6 REVISED CLIENT STATEMENT

After developing and reviewing objectives, constraints, and functions, the project definition was more clearly defined, encompassing the main goals for the project. The revised version of the initial client statement is shown below.

Design a specialty titanium or stainless steel bone plate and screw fixation system optimized for a circular tibial tuberosity advancement procedure. This device should ensure that the total joint force is perpendicular to the tibial plateau and eliminate cranial tibial thrust. The stabilization system must be able to withstand the peak vertical forces calculated from the weight of the canine for at least 18 weeks during the bone healing period.

4 PROJECT DESIGN

To create different design possibilities for the specialty cTTA bone plate, findings from research and input from advisors at SECUROS were utilized. Two existing plate designs (TPLO and TTA plates from SECUROS) were also used as a baseline for the cTTA designs in terms of size, material thickness, and general design properties. Although these plates are used for different types of procedures, the forces present in the stifle remain fairly consistent between procedures. The similarities between the TPLO, TTA, and cTTA procedures provided a reference for plate properties that could potentially work for a cTTA plate. Client feedback was obtained from veterinary surgeons and animal hospitals to help guide the design process.

4.1 SURGEON INTERVIEWS AND ANIMAL HOSPITAL PHONE SURVEY

Data was collected from animal hospitals in the Massachusetts area and three different veterinary surgeons to provide a baseline for the beginning of the design process. For animal hospitals, questions including available treatment for CCL tears, determining factors for the type of treatment received, and the cost of the treatment for the dog owners were discussed. The sample size was thirteen hospitals. Figure 4-1 below displays the types of treatment offered by the animal hospitals in the sample.



Figure 4-1: CCL Treatment Offered by Animal Hospitals: Lateral Sutures, Tibial Plateau Leveling Osteotomy (TPLO), Tibial Tuberosity Advancement (TTA), and No Treatment

As seen in Fig. 4-1, TPLO procedures were most commonly available. Of the ten hospitals that offered osteotomy procedures as a treatment method, forty percent offered both procedures. This information helped guide the design process; since many surgeons are familiar with TTA and TPLO technique, plate designs were modeled after existing designs and procedures. The average cost for

the dog owners for TPLO and TTA procedures were \$3500 and \$3200, respectively. This substantial cost confirmed the high market potential for the cTTA plate product.

Additional information was determined from veterinary surgeons: Dr. Chuck Walls and Dr. Fred Pike through collaboration with SECUROS and Dr. Kechia Davis from VCA South Shore Animal Hospital. Both Dr. Walls and Dr. Pike agreed that TPLO was the procedure they preferred and often used due to consistency and success in results, lower meniscal tear rates, and familiarity with the procedure. Dr. Davis bases her surgical decisions on certain factors. For a steeply sloped tibia (about 24 degrees) or a small and thin tibia, she performs a TPLO procedure. Complications that the surgeons encountered with TPLO procedures include slipping of the cut portion and implant infection. Plate contouring is another difficulty associated with TPLO procedures due to the more complex anatomy and surface structure of the load bearing region of the tibia. Stainless steel plates are easier to contour and correct mistakes during plate bending; titanium is stiffer and more difficult to work with because there is less room for error and bending cannot be "undone". However, locking plates which are generally titanium reduce the need for exact contouring which helps reduce these frustrations. For the TTA procedure, complications include patella misalignment, meniscal tears, and less consistent results in terms of eliminating tibia cranial thrust. Plates that require forks are more difficult to work with, but surgical complications are generally more technique related with this procedure. Dr. Pike also pointed out that although choosing a procedure on a case by case basis is ideal, surgeons generally choose to perform the procedure they are most familiar and comfortable with. Full interview transcripts are shown in Appendices A, B, and C.

These opinions and comments helped guide the design process. Since familiarity and ease of use is vital to the success of the cTTA procedure, TPLO and TTA surgical techniques were considered during the plate design process. Ease of plate bending was an important factor to consider. Additionally, it was determined from the interviews that either standard or locking screws would be utilized in the plate design to eliminate issues encountered with fork designs.

4.2 EVALUATION OF FUNCTIONS AND POSSIBLE MEANS

Each of the functions discussed in Chapter 3 were broken down into sub-functions to determine possible means for the project design. A chart outlining these functions, sub-functions, and possible means was used to help organize design possibilities (Table 4-1).

Table 4-1: Functions-Means Chart

Functions	Sub-Functions	Means					
Support	Plate Shape	Modified TTA	Modified	Check	Triangle	Bone	Bowling
average		Design	TPLO Design	Mark		Shape	Pin
stifle							Shape
forces	Plate	1mm	1.5mm	2mm	2.5mm	3mm	3.5mm
	Thickness						
	Angle of Pre-	0°	5°	10°	15°	20°	25°
	Bending						
Maintain	Security of	Conventional	Locking Screw				
90° angle	Plate	Screw System	System				
	Placement						
	Screw Hole	Circular	Ellipse				
	Shape	(Standard)	(Compression)				
	Number of	3	4	5	6	7	8
	Screws						
	Screw Size	3.5mm	2.7mm	2.4mm			
	Screw	1 screw in	2 screws in	3 screws			
	Placement	tuberosity	tuberosity	in			
				tuberosity			
Strength	Material	Titanium	Stainless Steel				
of							
materials							
support							
loading							

The means shown in Table 4-1 represent different design possibilities. However, some of the means are linked due to restrictions with manufacturing. Locking screw systems are only available in titanium through SECUOS manufacturing facilities; this restriction must be abided by. The type of screw system also dictates the amount of pre-bending or contouring necessary in the plate design. Locking screw systems do not require exact contouring of the plate to the shape of the bone because the system is stabilized by the locking of the screw head into the plate. Plates utilizing conventional screw systems must be more precisely contoured to the shape of the bone because the compression of the plate to the bone provides the stability of the system. In addition, all screw holes for locking systems are circular to match the head of the screw, while screw holes in conventional systems can additionally be elliptical to allow for compression of the plate to the bone depending on the orientation of the screw in the hole (see Fig. 2-12 in section 2.6.2).

4.3 CONCEPTUAL DESIGNS

Six different plate designs were developed based on the possible means discussed above. During this first phase of design, the angle of pre-bending of the plate, the plate material, and the type of screw system were not considered except for special circumstances, described below. The designs were developed based on sizing of existing plates and a medium-sized canine tibia model. In the interest of simplicity, all screws were the same size of 3.5mm. The screw sizes and plate dimensions were revisited after initial evaluation, but these concepts created the basis of each design. All design

alternatives were sketched by hand and then modeled using SolidWorks 2013. The images of the design options below are not to scale; images are intended to best show the features of each design.

