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Design of an Orthopedic Device to Prevent Lumbosacral Stenosis in Military Working Dogs

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Design of an Orthopedic Device to Prevent Lumbosacral Stenosis in Military Working Dogs

A Major Qualifying Project submitted to the Faculty of Worcester Polytechnic Institute in partial fulfillment of the requirements for the Degree of Bachelor of Science

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Abstract

The goal of this study was to design an inexpensive and implantable orthopedic device to alleviate spinal cord pressure in the lumbosacral joint of military working dogs. The primary objectives of this study were to design a safe, easily implantable, and manufacturable device to relieve pain caused by lumbosacral stenosis by reducing stresses on the lumbosacral facet joint. The loading on the this joint was determined to be up to 200N, and the displacement in the lumbosacral joint during normal canine movement to be 2mm during a cadaver dissection. The device is made up of three parts, a central spring and two accompanying endplates. The three pieces are micro-welded together. The plates are unique to be mounted on either the L7 or S1 vertebrae after the spinuous process has been removed. The spring is a commercially available product. Holes were incorporated into the design of the plate to accommodate 2mm self-tapping cortical screws and allow space for their countersinks to improve screw grip strength. Testing of the commercially available spring showed displacement capacity over 5mm and loads of up to 625N. After assembly, mechanical testing of the device withstood loads of 225N and displacements of 5mm. Thus, the device provides a means of alleviating stress in the lumbosacral joint while preserving range of motion.

1 Introduction

Humans have long used well-trained canines as a form of protection. In today's society, the role of canines in protection services has greatly evolved. Due to the large number of scent receptors in the canine nose, they are capable of detecting and distinguishing materials by scent alone, a task humans are incapable of accomplishing. As a result of this keen ability and the trainable nature of dogs, the United States military currently trains over 500 dogs per year through the Military Working Dogs Program. Huge amounts of time and money are invested in these animals; caretaking alone costs about $11,000 per year, per dog. The canines trained as Military Working Dogs are used worldwide to detect explosives, uncover narcotics, or serve as physical security.

When considering the monetary investment the military has made in these animals, the length of service is a primary concern. It is easier and more cost-effective for the military to care for older dogs than it is to train completely new ones. The longer dogs stay in service, the better the return on investment the military sees. One condition that has sidelined many dogs is lumbosacral stenosis, caused by a compression of the nerves in the lower back. This can lead to pain, lameness, an unwillingness to walk, jump, or crawl, and a generally poor quality of life for the dog. The pain and other symptoms from this condition can become so severe that dogs must be removed from military service. At that point, they may be adopted or euthanized.

The goal of this project is to design an implantable orthopedic device for canine use to relieve pressure on the spinal nerves, thereby alleviating pain and allowing for a return to normal function. Current surgical treatment methods are somewhat effective, but have undesirable consequences such as a reduced range of motion and a tendency for reoccurrence. By designing a new device to meet very specific needs, we hope to be able to allow military working dogs to be free from pain and return to service.

2 Background

2.1 Military Working Dogs Program

Canines have been used to protect human life and property for many years. Well-trained dogs have proven to very reliable in their detection of intruders, foreign substances, and other dangerous materials. This makes them appropriate companions for humans during times of war. Since World War II, the United States military has been training thousands of canines for use in detection and scouting teams. These highly trained dogs are valuable members of any military team because they can scout areas before soldiers enter to detect bombs or other destructive chemicals. The canine sense of smell is much greater than that of a human. Humans have approximately five to fifteen million smell receptors, whereas the number in a dog can range from 125 to 250 million. (Mott, 2003)

2.1.1 Types of Canines

The military working dogs (MWD) program currently employs two main types of canines for their training. The German Shepherd (Figure 1) and Belgian Malinois (Figure 2) are considered to be the best choices for the standard military working dog because they are intense, intelligent, and are known for their ability to work hard. (Mott, 2003)

Figure 1: German Shepherd (American Kennel Club, 2009)

Figure 2: Belgian Malinois (American Kennel Club, 2009)

The canines accepted into the MWD Program must be between twelve and thirty-six months of age and weigh at least fifty-five pounds. These dogs are chosen because they have the best overall combination of endurance, speed, strength, courage, intelligence, sense of smell, and adaptability to almost any climatic condition. German Shepherds and Belgian Malinois are the best suited for jumping, climbing, and standing, which are all necessary in the detection of explosives and other foreign materials. On average, these four-footed soldiers are 98% accurate in their detection abilities, and depending on the conditions can work for up to twelve hours per day.

MWDs are mostly purchased from American breeders (80%), but some are procured from foreign breeders (20%). Almost all of the foreign canines are purchased from French breeders, with an average cost of $4,000 per canine. Both genders are accepted for purchase; however, female dogs must be spayed before they are evaluated for acceptance into the training program. Before purchase, the canines are put through a number of tests to analyze their characteristics and skills. The temperamental attributes considered include gun shyness, aggressiveness, and their searching behavior. A physical examination is also conducted which includes blood testing for ringworms and heartworms, radiographic inspection of the hips and elbows, and a full-body examination of bone and muscle structure.

If a canine passes all of these exams, they may enter into the training program. (Mott, 2003) After the canines are admitted for training, the average cost to care and maintain the dogs is about $11,000 per year for each dog.

2.1.2 Training

Since the September 11, 2001 terrorist attacks on the United States the U.S. military has trained over 500 canines per year, a significant increase compared to years before that. The canines are a part of the 341st Training Squadron, formerly known as the Department of Defense (DoD) Military Working Dog School, located at Lackland Air Forces Base, TX. The Lackland Air Force Base MWD training facility consists of sixty-two training areas, encompassing over 3,350 acres, and 691 kennel spaces for training and housing the average population of 500 canines. (K-9 History: DoD MWD Training School, 2006)

The mission of the 341st Training Squadron is to provide trained military working dogs for use in patrol, drug and explosive detection, and specialized mission functions for the Department of Defense and other government agencies, including the Transportation Security Administration. The 341st Training Squadron also conducts operational training of MWD handlers and supervisors. Additionally, the squadron sustains the MWD program through logistical support, veterinary care, and research and development for security efforts worldwide.

Beginning in October 2002, the dog training section developed a new MWD course to monitor dog training. The class is divided into four blocks. Block one consists of instructing socialization and building a rapport with the assigned handler. Block two is basic obedience, including learning commands such as sit, down, and stay. Block three is detection, and block four is patrol. This is based on a 100-day training cycle to dually-certify and ship MWDs to the field. Explosive/patrol detector dogs are trained and certified to detect at or above a 95% accuracy rate. Dogs are taught nine different explosive odors and trained in many different environments such as offices, barracks, theaters, warehouses, aircraft, and vehicles. Drug/patrol detector dogs are trained and certified to detect at or above a 90% accuracy rate four different drugs in the same environments. After the MWD is trained in explosive or drug detection, it is then trained in patrol, which consists of obedience, out and guard, building search, gunfire, and scouting. (Parker, Emery, & Chandler, 2003)

This program includes initial training, proficiency training, weapon fire training, obedience course training, and decoy training. Initial training is performed at a basic level for both the handler and the dog, and is not intended to prepare either the handler or the dog for immediate duty in an MWD team. This training gives a basic overview of the MWD program, the health and care of MWDs, and proper training techniques. Proficiency training requires a standard of at least four hours of training each week in patrol and at least four hours of training each week in narcotic or explosive detection. The minimum standard of proficiency to maintain certification as a detector team is 90% or higher for narcotic detection dogs and 95% or higher for explosive detection dogs. No dog is allowed to produce a false positive rate of more than 10%.

Training on weapon firing ranges is essential for the patrol dog to become proficient at, and to not be deterred from, attacking agitators during gunfire. The dog must not attack the handler during gunfire. The firing of all weapons assigned to the handler should be done with the MWD present when possible. Patrol dogs can be desensitized with the firing of many different types of weapons. This is often accomplished by arranging for the handlers to take the dogs to weapon ranges of different units.

To determine the dog's reaction to the sound of gunfire, it may be necessary for the handler to use counter conditioning techniques until the desired proficiency is achieved. Counter conditioning techniques include starting at distances of 300 meters and slowly bringing the gunfire closer to the dog or, as safety allows, bringing the dog closer to the weapon. The goal of this training exercise is for the dog not to bark or show any signs of aggression when the handler fires all of the assigned weapons. This process can be slow and take several days.

The obedience course exposes the canines to various obstacles that simulate walls, open windows, tunnels, ramps, or steps. The dog's exposure to these obstacles reduces the amount of time required to adapt dogs to different environments. The dog learns to negotiate each of the obstacles. This ensures that when a dog is confronted with a similar obstacle in the working environment, it is not deterred from completing its mission. The obedience course also develops the handler's ability to control the dog's behavior both on and off a leash. However, the obedience course is not a substitute for exercise. A dog should never be required to complete the obedience course until he has been warmed up by proper exercise.

2.1.3 Types of Missions for MWD

After the canines have completed their training and are paired with their designated trainers and teams, the teams are briefed with the orders for their missions. Due to their basic training, most of the canines will work as patrol dogs (PD). These canines work with soldiers and officers on security and patrol. A few of the activities of a PD include: area security operations, route reconnaissance/surveillance operations, checkpoints, area defense, internment and resettlement operations, perimeter security, narcotic and/or explosives detection, police intelligence operations, law and order operations, and recovery operations (Riley, 2005). Area security operations can be further broken down into defensive operations and combat patrols.

Although all of the dogs are trained in the basics of patrolling and obedience, some of the dogs move on to become patrol narcotic detectors (PNDD), while others become patrol explosive detectors (PEDD). These are the classes of MWD. The different types of missions each class of MWD (PD, PEDD, PNDD) may be asked to complete is summarized in a table in Appendix A.

