In vitro evaluation of the Securos Cranial Cruciate Ligament Repair System and fluorocarbon leader line for use as lateral fabella-tibial sutures

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IN VITRO EVALUATION OF THE SECUROS CRANIAL CRUCIATE LIGAMENT REPAIR SYSTEM AND FLUOROCARBON LEADER LINE FOR USE AS LATERAL FABELLA-TIBIAL SUTURES

A Thesis

Submitted to the Graduate Faculty of the Louisiana State University and Agricultural and Mechanical College in partial fulfillment of the requirements for the degree of Master of Science

in

The Interdepartmental Program in Veterinary Medical Sciences through the Department of Veterinary Clinical Sciences

by

Max Nielsen Banwell
B.S., University of Nebraska – Lincoln, 1998
D.V.M., Kansas State University, 2000
May 2004
To my wife, mother, and father
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ABSTRACT

Cranial cruciate ligament (CCL) rupture is a common injury in the dog and major cause of degenerative joint disease. The pathophysiology of CCL rupture in the dog is well described. Osteoarthritis secondary to CCL rupture causes severe pain and lameness. There are many surgical techniques accepted for dogs with CCL rupture. A commonly performed technique is an extracapsular repair with a lateral fabella-tibial suture (LFS) using large diameter nylon leader line (NLL).

Mechanical demands placed upon the LFS are high requiring the material used be able to withstand a high amount of force, undergo minimal elongation, and have a high stiffness. Studies evaluating materials for use for LFS have found NLL to have the most appropriate mechanical profile for use. However, the large diameter, low coefficient of friction, and memory of NLL make knot security a concern, as well, the surgical handling of the material is not ideal. Our hypothesis stated that the Securos Cranial Cruciate Ligament Repair System™, a commercially available crimp-clamp system used to secure two ends of NLL together for a LFS, would perform mechanically superior to a clamped square knot using NLL. Furthermore, fluorocarbon (polyvinylidene fluoride; PVDF) a novel biomaterial of reduced diameter for a given tensile strength, would mechanically perform better than NLL using a clamped square knot.

The Securos Cranial Cruciate Ligament Repair System™ is an acceptable method of fixation of NLL loops used for LFS. Loops formed with 27 and 36 kgt NLL using the 36 kg Securos® crimp-clamps performed as well or better than a clamped square knot. However, loops secured with the 18 kg Securos® crimp-clamp system using 18 kgt NLL
did not perform as well as a clamped square knot, and their use cannot be recommended based on these results.

Fluorocarbon leader line (FCL) performed mechanically similar to NLL and eliminated elongation under low load observed with NLL. Steam sterilization has dramatic effects on FCL and is not recommended. Ethylene oxide sterilization showed no significant mechanical or structural changes to FCL and is recommended. Fluorocarbon leader line appears to be an acceptable alternative to NLL for use as a LFS.
CHAPTER 1. CRANIAL CRUCIATE LIGAMENT INJURY IN THE DOG AND MECHANICAL EVALUATIONS OF EXTRACAPSULAR REPAIR TECHNIQUES: INTRODUCTION AND LITERATURE REVIEW
1.1 INTRODUCTION

Cranial cruciate ligament (CCL) injury is one of the most common orthopedic injuries in the dog and a major cause of degenerative joint disease. Untreated animals show degenerative changes in the stifle joint within a few weeks, and will have severe degenerative changes within a few months (Piermattei and Flo 1997). The severe degenerative joint disease causes pain and decreased function of the affected limb. Cranial cruciate ligament rupture in the dog was first described in 1926. Since 1952, investigations on CCL rupture have been extensively published in the veterinary literature. These reports describe the nature of the injury, pathophysiology, and outcome in animals undergoing surgical stabilization (Vasseur 1993). Numerous surgical techniques for stabilization of the stifle after CCL rupture have been described for the dog (DeAngelis and Lau 1970; Flo 1975; Arnoczky et al. 1979; Hulse et al. 1980; Shires et al. 1984; Smith and Torg 1985; Slocum and Slocum 1993; Vasseur 1993; Piermattei and Flo 1997). But there remains a lack of objective results regarding clinical outcome in dogs. The results published to date show that clinical outcome is similar regardless of the procedure performed (Jevens et al. 1996; Moore and Read 1996). Hence, there is considerable debate regarding which surgical procedure affords the animal the best outcome. Popular techniques at present include extracapsular repair using a lateral fabella-tibial suture (Flo 1975), or tibial plateau leveling osteotomy (Slocum and Slocum 1993). The lateral fabella-tibial suture is used commonly because of its ease of application and good clinical outcome. This repair provides temporary stabilization of the stifle joint while periarticular fibrosis develops which provides long term stability. If the suture loosens or breaks before adequate fibrous tissue forms, the stifle becomes
unstable and degenerative joint disease will progress rapidly. High mechanical demands are placed on the suture after repair, prompting numerous studies to identify the most suitable suture material and method of fixation (Prostredny et al. 1991; Caporn and Roe 1996; Lewis et al. 1997; Anderson et al. 1998; Nwadike and Roe 1998; Huber et al. 1999; McKee and Miller 1999; Sicard et al. 1999; Peycke et al. 2002; Sicard et al. 2002). These studies have determined nylon leader line to have the most appropriate characteristics for use as a lateral fabella-tibial suture. Appropriate characteristics for use as a lateral fabella-tibial suture include a high force at failure, a small amount of elongation, and high stiffness (Huber et al. 1999). However, because of the NLL memory, low coefficient of friction, and large diameter, knot security may still be a problem.

This study evaluated the mechanical properties of a commercially available crimp-clamp system, used to tension and fasten the two ends of the nylon leader line. Furthermore, the mechanical properties of a novel biomaterial was evaluated to ascertain its suitability as a lateral fabella-tibial suture.

1.2 ANATOMY AND PATHOPHYSIOLOGY

1.2.1 ANATOMY – Briefly, the stifle joint is a complex condylar synovial joint functioning between the femur and tibia. The main spheroidal part is formed by the thick, roller-like condyles of the femur articulating with the flattened condyles of the tibia. The incongruence present between the condyles of the femur and tibial plateau is occupied by two fibrocartilages, or menisci. The stifle joint capsule in the dog is the largest of the body. There are many ligaments that provide stability to the stifle joint. Meniscal ligaments attach the menisci to the tibia and femur. The femorotibial ligaments
are the collateral ligaments and the cruciate ligaments. Lateral and medial collateral ligaments function to provide a great deal of stability and work together with the cruciate ligaments to provide a limitation of rotary movement and limit hyperextension (Evans 1993) (Figure 1.1 and 1.2).

![Figure 1.1 – Ligaments of the left stifle joint (Evans HE. Miller’s Anatomy of the Dog (Evans 1993); copyright permission pending.)](image1)

![Figure 1.2 – Menisci and ligaments of the left stifle joint, dorsal aspect (Evans HE. Miller’s Anatomy of the Dog (Evans 1993); copyright permission pending.)](image2)

The cruciate ligaments of the stifle joint are located within the joint cavity. The cranial cruciate ligament runs from the caudomedial part of the lateral condyle of the femur to the intercondyloid area of the tibia. The caudal cruciate ligament runs from the lateral surface of the medial femoral condyle caudodistally to the lateral area of the
popliteal notch of the tibia. The cruciate ligaments work together with the collateral ligaments to control rotary motion and prevent hyperextension (Evans 1993) (Figure 1.3).

**Figure 1.3** – Cruciate and meniscal ligaments of the left stifle joint, medial aspect (Evans HE. Miller’s Anatomy of the Dog (Evans 1993); copyright permission pending.)

The CCL prevents hyperextension of the stifle and limits internal rotation of the tibia in relation to the femur (Arnoczky 1988; Piermattei and Flo 1997). The CCL also stabilizes the stifle joint by preventing cranial translation of the tibia in relation to the femur. Both the CCL and caudal cruciate ligaments are dynamic structures, and their anatomy and spatial arrangements directly relate to their function of constraining joint motion.

The CCL is divided into craniomedial and caudolateral bands. The craniomedial band is taught in all phases of flexion and extension, whereas the caudolateral band is taut in extension but lax in flexion (Arnoczky 1988). The CCL is made from multiple fascicles, the basic unit of which is collagen. The entire continuum of fascicles forming
the ligament is surrounded by paratenon, a connective tissue covering. The majority of
the blood supply to the CCL enters from the surrounding synovium (Arnoczky 1993).

Flexion and extension of the stifle occur about a transverse axis, whereas rotary
movements of the tibia about the femur occur around the longitudinal axis. Rotary
movement is controlled by the geometry of the condyles and ligamentous constraints
(Arnoczky et al. 1977; Arnoczky 1993). The cruciate ligaments twist upon each other
when the limb is flexed, thus limiting the amount of internal rotation. The cruciate
ligaments also provide for cranio-caudal stability of the stifle. In general the CCL
prevents cranial translation of the tibia, and the caudal cruciate ligament (CdCL) prevents
caudal translation of the tibia.

1.2.2 PATHOPHYSIOLOGY – Rupture of the CCL causes hindlimb lameness in the
dog. The CCL may rupture due to acute traumatic injury, but more commonly, as a non-
specific injury causing chronic lameness in middle-aged dogs. Physical and radiographic
evidence of degenerative joint disease is frequently present. Rupture of the CCL occurs
more commonly in large breed dogs than small breeds (Piermattei and Flo 1997). Acute
traumatic injury is more commonly seen in dogs less than 4 years of age, while the
syndrome of chronic lameness and degenerative joint disease is seen most frequently in
middle-age dogs (Piermattei and Flo 1997). CCL rupture has been shown to have a
higher prevalence in spayed female dogs. Ovariection in rats decreases elastin content
and may affect collagen metabolism. The effects of chronic hypoestrogenemia on the
metabolism and mechanical properties of the ligament in the dog is unknown (Vasseur
1993). The tensile strength of a dog’s cruciate ligament deteriorates with aging, and
these changes are more pronounced and occur at an earlier age in large breed dogs
compared to dogs weighing less than 15 kg (Vasseur et al. 1985). Cranial cruciate ligament rupture may occur secondary to abnormal confirmation of the limb and secondary to immune-mediated arthropathies affecting the stifle joint (Vasseur 1993). Obesity has also been implicated (Vasseur 1993).

Partial ruptures of the CCL can also occur. Partial ruptures will progress to complete ruptures, often in less than one year. Dogs commonly present with pain, effusion, and degenerative joint disease similar to that observed in dogs with complete ruptures (Vasseur 1993). Approximately 50% of dogs with CCL rupture will have concurrent medial meniscal injury, and between 20-40 % of dogs will eventually rupture the contralateral CCL (Moore and Read 1996).