4.3.1 Design Option 1

For the first design option, SECUROS' existing TTA plate was used as a baseline for the plate design, and the precise measurements, curvature, and screw placement were designed to work specifically with the cTTA procedure.



Figure 4-2: Modified TTA Design

4.3.2 Design Option 2

Design option 2 used SECUROS' existing TPLO plate design as a baseline, again customizing measurements, curvature, and screw placement for a cTTA procedure.



Figure 4-3: Modified TPLO Design

4.3.3 Design Option 3

For the next two design options, the team explored the concept of using a fixation device that did not extend down the length of the tibia. Design option 3, the "check mark" design, allows for a variety of orientations. Due to the lack of stability associated with the size and placement of the plate (no extension beyond tuberosity) this plate design would likely require a locking screw system. Locked screws could help compensate for the stability of the plate and avoid slipping of the osteotomy, according to research and discussion with engineers at SECUROS, but would limit plate material to titanium. The plate initially involved three points of contact, one on the osteotomy and two on the tibia. However, to provide greater stability of the plate, the design was altered to include two points of fixation on both the osteotomy and the tibia.



Figure 4-4: Check Mark Design

4.3.4 Design Option 4

Design option 4 follows the same concept as design option 3 above, but with a slightly different triangular shape. The general shape of the tibia is a triangle which prompted the idea of mimicking that shape in a plate design. Initially the plate involved three points of contact, one on the osteotomy and two on the tibia, but the design was altered to include more points of fixation. The design involves five screw holes for fixation, two on the osteotomy and three on the tibia. This fixation strategy provides more support to the osteotomy, as one point of fixation would likely not

be enough to support the average forces within the stifle joint. Compared to design option 3, the additional material and additional fixation point could increase stability but would limit versatility.



Figure 4-5: Triangle Design

4.3.5 Design Option 5

Design option 5 was based on a "bone shape", with two slightly larger circular areas connected by a thinner middle portion. This design is slimmer than other options and could allow for a larger variety of positioning during the procedure and also accommodate for a wider range of canine anatomy.



Figure 4-6: Bone Shape Design

4.3.6 Design Option 6

Design option 6 utilized a more exaggerated version of the above design; the shape is reminiscent of a bowling pin. The large area of the bottom portion of the plate allows for more fixation points and potentially a more secure fixation of the osteotomy.



Figure 4-7: Bowling Pin Shape Design

4.4 PRELIMINARY EVALUATION

Various methods were used to evaluate and eliminate design alternatives.

4.4.1 Joint Force Analysis

A joint force analysis was developed to determine the applied loads for the FEA. To simplify the analysis, three main forces present in the stifle were used: the compressive joint force, the tensile patellar tendon force, and the ground reaction force. Using these three main forces allowed for a model that would be simple enough to perform an FEA while still providing fairly accurate results to evaluate the plate designs. The free body diagram and equations used to determine the maximum forces are discussed in section 2.2.2 (Joint Forces). The three main forces were calculated based the maximum values of a medium sized dog (65 pounds or 289 Newtons) during walking and galloping. Due to increased forces during extreme circumstances, such as jumping, a safety factor of 25% was incorporated in the analysis.

Ground Reaction Force (Walking) = 0.616(BW) = 0.616(289N) = 178N

Ground Reaction Force (Galloping) = 1.64(BW) = 1.64(289N) = 474N

With 25% safety factor, GRF = 2.05(BW) = 593N

Patellar Tendon Force = 3(GRF) = 3(593) = 1779N

Compressive Joint Force = 1.95(BW) = 564N

With 25% safety factor, JF = 2.44(BW) = 705N

These three forces created the basis for our finite element analysis.

4.5 RAPID PROTOTYPING AND MODELING

The six design alternatives were modeled using two methods: rapid prototyping (ABS plastic) and preliminary machined prototyping (aluminum sheet metal). Rapid prototypes were created via a 3D printer to create a solid model. Surface (.stl) files of the six design alternatives were submitted to the print shop at WPI and printed at high density. The models are made of ABS plastic and the thickness of each model varied for the different designs. Plate designs that were about 3mm thick were mostly solid, while the thinner plate designs, as thin as 1mm, were more flexible. The main purpose of these rapid prototypes was to provide three dimensional models to help visualize the design in three dimensions. These models were brought to Dr. Walls, who used the models to visualize how they would work in surgery and provide feedback and foreseen difficulties with each design, as well as possible improvements. This feedback helped address the "easy to use" design objective by providing insight on the surgical aspect of the design.

In addition, to-scale 3D models of each design were created from aluminum sheet metal. These 3D models were made primarily to visualize sizing and fit by assembling the plates on Sawbone models. Engineering drawings of the six design alternatives were printed at a 1:1 scale using the SolidWorks models previously created. SolidWorks drawings were generated from each model so that the view displayed was the front face that would eventually be applied to the bone. This resulted in either a top plane view or a front plane view depending on how the CAD model was oriented. Each printed drawing was measured using a ruler to confirm that the drawings were printed at the appropriate scale and that the dimensions were accurate.

The aluminum sheet metal used was approximately 2.5mm thick. Tools used include a scroll saw, drill press, drill bit, and end mill cutter. Supplemental tools include a variety of clamps, scribers, metal files, and sandpaper. The engineering drawing was taped to the metal. Using clamps to secure the metal in place, a drill press was used to drill the appropriate holes in the plate design, using the drill hole center marks on the engineering drawing as a guide. All screw holes were designed for 3.5mm screws. Then a scroll saw was used to cut along the outline of the plate shape. The plates were finished by filing the edges smooth using metal filers of varying surface textures. The process was repeated for all six plate designs. For the elliptical screw holes on the "Modified TPLO" plate design, an end mill cutter in the drill press was used to create the elongated hole. An image of the aluminum prototypes is shown below in Fig. 4-8.