2.2 Canine Anatomy

2.2.1 Spinal Structure

The anatomy of the canine spine is similar in structure to the human spine, but differs in the plane of action. The human spine performs in the vertical plane (y-axis), while the canine spine acts primarily in the horizontal plane (x-axis). Also, the canine spinal system has additional thoracic vertebra and two more lumbar vertebrae than the human spine. The canine spinal system is designed for support and movement. The spine has four primary regions: cervical, thoracic, lumbar, and sacral. The structure of the canine spine can be seen in Figure 3. The cervical region contains seven vertebrae, the thoracic contains thirteen, the lumbar seven, and sacral three. Along with these primary regions, the tail region contains vertebrae, but they do not have a great impact on the spinal structure of the animal.

The vertebrae most involved in canine back pain caused by lumbosacral stenosis (See Section 2.3 Lumbosacral Stenosis) are the seven lumbar and three sacral vertebrae. More specifically, there is a focus on the lower back region of L7-S3 (Figure 4). The lumbar vertebrae are rather large and are longer than most other vertebrae. The lumbar vertebrae face medially and laterally. Because of this orientation, the lumbar region of the spine is very well-suited for flexion and extension in the dorsoventral direction (Smith, 1999). The degree of motion for the vertebra is shown in Table 1, collected from an in vivo study measuring angle of rotation about the x, y, and z axes under a torque of 3Nm (Benninger M, 2004). The x, y, and z axes are oriented as shown in Figure 5.

These rotational angles support the conclusion that the lumbar region of the spine is very well-suited for flexion and extension due to L7-S1 having the highest degree of motion in flexion-extension. The sacral vertebrae are only present in the fetus and young dogs, up to eighteen months old, and then the three vertebrae fuse together to form the sacrum (Smith, 1999). Running through the sacrum is the sacral canal, which continues the spinal canal through this area. The sacrum serves as a support for the pelvis region. More support for the spine is credited to the various muscles, ligaments, and tendons that are connected throughout the spine to give the canine a strong horizontal plane.

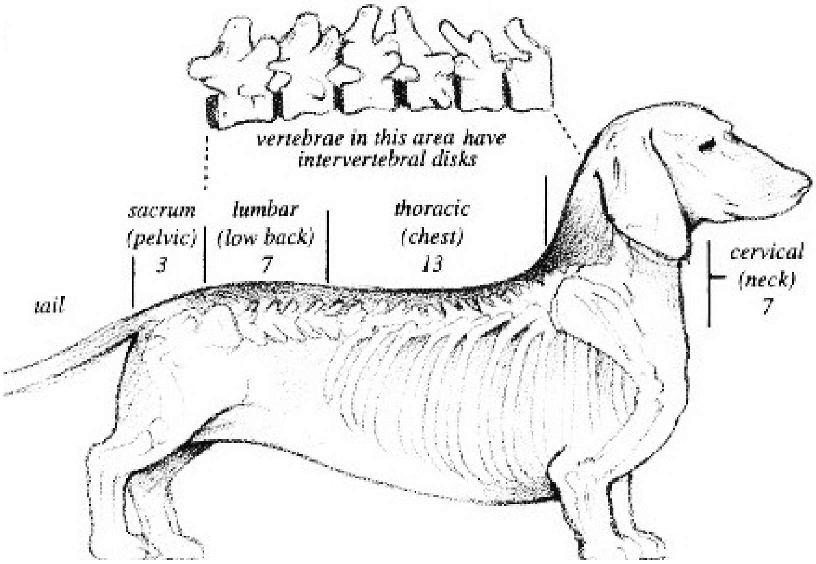


Figure 3: Anatomy of the Canine Spine (Wasserman, 2009)

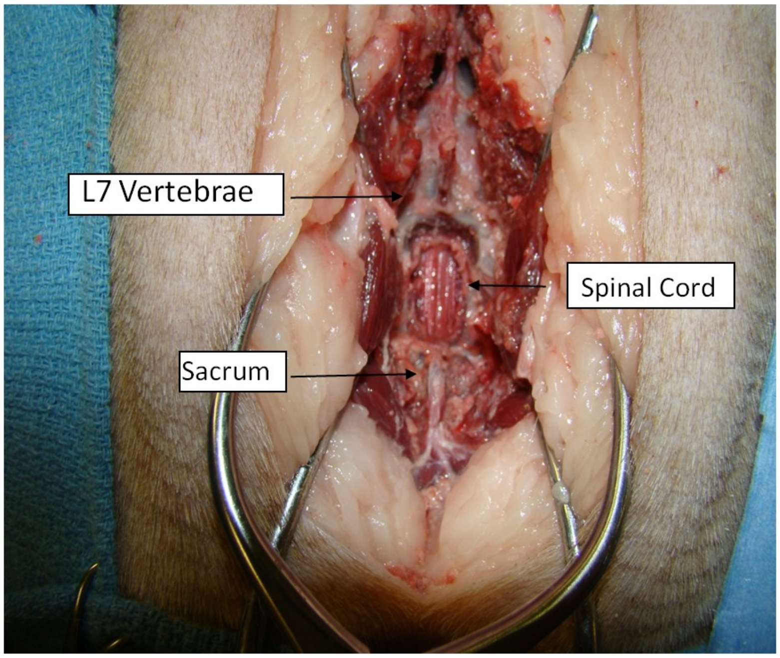


Figure 4: L7-S3 Cadaver Picture Taken at Tufts University, MA

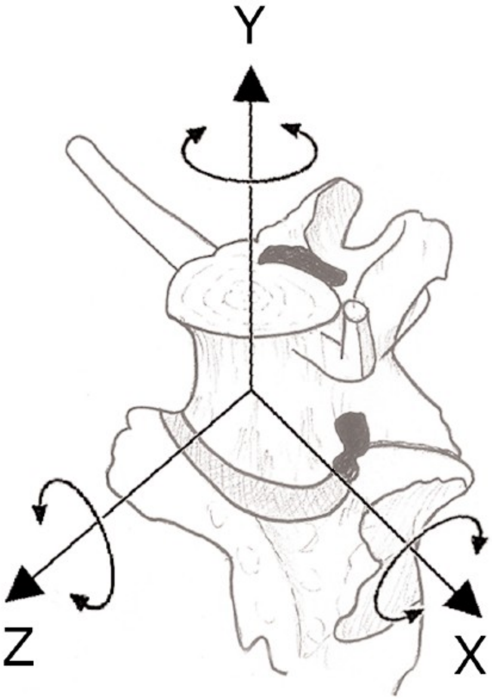


Figure 5: Orientation of X, Y, Z Axes in Rotational Testing (Benninger M, 2004)

Table 1: Degree of Motion for Vertebra (Benninger M, 2004)

Vertebral Level	Flexion –Extension	Axial Rotation	Lateral Bending
L4-5	7.2 ±2.0	1.9 ±0.9	19.0 ±4.0
L5-6	6.8 ±1.9	0.8 ±0.6	4.1 ±3.4
L6-7	11.8 ±2.9	0.7 ±0.5	7.1 ±3.5
L7-S1	37.0 ±5.7	2.0 ±1.2	9.5 ±2.6

Vertebrae consist of a thin ring of cortical bone. The cortical bone is very dense, and is thinner in the center with thicker ends. The vertebrae have two ends, superior and inferior, in which the outer cortical bone extends above and below. Two other facets of a vertebra are the pedicles and laminae. The pedicles are two small and rounded structures of thick cortical bone. In surgery, they can be easily removed and will not result in any difference for the function of the vertebra. The laminae are flattened bones that aid the pedicles. These pedicles extend from the vertebral body to the dorsal surface, while the lamina extends from the pedicles. These two structures combine to form the posterior wall of the vertebral foramen. The structure of a vertebra can be seen in Figure 6.

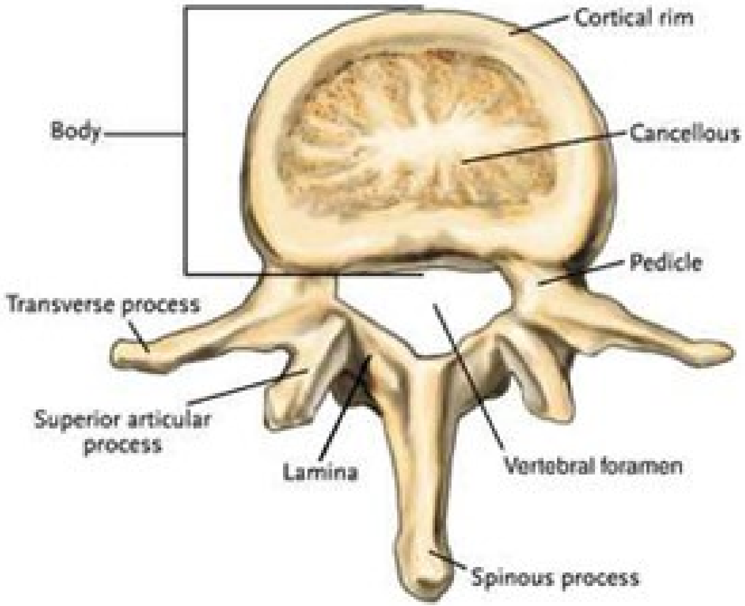


Figure 6: Anatomy of a Canine Vertebra (Wasserman, 2009)

In between each vertebra, except for two of the sacral vertebrae, are intervertebral discs. These discs are flat, rounded structures that act as a force absorber for the spine. When a weight or force is exerted on the spine, the discs allow for compression and spring back when the force is released. The two main components of the intervertebral disks are the annulus fibrosus and the nucleus pulposus. The annulus is composed of laminated fibrous tissue wrapped around the gelatinous nucleus pulposus (Wasserman, 2009). Individual annular fibers radiate outwardly at varying angles to accommodate all the directions from which forces can be applied to the disc. (Wasserman, 2009) The structure of the intervertebral disc can be seen in Figure 7.

The discs receive their blood supply through the movement of the spine, and expand while at rest to receive additional nutrients. This expansion is critical to the structure of the discs because if they are not supplied with sufficient nutrients, the discs can become thinner. Discs can also become thin due to repetitive movement and/or poor spinal posture. When the discs become thin, a canine is more susceptible to injury. Because of the demanding movements of a military canine, the risk of a degenerative disk is very likely. The lower spine of the canine endures the rigorous and repetitive movements of crawling, jumping and tense posture.