Diagnosis of CCL rupture is based on a history of lameness and physical examination findings. Presentation may vary between dogs presenting with acute traumatic ruptures and those with chronic degenerative processes. Dogs with acute traumatic rupture are severely lame and occasionally non-weight bearing on the affected limb. Joint effusion may be present within several days of the injury. These dogs do not exhibit obvious periarticular thickening. Dogs with chronic injuries have a variable degree of lameness that may only be present only after exercise. Varying degrees of muscle atrophy is evident and a prominent thickening of the medial aspect of the joint (medial buttress) may be present. The patella tendon is often indistinguishable from the surrounding tissues due to synovial effusion and periarticular thickening secondary to degenerative joint disease. Crepitus may be palpated when the joint is put through a range of motion (Vasseur 1993; Piermattei and Flo 1997).
The presence of cranial drawer motion or a cranial tibial thrust is pathognomonic for CCL rupture (Slocum and Devine 1983; Vasseur 1993). Cranial drawer motion can be detected with the dog standing or positioned in lateral recumbency. It is essential that the examiner’s fingers be placed on the proper landmarks to elicit this motion. The landmarks for palpation are the patella and lateral fabella on the femur, and the fibular head and tibial tuberosity on the tibia. The test is performed repeatedly with the limb in extension and in variable degrees of flexion. To elicit this motion the examiner places cranial force upon tibia while holding the femur still with the other hand. If a CCL rupture is present the tibia will shift forward in relation to the femur. With partial CCL ruptures the craniomedial band is usually damaged leaving the caudolateral band intact. Since the caudolateral band is taut in extension, cranial drawer motion may only be elicited with the limb in variable degrees of flexion. In some dogs with partial ruptures or dogs with chronic injuries, cranial drawer motion may not be detected due to stabilization of the joint from fibrous tissue (Vasseur 1993). Cranial tibial thrust takes into account the biomechanics of the stifle and includes the forces exerted by muscles during weight bearing. Cranial tibial thrust is an active force created by weight bearing plus muscular compression of the tibial plateau against the femoral condyles. Cranial tibial thrust is dependent on the amount of compression as well as the slope of the tibial plateau (Slocum and Devine 1983; Slocum and Slocum 1993). To evaluate cranial tibial thrust the stifle is held in a slight degree of flexion, and the hock is flexed while placing axial compression upon the tibia. The tibial tuberosity is palpated for cranial subluxation. The cranial drawer test is thought to be more reliable and easier to perform (Vasseur 1993).
Radiographs of the affected stifle are of little diagnostic value but will document the degree of osteoarthrosis (Piermattei and Flo 1997). Radiographic features consistent with osteoarthrosis include the presence of osteophytes, and increase in synovial mass and thinning of the infrapatellar fat pad. Radiographs of the affected stifle are important to rule out the presence of concurrent diseases (neoplasia, erosive arthopathies), and to measure the slope of the tibial plateau.

1.3 SURGICAL TECHNIQUES FOR DOGS WITH CRANIAL CRUCIATE LIGAMENT RUPTURE

Over the last 30 years, numerous techniques and modifications of them have been described for stabilization of the stifle after CCL rupture. Techniques can be categorized as; intracapsular, or extracapsular repairs, fibular head transposition, and corrective osteotomies.

Currently the most popular techniques are extracapsular repairs and corrective osteotomies. Although some surgeons continue to perform intracapsular repairs and fibular head transposition, most have gone to a more simple extracapsular repair or corrective osteotomies since reports show that the clinical outcome to be similar regardless of the technique used (Jevens et al. 1996; Moore and Read 1996). Biomechanical evaluation of the stability after several techniques showed fibular head transposition was superior to various intracapsular and extracapsular repairs in regards to immediate postoperative laxity and stiffness (Patterson et al. 1991). However, in follow-up clinical examinations extracapsular techniques resulted in better joint stability and limb function than fibular head transposition (Moore and Read 1996). Non-surgical treatment consisting of 4-6 weeks of strict kennel confinement is a treatment option for small dogs. Dogs weighing less than 15 kg had a satisfactory outcome after 3-6 weeks of
strict cage confinement, whereas dogs weighing greater than 15 kg were much less likely to have a satisfactory outcome after a similar confinement period (Vasseur 1984).

Most authors’ site 85-90% clinical success after intracapsular and extracapsular techniques (Shires et al. 1984; Moore and Read 1996; Piermattei and Flo 1997). Similarly, anecdotal reports cite up to 95% of dogs undergoing corrective osteotomies will have a good to excellent outcome (Slocum and Slocum 1993). It is difficult to find comparisons of surgical techniques and clinical outcomes. Evaluations tend to rely heavily upon client communications, and the techniques involved are not all inclusive (Denny and Barr 1984; Shires et al. 1984; Metelman et al. 1995; Jevens et al. 1996; Moore and Read 1996). Because there is no true “gold standard” surgical technique for dogs after CCL rupture, studies tend to compare across technique categories rather than between modifications within a technique. This being said, there is a consensus among surgical specialists that dogs weighing greater than 15 kg will benefit from having surgery, and it is estimated 85-95% of these dogs will have a good to excellent outcome after surgery, with return to normal or near normal weight bearing function.

1.3.1 INTRACAPSULAR TECHNIQUES – A variety of intracapsular techniques and modifications have been described. The principle of these techniques is to reconstruct the CCL using an autograft, allograft, or synthetic material. Autografts harvested from the hamstring, patellar tendon, fascia lata, or a combination of both are used most often (Arnoczky et al. 1979; Hulse et al. 1980; Arnoczky et al. 1982; Thorson et al. 1989; Lopez et al. 2003). Intracapsular techniques attempt to provide an anatomic or nearly anatomic replacement for the damaged ligament. An in vitro examination several intracapsular and extracapsular techniques indicated that intracapsular techniques resulted
closer to normal joint motion than extracapsular techniques (Arnoczky et al. 1977). However, a later study showed that the instant center of motion in the stifle with extracapsular suture placement techniques did not alter (Prostredny et al. 1991).

1.3.2 EXTRACAPSULAR TECHNIQUES – The first extracapsular techniques were described by DeAngelis and Flo and variations of these are currently used (DeAngelis and Lau 1970; Flo 1975). One or two strands of large monofilament nylon leader line is passed around the lateral fabella, under the patellar tendon, through a hole drilled in the tibial crest, and secured by a knot or crimp-clamp system. This technique is easy to apply and provides consistent and satisfactory clinical results.

1.3.3 FIBULAR HEAD TRANSPOSITION – Fibular head transposition was introduced as a surgical technique for the stifle after CCL rupture in 1985 (Smith and Torg 1985). This technique moves the fibular head cranially with the lateral collateral ligament attached, thus altering the orientation of the lateral collateral ligament and preventing cranial drawer motion and internal rotation of the tibia. Clinical results after this technique are similar to the aforementioned techniques, however, surgical expertise is required. The mechanical stability of fibular head transposition immediately post-operatively was shown to be superior to intracapsular and extracapsular techniques (Patterson et al. 1991). This result prompted the recommendation to use this technique for larger dogs that may place a high load on an intracapsular or extracapsular prosthesis.

1.3.4 CORRECTIVE OSTEOTOMIES – Two corrective osteotomies have been described for the stifle after CCL rupture. Cranial tibial wedge osteotomies (TWO) (Slocum and Devine 1984) and tibial plateau leveling osteotomy (TPLO) (Slocum and Slocum 1993) have recently become popular for large dogs after anecdotal reports
suggested that large dogs did better after these techniques than others. Neither of these techniques restore the stability of the stifle by mimicking the action of the CCL. Both alter the joint biomechanics by changing the tibial plateau angle, thus eliminating cranial tibial thrust. It has been proposed that cranial tibial thrust is the pathologic alteration of motion that occurs after CCL rupture under normal weight bearing conditions. The TPLO was shown to eliminate cranial tibial thrust in an in vitro study (Warzee et al. 2001). However, objective comparisons of the clinical outcomes after these techniques and others is lacking. A great deal of controversy exists regarding TPLO since the technique is patented. One must attend a course and become certified before performing this technique.

1.4 BIOMECHANICS FOR TESTING BIOMATERIALS

Biomechanics is simply the application of mechanical engineering principles to biologic systems to gain information on (1) the material and structural characteristics of living tissues and biomaterials, (2) the impact of intrinsic and extrinsic physiologic and nonphysiologic forces on a biological system, and (3) the influence of an object on a biological system (Lucas et al. 1999).

Mechanics is the branch of physics and engineering that deals with forces and the effects produced when forces are applied to objects. When a force acts on an object, that object changes in some way. Force (force = mass X acceleration) is any agency acting on an object that causes it to move, change its motion, or change its size or shape. Force is commonly referred to as load, and when applied to a biologic system leads to deformation or a change in shape (Radin et al. 1992; Burstein and Wright 1994; Lucas et al. 1999). Isaac Newton is credited with the first correct statement of the laws governing
the events that occur when a force is applied to an object. Simply, these statements or laws are the following: (1) A object at rest will stay at rest, (2) if a force is applied to an object its velocity will change in proportion to that force, (3) if a force is applied to an object and no acceleration occurs there must be an equal and opposite force acting on the object. The basic unit of force is the Newton (N) where 1N = 0.225 X 1 lb (force) (Lucas et al. 1999).

To understand how a force affects a structure on which it acts one must have an understanding of a basic load–deformation curve. The load–deformation curve evaluates the behavior of a whole object and identifies several important structural characteristics about an object. The most important characteristics that can be identified from a curve are: (1) the load an object can withstand prior to failure, (2) the stiffness of the object or its ability to resist a change in shape, (3) the amount of energy an object can absorb prior to its failure (Figure 1.4).

![Load - Deformation](image)

**Figure 1.4** – A theoretical load – deformation curve. Point (A) is the point when load is applied to an object, (B) is the yield point, (C) is the point where failure occurs.
If a load is applied in the elastic region (A-B) and then released, no permanent deformation occurs. A load is applied past the yield point (B) into the non-elastic or plastic region of the curve (B-C), permanent deformation will occur even if the load is released. If loading is continued into the non-elastic region, an ultimate failure point is reached (C). The area under the curve represents the amount of energy absorbed by the object prior to failure. Stiffness (the ability of the object to resist a change in shape) is calculated from the slope of the linear portion of the curve (Lucas et al. 1999).

To standardize representation of the mechanical behavior of a material (as opposed to an object), it is necessary to normalize the load–deformation measurements and eliminate the influence of geometry and dimensions. A stress–strain curve can be used to evaluate a material and eliminates the influence of geometry and dimensions (Figure 1.5).