Figure 4-8: Aluminum Prototypes

4.5.1 Plate and Bone Assembly

The aluminum prototypes were used to better determine the fit and sizing of each plate design. Six canine tibia Sawbone models were obtained and a radial osteotomy cut was made using a scroll saw. The plates were assembled on the models using a screwdriver and sheet metal screws. Additionally, a small screw was inserted in the top of the tuberosity to mimic the patellar tendon, providing a method to apply minimal force to the model to estimate the stability of each design. Factors analyzed on each of the assembled models included:

- Size
- Screw placement
 - Specifically distances between screws and the osteotomy/edge of bone
- Stability
 - Position of the osteotomy
 - Bone on bone contact

Design Option 1: "Modified TTA"



Figure 4-9: Modified TTA Plate and Sawbone Assembly

This design met almost all of the requirements, exhibiting good bone-on-bone contact and adequate space for all screws. When evaluating the stability of the system, this design worked fairly well, allowing minimal movement of the proximal portion of the tibia.

Design Option 2: "Modified TPLO"



Figure 4-10: Modified TPLO Plate and Sawbone Assembly

This design provided the most stability of all options with excellent bone-on-bone contact. The major issue seen with this option was the sizing of the plate. The overall design was too large for the size of the tibia model. Additionally, the proximal portion did not allow for insertion of all three screws because the top screw hole was directly in line with the osteotomy.

Design Option 3: "Check-mark"



Figure 4-11: Check Mark Plate and Sawbone Assembly

Several issues were encountered with this design option. First, the elbow of the plate provided a pivoting point for the proximal portion of the tibia, resulting in very poor bone-on-bone contact and stability. The sizing was also inaccurate so one of the screw holes could not be used. Despite the plate's versatility, it ultimately did not meet the most important design requirement, so this option was eliminated.

Design Option 4: "Triangle"



Figure 4-12: Triangle Plate and Sawbone Assembly

This design exhibited good stability as well as proper fit and screw placement.

Design Option 5: "Bone Shape"



Figure 4-13: Bone Shape Plate and Sawbone Assembly

Although sizing and fit were adequate for this design, having only one fixation point in the proximal portion of the tibia compromised the stability of the system, and this design was eliminated.

Design Option 6: "Bowling Pin Shape"







Figure 4-14: Bone Shape Plate and Sawbone Assembly

This design exhibited good stability and bone-on-bone contact, but there were several issues with fit and screw placement. In the proximal portion, the side-by-side screws did not fit well on the shape of the osteotomy; the tight fit resulted in very little space between the screws and the outer portion of the bone. This resulted in poor screw purchase, decreased stability, and a higher likelihood of failure. The same issue was seen in the distal portion of the plate. Additionally, the clustered orientation of screws would negatively affect the stress distribution in the plate. For these reasons, this design was also eliminated.

4.5.2 Surgeon and Engineer Feedback

After initial evaluation through the Sawbone model assemblies, the 3D printed prototypes of the three final design possibilities were brought to Dr. Walls, who provided his opinions on the designs as well as advice for improvement. He believed the "Modified TTA" design was the most promising since this plate would provide increased stability in the moment arm through axial screw placement. To optimize the design, he suggested extending the distal screw closer to the edge of the plate. Dr. Walls felt that the Triangle design was too condensed and would result in high stresses and strains. Another concern for this design was the shearing of screw heads as a result of the compact screw placement.

We also obtained opinions and suggestions from engineers at SECUROS. They suggested using smaller screws in the proximal tuberosity portion of each plate and ensuring all screws have adequate space between them to reduce stress risers, increasing plate thickness to a minimum of 2mm for sufficient strength, and eliminating any wasted plate space by adjusting screw placement for maximum plate strength and value from a manufacturing standpoint. Hole and countersink sizing were adjusted to conform to industry standards.

4.6 DESIGN OPTIMIZATION

Based on assessment of the original plates, the three designs were reevaluated and revised to address certain areas that could be improved. The following designs were the final versions used to manufacture prototypes for testing. Due to manufacturing time constraints, all final designs were made with conventional screw holes rather than the locking screw system. Using the same screw system throughout all designs also reduced the number of variables that could affect mechanical testing. All designs were revised to conform to industry standards. Screw hole sizes for 3.5mm screws were set to 4.2mm diameter with a 90 degree countersink and a countersink diameter of 5.8mm; holes for 2.7mm screws were set to 3mm diameter with a 90 degree countersink and a countersink and a countersink diameter of 4.2mm. Designs were later revised for 2.4mm screws for manufacturing. Countersinks were added to both sides of the plate to make them universal, for both left and right tibias. Revisions specific to each plate design are discussed below.

4.6.1 Modified TTA

The final design for the Modified TTA plate was 2mm thick, which is thicker than the SECUROS TTA plate but provides additional strength and stability necessary for the cTTA procedure. The final design included three countersunk holes for 3.5mm screws in the distal portion and two countersunk holes for 2.4mm screws in the proximal portion. This proximal portion of the plate was angled cranially in order to provide a better fit of the proximal screw holes on the osteotomy. The final Modified TTA plate design is shown in Fig. 4-15.



Figure 4-15. CAD Model of Final Modified TTA Plate Design

4.6.2 Triangle Plate

The final design for the Triangle plate consisted of five countersunk holes; three of these were evenly spaced along the caudal portion of the plate, while the other two were on the cranial portion for attachment to the tuberosity. The final plate thickness was kept at 2.5mm. This thickness was deemed to be the minimum that would be effective for this design because all attachment points were in the proximal part of the tibia, which would require the plate to bear more of the load placed on the bone. All five holes were designed for use with 2.4mm screws. In the final plate design, all screw holes were closer to the edge of the plate than in previous versions of the design. This strategy was used to make efficient use of the plate's material, leaving minimal extra material along the outside of the screw holes and thereby minimizing manufacturing costs. The CAD model of the final Triangle plate design can be seen in Figure 4-16.



Figure 4-16. CAD Model of Final Triangle Plate Design

4.6.3 Modified TPLO

The final design of the Modified TPLO plate utilized compression screw holes in the proximal portion. These holes would compress the osteotomy toward the tibia when in place in an attempt to provide better bone healing. The screw holes in the distal portion of the plate were conventional countersunk holes for 3.5mm screws. This plate, like the other two final designs, was 2.5mm thick. In late versions of the Modified TPLO plate design, the caudal aspect of the proximal portion of the plate was reduced in order to lower manufacturing costs by removing unused material, but this was not carried over into the final design because the material reduction would likely cause high stress on the thin part of the plate. The distal screw holes were spaced evenly and with increased distance between each screw on the final design to evenly distribute stress throughout the plate. The final CAD model of the Modified TPLO design is shown in Figure 4-17.