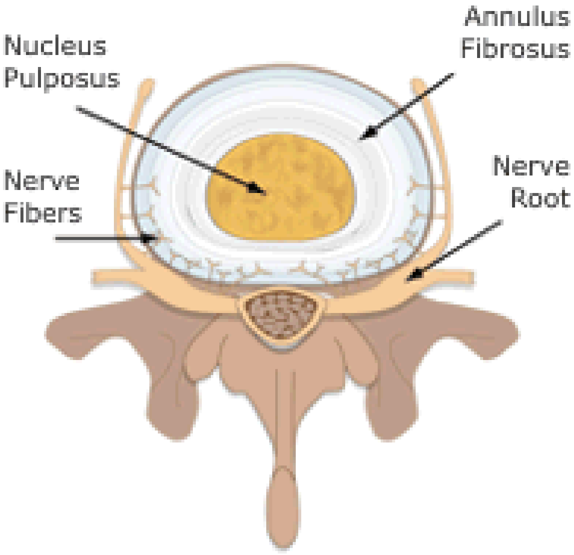


Figure 7: Anatomy of a vertebral disc (An Introduction to Discogenic Chronic Low Back Pain, 2009)

To aid the intervertebral disks in movement are the various tendons, ligaments, and muscles of the spine. Most notably are the facet joints and ligamentum flavum. The facet joints allow for the rotational movements, such as bending backward and forward, of the spine. There is a facet joint in each posterior section of the vertebrae. The facet joint consists mainly of smooth cartilage that connects to the two vertebras above and below the specific vertebrae. The facet joints, as well as the overall structure of the spine, can be seen in Figure 8. The ligamentum flavum acts primarily as a structural support and is the strongest spinal ligament. It connects to the laminae and also supports the posterior wall of the vertebrae. Furthermore, the ligamentum flavum protects the neural properties and stability of the spinal column.

The major overall components of the spinal structure are the spinal canal and cord. The spinal canal acts as the protective covering for the spinal cord. Its major functions are: to support the organs of the abdomen and thorax via ribs, skin, and muscles; to furnish points of muscle attachment for support and mobility of the entire body; and to protect the cord of nerve tissue that emanates from the brain and branches out into fibers serving nearly all parts of the body. (Lanting, 2007) The bones and ligaments of the spine form the spinal canal, most importantly the dura mater. The dura mater is a very hard structure that operates as the support for the spinal cord. The spinal cord is a part of the central nervous system that conducts electrical signals from the brain to the rest of the body via nerves. It is a very fragile structure that needs the spinal canal to protect it.

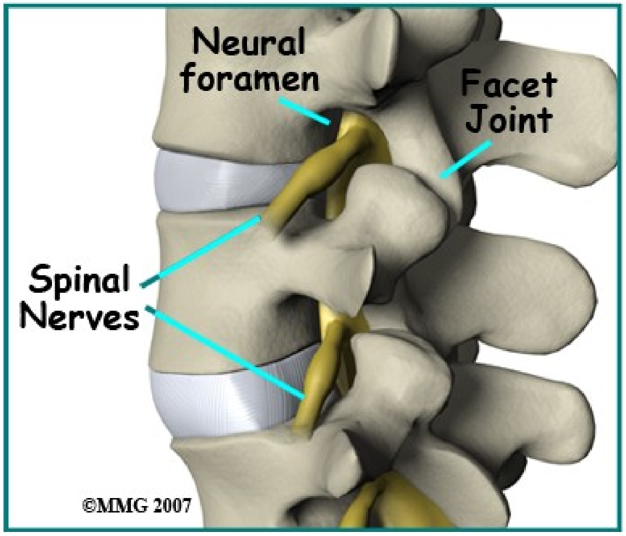


Figure 8: Anatomy of a normal spine (Schultz, 2009)

2.2.2 Biomechanics of the Spine

As previously stated, the principal function of the spine is to protect the spinal cord. Along with this protection, the spinal column needs to support the head, neck, upper extremities, transfer loads and allow a variety of movements. Different movements will cause various types of forces applied to a canines' spine. The facet loading of these different movements are shown in Table 2 (Buttermann & Schendel, 1992).The primary load of a canine is generated from the upper trunk while the hind legs and pelvis provide the power (Figure 9).

Table 2: Facet Loading with Different Movements (Buttermann & Schendel, 1992)

Facet loading with different movements (Buttermann & Schendel, 1992)	
Movement	Loading (Newtons)
Flexion & Lying	0N
2-Leg Standing Erect	185N
Standing	26 ±15 N
Walking Erect	55 N
Climbing Stairs	170 N
Walking	107 ±27 N

When a canine exerts energy to begin walking and/or running, the legs absorb the energy that is being put forth by the ground and is generated to the hip joint. The hip joint must be a powerful and strong component of the canine because all the force that comes through it must be then directed forward toward the spine. The stress on the hip, specifically in military working dogs, adds to the deterioration of the hip joint which makes the canine have difficulty applying any force through the hip.

Once the hip joint absorbs the force, it is then focused through the pelvis to the sacral joint. The sacral joint is where the pelvis and the spine meet. The natural slope of a canine is minute and gradual, which allows for the pelvis to alleviate some of the stress exerted upon the sacral and hip joints. If the slope of the spine becomes too great or too small, the stress will be concentrated on different parts of the skeleton. When the slope is too great, the sacral joint must absorb more energy than normal, which can lead to deterioration of the sacral joint. In comparison, when the slope is decreased, the energy becomes focused on the hips, which can lead to serious hip injuries such as hip dysplasia.

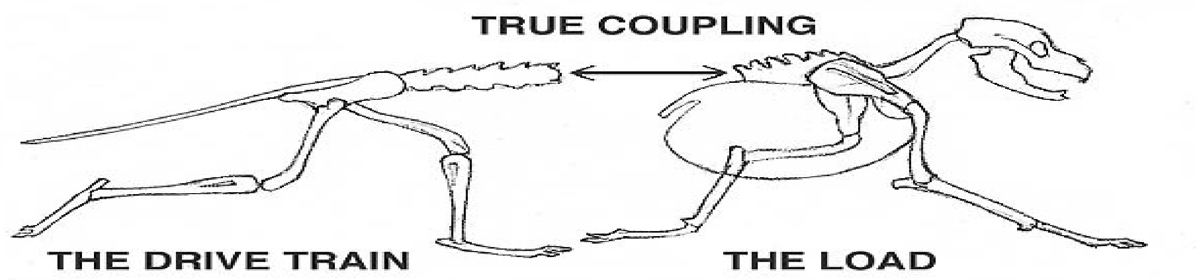


Figure 9: Canine Propulsion Generation (Shaw, 2003)

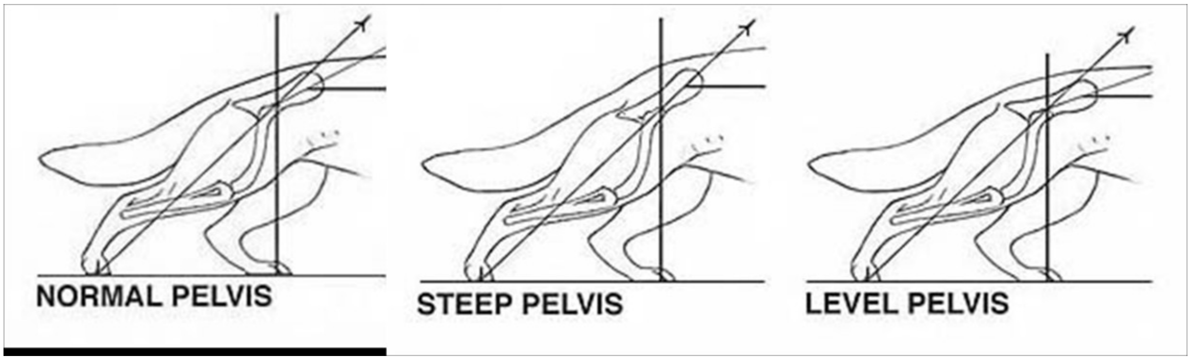


Figure 10: Slope of Canine Pelvis (Shaw, 2003)

The vertebrae that have the most stress placed on them in military working canines are the lumbar. These are thick, massive disks that can absorb large amounts of energy, and are the anchor points for many of the large muscles that help pull the leg forward and arch the spine (Shaw, 2003). Overall, they are the major generator of power in the hind legs.   Along with generating power, the lumbar must also support the weight of the canine’s entire upper trunk when it is suspended in motion. During motion, the lumbar vertebrae should be horizontal and straight so it can carry energy.   If the vertebrae become weak and begin assume a sagging position, the spine’s overall ability to absorb a powerful rear thrust can become compromised, which in turn can cause a military working dog to be forced to retire or get surgery.

2.3 Lumbosacral Stenosis

Lumbosacral stenosis is a neuro-orthopedic condition caused by the compression of the nerve roots in the lumbosacral region of the canine spine. (Suwankong, et al., 2007) This condition is also described as cauda equina syndrome, with some sources considering lumbosacral stenosis to be a cause of cauda equina syndrome. (Mattoon & Koblik, 1993) There is much disparity in the use of these terms, but lumbosacral stenosis will be used to mean a condition caused by the compression of spinal nerves when discussed in this paper. The effects that this condition has on a dog can vary greatly and range from mild to severe, depending on the extent of the compression. In the case of military working dogs, these effects can produce even greater consequences. Dogs experiencing this condition may not be able to fully perform their designated duties. There are some medicinal and surgical practices currently in use to combat this disease, but some of the dogs cannot be helped. The future of military working dogs with lumbosacral stenosis depends on many factors, including age and severity of the affliction. Some dogs are able to recover after their treatment, while others cannot. The dogs who cannot cope well enough may be taken out of service, retired, adopted, or even euthanized.