Figure 1.5 – A theoretical stress – strain curve

For comparison of specimens of varying lengths deformation must be normalized to the original specimen length. Strain is the normalization of deformation to the original
length. Thus, specimens of varying lengths can exhibit the same strain when a similar load is applied. Strain had no units since it is normalized to length.

*Stress* is the normalization of applied force to the original cross-sectional area. It can be thought of as the internal force intensity (force per unit area) at any given point or plane. When evaluating the stress–strain curve the slope of the line relates the stress and strain. The slope of the linear elastic region of the stress–strain curve is referred to as the elastic modulus or modulus of elasticity. *Modulus of elasticity* is the material property that relates stress to strain and is used to describe how stiff a material is in tension and compression. The modulus of elasticity is known for a variety of biologic materials and is used for comparisons. The unit for modulus of elasticity is the giga-pascal (GPa). For example, the modulus of stainless steel is 200 GPa whereas, cortical bone is 20 GPa, thus stainless steel is 10 times stiffer than cortical bone (Burstein and Wright 1994; Lucas et al. 1999). Mechanical evaluation of materials can be complex and difficult to understand. Most reports in the veterinary literature evaluate load–deformation or stress–strain.

Appropriate mechanical testing of biomaterials varies depending on the type of material being tested. Some materials are affected more by their biologic environment. And special considerations may apply when synthetic biomaterials are tested. For example, implanted biomaterials are used at body temperature but testing is performed at room temperature. Will the material behave in the same manner when exposed to body temperature versus room temperature? One should attempt to mimic the environment the material will be subjected to as close as possible. Although it would be ideal to test all materials at body temperature while being exposed to body fluids, the chambers necessary to complete testing of this nature can be prohibitively expensive.
The properties of metals are not severely affected by their environment. However, the properties of polymeric materials may be. Polymers are sensitive to small changes in their environment and are likely to interact with their surrounding environment. The testing rate and frequency of polymeric materials is also important. Time-dependent tests such as fatigue testing should be performed at a rate similar to what the material will be subjected to in vivo (Lucas et al. 1999).

1.5 MECHANICAL EVALUATIONS OF EXTRACAPSULAR REPAIRS USING NYLON LEADER LINE

Most techniques used for CCL rupture attempt to eliminate cranial translation of the tibia in relation to the femur, and prevent excessive internal rotation of the tibia. Extracapsular techniques using a lateral fabella-tibial suture (LFS) of large diameter nylon leader line (NLL) is well accepted and commonly performed (Caporn and Roe 1996). Studies have shown that NLL has the most appropriate characteristics (high force at failure, minimal elongation, and high stiffness) for use in LFS stabilization of the cruciate deficient stifle. However because of its memory, lower coefficient of friction, and larger diameter compared to other materials commonly used, knot security may be a concern (Caporn and Roe 1996; Lewis et al. 1997; Anderson et al. 1998; Nwadike and Roe 1998; Huber et al. 1999). The LFS using NLL provides short term stabilization of the stifle while periarticular fibrosis develops, resulting in long-lasting stifle stability (Piermattei and Flo 1997). Before the use of NLL, surgeons employed large diameter, commercially available suture material. The LFS, regardless of size or composition, must withstand forces generated by cyclic loading during weight-bearing, tension, and deformation generated by the formation of a knot, or produced by the application of a crimp-clamp. The cyclic loading forces may cause the material may cause it to break or
loosen after surgery. If the LFS breaks or loosens before adequate periarticular fibrosis has developed, stifle instability remains. Thus, material for use as a LFS is important and has prompted many biomechanical evaluations in attempt to discern the best knot method (Nwadike and Roe 1998; Huber et al. 1999), the most mechanically stable material (Caporn and Roe 1996; Lewis et al. 1997; Huber et al. 1999; Sicard et al. 1999; Sicard et al. 2002), alternatives to knot tying with the use of a crimp-clamp system (Anderson et al. 1998; Peycke et al. 2002; Sicard et al. 2002), and the effects of sterilization methods (Caporn and Roe 1996) on the biomechanical properties of NLL and nylon fishing line (NFL) used in LFS stabilization.

A common problem during placement of the LFS technique is loss of tension in the NLL during knot tying (Caporn and Roe 1996). Because of this problem variations of knot types and fixation methods have been evaluated in the literature. Results vary, a clamped square knot, square knot, slip knot, and crimp-clamp systems have all been found to be acceptable methods of fixation of NLL (Anderson et al. 1998; Nwadike and Roe 1998; Huber et al. 1999; Peycke et al. 2002; Sicard et al. 2002). It is known that the structural properties of suture material are best preserved when a square knot is used (Price 1948; Hermann 1971; Rosin and Robinson 1989). Tightening of the large diameter NLL may result in stress concentration and weakening of the knot (Caporn and Roe 1996).

Caporn and Roe (Caporn and Roe 1996) determined that the mechanical properties of NLL were not significantly altered when steam or ethylene oxide sterilization methods were used compared to unsterilized controls. This study also found that the mechanical performance of NLL was superior to NFL for use as a LFS. Poorer
performance of 36 kg test NLL versus 27 kg test NLL during cycled testing was felt to be the result of the inability to form a tight knot when using the larger material.

Huber and Egger (Huber et al. 1999) compared the mechanical characteristics of several knot formations of large diameter monofilament materials. These authors proposed that stiffness and yield are the most clinically relevant parameters for knot assessment since the elongation knotted loops demonstrate prior to failure is to such a degree that joint stability and or tissue coaptation in vivo would be compromised well before this degree of elongation could actually occur. They concluded that clamping the first throw of a square knot of NLL is preferable to maintain tension on the suture and facilitate performing a tight knot. Clamping did not significantly alter the mechanical properties and increased the structural stiffness of the material. They proposed that clamping of the first throw creates a partial deformation under tension, thus allowing for the formation of a more secure knot.

Knotting techniques using NLL require a minimum of 5 throws resulting in a large, bulky knot that is irritating to the soft tissues (Caporn and Roe 1996). Some knotting techniques also require an assistant for knot tensioning. The Securos® clamping system was designed to fasten two ends of the NLL together using a crimped metal tube and can be performed without assistance. Loops secured with privately designed crimp-clamps were evaluated using 27 kg test NLL and was shown to provide superior in vitro mechanical performance compared to loops secured with clamped square knots (Anderson et al. 1998). Two recent reports evaluated the 36 kg Securos® system (Peycke et al. 2002; Sicard et al. 2002). The first study evaluated the 36 kg Securos® system and reported significantly less elongation occurred in crimped loops compared to
knotted samples, although these investigators found that the crimped loops had significantly less tensile strength compared to knotted loops (Sicard et al. 2002). However, the authors concluded that elongation may be more relevant than ultimate tensile strength to the maintenance of joint stability, and should be the primary consideration during suture material selection, and method of fixation for LFS security. Another study evaluating the 36 kg Securos® system using both 27.3 kg test and 36.4 kg test NLL against other knotted loops reported crimped loops performed as well or better than traditional knotted loops (Peycke et al. 2002).

Despite limited mechanical data, the Securos® system has achieved widespread clinical use. There is no mechanical data reported for the 18 kg Securos® system. Biomechanical evaluation of this system should be tested against other accepted methods before this system is used in vivo.

1.6 POLYVINYLIDENE FLUORIDE (FLUOROCARBON) AS AN ALTERNATIVE MATERIAL TO NYLON FOR EXTRACAPSULAR REPAIR

Recent reports have looked at the suitability of polyvinylidene fluoride (PVDF) for use as a suture material (Urban et al. 1994; Laroche et al. 1995; Laroche et al. 1995; Mary et al. 1998). PVDF has intrinsic elastic properties under tension which allow for improved surgical handling and knot formation, and PVDF shows excellent biocompatibility (Laroche et al. 1995). In a long-term in vivo implantation model in the dog, PVDF was more stable and retained its surface properties better than polypropylene. The PVDF is available as fluorocarbon fishing leader material and fishing line. It is manufactured in tensile strengths up to 200 pounds. This material may be an alternative to NLL for LFS stabilization because of its better surgical handling characteristics, improved knot strength, smaller diameter for a given tensile strength, and decreased
absorption of water under physiologic conditions. A smaller diameter material will form a smaller knot for a given tensile strength which would be less irritating to the soft tissues.

1.7 REFERENCES


CHAPTER 2. *IN VITRO* EVALUATION OF THE 18 KG AND 36 KG SECUROS CRANIAL CRUCIATE LIGAMENT REPAIR SYSTEM™
2.1 INTRODUCTION

Cranial cruciate ligament (CCL) rupture is a common injury causing stifle instability and secondary degenerative joint disease. The CCL prevents hyperextension of the stifle and limits internal rotation of the tibia in relation to the femur (Arnoczky 1988; Piermattei and Flo 1997). Surgical stabilization of the stifle after CCL rupture is recommended for dogs weighing more than 15 kg (Vasseur 1984).

Many surgical techniques for stabilization of the stifle after CCL rupture have been described (Flo 1975; Shires et al. 1984; Smith and Torg 1985; Slocum and Slocum 1993). Techniques can be classified as intracapsular, extracapsular, fibular head transposition, and corrective osteotomies. Extracapsular repair with a lateral fabella-tibial suture (LFS) of large diameter monofilament nylon leader line (NLL) is a well accepted and commonly performed technique (Caporn and Roe 1996). The LFS provides short-term stabilization of the stifle while periarticular fibrosis develops, which causes long-term stifle stability (Piermattei and Flo 1997).

Extracapsular stabilization using a LFS requires a strong suture material that minimizes bacterial adherence and has minimal plastic deformation (Nwadkie and Roe 1998). This material must withstand cyclic loading and tension. In addition, it must withstand deformation during knot tying, or during application of a crimp-clamp. Loading and tension on the material may lead to excessive elongation or disruption of the LFS in vivo prior to the formation of adequate periarticular fibrosis. If this occurs, stifle instability remains.

Evaluations of various suture materials, knot types, and other methods of fixation of the suture have attempted to discern the best knot or fixation method (Nwadkie and
Roe 1998; Huber et al. 1999), the most mechanically suitable material (Caporn and Roe 1996; Lewis et al. 1997; Huber et al. 1999; Sicard et al. 1999; Sicard et al. 2002), and the effect of sterilization methods (Caporn and Roe 1996; Sicard et al. 2002) on the mechanical properties of NLL and nylon fishing line (NFL).