Figure 4-17: CAD Model of Final Modified TPLO Plate Design

5 DESIGN VERIFICATION

Following the revisions of the CAD models, the goal was to verify the designs through finite element models and mechanical testing.

5.1 FINITE ELEMENT ANALYSIS

The finite element model was loaded according to a joint force analysis of the canine stifle during highest loading conditions discussed in section 4.4.1. The plates were mounted on an estimated tibia model designed in SolidWorks and analyzed using ANSYS Workbench with cylindrical supports at each screw location. Plate material was defined using the stainless steel option available in "General Materials" in ANSYS and the tibia model material was defined using bone properties: linear isotropic elastic, Young's modulus of 17GPa, and Poisson's ratio of 0.4. The entire assembly was meshed using the fine meshing option, and resulting von Mises stresses in the plates were analyzed. Results of the analysis are displayed in Fig. 5-1, showing increased stress concentrations at screw locations. Also, higher stresses were seen in the thinner Modified TTA plate.



Figure 5-1: Finite element models of Modified TTA, Triangle, and Modified TPLO plate designs where red represents highest von Mises stress and blue represents lowest von Mises stress

5.2 MANUFACTURED PROTOTYPE PRODUCTION

The plate designs chosen for manufacturing were the Modified TTA, Modified TPLO and Triangle plate discussed in section 4.6 above. The final design specifications were provided to SECUROS and manufactured at one of their facilities. Ten copies of each plate were manufactured in medical grade stainless steel and produced for verification testing.

5.3 MECHANICAL TESTING

Given the force analysis discussed in section 4.4.1, testing aimed to mimic the forces within a canine stifle. The three main forces within the stifle are the total joint force, the patellar tendon force and the ground reaction force. For testing, the effect of tension in the patellar tendon was analyzed.

Since the cTTA procedure utilizes plating on the tibial tuberosity where the patellar tendon is attached and focuses on realignment of the tendon, this force would have the greatest impact on the stabilization system. The patellar tendon is responsible for the greatest force on the canine stifle, averaging between 530N and 1700N for walking and running forces, respectively. It was necessary that the testing set up be able to withstand the high forces attributed to the patellar tendon and continue to mimic the canine model without interfering with the performance of each plate.

5.3.1 Methods

The testing setup involved two parts: a potting mechanism to hold the bone and an Instron attachment to attach the pot to the Instron machine. Since attachments for the Instron machine were limited and did not provide appropriate options for fixation, a custom designed Instron attachment and potting mechanism were machined. The Instron attachment in Fig. 5-2 was attached to the final pot using two screws. The attachment allowed for adjustable displacement between the patellar tendon and the end of the bone. That flexibility allowed for angular alignment of the bone, respective to the canine model's anatomy, while ensuring that the patellar tendon was held vertically. Trial runs of the test set up caused bending of the screws used to fixate the attachment to the Instron machine, so Bondo[®] was applied to the screws to provide a stronger fixation.



Figure 5-2: Instron attachment "table", providing adjustable fixation for potting mechanism

5.3.1.1 Simple Potting Method

In the initial phases of the test set up, the primary objective was to mimic the forces of the patellar tendon and the angle at which they act. The first attempt at testing utilized a simple potting fixation system of a PVC pipe and Bondo[®] (Fig. 5-3). The end of the tibia was placed into the pot at a 60-degree angle to mimic that of a canine leg. The system was tested by pulling the cut portion of the bone upwards and received negative results. The bone broke out of the Bondo[®], proving that the mechanism required revision. For a second attempt, screws were drilled into the end of the bone providing a larger surface area for the Bondo[®] to attach to. The revised system was tested, but also received poor results at low forces.



Figure 5-3: Simple potting method

5.3.1.2 Advanced Potting Method

The poor results in the initial potting system of fixation for the bone led to a more advanced system which utilized a square aluminum pot with holes on each side. The holes allowed for threaded rods to be drilled through the end of the bone and attach to the aluminum pot. This potting method is shown in Fig. 5-4. Once the threaded rods were placed and the bone was potted, Bondo[®] was poured into the pot to further secure the bone. This set up was tested in a similar manner by pulling up on the patellar tendon with the Instron. Again, the bone ripped out of the potting mechanism, indicating that a more secure fixation was needed.





Figure 5-4: Advanced potting method

5.3.1.3 Final Method of Fixation

The final method of fixation utilized a two piece set including the aluminum pot and an aluminum backboard. The backboard was attached to the bone to provide stability and prevent bone breakage seen in previous attempted methods of fixation. The bone was attached by a 2.7mm cortical bone screw near the bottom of the bone and by use of zip ties and 2mm soft stainless steel wire that were wrapped around the bone and the backboard through holes in board. Gauze was tightly packed into

any remaining space between the bone and the board for better distribution of forces and added stability. The backboard was secured in the aluminum pot by two small steel pins that attached through a hole in the backboard, providing a pivoting point. The top of the backboard contained 2 threaded holes for 6-32 screws; a metal plate attached the top of the backboard to the pot utilizing these holes, which securely held the bone at a 60-degree angle. The test set up is pictured in Fig. 5-5. A test run of the system was performed with an un-cut, un-plated bone. The final test fixation system remedied the problems seen in previous methods and allowed for the completion of validation testing of each plate design.



Figure 5-5: Final method of fixation

5.3.1.4 Canine Cadaver Tibia Preparation

To achieve useable results, it was necessary to perform testing on canine cadaver bones, which provided the best representation of living bone properties. Sawbones were initially used for visual testing, but all additional mechanical tests were executed on canine cadaver tibias. Nine tibias were obtained from SECUROS, cleaned, and preserved by freezing until use. A scroll saw was used to create the circular osteotomy needed for the cTTA procedure. The cuts were made respective to the tuberosity size and plate being used. The surgical circular saw blade used for TPLO procedures was utilized to trace the osteotomy onto the tibia according to cTTA guidelines as closely as possible, but the saw could not be used to perform the cut due to tool availability. Although it was difficult to replicate the perfect circular cut made by surgeons using appropriate bone saws, osteotomies were made as accurate as possible. The tibias were grouped in sets of three based on average size. Each tibia was measured to determine average diameter, total length after removal of the ankle, and tuberosity (cut bone segment) size. The diagram below (Fig. 5-6) illustrates the specific locations for each measurement. Arcs were measured along the arc boundary. All measurements were recorded (Appendix D).