2.3.1 Causes

The causes of lumbosacral stenosis can vary greatly, in both congenital and acquired forms. (Watt, 1991) Congenital lumbosacral stenosis can be caused by spinal canal stenosis or vertebral malformations such as hemi vertebrae, block vertebrae, spina bifida, and the lumbarisation of the S1 vertebrae. (Watt, 1991) Acquired causes can be more varied such as, discospondylitis, neoplasia, intervertebral disc disease, trauma, fibrocartilaginous emboli, iatrogenic complications (Watt, 1991), disc protrusion, ligament hypertrophy, and lumbosacral instability. (Suwankong, et al., 2007) The lumbosacral joint, where the transition from the lumbar to the sacral region occurs, often has the highest degree of mobility among canine vertebrae. This transitional area is also a zone of force concentration between the lumbar and the sacrum. The increased mobility and forces leave the lumbosacral joint particularly susceptible to lumbosacral stenosis changes. (Van Klaveren, et al., 2005)

Table 3: Nerves affected by lumbosacral stenosis (adapted from (Watt, 1991))

Nerve	Spinal Segment	Sensory Function	Motor Function
Sciatic	L6-S1	Hindlimbs	Extends hip, hock, digits Flexes stifle
Pudendal	S1-S3	Perineum	Anal and urinary sphincters
Pelvic	S1-S3	Pelvic viscera	Bladder, rectum Erectile tissue
Coccygeal	Co1-Co5	Tail	Tail

Because lumbosacral stenosis occurs in the lumbosacral region of the spine, it may only affect specific nerves. Lumbosacral stenosis has been shown to compress the sciatic, pudendal, pelvic, and in some cases the coccygeal, nerves. A summary of the affected nerves, the spinal region where they are impacted, and the functions these nerves serve can be seen in Table 3. (Watt, 1991)

2.3.2 Signs and Symptoms

The effects of lumbosacral stenosis can vary greatly depending on the degree of nerve compression, and specifically which nerves are under compression. For military working dogs, who are required to routinely perform acts of athleticism, the first signs a handler may see are caudal lumbar pain, difficulty rising, reluctance to jump or climb stairs, pelvic limb lameness. (Suwankong, et al., 2007) Additional signs include lumbosacral pain, hindlimb paresis, proprioceptive deficits, lameness, flaccid tails, and urinary dysfunction. (Watt, 1991) Lumbosacral pain is by far the most common symptom. In a 1991 study of eighteen dogs, the primary symptom was recorded and the results are seen in

Table 4. Up to 25% of cases may present with urinary difficulties, though this symptom often arises much later in the disease. (Linn, Bartels, Rochat, Payton, & Moore, 2003)

The pain experienced due to lumbosacral stenosis may be the most prevalent, but it is not the most serious. Oftentimes, due to the pain dogs with restrict their own movements. While this may reduce the pain they experience, it produces another set of side effects; the reduced use of limbs results in muscular atrophy. (Suwankong, et al., 2007) This atrophy results in reduced strength and an increased inability to move, and in military working dogs a sharp decrease in effectiveness. The propulsive forces of the rear limbs are reduced as a result of lumbosacral stenosis (Suwankong, et al., 2007), and muscular atrophy reduces this effect even more.

The diagnosis of lumbosacral stenosis is a complex process. While a dog may exhibit some of the symptoms, the cause of these reactions could be caused by another stimulus, such as old age. A diagnosis is made using a collection of patient history, clinical signs, a clinical examination, electromyography, contrast radiography, computed tomography, and magnetic resonance imaging. (Suwankong, et al., 2007) Of those diagnosis options, magnetic resonance imaging is the most effective because of the high contrast of the nucleus pulposus region of the intervertebral discs. (Rossi, Seiler, Busato, Wacker, & Lang, 2004) This allows veterinarians to clearly see whether a spinal disc is impinging on the nerve. Magnetic resonance imaging devices are also rarely used in veterinary practice due to their high cost, making the technology unavailable in most cases. (de Haan, Shelton, & Ackerman, 1993) Some studies have produced positive diagnosis results using electromyographic testing (Linn, Bartels, Rochat, Payton, & Moore, 2003), however other sources refer to electromyographs being unable to assist in diagnosis.

In a study of twenty-nine military working dogs (Linn, Bartels, Rochat, Payton, & Moore, 2003) with lumbosacral stenosis, many variables were examined. These data included clinical symptoms presented by the dogs, among others. The full data can be seen in Appendix B. In this study, the most common clinical signs were lameness and pain in twenty-one dogs each. The second most-common clinical sign was conscious proprioceptive deficits (sixteen dogs).

Table 4: Prevalence of Symptoms in Dogs With Lumbosacral Stenosis (Watt, 1991)

Symptom	Percentage of Affected Dogs With Lumbosacral Stenosis

Lumbosacral Pain	89%
Proprioceptive deficits and/or paresis	55.6%
Lameness	44%
Raised Hindlimb	33%
Flaccid Tail	22%
Urinary Incontinence	5.5%
Detrusor Atony	11%
Self-inflicted Dermatoses	5.5%

2.3.3 Current treatment Options

2.3.3.1 Non-surgical Approaches

The only non-surgical treatment option is to restrict the movement of the dog restriction and to treat anti-inflammatory and pain killing drugs. (Suwankong, et al., 2007) While this may alleviate the pain, it does not remove the underlying condition, spinal nerve compression, and can lead to other complications such as accelerated muscular atrophy.

2.3.3.2 Surgical Solutions

There are a number of surgical techniques used to treat the symptoms of lumbosacral stenosis. Due to the potential complications present for any type of surgery, surgical treatment is only recommended when the pain is severe and the dog does not respond to medicinal therapies. (Suwankong, et al., 2007) The type of surgical procedure is determined by the exact cause of nerve compression. Surgical procedures currently practiced to remove pressure from the cauda equina are a dorsal laminectomy, fenestration, or partial discectomy. These surgical procedures have a success rate of 41-78%. (Suwankong, et al., 2007) The success of a foraminotomy may be improved by using an endoscope for visual assistance. (Wood, Lanz, Jones, & Shires, 2004) Spinal fusion is used to secure the vertebrae if a substantial amount of disc or other material is removed; a pin fixation-fusion technique has been developed for this purpose. (Watt, 1991)

2.3.4 Effectiveness of Current Treatments

The success of a surgical treatment can vary based on many factors including age, extent of surgery, and other pre-existing conditions. There are indications, however, that dogs treated by surgical means have a good likelihood of a return of function. This is true even for military working dogs. (Linn, Bartels, Rochat, Payton, & Moore, 2003) In one study of twenty-two dogs, owners reported 73% showed signs of improvements, while 46% reported that their dog had returned to completely normal function. (Suwankong, et al., 2007) However, instances of a return to normal function for working dogs have been much rarer than that. (Linn, Bartels, Rochat, Payton, & Moore, 2003) Surgical treatments have been shown to restore propulsive forces to the limbs after a six month period. (Van Klaveren, et al., 2005) Decompressive laminectomies have produced positive results but are less effective in dogs that have presented with urinary incontinence symptoms. (De Risio, Sharp, Olby, Munana, & Thomas, 2001)

Looking again at the study of twenty-nine military working dogs (Linn, Bartels, Rochat, Payton, & Moore, 2003) one can evaluate the effectiveness of many treatment options. The three most common clinical signs in this study, lameness, pain, and CP deficits, were left unchanged in 23.8%, 19%, and 31.3% of dogs, respectively. These percentages refer to the number of dogs who presented with these symptoms, and after surgical treatment showed no improvement in these areas. Specific treatment procedures were also analyzed. The dorsal laminectomy and discectomy produced no change in 42.9% and 27.3% of dogs who underwent those therapies. The facetectomy, foraminotomy, and traction-fusion surgical treatments produced some improvement in all dogs that received those procedures. Finally, this study investigated the lifespan of dogs with lumbosacral stenosis after receiving therapy. At the time of publication, of the twenty-nine dogs treated, twelve had passed away. The average time between surgery and death was fifteen months. The full data of this study can be found in Appendix B.

2.3.5 Prevalence of Lumbosacral Stenosis

Affirmative diagnosis of lumbosacral stenosis is difficult, as many old dogs without clinical signs will show radiographic findings very similar to lumbosacral stenosis. (Watt, 1991) The average age of dogs included in two lumbosacral stenosis studies were 7.7 years (Watt, 1991) 5.7 years (Rossi, Seiler, Busato, Wacker, & Lang, 2004), and 6.08 years (Linn, Bartels, Rochat, Payton, & Moore, 2003). Lumbosacral stenosis occurs more often in older, large-breed and working dogs, particularly German shepherds. (Linn, Bartels, Rochat, Payton, & Moore, 2003) There are breed-specific differences in the structure of the lumbosacral region of the spine which can account for the increase in lumbosacral stenosis in some breeds. (Rossi, Seiler, Busato, Wacker, & Lang, 2004) German shepherds also have shown higher instances of disc degeneration and herniation between the L7 and S1vertebrae, which could also account for the increased rate of lumbosacral stenosis in that breed. (Rossi, Seiler, Busato, Wacker, & Lang, 2004)

In addition to German shepherds showing an increase in the occurrence of lumbosacral stenosis, male dogs also appear to be more affected. (Linn, Bartels, Rochat, Payton, & Moore, 2003)

3 Project Approach

3.1 Initial Client Statement

Due to their heightened sense of smell and versatile nature, canines are aptly suited for detecting explosives, narcotics, and other dangerous items. The United States military has employed these animals for years to help defend our country. However, due to the strenuous nature of their work, including continuous stretching and jumping, many dogs are retired from service due to back pain. Some of these dogs are adopted or given other roles, and still some are euthanized. If a device could be developed to treat this issue, dogs could be freed from pain and allowed to live out the rest of their lives. It is for this reason that our client, Securos, has approached us to design, develop, and validate an orthopedic device to alleviate canine back pain.

3.2 Objectives

After performing a background and literature review of the topic we outlined the main objectives for our project. These objectives are based on our own assumptions about the product, and a short questionnaire completed by our primary client Harry Wotten, President/CEO of Securos. Mr. Wotten's answers to the questionnaire provided much more direction to the project, including a specific condition to treat: lumbosacral stenosis. The original client statement called for a device to relieve back pain, which left the project very open-ended. Once we received a specific condition to treat, the project took on a new meaning.