The Securos Cranial Cruciate Ligament Repair System™ was designed to fasten two ends of NLL together using a crimped metal tube. A tensioning device provided by the manufacturer is used to tension the loop and fasten the crimp-clamp without assistance. This system eliminates the bulky knot formed with knotting techniques. Two systems are available for 18 kg test (kgt) and 36 kgt NLL. A similar crimp-clamp system for 27 kgt NLL demonstrated superior in vitro mechanical performance compared to clamped square knots using 27 kgt NLL, resulting in loops that had a higher force at failure and less elongation (Anderson et al. 1998). The 36 kg Securos® crimp-clamp system resulted in loops with significantly less strength and less elongation than knotted samples for 36 kgt NLL (Sicard et al. 2002). In a second study, the 36 kg Securos® crimp-clamp system on both 27.3 kgt and 36.4 kgt NLL resulted in loops that performed similar to or had superior mechanical performance than knotted loops (Peycke et al. 2002). Despite limited data on mechanical testing of the 36 kg system, and on the 18 kg system, the Securos® crimp-clamp system has achieved widespread clinical use.

This study evaluated the force at failure, loop elongation, and stiffness of unsterilized NLL loops secured with the 18 kg and 36 kg Securos Cranial Cruciate Ligament Repair System™ compared to a clamped square knot technique. Eighteen, 27 and 36 kgt NLL was used under non-cycled and cycled testing conditions.
2.2 MATERIALS AND METHODS

The materials tested were 18.2, 27.3, and 36.4 kgf monofilament NLL\textsuperscript{a,b}. Eighty strands of each material were cut to a length of 40 cm. Forty strands of each size were secured with: 1) Square knot clamped after the first throw with a total of five throws (CSK), and 2) Securos crimp-clamp system (SCC)\textsuperscript{c}.

2.2.1 LOOP ASSEMBLY – Loops were fixed by the same surgeon (MNB) around a customized 42.42 mm outer diameter polyvinyl-chloride pipe to ensure a consistent sized loop. The pipe was customized for the application of the crimping device or needle holders by cutting a 1.5 cm X 5 cm slot out of each end of the pipe. The edges of the slot were covered with tape to prevent damage to the NLL during loop fixation. The ends of all loops were cut 3 mm from the knot or clamp. All strands of NLL were passed through room temperature 0.9\% NaCl solution\textsuperscript{d} at room temperature prior to loop formation. Clamped square knots were formed by clamping the first throw of the knot with modified 7 inch Mayo-Hegar needle holding forceps\textsuperscript{e} (modified by filing the surface of the jaws so they were completely smooth) closed to the third lock. The Securos\textsuperscript{®} crimp-clamp system was used according to the manufacturer’s recommendations\textsuperscript{c}. Both strands of the NLL were passed through the primary crimp tube. Secondary crimp tubes were placed 10 mm from the primary tube on each tag end and crimped twice. The tensioning device was then placed to distract the secondary clamps to a predetermined point on its locking mechanism. The primary crimp tube was then clamped three times with the crimping tool designed for this system. The 36 kg Securos\textsuperscript{®} system was used for both the 27.3 and 36.4 kgf SCC samples.
2.2.2 MECHANICAL TESTING – One group of 27 kgt NLL loops was tested at 40° C. These samples were incubated in the mechanical testing machine chamber for 20 minutes at 40° C prior to testing. For all other groups testing was performed at room temperature (20° C). All loops were mounted onto an IPC Digital Servo Machine between two horizontally-oriented polished steel hooks set 56 mm apart.

For the non-cycled testing, tension was applied at a constant distraction rate of 500 mm/min until the loops failed by breaking or slipping. Force at failure, elongation, and stiffness were recorded and compared across sizes of NLL and fixation method. The stiffness measurement reported was the maximum recorded value obtained from the linear portion of the load vs. elongation curve for each trial.

For the cycled testing, tension was applied at a constant distraction rate of 500 mm/min to a distraction limit of 7.5 mm for 49 cycles. The 18.2 kgt NLL samples were not able to complete this cycled protocol. The protocol was then altered so the 18 kgt loops were tested at a distraction limit of 6.0 mm. The loops were tensioned at a constant distraction rate of 500 mm/min until the loops failed by breaking or slipping. Calculations to determine force at failure, elongation, and stiffness were collected from the final load to failure cycle for each trial. Force at failure, elongation, and stiffness were recorded and compared across sizes of NLL and fixation method. The stiffness measurement reported was the maximum recorded value obtained from the linear portion of the load vs. elongation curve for each trial.

2.2.3 STATISTICAL METHODS – The force at failure, elongation, and stiffness were considered continuous and evaluated for normality using the Shapiro-Wilk test with the null hypothesis of normality rejected at p<0.05. Non-normal data was transformed. All
data was summarized as mean +/- SEM. The data for non-cycled and cycled loops was analyzed separately using a two-way analysis of variance to evaluate the effect of loop fixation method (Securos® vs. clamped square knot), and NLL size (18, 27 vs. 36 kgt) on force to failure, elongation and stiffness. Where there were significant interaction effects at p<0.05, pre-planned comparisons were made using the Scheffé’s procedure maintaining type I error at 0.05. Thus, when specified, significant differences are established at p ≤ 0.05. For comparisons of the force at failure for noncycled vs. cycled loops, the data was analyzed using a three-way analysis of variance to evaluate the effect of loop fixation method (Securos® vs. clamped square knot), NLL size (18, 27 vs. 36 kgt) and cycling (non-cycled vs. cycled). Where there were significant interaction effects at p<0.05, pre-planned comparisons were made using the Scheffé’s procedure maintaining type I error at 0.05. Thus, when specified, significant differences are established at p ≤ 0.05. PROC UNIVARIATE and PROC ANOVA® (SAS v 8.2, SAS Institute, Cary, NC) were used for all analyses.

2.3 RESULTS

2.3.1 NON-CYCLED TESTING – All of the loops failed at a portion originally contained within the knot or crimp-clamp. All the 27.3 and 36.4 kgt SCC non-cycled loops failed within the clamp. Conversely, all 18.2 kgt SCC non-cycled loops pulled through the clamp rather that the NLL breaking.

The force at failure was significantly greater in all SCC loops than the CSK loops, except for the 18.2 kgt group where the CSK was significantly greater (Table 1). The force at failure was significantly greater in CSK loops than the CSK40°C loops for the 27.3 kgt NLL. The 36.4 kgt loops were significantly stronger (force at failure) than the
27.3 kgt loops, which were stronger than the 18.2 kgt loops. The CSK loops showed greater elongation than the SCC loops within each size group of NLL. There was no significant difference in elongation between CSK loops and CSK40°C loops for the 27.3 kgt NLL. The 36.4 kgt loops had significantly greater elongation than the 27.3 kgt loops. Stiffness was not significantly different between SCC and CSK 18.2 kgt loops. The SCC loops had significantly greater stiffness than CSK and CSK40°C loops for 27.3 kgt and the CSK for 36.4 kgt NLL. Stiffness was not significantly different between CSK and CSK40°C loops for 27.3 kgt or 36.4 kgt NLL groups or between SCC loops for 27.3 and 36.4 kgt NLL.

**Table 2.1.** Mean (SEM) force at failure, elongation, and stiffness for non-cycled loops formed with a clamped square knot (CSK) or the Securos® crimp clamp system (SCC) using monofilament nylon leader line. The coefficient of variation (CV = mean/SD X 100) of the force and elongation is also reported. Within each nylon leader line size, measurements with the same superscript are not significantly different. For comparisons between 27.3 kg and 36.4 kg nylon leader line, means with the same superscript are not significantly different. Note that type I error was maintained at 0.05 for all comparisons, hence where significant, \( p \leq 0.05 \).

<table>
<thead>
<tr>
<th>Knot Method</th>
<th>Force (N)</th>
<th>CV (%)</th>
<th>Elongation (mm)</th>
<th>CV (%)</th>
<th>Stiffness (N/mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>18.2 kg (40 lb)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CSK</td>
<td>265.5 (3.6)</td>
<td>6.1</td>
<td>11.5 (0.2)</td>
<td>9.7</td>
<td>34.0 (1.7)</td>
</tr>
<tr>
<td>SCC</td>
<td>132.9 (8.8)</td>
<td>29.6</td>
<td>6.9 (0.3)</td>
<td>18.3</td>
<td>32.0 (1.0)</td>
</tr>
<tr>
<td>27.3 kg (60 lb)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CSK40°C</td>
<td>358.4 (6.0)</td>
<td>7.4</td>
<td>14.0 (0.3)</td>
<td>10.9</td>
<td>27.7 (0.7)</td>
</tr>
<tr>
<td>CSK</td>
<td>387.7 (4.5)</td>
<td>5.2</td>
<td>14.3 (0.4)</td>
<td>11.2</td>
<td>28.6 (0.6)</td>
</tr>
<tr>
<td>SCC</td>
<td>416.4 (8.8)</td>
<td>9.5</td>
<td>12.3 (0.3)</td>
<td>11.5</td>
<td>38.7 (0.4)</td>
</tr>
<tr>
<td>36.4 kg (80 lb)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CSK</td>
<td>498.1 (3.6)</td>
<td>3.3</td>
<td>18.7 (0.2)</td>
<td>4.6</td>
<td>28.5 (0.6)</td>
</tr>
<tr>
<td>SCC</td>
<td>522.0 (9.4)</td>
<td>8.0</td>
<td>15.2 (0.2)</td>
<td>6.2</td>
<td>38.6 (0.3)</td>
</tr>
</tbody>
</table>
2.3.2 CYCLED TESTING – All of the loops failed at a portion originally contained within the knot or crimp-clamp. All of the 36.4 kgt SCC and CSK cycled samples completed the cycled protocol. One 27.3 kgt CSK cycled sample failed by breaking prior to completion of cycled protocol. Two 27.3 kgt SCC cycled samples failed by breaking prior to completion of the cycled protocol.

The original protocol for cycled testing had to be altered due to the inability of the 18.2 kgt SCC samples to complete the protocol. The distraction limit for the cycles was then reduced to 6 mm. Two 18.2 kgt CSK loops failed by breaking prior to completion of the revised cycled protocol. Two 18.2 kgt SCC cycled samples failed by pulling through the clamp prior to completion of the revised cycled protocol. All of the 18.2 kgt SCC loops continued to pull through the clamp rather than the NLL breaking within the clamp.

The SCC loops were significantly stronger (force at failure) than the CSK loops for 36.4 kgt NLL (Table 2.2). The CSK loops were significantly stronger than the SCC loops for 27.3 kgt NLL. Similarly, the 36.4 kgt NLL loops were significantly stronger than the 27.3 kgt NLL loops. The strength of SCC loops and CSK loops were not different for 18.2 kgt NLL.