Figure 5-6: Dimension measurement guide for cadaver tibia samples

Surgical materials were obtained from SECUROS for plate assembly, including 3.5mm, 2.7mm, and 2.4mm cortical bone screws of varying lengths and their respective drill bits (2.5mm, 2.0mm, and 1.8mm), a drill guide, plate benders, clamps, and scalpels. Additional materials used during the testing process include a scroll saw, an electric drill, 2mm metal wire, zip ties, and gauze.

5.3.1.5 Testing Details for Instron Methodology

Testing methods were performed on the Instron 5544 machine in Goddard Hall 207. Testing methods were written using BlueHill software. All methods were run in tension. Testing of the plate-bone assemblies involved three different phases: walking phase, running phase and test to failure. Each phase involved different testing details within the BlueHill software.

The first test simulated the forces attributed to walking on the bone-plate assembly. These forces provided results for the minimum force range the canine would experience. Each tibia was tested in cyclic loading for 40 cycles. A 530N force was applied at a rate of 800N per minute, simulating the force applied from the patellar tendon during walking, calculated according to the joint force analysis in section 4.4.1.

The next phase of testing involved the simulation of running forces on the bone-plate assemblies. Following the walking analysis, each tibia underwent a cyclic test at 1420N at 1700N per minute for 40 cycles or until failure. Testing at both walking and running forces simulated what would occur in an actual canine model.

5.3.2 Results

Results of the mechanical testing discussed above are summarized in Table 5-1.

Plate	Sample	"Walking" Cycles (number completed)	"Running" Cycles (number completed)	Point of Failure (Newtons)
Modified TTA	Sample 1	40	< 1	512
Modified TTA	Sample 2	< 1	0	452
Modified TTA	Sample 3	40	< 1	Unknown- broken tendon
Modified TTA	Sample 4	< 1	0	466
				Average= 477
Triangle	Sample 1	40	< 1	757
Triangle	Sample 2	< 1	0	398
Triangle	Sample 3	40	< 1	1015
				Average= 723
Modified TPLO	Sample 1	40	7	1421
Modified TPLO	Sample 2	40	< 1	1143
Modified TPLO	Sample 3	40	< 1	1137
				Average= 1233

Table 5-1: Mechanical Testing Results Summary

Figures 5-7 through 5-9 display the failure data for all samples. Each graph plots the load versus the extension of the sample. Peaks in each graph represent the point of failure for the sample. The graphs clearly display the failure load and variation of failure between each sample, however the extension values do not provide and accurate measurement of the extension or displacement of the tuberosity because the patellar tendon is taken into account for this measurement.



Figure 5-7: Modified TTA Sample Failure





Figure 5-8: Triangle Sample Failure

Failure occurrence in the Triangle plate samples was more varied.



Figure 5-9: Modified TPLO Sample Failure

Performance of the Modified TPLO plate was superior to the other designs, with consistent failure rates over 1000N. Sample 1 with a Modified TPLO plate was the only sample to withstand several of the high force running cycles.

Observational data was also collected during the mechanical testing process, including ease of implementation of the plate, fit on the bone, displacement and rotation of the osteotomy during and after loading, and location and condition of failure. The Modified TTA plates provided ease of use with contouring but added difficulty with positioning and assembling because the tilted proximal head did not fit properly on the osteotomy. The bottom portion of the cut bone segment did not contain fixation points, which caused significant displacement and rotation of the osteotomy during loading (Fig. 5-10).



Figure 5-10: Tuberosity displacement of Modified TTA Sample, before (left photo) and during (right photo) low force cycling

Failure loads for the Triangle plate samples were more scattered, so these data were more difficult to interpret. However, severe osteotomy failure was observed in these samples (Fig. 5-11). Other designs displayed failure at the screw interface in the tuberosity, while the Triangle samples consistently exhibited nearly full detachment of the osteotomy at the point of failure.



Figure 5-11: Bone failure in Triangle plate sample

From Fig. 5-9 above it is clear that the Modified TPLO samples withstood the highest loads. Figure 5-12 below displays the superior stability also seen in this design, as the three osteotomy fixation points via compression screw holes prevented displacement and rotation of the cut bone segment.



Figure 5-12: Tuberosity displacement of Modified TPLO sample during low force cycling

5.4 LOCKING SCREW (PAX) DATA ANALYSIS

Since the project timeline did not allow for manufacture of plates utilizing locking screw technology, existing published data was analyzed to determine effects on plate performance. Locking screw plates are beneficial due to their high bending stiffness, high bending strength, high push out force, little to no screw loosening and wide degree of screw insertion angle variability. Several studies have been done to test the range of abilities for locking screw plates. Vet Comp Orthop Traumatol published data attesting to the mechanical strength of locking plates. The study compared conventional screw plates with locking plates of various sizes and materials. The results are shown in the figure below.

Plate Type	Bending Stiffness (N/mm)	Bending Structural Stiffness (Nm ²)	Bending Strength (Nm)
DCP	69.0 ±17.9	7.57 ±1.94	9.76 ±2.51
SS LC- DCP	57.4 ±0.44	6.22 ±0.05	9.16 ±0.34
Ti LC-DCP	43.5 ±3.39	4.71 ±0.37	6.32 ±0.84
LCP	60.91 ±12.56	6.60 ±1.36	10.12 ±3.65
ALPS-10	39.6 ±2.45	4.29 ±0.26	5.20 ±1.28
ALPS-11	74.88 ±3.32	8.11 ±0.36	11.79 ±0.52
SOP	75.96 ±6.89	8.23 ±0.75	12.74 ±2.10
Fixin	45.97 ±1.47	4.98 ±0.16	6.68 ±2.79

Table 5-2: Summary of Data for Mechanical Testing of Locking Plates

The results show that the three conventional plates (DCP, SS LC-DCP, Ti LC-DCP) had relatively lower bending stiffness and bending strength compared to the five locking plates (LCP, SOP, Fixin, ALPS 10 and ALPS 11). A second important result shows the difference in performance between the stainless steel plate and the titanium plate. The titanium plate, although it offers more flexibility, had a lower bending stiffness and bending strength than the stainless steel plate. All samples were tested with a single cycle ramped loading in a four point bending set up (VCOT, 2011).

The second study completed by the Vet Comp Orthop Traumatol investigated screw push out forces attributed to locking plates and other factors. The study tested nine different implant systems at screw insertion angles between 0 and 10 degrees. The plates were also tested at two different torques to push out the screw. The figure below shows the results.