To begin identifying the intended objectives of our project, a crucial decision had to be made: was this device envisioned to be an internal or external piece. That is, should the device be something implanted into affected dogs, or is it something affected dogs would wear. After considering the matter carefully and gather Mr. Wotten's opinion, it was decided to pursue an implantable design. From there, we established our top-tier objectives. The device must be safe, effective, easily implanted, and easily manufactured. All the other possible objectives stem from, and can be summed up by, these four. Each main objective has three to five sub-objectives. A full outline of our objectives can be seen in Figure 11.

To aid in the selection of design alternatives, the top six objectives were isolated. These objectives provide the foundation for a successful device, and the other objectives almost rely on them to be met. These six objectives were compared against each other in a pairwise comparison chart. The chart shown in Table 5 was completed by the design team and indicates that the most important objective is to relieve compression on the nerve, while the least important is that the device be made of minimal pieces.

Table 5: Pairwise Comparison Chart of Objectives

	EASY TO MANUFACTURE	MINIMAL PIECES	EASILY IMPLANTABLE	MINIMAL WEAR (SAFETY)	RELIEVE COMPRESSION ON NERVE	RETURN TO NORMAL FUNCTION	TOTAL
EASY TO MANUFACTURE	X	1	0	0	0	0	1
MINIMAL PIECES	0	X	0	0	0	0	0
EASILY IMPLANTABLE	1	1	X	.5	0	0	2.5
MINIMAL WEAR (SAFETY)	1	1	.5	X	0	1	3.5
RELIEVE COMPRESSION ON NERVE	1	1	1	1	X	1	5
RETURN TO NORMAL FUNCTION	1	1	1	0	0	X	3

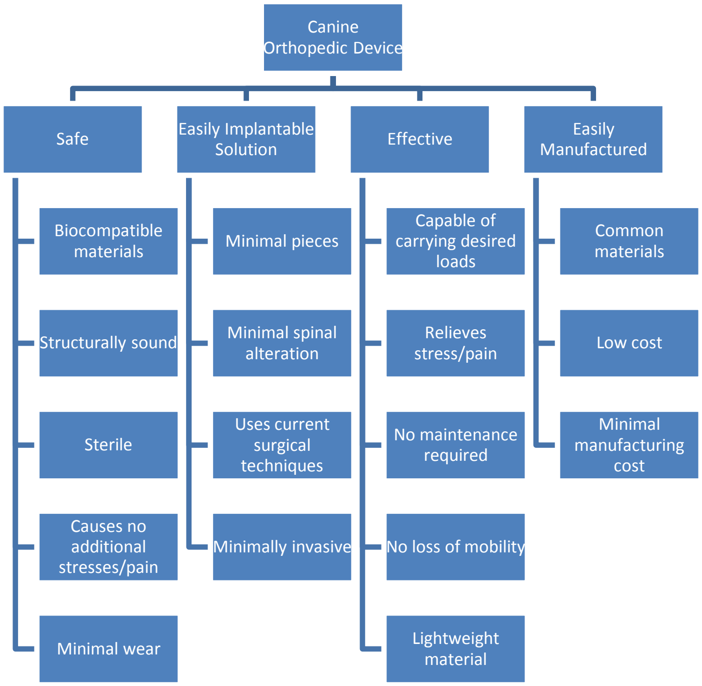


Figure 11: Project Objectives

3.3 Revised Client Statement

The new goals established by our outlined objects, as well as Mr. Wotten's input, allowed for an elaboration of the initial client statement. The initial client statement focused primarily on background information and why this project is important, but provided little direction as to what this project should accomplish. Our more-defined goal was to design an easily implanted and safe orthopedic device for use in canines. The device must be effective at carrying spinal loads, alleviate pain in the spine, and retain the dog's range of motion. The condition lumbosacral stenosis is caused by a compression of nerves in the spinal canal, so our device must remove any impinging material while leaving as much of the original spine intact as possible. Finally, the finished device should be easily manufactured and cost-effective.

4 Project Design

4.1 Needs Analysis

In a study of forces in the lumbosacral joint during various canine activities, the maximum force observed was 185N (See Section 2.2.2 Biomechanics of the Spine). The dogs involved in this study were approximately 55 to 75 pounds, slightly smaller than the average military working dog. To estimate a valid experimental force, analysis of designs will consider a 200N force. (Buttermann & Schendel, 1992)

The device also must be able to displace to preserve range of motion in the affected dogs. This includes compression coupled with the vertebral disk or rotational abilities in the three directions outline in Section 2.2.2 Biomechanics of the Spine. Specifically, the device should allow for compressive displacements of at least 2mm. As detailed in the next section, there is about a 2mm difference when a dog is standing compared to the dog sitting/laying with the legs underneath the trunk.

4.2 Functions (Specifications)

The two crucial elements considered while drafting alternative designs are the present size constraints and material properties. Material properties include biocompatibility and mechanical properties. Three primary materials were considered for the designs, Ti-6Al-4V, Type 316L Stainless Steel, and Nitinol. All three of these materials have good biocompatibility properties and are commonly used in implants currently available. Solidworks Finite Element Analysis was performed on all the design alternatives using these materials, which were available in the Solidworks default materials database. Titanium had the highest strength characteristics while Nitinol allowed for hyperelastic deformation. After consulting with the WPI machine shop, we learned of the difficulties of processing titanium alloys or Nitinol with the equipment available. Because of the manufacturing difficulties presented by titanium and Nitinol, Type 316L Stainless Steel was selected as a final design material.

Size constraints required more investigation. The design team observed a cadaver dissection at Tufts Veterinary School in Grafton, MA performed by Dr. Julien Cabassu. Dr. Cabassu demonstrated the dorsal and ventral approaches to the lumbosacral joint. These are the two standard approaches used in veterinary surgery; the dorsal approach is much more common. After observing both approaches, the design team concluded that the ventral approach to the region is much more complicated than the dorsal approach. The ventral approach requires carefully bypassing several major internal organs.

The cadaver dissection also afforded the design team the opportunity to take in vivo measurements of the space to be considered. The cadaver dissection was photographed at multiple stages. The National Institute of Health’s ImageJ Image Analysis software package was used to take measurements from the photographs.

Previous literature on spinal fixation indicated prominent locations for fixation screws to be embedded in the vertebrae. The current design proposals intend to use those same fixation locations. The current fixation locations are show in Figure 12. (Meij, Suwankong, Van Der Veen, & Hazewinkel, 2007)

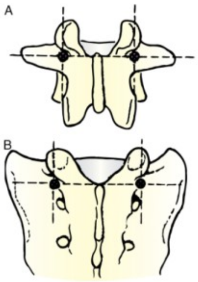
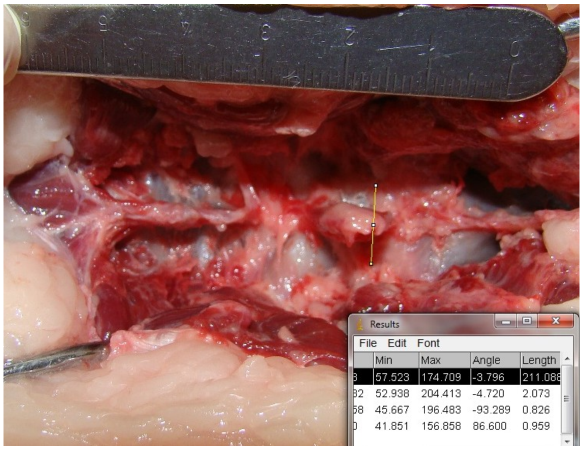


Figure 12: Schematic Diagram of Fixation Screw Locations (Meij, Suwankong, Van Der Veen, & Hazewinkel, 2007)

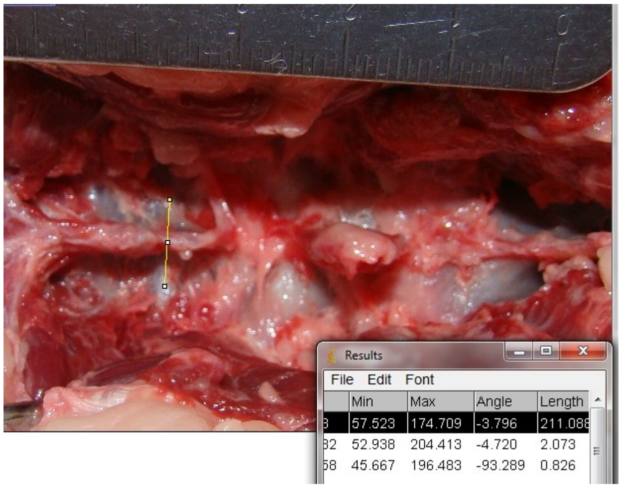
Using the schematic shown in Figure 12 and photographs taken during the cadaver dissection, measurements were made about the spaces between the fixation locations. The distance between the L7 fixation locations was measured to be approximately 0.959cm (Figure 13). The distance between the S1 fixation locations was observed to be approximately 0.826cm (Figure 14). The distance between the L7 and S1 fixation locations was measured to be approximately 2.073cm (Figure 15). These sizes were used in the drafting of the design alternatives to provide a sense of scale and design criteria for the design alternatives.

During the cadaver surgical approach observation, measurements were taken to investigate the range of motion of the lumbosacral joint. First the dog was laid out with its back straight. The legs were spread to either side of the trunk. Photographs of the spine were taken at this time. Next the legs were placed underneath the dog, as if it were laying/sitting. This causes the spine to extend, increasing the distance between the vertebrae. This distance was approximately two millimeters longer than the original distance. From these measurements, a minimum displacement capability of two millimeters was added to the design criteria of the device.