The SCC loops showed significantly greater elongation than the CSK loops for 36.4 kgt NLL. The CSK loops showed significantly greater elongation than the SCC loops for 27.3 kgt NLL. The 36.4 kgt SCC loops had significantly greater elongation than all 36.4 kgt NLL and 27.3 kgt NLL loops. The CSK loops showed no difference in
elongation for 36.4 kgt and 27.3 kgt NLL. The SCC loops and CSK loops showed no difference in elongation for 18.2 kgt NLL.

The SCC loops showed significantly greater stiffness than CSK loops for 36.4 kgt NLL. The SCC loops showed significantly greater stiffness than CSK loops for 27.3 kgt NLL. The 36.4 kgt SCC loops showed significantly greater stiffness than 27.3 kgt SCC loops, which were significantly stiffer than 36.4 kgt CSK loops, which were significantly stiffer than 27.3 kgt CSK loops. The SCC loops showed significantly greater stiffness than CSK loops for 18.2 kgt NLL.

**Table 2.2.** Mean (SEM) force at failure, elongation, and stiffness for cycled loops formed with a clamped square knot (CSK) or the Securos® crimp clamp system (SCC) using monofilament nylon leader line. The coefficient of variation (CV = mean/SD X 100) of the force and elongation is also reported. Within each nylon leader line size, means with the same superscript are not significantly different. For comparisons between 27.3 kg and 36.4 kg nylon leader line, means with the same superscript are not significantly different. Note that type I error was maintained at 0.05 for all comparisons, hence where significant, \( p \leq 0.05 \).

<table>
<thead>
<tr>
<th>Knot Method</th>
<th>Force ( (N) )</th>
<th>CV ( (%) )</th>
<th>Elongation ( (\text{mm}) )</th>
<th>Stiffness ( (N/\text{mm}) )</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>18.2 kg (40 lb)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CSK-C</td>
<td>( ^a268.1 (3.2) )</td>
<td>5.4</td>
<td>( ^a8.2 (0.2) )</td>
<td>( ^a37.0 (0.6) )</td>
</tr>
<tr>
<td>SCC-C</td>
<td>( ^a286.9 (11.9) )</td>
<td>17.6</td>
<td>( ^a7.6 (0.3) )</td>
<td>( ^b45.7 (0.6) )</td>
</tr>
<tr>
<td><strong>27.3 kg (60 lb)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CSK-C</td>
<td>( ^p386.8 (4.5) )</td>
<td>5.0</td>
<td>( ^p9.1 (0.2) )</td>
<td>( ^p48.3 (0.5) )</td>
</tr>
<tr>
<td>SCC-C</td>
<td>( ^a359.9 (17.3) )</td>
<td>20.4</td>
<td>( ^a6.7 (0.3) )</td>
<td>( ^a58.1 (1.3) )</td>
</tr>
<tr>
<td><strong>36.4 kg (80 lb)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CSK-C</td>
<td>( ^t445.3 (5.2) )</td>
<td>5.2</td>
<td>( ^p9.5 (0.2) )</td>
<td>( ^t53.8 (0.6) )</td>
</tr>
<tr>
<td>SCC-C</td>
<td>( ^s564.5 (6.6) )</td>
<td>5.2</td>
<td>( ^t10.8 (0.4) )</td>
<td>( ^s68.8 (0.7) )</td>
</tr>
</tbody>
</table>
A comparison between non-cycled loops vs. cycled loops showed SCC cycled loops were significantly stronger than SCC non-cycled loops, which were significantly stronger than CSK non-cycled loops, which were significantly stronger than the CSK cycled loops for the 36.4 kgt NLL (Table 2.3). The SCC non-cycled loops were significantly stronger than CSK non-cycled and cycled loops, which were significantly stronger than the SCC cycled loops for the 27.3 kgt NLL. The SCC cycled loops and CSK cycled and non-cycled loops were significantly stronger than the SCC non-cycled loops for 18.2 kgt NLL.

**Table 2.3.** Mean (SEM) force at failure for non-cycled loops and cycled loops (+C) formed with a clamped square knot (CSK) or the Securos® crimp clamp system (SCC) using monofilament nylon leader line. Within each nylon leader line size, means with the same superscript are not significantly different. For comparisons between 27.3 kg and 36.4 kg nylon leader line, means with the same superscript are not significantly different. Note that type I error was maintained at 0.05 for all comparisons, hence where significant, \( p \leq 0.05 \).

<table>
<thead>
<tr>
<th>Knot Method</th>
<th>Force (N)</th>
<th>Knot Method</th>
<th>Force (N)</th>
<th>Knot Method</th>
<th>Force (N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>18.2 kg (40 lb)</td>
<td>( ^{a}265.5 \text{ (3.6)} )</td>
<td>27.3 kg (60 lb)</td>
<td>( ^{p}387.7 \text{ (4.5)} )</td>
<td>36.4 kg (80 lb)</td>
<td>( ^{g}498.1 \text{ (3.6)} )</td>
</tr>
<tr>
<td>CSK</td>
<td>( ^{a}268.1 \text{ (3.2)} )</td>
<td>CSK+C</td>
<td>( ^{p}386.8 \text{ (4.5)} )</td>
<td>CSK+C</td>
<td>( ^{l}445.3 \text{ (5.2)} )</td>
</tr>
<tr>
<td>SCC</td>
<td>( ^{b}132.9 \text{ (8.8)} )</td>
<td>SCC+C</td>
<td>( ^{q}416.4 \text{ (8.8)} )</td>
<td>SCC</td>
<td>( ^{n}522.0 \text{ (9.4)} )</td>
</tr>
<tr>
<td>SCC+C</td>
<td>( ^{a}286.9 \text{ (11.9)} )</td>
<td>SCC+C</td>
<td>( ^{r}359.9 \text{ (17.3)} )</td>
<td>SCC+C</td>
<td>( ^{v}564.5 \text{ (6.6)} )</td>
</tr>
</tbody>
</table>

### 2.4 DISCUSSION

The Securos Cranial Cruciate Ligament Repair SystemTM has advantages over knotting methods for NLL loop fixation by eliminating the bulky knot, and not requiring assistance. Crimp-clamp systems manufactured by Securos, Inc, are for use with 18.2 kgt
NLL and for use with 36.4 kgt NLL. We also evaluated 27.3 kgt NLL secured with the
36.4 kg Securos® crimp-clamp system for comparison to other studies (Anderson et al.
1998; Peycke et al. 2002). The results of our study support the use of the 36 kg Securos®
crimp-clamp system for both 27.3 and 36.4 kgt NLL. In both non-cycled and cycled
testing the SCC loops formed with 27.3 kgt or 36.4 kgt NLL performed as well or better
than a clamped square knot resulting in loops that were strong, undergoing minimal
elongation, and having high stiffness.

The 18.2 kg Securos® crimp-clamp system appears to be unsatisfactory. The
Securos® crimp-clamp system designed for use with 18.2 kgt NLL did not perform as
well mechanically in non-cycled testing as did clamped square knots for loops of the
same size NLL. All 18.2 kgt NLL loops secured with the Securos® crimp-clamps failed
by pulling through the crimp-clamps rather than the NLL breaking within the clamp.
Considerable variability was observed in the force at failure and elongation reflected by
coefficient of variations of 29.6% and 18.3%, respectfully. In cycled testing, the 18.2 kgt
SCC loops failed prior to completion of the original cycled protocol by pulling through
the clamp. Once the displacement was reduced, most 18.2 kgt SCC samples completed
the cycled protocol, but still ultimately failed by pulling through the clamp. These
findings raise concern about a design flaw with the original crimp tube diameter (pre-
clamping), or that the crimping instrument used with this system may not crimp the tube
to the appropriate diameter.

In contrast the 27.3 kgt and 36.4 kgt NLL secured with the 36 kg Securos®
crimp-clamp system had superior to or equivalent mechanical performance than CSK
loops of the same kilogram-test NLL resulting in loops that had a high force at failure,
minimal elongation and high stiffness. The 36 kg Securos® crimp-clamps are not
designed for use with the 27.3 kgt NLL. During cycled testing, two of the 27.3 kgt SCC
loops failed prior to completion of the protocol. However, these loops failed by the NLL
breaking within the clamp and not pulling through the clamp as was observed with the
18.2 kgt SCC loops.

Two available reports on the use of the 36 kg Securos® crimp-clamp system had
differing results (Peycke et al. 2002; Sicard et al. 2002). The first study (Sicard et al.
2002) reported SCC loops of 36.4 kgt NLL were significantly weaker than knotted
samples and exhibited significantly less elongation. This study differed from ours by
comparing to a control loop formed by a square knot with five throws (not clamped), and
a cycled testing protocol with a final loading rate of 1000 mm/min until failure. Stiffness
of the loops was not reported.

The second study (Peycke et al. 2002) used 36 kg Securos® crimp-clamp system
for both 27.3 kgt and 36.4 kgt NLL. This study utilized the same non-cycled testing
protocol as our study and reported that SCC loops of 27.3 kgt and 36.4 kgt NLL secured
with the Securos® crimp-clamps were as strong or stronger and showed similar to less
elongation than CSK using large diameter NLL.

The cycled testing protocol used in this study was derived from the results of non-
cycled testing. Load vs. elongation curves were evaluated to determine the distraction
limit that represented approximately 50% of the failure load for the loops. It was difficult
to determine the 50% failure load for the 18.2 kgt loops due to the variability of the 18.2
kgt SCC samples. A distraction limit of 7.5 mm was determined based upon the above
observations and used initially for all loops for consistency. The protocol was changed to
6.0 mm for the 18.2 kgt loops due to the inability of the 18.2 kgt SCC samples to withstand the protocol. The results obtained for the cycled testing were taken from the last load to failure cycle for each loop. The force at failure measurements should be an accurate representation of the materials properties when subjected to repeated loads. However, these measurements then do not account for material elongation that may have occurred during cycling, thus the ability to draw conclusions from the elongation and stiffness values obtained from the cycled testing may be limited.

Polymeric materials are sensitive to temperature, environment, and rate of testing. These factors may have a significant effect upon the results of mechanical testing. However, mechanical testing chambers that contain bodily fluids and can be temperature regulated are very expensive. Polymers such as NLL are sensitive to small temperature changes and are much more likely to interact with their environment than metals. Polymers are more likely to absorb water and other molecules in the surrounding fluid (Lucas et al. 1999). Previous studies evaluating NLL have performed all mechanical testing at room temperature. One group of 27.3 kgt NLL (CSK40°C) was tested at 40°C to determine the effect of temperature on the mechanical behavior of NLL. The force at failure was significantly lower in the loops tested at 40°C compared to loops of the same size NLL tested at room temperature. There were no significant differences in elongation and stiffness between the two groups.