Table 5-3: Summary of Push-out Force Data

		Push-out Force (N)	
Factor	Level	Torque of 2.5Nm	Torque of 3.5Nm
Angle	0	1350±72.4	1710±131
	5	1250±224	1620±192
	10	825±197	1340±194

In fractures, the overall stability is determined by the stiffness of the locking plate and the strength of the locking interface. It is necessary that the plate used have several components including a high stiffness, a high bending strength and a high push out force. From the data, it was determined that higher angles of screw insertion lead to lower screw push out forces and that the optimal range is between 0 and 5 degrees with a higher torque (VCOT, 2013).

The final study was completed by the American College of Veterinary Surgeons. The study focused primarily on the polyaxial (PAX) advanced locking system designed by SECUROS. The plate material is titanium alloy, making it harder than existing PAX plates. The PAX screws have a multidirectional angle of insertion range of 0 to 10 degrees. The PAX plates performed well by maximizing fracture support until functional unions could be formed in the bone fractures. However, it is important to note that for optimal performance, no more than three locking screws should be placed on either side of the bone fracture since it does not improve stiffness and it increases stress concentrations in the plates (Veterinary Surgery, 2012).

Locking plates are good for orthopedic use for many reasons. They have the ability to maintain periosteal vascular integrity, involve minimally invasive surgical applications, and decrease risk of fracture reduction due to screw tightening. By using these plates there is a minimized need for specific contouring of the plate to the anatomy of the bone. The PAX plates produced by SECUROS could have potential in further developing the plate for the cTTA procedure. Using locking plates would provide all the benefits listed above as well as minimal screw loosening and a reduced level of stress shielding on the bone. The wide range of the angle of screw insertion is also beneficial to the cTTA procedure, since positioning was an issue encountered during plate assembly with conventional screw holes. The range could account for varying anatomical differences and reduce the amount of time spent contouring the bone plates.

6 **DISCUSSION**

In all samples tested, the failure occurred at the screw fixation points to the osteotomy. From this trend, it was determined that the location and close proximity of the screw holes to each other caused high stress concentrations in the osteotomy, ultimately leading to failure. During test setup, many of the samples experienced slippage or breakage of the patellar tendon in the Instron machine during the first testing attempt. Such samples consequently underwent additional cycles before the actual testing could take place, which could have fatigued the samples further than samples that did not experience slippage. In addition, due to varying anatomies, the patellar tendons of each sample were different lengths, leading to tension being applied closer to or farther away from the osteotomy in some samples.

6.1 MODIFIED TTA DESIGN

The final Modified TTA design included a tilted proximal head, which was intended for better placement on the osteotomy. However, when assembling the bones for testing, this feature did not provide the expected fit to the tuberosity. The two screw fixation points on the proximal head of the plate were located close together and both were near the proximal part of the tuberosity, leaving the distal portion prone to displacement and rotation, an outcome observed during the low-force walking cycles.

From the results, it could be seen that the Modified TTA design was insufficient for the higher loading cycles. Two of the four samples successfully completed the walking cycle testing, which indicates that the plate has potential under lower forces, but is not adequate for the magnitude of the actual forces that would be found in the stifle post-operative. The other two samples failed in the osteotomy during the first cycle of the walking test. This discrepancy between samples could be due to inconsistent bone properties or to differences in the assembly of the plates, which will be discussed further in section 6.4, Limitations.

6.2 TRIANGLE DESIGN

The unique shape of the Triangle design offered easy placement and attachment onto the bones, making assembly with this plate desirable. However, the prototype was slightly larger than intended, and the third, distal-most hole did not fit on any of the tibia samples. Such a problem would have been remedied if the samples available had been larger, but could also speak to the design's ability to be used on various bone anatomies. Since the bulk of the plate was in the proximal part of the tibia, the specific anatomy of both the tibial tuberosity and plateau affected the fit of the plate. The other designs, which extended distally, did not have this limitation to the same extent because the long axis of each tibia was a more universal anatomy feature. Customization to specific anatomies was also difficult because the shape and thickness of this plate made it difficult to contour.

The Triangle plates exhibited a wide array of results across all samples tested, with a failure point variance of over 600N. This inconsistency made the results for the Triangle design difficult to interpret, but the results did prove that the plate was capable of withstanding higher loading under some circumstances. Similar to the Modified TTA design, factors that affected bone properties could

have caused varied results. It could therefore not be concluded from this study whether the design could reliably withstand high-force loading.

6.3 MODIFIED TPLO DESIGN

From the results, the Modified TPLO design exhibited the highest level of performance. There was little to no observable displacement or rotation seen in the osteotomy throughout testing, which implies that the design would successfully maintain adequate bone-on-bone contact. One of the Modified TPLO samples was the only sample to successfully withstand multiple cycles of the running force, and both other samples also proceeded past the walking force cycles. Although these results did not fully meet the criteria of 40 running cycles, they did indicate that the Modified TPLO was the most promising of the three final designs. The positive results seen with this design could mean not only that the plate itself is capable of high performance, but also that the design allows for more consistent assembly and thus less variable testing results.

6.4 LIMITATIONS

There were several limitations associated with mechanical testing. The timeline of the project proved to be the major limitation, affecting many testing factors. Cadaver tibias were provided by SECUROS, however, pre-osteotomy preparation was a time consuming process and the size of the sample was unknown until after the preparation process was complete. Prior to Instron testing, all samples required osteotomies, customized plate contouring, plate assembly, and bone assembly in the Instron jig. Testing could then be performed; the duration of the walking cycle test and running cycle test was about 30 minutes each. Due to this time intensive process and the limited availability of cadaver samples, only three samples per plate design could be tested. As seen in the results section (5.3.2), many samples failed prematurely, which could be due to issues with bone quality and properties. Again, time constraints limited the testing timeline because a sample could not be taken through the entire procedure at one time and instead bones were preserved through freezing. Repeated freezing and thawing was necessary, which could have led to diminished bone properties. Additionally, a lack of experience with surgical tools and techniques limited the quality and accuracy of osteotomies and plate assemblies. Finally, the cadaver samples varied in size and anatomy, and these inconsistencies influenced testing results. Specifically, the size and shape of the tuberosity greatly affected the place placement. The length and quality of the patellar tendon also had an impact on testing; depending on where the Instron grip could be secured, the force was applied to the osteotomy at varying distances. Testing variables were controlled as much as possible, but there were several limitations that influenced results.