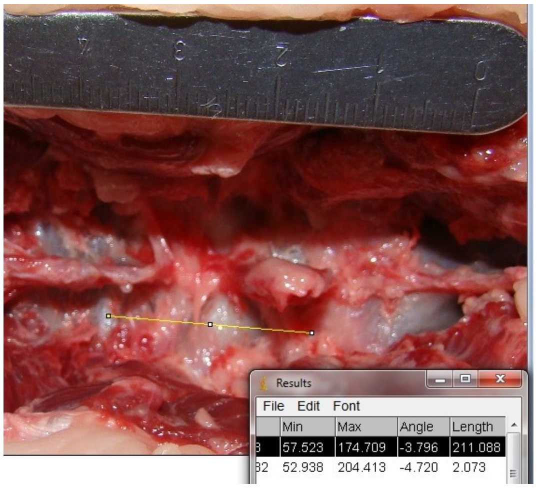
	Min	Max	Angle	Length
3	57.523	174.709	-3.796	211.08
32	52.938	204.413	-4.720	2.073
58	45.667	196.483	-93.289	0.826
0	41.851	156.858	86.600	0.959

Figure 13: Measurement of Space Between L7 Spinal Fixation Locations



	Min	Max	Angle	Length
3	57.523	174.709	-3.796	211.08
32	52.938	204.413	-4.720	2.073
58	45.667	196.483	-93.289	0.826

Figure 14: Measurement of Space Between S1 Spinal Fixation Locations



	Min	Max	Angle	Length
3	57.523	174.709	-3.796	211.088
32	52.938	204.413	-4.720	2.073

Figure 15: Measurement of Space Between L7 and S1 Spinal Fixation Locations

To implants any of the conceptual design, the vertical spinuous process must be trimmed from the vertebrae. All the designs use the spinal fixation holes and a flat endplate system. The spinuous process must be removed and the resulting area relatively leveled before implantation may occur.

4.3 Conceptual Designs

4.3.1 Design Alternative 1

Alternative Design 1 is a basic helix design. There is one full rotation of the helix at a pitch of 4mm. The device is a three millimeter diameter circular cross section swept through the helix with one centimeter arms on each side of the helix. These arms are the location of the screw holes for mounting. The device pictured in Figure 16 is one of two possible designs. The device could mount over the midline axis of the spine, with a wider plating design to accommodate two screw holes or be two separate devices mounted on each side of the spine's midline. The design presented here is plated to be two separate devices.

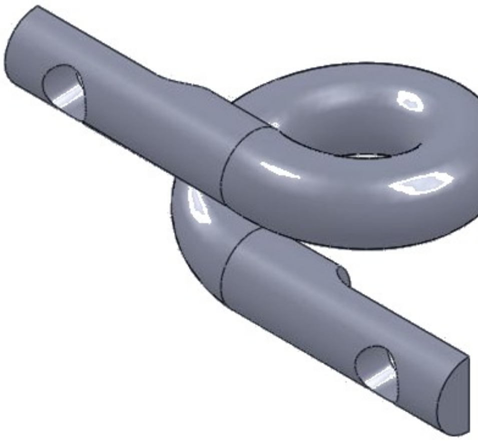


Figure 16: Design Alternative 1

4.3.2 Design Alternative 2

Design Alternative 2 (Figure 17) is an elliptical centerpiece with mounting plates on either end of the minor axis. The ellipse is a sweep of a 5mm diameter circle and is 20 mm along the major axis and 11mm along the minor axis. This design is intended to be mounted over the midline of the spinal column.

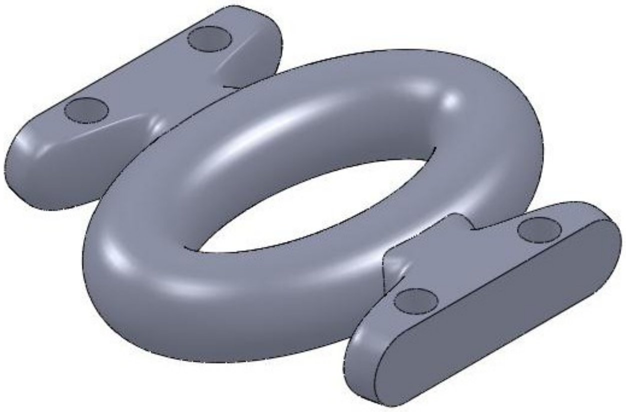


Figure 17: Design Alternative 2

4.3.3 Design Alternative 3

Design Alternative 3 (Figure 18) is a wire mesh design between two endplates. There are three points of contact with the endplates, each spawning two mesh paths, which makes six total mesh parts. All mesh parts meet at 90° angles are equal length. The mesh has a 1.5mm diameter circular cross section. The design of this device was inspired by coronary catheters and was specifically intended to be constructed out of Nitinol. Due to manufacturing capabilities, Nitinol was ruled out as a possible material, and modeling of this design was conducted using Type 316L Stainless Steel.

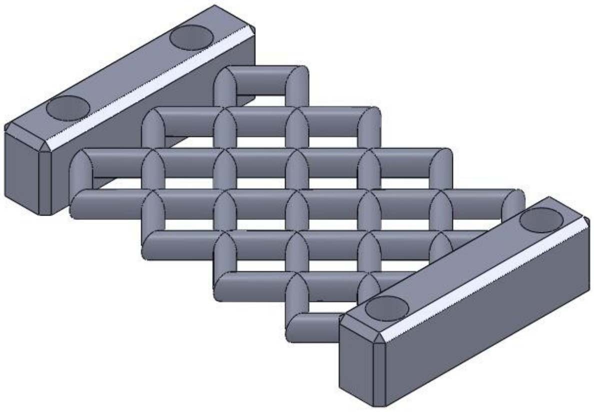


Figure 18: Design Alternative 3

4.3.4 Design Alternative 4

Design Alternative 4, seen in Figure 19, is a curved piece located between the two endplates. The curved piece contains two hairpin turns. It is envisioned that the two hairpin turns will allow for the necessary compressive strength and allow for the sufficient side to side motion needed for lateral bending of the spine. The curved piece is a square design, 5mm on each side, to maximize cross sectional area and increase its ability to handle large loads.

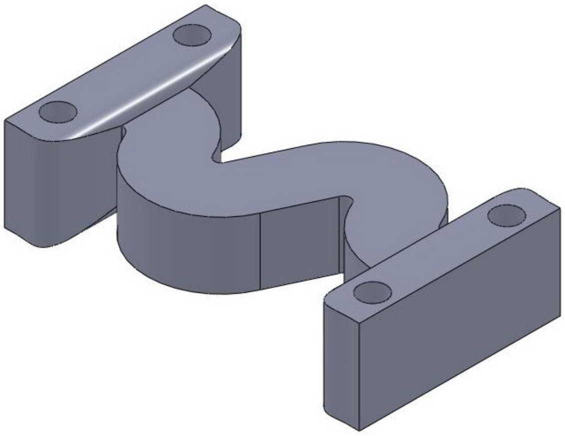


Figure 19: Design Alternative 4

4.3.5 Design Alternative 5

Design Alternative 5, Figure 20, is a curved piece located between the two endplates. The curved piece contains a single hairpin turn. The device is designed to be mounted either centrally over the midline of the spine, or as two separate devices on either side of the midline. The pictured design is for one device mounted over the midline. The curved piece is a square design, 5mm on each side, to maximize cross sectional area and increase its ability to handle large loads.

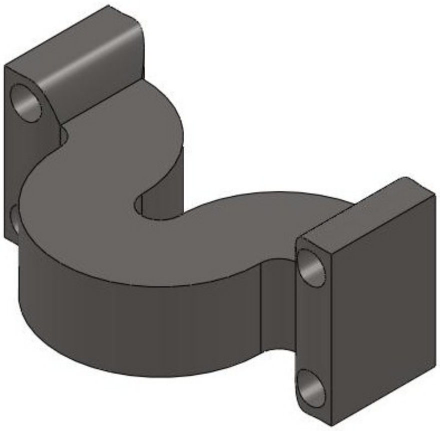


Figure 20: Design Alternative 5

4.3.6 Design Alternative 6

Design Alternative 6, seen in Figure 21, is a curved piece located between the two endplates. The curved piece contains three hairpin turns. It is envisioned that the three hairpin turns will allow for the necessary compressive strength and allow for the superior side to side motion needed for lateral bending of the spine. The curved piece is a circular design, 3mm in diameter. The material path of this device is intended to preserve range of motion in the spine after implantation by allowing for significant compressive or lateral displacements.

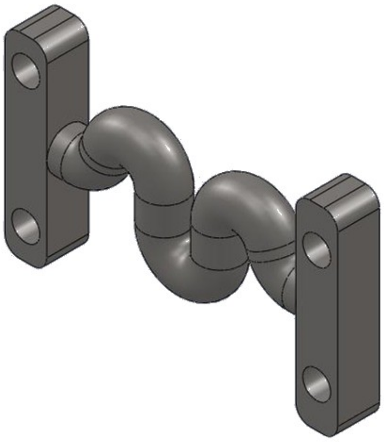


Figure 21: Design Alternative 6

4.3.7 Design Alternative 7 (Final Design)

Design Alternative 7 was the final design developed (Figure 22). After reviewing the results of the previous six designs, it was clear that a solid device would not produce the deformation/plate displacement necessary to preserve range of motion in the spine. Essentially what was necessary was a design that behaved like a spring, capable of withstanding significant loads and producing large displacements. The spring served as the basis for this design. The spring is fixed between two endplates, which are dimensioned for their appropriate vertebrae. After discussing construction material selection with the WPI Machine Shop, Type 316L Stainless Steel was selected as the material for the endplates. It was acquired from McMaster-Carr (Robbinsville, NJ).