Crimp clamps allow fixation of a loop by generating friction between the surface of the clamp and the material being fastened. Clamp placement causes a local deformation of the material that occurs at the clamp-material interface. This induces a bending moment in the NLL near the clamp. Local deformation and bending moments
also occur when the NLL is knotted making this portion of the loops the weakest (Anderson et al. 1998). Crimp-clamp systems for fixation of NLL loops used for LFS were proposed to eliminate elongation of the loop during knot slippage of large diameter NLL. A study using a novel crimp-clamp system for 27.3 kgt NLL found significantly less elongation and greater load to failure in crimped loops compared to knotted loops (Anderson et al. 1998). These findings are similar to our results, however, the crimp-clamp system used in that study was a novel design and not commercially available.

A clamped square knot with a total of five throws was used as a control in our study similar to previous reports (Caporn and Roe 1996; Lewis et al. 1997; Huber et al. 1999). A load to failure rate of 500 mm/min was also based on previous work with NLL (Caporn and Roe 1996; Anderson et al. 1998; Peycke et al. 2002). Unsterilized NLL was used for all samples. The effects of sterilization on material properties of NLL have been extensively examined (Caporn and Roe 1996; Lewis et al. 1997; Anderson et al. 1998; Peycke et al. 2002; Sicard et al. 2002) and have found conflicting results for steam vs. ethylene oxide sterilization protocols on the mechanical properties of NLL.

We conclude that the Securos Cranial Cruciate Ligament Repair System™ is an acceptable method for fixation of NLL loops used for LFS. This study supports the use of the 36 kg Securos® crimp-clamps with both 27.3 and 36.4 kgt NLL. However, use of the 18.2 kg Securos® crimp-clamp system cannot be recommended. The significantly less force required for failure in non-cycled testing, the high variability, and the tendency to pull through the clamps rather than the NLL breaking suggest that the crimp tube diameter or the crimping device may be inappropriate for use with 18.2 kgt NLL.
2.5 END NOTES

- Mason Hard Type Leader Material; Mason Tackle Company., Otisville, MI, USA
- Labeled as 40, 60, and 80 pound test, respectively
- Securos, Inc., E. Brookfield, MA 01515, USA
- Abbott Labs, N. Chicago, IL 60064, USA
- Weck Instruments, KMedic, 190 Veterans Drive, Northvale, NJ, USA
- Industrial Process Controls, Melbourne, Australia
- SAS v 8.2, SAS Institute, Cary, NC, USA

2.6 REFERENCES


CHAPTER 3. IN VITRO EVALUATION OF FLUOROCARBON LEADER LINE FOR USE AS A LATERAL FABELLA-TIBIAL SUTURE*

3.1 INTRODUCTION

Cranial cruciate ligament (CCL) rupture is a common injury causing stifle instability in dogs, which is a major cause of degenerative joint disease (Piermattei and Flo 1997). Surgical stabilization of the stifle after CCL rupture is recommended for dogs weighing more than 15 kg (Vasseur 1984). A variety of surgical techniques for stabilization of the stifle after CCL rupture have been described (Flo 1975; Shires et al. 1984; Smith and Torg 1985; Slocum and Slocum 1993). There remains considerable debate regarding which surgical technique leads to the best clinical outcome. A commonly performed technique is extracapsular stabilization with a lateral fabella-tibial suture (LFS), using large diameter nylon leader line (NLL) (Caporn and Roe 1996). The LFS provides short-term stabilization of the stifle while periarticular fibrosis develops, causing permanent stifle stability (Piermattei and Flo 1997).

Extracapsular stabilization using a LFS requires a strong suture material that minimizes bacterial adherence and has minimal plastic deformation. The implant material must withstand cyclical loading and tension of approximately 120 N to 600 N, during normal activity in the dog (Nwadike and Roe 1998). In addition, it must withstand deformation during knot tying, or during the application of a crimp-clamp. Loading and tension of some materials may lead to excessive elongation or failure of the LFS prior to the formation of adequate periarticular fibrosis. If this occurs, the repair fails.

Because of the mechanical demands placed on the LFS there have been many studies evaluating the properties of NLL and other commercially available materials. These studies have attempted to discern the: best knot or fixation method, the most
mechanically suitable material, and the effects of sterilization on NLL and nylon fishing line (NFL) (Caporn and Roe 1996; Lewis et al. 1997; Anderson et al. 1998; Nwadike and Roe 1998; Huber et al. 1999; Sicard et al. 1999; Peycke et al. 2002; Sicard et al. 2002). These studies have shown that NLL appears to have suitable mechanical properties for use as a LFS, however; inherent properties of NLL such as memory, low coefficient of friction, and large diameter may compromise knot security.

The ideal suture material has long been recognized as one that handles easily, holds securely when knotted, has sufficient strength for its intended purpose, and is non-capillary, non-allergenic and non-carcinogenic. When considering the LFS, mechanical forces on the suture necessitate a material that has a high tensile strength, minimal elongation and high stiffness (Huber et al. 1999). Following the general principles of suture selection in surgery, the smallest suture providing adequate strength should be used. Smaller suture diameter results in the formation of a more secure knot. A knot related effect has been demonstrated when using the larger 36 kgt NLL. Use of the larger diameter and stiffer NLL results in a mechanically inferior loop, thus any benefit to be gained from using a high tensile strength material may be lost (Caporn and Roe 1996).

Fluorocarbon (polyvinylidene fluoride; PVDF) has been investigated as a biomaterial for a variety of surgical implants (Brosnahan et al. 1981; Urban et al. 1994; Laroche et al. 1995; Klinge et al. 2002). Both PVDF and PVDF copolymers are available as monofilament suture material worldwide. Studies have shown PVDF to have superior handling characteristics, excellent biocompatibility, and less susceptibility to iatrogenic damage from placement of needle holders than is polypropylene (Urban et al. 1994). PVDF has a similar mechanical profile when compared to polypropylene for use as a
vascular suture material (Urban et al. 1994; Hong et al. 1998). When used for tendon reconstruction, PVDF monofilament suture was found to be superior to polypropylene suture, which resulted in a greater tendon gap and breaking strengths (Wada et al. 2001).

A PVDF monofilament is available as fluorocarbon leader line (FCL) from a variety of companies that market fishing lines. These lines are marketed as being superior to nylon because of superior knot strength, less water absorption, and greater stiffness. For a given tensile strength, FCL is approximately one-half the diameter of NLL of the same tensile strength. The smaller diameter FCL could eliminate some of the problems encountered with knot security and handling of NLL. In addition, the smaller diameter of FCL would result in less foreign material being implanted and a less bulky knot, resulting in less tissue irritation in the region of implantation. If this is true, FCL may prove to be superior to NLL for use as a LFS.

Our study evaluated the effects of sterilization on length and diameter and the mechanical performance of 18, 27, and 36 kg test (kgt) FCL constructed with a clamped square knot. Mechanical performance was compared to non-sterilized clamped square knots constructed with the same tensile strength NLL. Force at failure, loop elongation, and stiffness were recorded under non-cycled testing conditions.

3.2 MATERIALS AND METHODS

The materials tested were 18.2, 27.3, and 36.4 kgt fluorocarbon leader line (FCL) and nylon leader line (NLL). The manufacturer reported diameters of the materials were: 0.60, 0.73, 0.91 mm and 0.91, 1.07, 1.17 mm for the 18.2, 27.3, and 36.4 kgt FCL and NLL, respectively. Sixty strands of each tensile strength FCL were cut to a length of 40 cm. Twenty strands of each tensile strength of FCL were sterilized by:
1) steam sterilization, 30 minutes at 270°F and by,

2) ethylene oxide sterilization, 100% ethylene oxide for 4 hours at 133°F.

Twenty strands of each tensile strength FCL were non-sterilized as controls. Twenty strands of each tensile strength NLL were cut to a length of 40 cm and non-sterilized as controls. All loops for each material tensile strength and type were fixed by one surgeon around a customized 42.42 mm outer diameter polyvinyl chloride pipe to ensure a consistent-size loop. The pipe was customized to allow for the application of needle holders by cutting a 1.5 cm by 5 cm slot out of each end of the pipe using a small burr. The edges of the slot were taped in order to prevent damage to the materials during loop formation, prior to loop formation, each strand was passed through room temperature 0.9% NaCl solution and every strand of each material type and tensile strength was secured by means of a clamped square knot. The clamped square knots were formed by clamping the first throw of the knot with a pair of 17.7 cm Mayo-Hegar needle holding forceps (modified by filing the surface of the jaws so they were completely smooth) closed to the third ratchet of the locking mechanism. A total of five throws were placed for each clamped square knot.

All of the mechanical testing was performed at room temperature (20°C). All loops were mounted onto an IPC Digital Servo Machine between two horizontally-oriented polished steel hooks set 56 mm apart and tension was applied to each loop at a constant distraction rate of 500 mm/min until the loops failed by breaking or slipping. The force at failure, elongation, and stiffness were recorded and compared between groups. The stiffness measurement recorded was the maximum value obtained from the linear portion of the load vs. elongation curve for each trial.
Twenty strands of FCL of each tensile strength were cut to a length of 30 cm. The diameter measurements were taken from three points, randomly selected on each strand, using a digital micrometer calibrated to $10^{-2}$ mm. Ten strands from each tensile strength FCL were then sterilized by steam and ten by ethylene oxide gas, as has been previously described. The measurements were then repeated to determine changes in post-sterilization length and diameter.

3.2.1 STATISTICAL METHODS – The force, elongation, stiffness, length and diameter measurements were considered continuous and found to follow a normal distribution using the Shapiro-Wilk test with failure to reject the null hypothesis of normality at $p \leq 0.05$. All of the data was summarized as mean +/- SEM.

For evaluation of force, elongation and stiffness of FCL, the data for each size was analyzed using a one-way analysis of variance so as to evaluate the effect of sterilization. Where there was a significant effect of sterilization at $p \leq 0.05$, comparisons between steam, ethylene oxide and non-sterilized samples were made using Scheffe’s procedure maintaining type I error at 0.05.

For comparison of force, elongation and stiffness of non-sterilized FCL and non-sterilized NLL, in order to evaluate the effect of material and size the data was analyzed using a two-way analysis of variance. Where there was significant interaction of material and size at $p \leq 0.05$, comparisons across material type and sizes were made using Scheffe’s procedure maintaining type I error at 0.05.

For evaluation of the length and diameter changes of FCL, the data for each size was analyzed using a one-way analysis of variance to evaluate the effect of sterilization. Where there was a significant effect due to sterilization at $p \leq 0.05$, comparisons between
steam, ethylene oxide and non-sterilized samples were made using Scheffe’s procedure maintaining type I error at 0.05.