6.5 IMPACT

Economically, this project would have no significant impact. The plates were manufactured to the exact specifications and materials of existing SECUROS products. Therefore, there would not be any substantial increase or decrease in pricing of the final product. Although the final plate design would hypothetically reduce surgery time due to ease of implantation and familiarity with the plate design, there is no guarantee that the new plate would decrease the cost of surgery previously mentioned in section 4.1. Though economics are a factor to consider in this project, the project work will have little political ramifications due to similarities in existing procedures and products on the market.

The societal impact of this project would be involved in the general use of the plate in addition to the cTTA procedure. The plate design was optimized for surgeon use in terms of ease of implantation, familiar design and usability of existing surgical tools. The plate is making the cTTA surgery more accessible to the general public. The cTTA combines the best features of existing surgeries and the plate allows for more frequent use of this procedure.

Since the FDA does not regulate veterinary medicine, it was important to consider ethical factors when designing the plate for optimal safety of the canine once implanted. Ethics will be important to consider in further testing to ensure the health and safety of surgeons and canine patients during *in vivo* testing.

Since the cTTA plate designs are comparable in size and material to existing plates used for CCL osteotomy surgeries, there will be no significant effect on manufacturability, environmental impact, or sustainability.

7 FINAL DESIGN

Based on the findings through all evaluations, the proposed final design is the Modified TPLO design. Specifically, this design provided the best fit on the tibia after the cTTA procedure was performed and resulted in the best performance under loading. A few modifications to the design could potentially enhance the design for even better fit and performance. First, a steeper angle of the distal stem of the plate would provide better alignment on the long axis of the tibia, resulting in improved screw positioning for more appropriate stress distribution. Additionally, the thickness of the plate offers strength but would increase stress shielding effects. By slightly reducing the thickness of the plate to 2mm, the design would likely be strong enough to withstand stifle forces but decrease the negative influences of stress shielding. This material reduction would also yield a more cost effective design. A SolidWorks model of the proposed final design with angle adjustments is shown below in Figure 7-1.



Figure 7-1: Proposed final design with revisions

8 **CONCLUSIONS AND RECOMMENDATIONS**

Testing data and observational results led to several conclusions about design success, and from these results recommendations can be made for future project work. The Modified TTA plate did not test very successfully. The Modified TTA also had varied results with two samples that failed during the walking cycle testing and two samples that failed during the running cycle testing. Although two samples did qualify for the higher applied loading, the displacement and rotation of the osteotomy seen in the walking cycle alone was enough data to determine the design unsuccessful. The Triangle design offered positive aspects in ease of assembly, but had traumatic failure profiles at higher loading applications. The Triangle plate design had good results during walking loads. There was little to no displacement between the tibia and osteotomy. However, the failure at higher loading, although at higher forces that the Modified TTA, was much more dramatic than other designs. In some samples the entire osteotomy was ripped from the tibia. In this plate, failure was not just observed at screw fixation points, but in the entire osteotomy. The Modified TPLO plate offered the best performance in terms of the functional specifications assigned to the plate design. All plate TPLO samples performed well during the lower applied force walking cycles and all samples were able to withstand over 1000N in the higher applied force running cyclic loading. In our observations, the Modified TPLO offered the highest force resistance along with the lowest displacement and osteotomy rotation for all forms of cyclic loading. The results of the mechanical testing suggested that the Modified TPLO design was the most successful in supporting average stifle forces for both walking and running while also minimizing displacement and osteotomy rotation. The results also suggested that screw placement in the tuberosity led to high stress concentrations and ultimately failure of the osteotomy. A significant number of samples failed at the points of screw fixation in the osteotomy.

The results of the completed finite element analysis and mechanical testing also determined several design and testing method recommendations for future projects. Each plate design was mechanically tested on three cadaver samples. Although this number allowed inference of data, it was not enough to prove our data statistically significant. More samples would have to be tested to decrease the effect of bone and osteotomy variation. In addition to more samples, testing with optimal bone preparation and preservation would be necessary for further research. The bone preservation techniques used could have affected the material properties and additionally the performance results of each plate. The techniques used to perform the osteotomy for each sample were also a factor that had the potential to affect the results. We would recommend that the osteotomy be performed and the plates be assembled to a medical standard by practiced surgeons with further testing. Following more testing with additional samples with optimal bone preparation and preservation, design revisions can be made. Although from our research we would recommend continued design revision on primarily the TPLO plate, other factors could be considered. The finite element analysis performed on the top three designs was just a basic modeling of what could occur at higher loading. We would recommend further FE analysis utilizing an anatomically accurate model. The FEA performed utilized a simplified tibia model, but an anatomically correct model would provide more accurate and more significant results. The more accurate model would also provide an opportunity for better preliminary analysis after design revisions are made.

The plate designs also only utilized conventional screws to fixate the plate to the bone. Another option would be to utilize locking screws to test each of the final designs. Locking screws could provide additional fixation of the plate to the bone with limited stress shielding. Plates

manufactured with locking screws would provide results pertinent to potential design revisions of the plates.

In summary, we concluded that the Modified TPLO design performed the best, but testing included several limitations that could have altered the final results. We recommend further testing using optimal bone preparation, including proper osteotomy and plate assembly, proper preservation techniques, and more samples tested before any design revisions are made. We also recommend a finite element analysis be completed with an anatomically correct tibia model for more accurate stress distribution results. Our final design was the first plate manufactured and tested for the cTTA procedure. Additional testing and design revisions are necessary to further optimize the plate design before implantation for *in vivo* testing.

APPENDICES

APPENDIX A: INTERVIEW WITH DR. CHUCK WALLS

MQP Team:	Which surgical procedure do you most frequently use for treating stifle instability in the dog? Why?
Dr. Walls:	TPLO, it is the most consistent procedure in my hands that consistently eliminates dynamic cranial tibial thrust, minimizes progressive arthrosis/ joint soft tissue thickening and results in a higher consistent level of function.
Team:	What are the most common problems/challenges you encounter during CCL procedures, especially regarding the implants/instruments used, during the surgery and postoperative? Do you have any suggestions that might help reduce these frustrations?
Walls:	
Post-oLateraLockinViable	perative soft tissue/ implant infection with TPLO procedure l suture loosening with all extracapsular techniques. g plate technology to minimize periosteal tissue necrosis from compression intracapsular technique to mimic and re-establish cranial cruciate ligament function.
Team:	Do you use a jig to stabilize the stifle during surgery? If so, what do you like about the jig? What problems have you encountered while using it?
Walls:	Yes, I feel it is mandatory. Helps maintain saggital limb alignment. Only way to truly assess iatrogenic, intra-operative varus deformity, no problems with it
Team:	Are you familiar with the cTTA procedure? If so, have you performed/how often do you perform this procedure in comparison with TTA and TPLO?
Walls:	Familiar with it, but have not performed.
Team:	What plate(s) do you most frequently use for cTTA procedure, and why?
Walls:	Trying to develop a plate now with SECUROS

APPENDIX B: INTERVIEW WITH DR. FRED PIKE

MQP Team: Which surgical procedure do you most frequently use for treating stifle instability in the dog? Why?