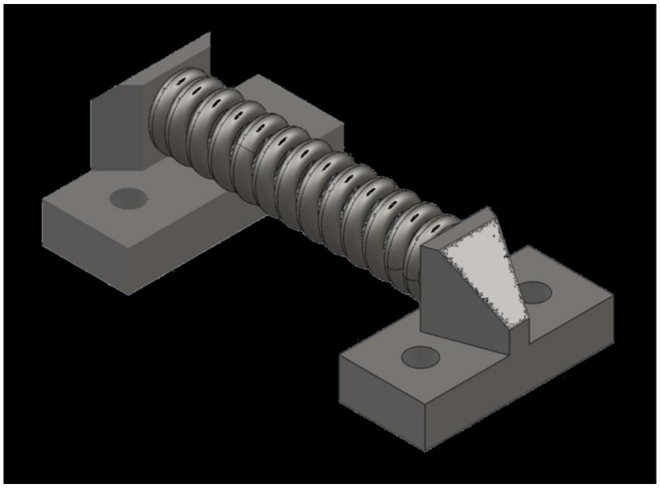


Figure 22: Design Alternative 7 (Selected as Final Design)

The spring is the KK-99 compression spring purchased from Century Spring Corporation (Los Angeles, CA). The design team pursued the creation of a custom spring for this application, but the production costs were too great for the budget of this project. When a custom spring was ruled out as a possibility, spring manufacturers were contacted with specifications and were asked to provide any springs in their commercial inventory. The manufacturers were asked for a spring as close to two centimeters in length as possible, at most five millimeters in diameter, and able to withstand at least 200N. The only spring provided was the Century Spring KK-99. The properties of this spring can be seen in Table 6 (as provided by Century Spring Corp.).

For fixation to the bone, 2mm x 8mm self-tapping cortical screws were selected. These screws were provided by Securos. Stainless steel bone screws were selected to reduce galvanizing corrosion between the screws and the endplates. Countersinks were added to the endplates of the device to increase the screw's hold. The countersinks affected the positioning and shape of the vertical spring mounting locations on the endplates, accounting for the endplates' varying designs.

Drawings of this design can be seen in Appendix C.

Table 6 : Properties of the KK-99 Spring

Property	English Units	Metric Units
Spring Rate (R)	179 lb/in	31 N/mm
Spring Length	0.81 in	20.6mm
Spring OD (OD)	0.188 in	4.78mm
Spring ID (ID)	0.98 in	2.5mm
Spring Mean Diameter (D)	0.188-0.045=0.143 in	3.6322mm
Spring Shear Modulus (G)	11500000 psi	79.3 GPa
Wire Diameter (d)	0.045 in	1.1mm
Total Coils (N)	13.5	
Active Coils (n)	13.5-2= 11.5	

4.4 Design Evaluation/Modeling

Each design alternative was fully drafted in the SolidWorks Computer Animated Design software suite. SolidWorks has a built-in SolidWorks Simulation tool. SolidWorks Simulation allows for the simulation of designs under various loading circumstances. Compressive loading simulations were conducted for each design alternative. The ability to withstand the necessary loadings is one of the primary objectives of the design. The compressive loading is the greatest load, and therefore the most likely to cause failure.

To complete the compressive loading simulation, the endplate screw holes were used to either fix the device or apply the load. One end fixed the device and was unable to move during the simulation. The other end had the force applied to the interior of the screw holes, perpendicular to the longitudinal view. The devices were tested using a test force of 200N to determine whether they can withstand the required stresses. All devices were modeled as 316L Stainless Steel using the properties in the SolidWorks database.

The results of 200N compressive testing for Design Alternative 1 can be seen in Figure 23 and Figure 24. As seen in the displacement plot, the device allowed for a displacement of approximately 0.2mm, far below the design criteria. Additionally, the stresses in the device far exceeded the yield strength of the material, indicating that the device would fail. Because this device does not meet the loading or displacement design criteria, it was not selected as the final design.

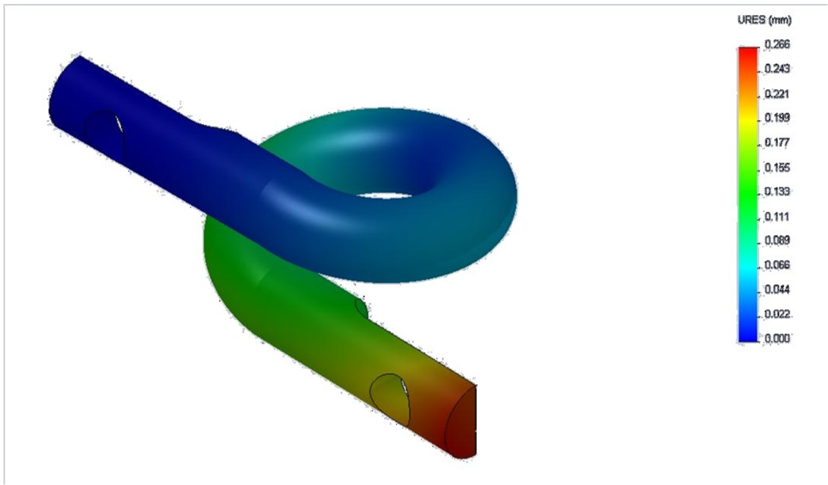


Figure 23: Displacement Model of Design Alternative 1

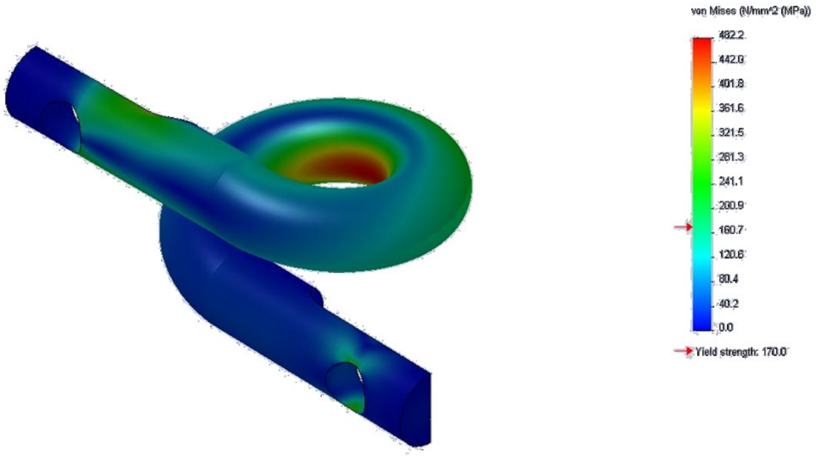


Figure 24: Stress Model of Design Alternative 1

The computer modeling results of Design Alternative 2 can be seen in Figure 25 and Figure 26. The resulting displacement is only 0.005mm, far below the design criteria value of 2mm. This device does have the required mechanical strength; the resulting stress is below the yield strength of the material. Additionally, after consulting with the WPI Machine Shop, this device would be impossible to manufacture at WPI. Because this device does not meet the displacement design criteria and is not able to be manufactured at WPI, it was not selected as the final design.

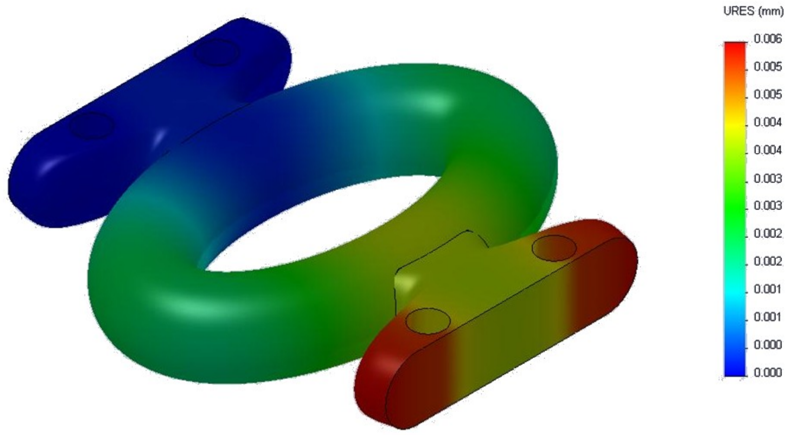


Figure 25: Displacement Model of Design Alternative 2

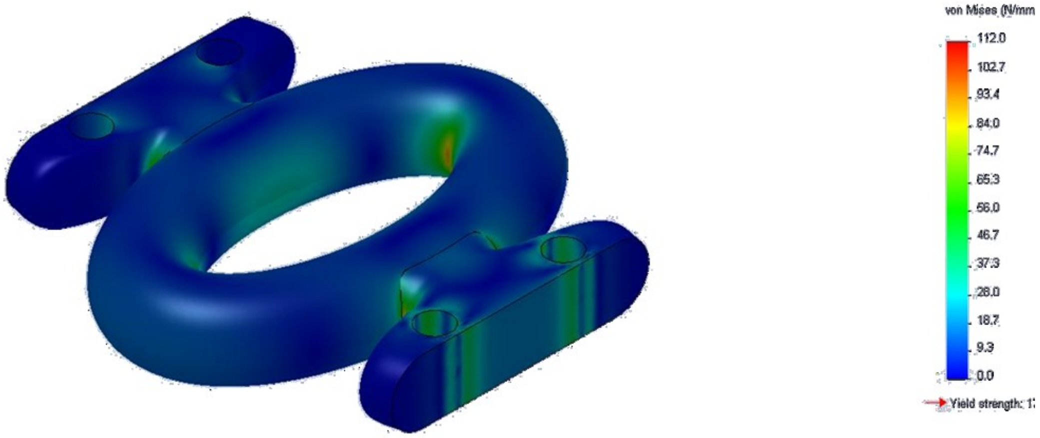


Figure 26: Stress Model of Design Alternative 2

The results of the 200N compression test for Design Alternative 3 can be seen in Figure 27 and Figure 28. As shown in the resulting displacement plot, this device displaces 0.005mm. The resulting stresses are below the yield strength of Type 316L Stainless Steel, indicating that the design meets the loading design criteria. Like Design Alternative 2, however, this device was not able to be manufactured at WPI. Because this device failed to meet the displacement design criteria and could not be manufactured at WPI, it was not chosen as the final design.