Thus, where significance is noted in the results, unless specified, \( p < 0.05 \). PROC UNIVARIATE and PROC ANOVA was used for the analysis.

### 3.3 RESULTS

All of the loops were successfully constructed around the customized polyvinyl chloride pipe. Subjectively, handling and pliability was superior when using the FCL when compared to the NLL. Handling and pliability of FCL did not appear to be affected by ethylene oxide sterilization. Some difficulty in handling and reduced pliability of FCL was experienced when steam sterilized, especially when constructing loops with 36.4 kgt FCL.

For 18.2 and 27.3 kgt FCL, all of the loops failed at a portion originally contained within the knot. The force at failure was significantly greater in steam sterilized loops than non-sterilized and ethylene oxide sterilized loops (Table 3.1). For 36.4 kgt FCL, loops that had been steam sterilized elongated to the limit of the machine without failure, hence mechanical data was not collected. The force at failure for all sizes of FCL was not significantly different between non-sterilized and ethylene oxide sterilized loops.

For 18.2 and 27.3 kgt FCL, elongation was significantly greater in steam sterilized loops than non-sterilized and ethylene oxide sterilized loops. For all of the sizes of FCL, the elongation was not significantly different between non-sterilized and ethylene oxide sterilized loops. For 18.2 kgt FCL, stiffness was significantly greater in ethylene oxide sterilized loops than in the steam sterilized FCL loops, but the stiffness was not significantly different between the ethylene oxide sterilized loops and the
**Table 3.1.** Mean (SEM) ultimate force, elongation, and stiffness for non-sterilized and sterilized clamped square knot loops constructed with fluorocarbon leader line (n=20 for each group). The coefficient of variation (CV = mean/SD X 100) of the force and elongation is also reported. For force, elongation, and stiffness within each fluorocarbon leader line size, means with the same superscript are not significantly different. Note that type I error was maintained at 0.05 for all comparisons, hence where significant, $p \leq 0.05$.

*Steam sterilized samples of 36.4 kg fluorocarbon leader line elongated under load to the limits of the testing machine without failure, hence no data is reported.*

<table>
<thead>
<tr>
<th>Size</th>
<th>Force (N)</th>
<th>CV (%)</th>
<th>Elongation (mm)</th>
<th>CV (%)</th>
<th>Stiffness (N/mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>18.2 kg (40 lb)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unsterilized</td>
<td>283.4 (4.5)</td>
<td>7.1</td>
<td>13.3 (0.2)</td>
<td>6.5</td>
<td>30.6 (3.4)</td>
</tr>
<tr>
<td>Steam sterilized</td>
<td>316.8 (2.8)</td>
<td>3.9</td>
<td>21.9 (0.2)</td>
<td>3.9</td>
<td>24.2 (1.7)</td>
</tr>
<tr>
<td>Ethylene oxide sterilized</td>
<td>285.7 (5.5)</td>
<td>8.6</td>
<td>13.1 (0.2)</td>
<td>8.1</td>
<td>38.3 (3.8)</td>
</tr>
<tr>
<td>27.3 kg (60 lb)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unsterilized</td>
<td>386.3 (5.8)</td>
<td>6.7</td>
<td>14.2 (0.2)</td>
<td>7.8</td>
<td>29.0 (1.0)</td>
</tr>
<tr>
<td>Steam sterilized</td>
<td>411.0 (2.8)</td>
<td>3.1</td>
<td>21.8 (0.1)</td>
<td>3.1</td>
<td>23.2 (1.6)</td>
</tr>
<tr>
<td>Ethylene oxide sterilized</td>
<td>371.4 (5.9)</td>
<td>7.1</td>
<td>13.6 (0.2)</td>
<td>7</td>
<td>32.4 (1.6)</td>
</tr>
<tr>
<td>36.4 kg (80 lb)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unsterilized</td>
<td>493.6 (10.4)</td>
<td>9.5</td>
<td>21.1 (0.2)</td>
<td>4.2</td>
<td>23.4 (0.3)</td>
</tr>
<tr>
<td>Steam sterilized</td>
<td>n/a*</td>
<td>n/a*</td>
<td>n/a*</td>
<td>n/a*</td>
<td>n/a*</td>
</tr>
<tr>
<td>Ethylene oxide sterilized</td>
<td>513.1 (12.0)</td>
<td>10.5</td>
<td>21.3 (0.3)</td>
<td>7.1</td>
<td>25.1 (1.0)</td>
</tr>
</tbody>
</table>
non-sterilized loops, nor between the non-sterilized and steam sterilized loops. For 27.3 kgt FCL, stiffness was significantly greater in the non-sterilized and ethylene oxide sterilized loops than the steam sterilized loops, but the stiffness was not significantly different between non-sterilized and ethylene oxide sterilized loops. For 36.4 kgt FCL, stiffness was not significantly different between non-sterilized and ethylene oxide sterilized loops.

Load vs. elongation curves were plotted for each tensile strength and type of material tested (Figure 3.1). When comparing non-sterilized FCL to equivalent tensile strength non-sterilized NLL, the larger diameter (27.3 and 36.4 kgt) NLL undergoes a noticeable amount of elongation under a fairly low load. This was not observed with any tensile strength FCL and was less obvious for the 18.2 kgt NLL.

When comparing non-sterilized FCL to equivalent tensile strength non-sterilized NLL, the force at failure was not significantly different between FCL loops and NLL loops for any size tested (Table 3.2). For 18.2 kgt material, elongation was significantly greater in FCL loops than NLL loops. For 27.3 kgt material, elongation was not significantly different between FCL loops and NLL loops. For 36.4 kgt material, elongation was significantly greater in FCL loops than NLL loops. The stiffness was not significantly different between FCL loops and NLL loops for any size tested.

There was a consistent, significant effect of sterilization method on the diameter and length of the FCL for each tensile strength tested. All of the steam sterilized samples showed a significant reduction in length when compared to non-sterilized and ethylene oxide sterilized samples (Table 3.3). All steam sterilized samples showed a significant increase in diameter compared to non-sterilized and ethylene oxide sterilized samples.
Figure 3.1. Load vs. elongation curves for 18.2, 27.3, and 36.4 kgf non-sterilized fluorocarbon leader line (FCL) and nylon leader line (NLL). Note the pronounced early elongation under minimal load for the NLL compared to the FCL. This phenomenon is particularly noticeable for the larger diameter materials (27.3 and 36.4 kgf NLL). Load vs. elongation curves do not include all data points to failure.
Table 3.2. Mean (SEM) ultimate force, elongation, and stiffness for non-sterilized clamped square knot loops constructed with fluorocarbon leader line (FCL) and nylon leader line (NLL) (n=20 for each group). The coefficient of variation (CV = mean/SD X 100) of the force and elongation is also reported. For comparisons across size and type of material, down each column, means with the same superscript are not significantly different. Note that type I error was maintained at 0.05, hence where significant, p ≤ 0.05.

<table>
<thead>
<tr>
<th>Size</th>
<th>Force (N)</th>
<th>CV (%)</th>
<th>Elongation (mm)</th>
<th>CV (%)</th>
<th>Stiffness (N/mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Method of Sterilization / Type</td>
<td>18.2 kg (40 lb)</td>
<td></td>
<td></td>
<td>27.3 kg (60 lb)</td>
<td></td>
</tr>
<tr>
<td>Unsterilized / NLL</td>
<td>265.5 (3.6)</td>
<td>6.1</td>
<td>11.5 (0.2)</td>
<td>9.7</td>
<td>34.0 (1.7)</td>
</tr>
<tr>
<td>Unsterilized / FCL</td>
<td>283.4 (4.5)</td>
<td>7.1</td>
<td>13.3 (0.2)</td>
<td>6.5</td>
<td>30.6 (3.4)</td>
</tr>
<tr>
<td>Unsterilized / NLL</td>
<td>387.7 (4.5)</td>
<td>5.2</td>
<td>14.3 (0.4)</td>
<td>11.2</td>
<td>28.6 (0.6)</td>
</tr>
<tr>
<td>Unsterilized / FCL</td>
<td>386.3 (5.8)</td>
<td>6.7</td>
<td>14.2 (0.2)</td>
<td>7.8</td>
<td>29.0 (1.0)</td>
</tr>
<tr>
<td>Unsterilized / NLL</td>
<td>498.1 (3.6)</td>
<td>3.3</td>
<td>18.7 (0.2)</td>
<td>4.6</td>
<td>28.5 (0.6)</td>
</tr>
<tr>
<td>Unsterilized / FCL</td>
<td>493.6 (10.4)</td>
<td>9.5</td>
<td>21.1 (0.2)</td>
<td>4.2</td>
<td>23.4 (0.3)</td>
</tr>
</tbody>
</table>
Table 3.3. Mean (SEM) length and diameter of non-sterilized, steam sterilized, and ethylene oxide sterilized fluorocarbon leader line. Within each size of fluorocarbon leader line means down each column with the same superscript are not significantly different. Note that type I error was maintained at 0.05, hence where significant, \( p \leq 0.05 \).

<table>
<thead>
<tr>
<th>Method of Sterilization</th>
<th>Length (mm) 18.2 kg</th>
<th>Diameter (mm) 18.2 kg</th>
<th>Length (mm) 27.3 kg</th>
<th>Diameter (mm) 27.3 kg</th>
<th>Length (mm) 36.4 kg</th>
<th>Diameter (mm) 36.4 kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unsterilized</td>
<td>b30.00 (0.00)</td>
<td>b0.62 (0.00)</td>
<td>q30.00 (0.00)</td>
<td>q0.74 (0.00)</td>
<td>y30.00 (0.0)</td>
<td>y0.91 (0.00)</td>
</tr>
<tr>
<td>Steam sterilized</td>
<td>a26.26 (0.05)</td>
<td>a0.67 (0.00)</td>
<td>p26.53 (0.05)</td>
<td>p0.78 (0.00)</td>
<td>x23.24 (0.06)</td>
<td>x1.03 (0.00)</td>
</tr>
<tr>
<td>Ethylene oxide sterilized</td>
<td>b29.99 (0.04)</td>
<td>b0.63 (0.00)</td>
<td>a30.00 (0.00)</td>
<td>a0.74 (0.00)</td>
<td>y29.95 (0.05)</td>
<td>y0.91 (0.00)</td>
</tr>
</tbody>
</table>
There was not any significant difference in length or diameter between non-sterilized and ethylene oxide sterilized samples.