Dr. Fred Pike:

- 90-95% of surgical CCL treatments- TPLO
 - Familiarity and comfort zone- have performed thousands, results are effective and attainable
 - Protects meniscus- TPLOs have a lower meniscal tear rate
- TTAs are less consistent
 - Have performed about 100-150, results are less consistent
 - Switched back to TPLO
- There are many factors that come into play with CCL issues: anatomy of proximal tibia, conformation of tibia and femur, body condition, etc.
 - Ideally, procedure would be selected based on these factors
 - However, usually comes down to surgeon familiarity
- Will do a TTA when treating patellar luxation and CCL tear/instability at the same time

Team: Would you consider performing a cTTA procedure?

Pike:

- Yes, would consider
- Concerned about the effects on the meniscus and degenerative joint disease
- Would require large number of clinical trials to determine success/effectiveness
- Team: What are the most common problems/challenges you encounter during CCL procedures, especially regarding the implants/instruments used, during the surgery and postoperative?

Pike:

- With TPLO:
 - Plate contouring
 - Locking plate reduces this frustrations
 - Use Synthes locking plate system (best)
 - Not frequently used
 - With non-locking, stainless steel is easier to contour
 - Titanium is harder, stiffer, not easy to bed, and little room for error
 - Once it is bent, cannot be bent back in the opposite direction
 - Must be cautious of fatigue of the material, effects strength
 - Some issues with different screws (titanium) not fitting in standard screw drivers
 - Don't have the same issue with stainless steel screws
- With TTA:
 - Forks are a challenge to actively engage and align
 - Not many problems with cages

- Complication rate is technique related
- Learning curve \rightarrow minimize complication rate
- Team: Do you think the bone-on-bone contact of the cTTA procedure would improve/reduce complications with the TTA procedure?

Pike:

- Could possibly decrease complications over time
- Believe it is more related to surgeon experience; more experience \rightarrow less complications

Team: Do you use a jig to stabilize the stifle during surgery? (Either procedure) If so, what do you like about the jig? What problems have you encountered while using it?

Pike:

- No jig for TTA
 - Osteotomy does not affect alignment of bone
- The jig used with TPLOs prevents misalignment with radial cut
- Only use the jig for a patient with abnormal limb alignment
- Find that the jig is cumbersome, increases the total time of the surgery, and increases the number of pin holes in the tibia
 - Increases morbidity
 - Have encountered problems with the distal jig pin
- Advocate use of jig for new surgeons
 - With experience, it is not imperative
- Having a better designed jig is important

APPENDIX C: INTERVIEW WITH DR. KECHIA DAVIS (VCA SOUTH SHORE ANIMAL HOSPITAL)

MQP Team: What osteotomy treatments do you perform for CCL tears/instabilities?

Dr. Davis:

- most often TTA or TPLO
- sometimes "TWO" tibial wedge osteotomy- like TPLO but with straight cut or chevron (W) cut to avoid slipping that is sometimes seen with TPLO
- also familiar with Australia procedure- TTA w/ wedge cut, wire to stabilize (no plating)

 in Australia, as commonly used as TPLO

Team: Which procedure do you prefer?

Davis:

- definitely case by case basis
- steep slope (~24 degrees) \rightarrow TPLO
 - TPLO helps neutralize
- Wouldn't say that I have a personal preference, make decisions based on individual dog
 - Usually greyhounds require TPLO (small, thin tibia)
 - TPLO is more forgiving with complications
 - With TTA, see problems with knee caps popping out post op, avoid with any dog prone to this problem
- Team: What brand of plate/system do you use/prefer for these procedures and why?

Davis:

- Synthes
 - Pre-bending is the most anatomical I've encountered, locking, less nicks in surface of plate decrease risk of infection
 - Limited bending/contouring required during surgery
 - Synthes Broad plates- more expensive
- Team: Are you familiar with the circular tibial tuberosity advancement (cTTA) procedure to treat CCL tears/instability?

Davis: No, I have not heard of that one.

APPENDIX D: SPECIMEN LOG

Specimen Number (Modified	Туре	Average Diameter	D1	D2	D3	Length	Tuberosity a	Tuberosity b	Tuberosity c
TTA Samples)		(cm)	(cm)	(cm)	(cm)	(cm)	(cm)	(cm)	(cm)
1	Left	1.9947	1.973	1.846	2.164	16.0000	3.8000	0.9000	4.2000
			5	0	5				
2	Right	2.0584	2.069	1.814	2.291	16.4000	3.5000	0.9000	4.0000
			0	4	8				
3	Right	2.0584	1.623	1.909	2.642	16.5000	4.2000	2.0000	5.6000
			4	9	0				
4	Right	1.4006	1.973	1.718	0.509	15.5000	3.4000	1.5000	4.2000
			5	9	3				
Specimen Number (Triangle	Туре	Average Diameter	D1	D2	D3	Length	Tuberosity a	Tuberosity b	Tuberosity c
Samples)									
4	Right	2.1221	2.387	1.941	2.037	16.3000	3.8000	1.5000	4.5000
			3	7	2				
5	Right	2.0690	2.355	1.941	1.909	15.8000	4.0000	1.7000	4.1000
			5	7	9				
6	Right	2.0266	2.100	1.846	2.132	16.4000	3.9000	2.0000	4.2000
			8	2	7				
Specimen Number (Modified	Туре	Average Diameter	D1	D2	D3	Length	Tuberosity a	Tuberosity b	Tuberosity c
TPLO Samples)									
7	Left	1.9523	2.005	1.718	2.132	15.6000	4.3000	1.2000	4.1000
			4	9	7				
8	Right	1.8886	1.941	1.655	2.069	15.7000	3.4000	1.0000	4.3000
			7	2	0				
9	Right	1.6977	1.655	1.687	1.750	15.5000	3.8000	1.1000	3.6000
			2	0	7				

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