3.4 DISCUSSION

For a new biomaterial to be considered for clinical application, it should not only possess equivalent characteristics to existing materials in use, but also perform significantly better than the currently used material. Evaluation of material for a LFS should consider both the mechanical and handling characteristics (Peycke et al. 2002). The results of this study suggest that non-sterilized FCL possesses equivalent mechanical characteristics to that of non-sterilized NLL. The reduced diameter and pliability of FCL make its handling characteristics superior to NLL. In addition, ethylene oxide sterilization does not significantly affect the mechanical or handling characteristics of FCL.

There was not any significant difference in force at failure and stiffness for any tensile strength FCL and NLL tested. When choosing a material for use as a LFS desirable mechanical properties include high tensile strength, minimal elongation, and high stiffness. Although we were unable to show any significant differences in force at failure and stiffness between FCL and NLL, elongation was greater in the 18.2 and 36.4 kgt FCL when compared to the same size NLL. However, the clinical importance of evaluating elongation of materials for LFS has been questioned by previous investigators (Huber et al. 1999). Ideally, a strong material with a high stiffness is desirable since it would allow minimal elongation when subjected to loads less than that of failure. With this consideration, FCL appears to be mechanically equivalent to NLL of the same tensile strength.
Evaluating the load vs. elongation curves for each tensile strength and type of material tested revealed an interesting trend (Figure 3.1). The larger diameter (27.3 and 36.4 kgt) NLL underwent a noticeable amount of elongation under a fairly low load. This was not noticed with any tensile strength FCL and was less obvious for the 18.2 kgt NLL. The diameters of the FCL tested were 0.60, 0.73, 0.91 mm for the 18.2, 27.3, and 36.4 kgt, respectively, compared to 0.91, 1.07, 1.17 mm for the 18.2, 27.3, and 36.4 kgt NLL. The 36.4 kgt FCL then has the same diameter of the 18.2 kgt NLL. Since the tendency for this elongation at a low load was less obvious in the 18.2 kgt NLL, we speculate that this trend is related to the large diameter of the NLL. The large diameter makes forming a tight knot difficult. This initial elongation could represent knot tightening under low load or could be a result of a material property of the NLL. Previous studies have demonstrated similar findings regarding 36.4 kgt NLL. Unacceptable elongation with the 36.4 kgt NLL, using traditional knotting methods, is proposed to be from the inability to form a tight knot (Caporn and Roe 1996). However, this phenomenon was also apparent when looking at the 27.3 kgt NLL. Although we can only speculate as to the mechanical behaviour of these materials *in vivo*, the resultant stifle instability occurring due to elongation of the NLL at low loads may be eliminated by the use of FCL.

In order to eliminate cranial drawer sign previous authors have recommended the placement of a LFS with the tightest and most secure knot possible (Nwadike and Roe 1998). The only way to increase knot security when choosing a high tensile strength material is to reduce the diameter of the material, or change the method of fixation. Previous investigators have demonstrated equivalent to superior mechanical performance
of NLL when privately designed or commercially available crimp-clamp systems are used (Anderson et al. 1998; Peycke et al. 2002; Sicard et al. 2002). Crimp-clamps are used to secure FCL when making commercial fishing leaders, which would make it possible to develop a crimp-clamp system for use with FCL thus eliminating the knot, reducing the irritation to the soft tissues, and potentially improving its mechanical performance.

Steam sterilization had profound effects on each tensile strength of FCL tested. A significant reduction in length and significant increase in diameter were observed. These effects were proportional to the size of the material, with the greatest effect seen with the 36.4 kgt FCL. Steam sterilization also changed the handling properties of the FCL during loop formation. Significant increases in elongation, as well as reduction of stiffness make the mechanical properties of steam sterilized FCL unacceptable for use as a LFS. There were not any significant changes in mechanical properties when FCL was ethylene oxide sterilized. Based on these findings, we recommend that FCL be ethylene oxide sterilized when used for a LFS. There are environmental concerns in regards to ethylene oxide gas sterilization because of the addition of diluent gases containing chlorinated fluorocarbons. There are currently available means of reducing the environmental contaminants by adding nitrogen as a diluent, or using 100 % ethylene oxide gas, which was used in this study. Previous studies have also shown that PVDF monofilaments can be sterilized by β and γ radiation without significant structural or mechanical change (Urban et al. 1994).

Other studies have demonstrated a variety of potential benefits of PVDF suture material compared to polypropylene. When compared to polypropylene, PVDF suture
induces a minimal inflammatory response, and has shown superior long-term stability by retaining 93% of its initial tensile strength over a nine year period, when compared to 53% for polypropylene (Laroche et al. 1995). PVDF suture has demonstrated greater knot pull strength and greater creep resistance when compared to polypropylene (Urban et al. 1994; Wada et al. 2001). PVDF sutures have also been shown to be more resistant to iatrogenic damage caused by needle holders (Urban et al. 1994).

There has been a variety of studies looking at various knot formations and alternatives to knotting when using NLL (Anderson et al. 1998; Peycke et al. 2002). A clamped square knot and sliding half-hitch have both been shown to perform well. A sliding half-hitch has been recommended for use with 27 kgt NLL (Nwadike and Roe 1998). Clamping the first throw of a square knot was found to increase the structural stiffness of the loop, also allowing for the formation of a tighter, more secure knot (Huber et al. 1999). Based on these previous studies we chose to use a clamped square knot as the method of loop fixation. It was outside the scope of this study to evaluate all the potential knotting methods and their effects regarding the use of FCL. Further studies looking at various knot formations and crimp-clamps would be indicated before their use in a clinical setting.

In conclusion, FCL affords the veterinary surgeon another option when considering a LFS. Polyvinylidene fluoride is a biologically inert, biocompatible material. The reduced diameter and desirable material properties of FCL compared to NLL allow for superior handling, formation of a less bulky and potentially more secure knot, and less foreign material in the region of implantation. When a clamped square knot is used FCL performs mechanically similar to NLL and eliminates elongation under
low load observed with NLL. Steam sterilization is not recommended when using FCL. FCL has the potential to be used with a variety of knot configurations and crimp-clamp systems, which could further improve its clinical performance.

3.5 END NOTES

a  Seagaur Fluorocarbon Leader Line; GBS Distribution, Port St. Lucie, FL, USA
b  Mason Hard Type Leader Material; Mason Tackle Co., Otisville, MI, USA
c  Labelled as 40, 60, and 80 pound test, respectively
d  Amsco (Prevac) Steam Sterilizer, Steris Co., Mentor, OH, USA
e  H.W. Anderson Products, Chapel Hill, NC, USA
f  Abbott Labs, N. Chicago, IL, USA
g  Weck Instruments, K Medic, Northvale, NJ, USA
h  Industrial Process Controls, Melbourne, Australia
i  Preisser Digital Micrometer, Erich Preisser Co., West Germany
j  SAS v 8.2, SAS Institute, Cary, NC, USA

3.6 REFERENCES


ASAIO J 44: 776-785.


4.1 SUMMARY

Cranial cruciate ligament (CCL) rupture continues to be a debilitating injury in the dog. Untreated dogs show degenerative joint disease in the stifle within a few weeks, and will have severe changes within a few months. Currently there are no means to reverse the degenerative joint disease that develops. With current surgical techniques, dogs will improve after surgery but will continue to have pain and lameness originating from the stifle for the remainder of their life. This pain and lameness can dramatically inhibit the performance of sporting breeds and disable the working dog, thus having a dramatic impact on dogs and their owners. Surgeons continue to look for a better means to stabilize the stifle joint in dogs with CCL rupture in order to reduce the degree of degenerative joint disease that develops. Research in both humans and animals continue to investigate methods to regenerate damaged cartilage. At this time there are no feasible clinical techniques for hyaline cartilage regeneration in the dog. Thus, treatment for CCL rupture relies upon surgical stabilization of the stifle and medicinal therapies to alleviate pain. Physical rehabilitation to improve muscle mass and joint range of motion can also aid in recovery of dogs with CCL rupture.

Extracapsular surgical techniques using a lateral fabella-tibial suture (LFS) is a commonly performed technique in dogs with CCL rupture. Compared to other techniques, the LFS is less technically demanding and awards good to excellent clinical results. Studies have demonstrated nylon leader line (NLL) to have appropriate material properties for use, however, knot security may be compromised and NLL is difficult to handle. To eliminate the bulky knot formed with NLL, crimp-clamp systems have been used. The surface interactions between the clamp and the NLL generate friction to secure
the two ends of the NLL together. Having the appropriate crimp tube diameter pre- and post-crimping is essential to generate enough friction to prevent pull-through yet not extremely deform the material, and weaken the loop. The Securos Cranial Cruciate Ligament Repair System™ is a crimp-clamp system that allows for tensioning and securing the loop of NLL without assistance. The 36 kg Securos® system using both 27 and 36 kgt NLL performed well in this study, resulting in loops that had a high force at failure, minimal elongation, and a high stiffness. We support the use of the 36 kg Securos® system for use as a LFS using both 27 and 36 kgt NLL. The poor performance of the 18 kg Securos® system when compared to a clamped square knot appears to be due to inappropriate design of the crimp tube or an inadequate crimping device applied for this system. The fact that the NLL pulled through the clamps and loops exhibited a considerable variability in the force at failure and elongation suggests there is insufficient friction generated between the clamp and material. We do not recommend use of the 18 kg Securos® system due to its unpredictable performance during in vitro testing.

Fluorocarbon (polyvinylidene fluoride; PVDF) leader line has many desirable qualities for use as a LFS. Its small diameter to tensile strength ratio and pliable feel facilitate the formation of a tight knot. As well, its increased abrasion resistance makes it less likely to be damaged by the placement of needle holders during the formation of a CSK. In this study, fluorocarbon leader line (FCL) had similar mechanical performance to NLL when secured with a clamped square knot. As well, elongation under low load observed with NLL was not observed with FCL. Fluorocarbon and fluorocarbon co-polymer have become available world-wide as commercial suture materials.
Fluorocarbon suture is being marketed as a replacement to polypropylene due to its excellent biocompatibility, long-term structural integrity, and ease of handling. Fluorocarbon leader line is an acceptable alternative to NLL for use as a LFS.
APPENDIX

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Max Nielsen Banwell was born June 28, 1974, and was raised in Lincoln, Nebraska. He graduated from Lincoln High School in 1992. He attended the University of Nebraska at Lincoln from 1992 to 1996. He was an active member of the Sigma Chi fraternity at the University of Nebraska. He received his bachelor’s degree in Veterinary Science in August of 1998 from the University of Nebraska at Lincoln. He was accepted to Kansas State University College of Veterinary Medicine in Manhattan, Kansas in 1996, and graduated *cum laude* with a Doctor of Veterinary Medicine degree in 2000.

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