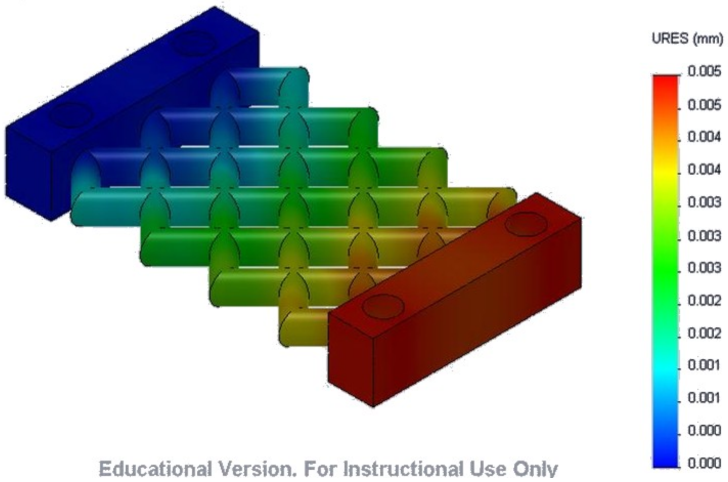


Figure 27: Displacement Model of Design Alternative 3

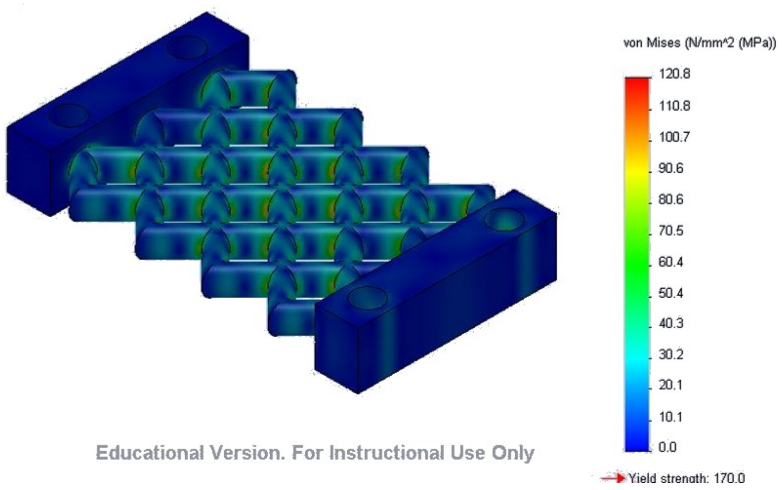


Figure 28: Stress Model of Design Alternative 3

Design Alternative 4's performance during the 200N compression simulation can be seen in Figure 29 and Figure 30. According to the simulation, this device displaced 0.02mm. Additionally, the resulting stresses were far above the yield strength of the material. Because this design failed to meet both the displacement and loading design criteria, it was not selected as the final design.

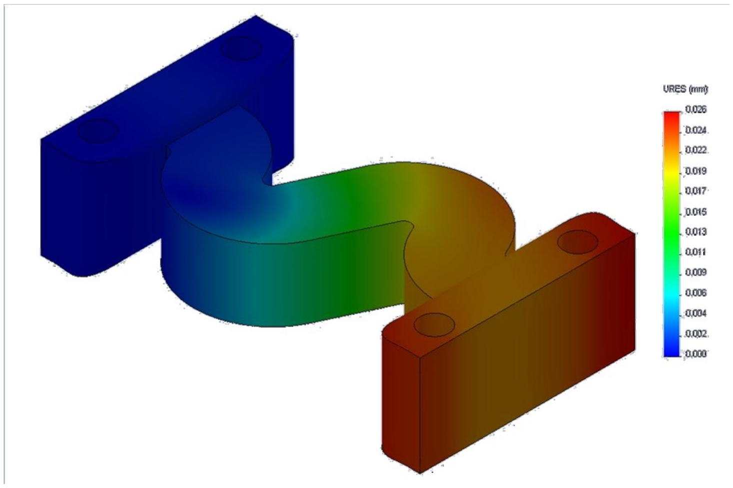


Figure 29: Displacement Model of Design Alternative 4

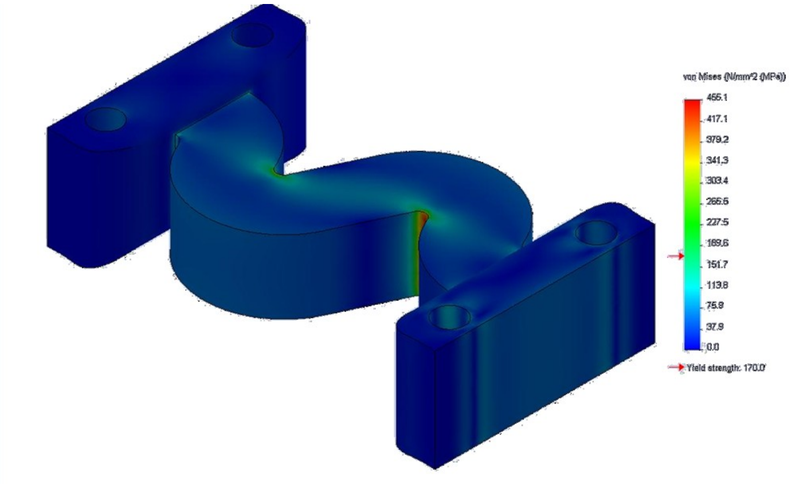


Figure 30: Stress Model of Design Alternative 4

Figure 31 and Figure 32 show the simulation results for Design Alternative 5. This device displaced 0.02mm, failing to meet the design criteria. The resulting stress was 135 MPa, below the yield strength of the material. Because this device failed to meet the displacement design criteria, it was not selected as the final design.

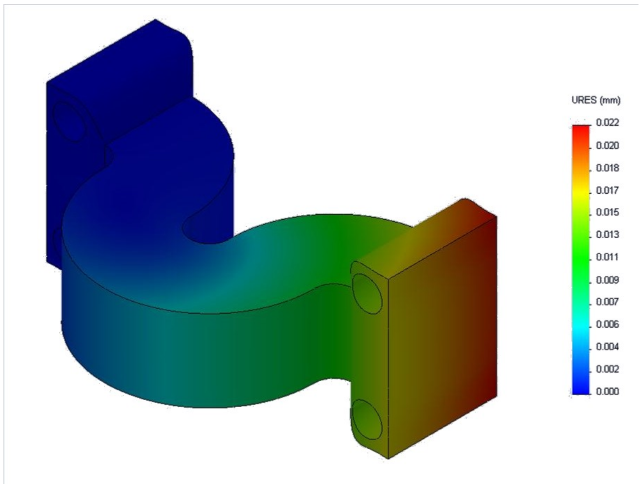


Figure 31: Displacement Model of Design Alternative 5

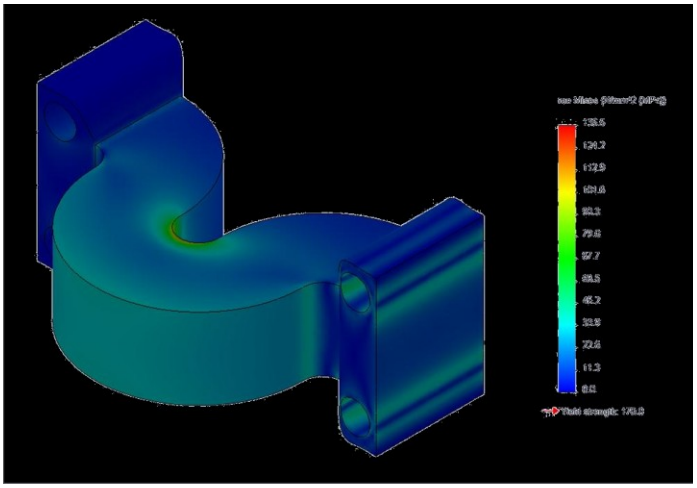


Figure 32: Stress Model of Design Alternative 5

The simulation results of Design Alternative 6 can be seen in Figure 33 and Figure 34. This design displaced 0.03mm, failing to meet the design criteria. The resulting stresses on the interior surfaces of the hairpin curves far exceeded the yield strength of the material. Because this device design failed to meet either the displacement or loading design criteria, it was not selected as the final design.

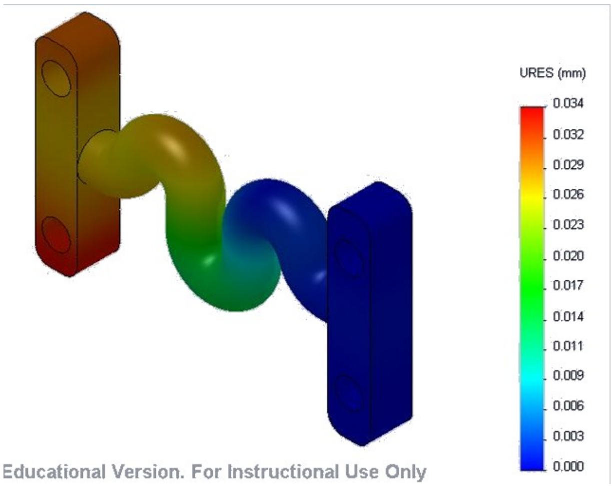


Figure 33: Displacement Model of Design Alternative 6

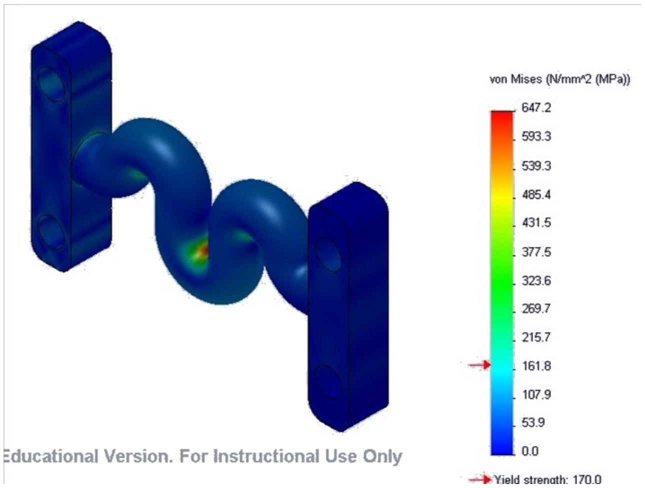


Figure 34 : Stress Model of Design Alternative 6

The final design is investigated in detail in the next Chapter.

5 Design Verification

5.1 Preliminary Spring Data

Before assembling the final device, the KK-99 spring must be confirmed appropriate for the application. The data provided by the manufacturer (Table 6) provide an indication that the spring will operate effectively. This needed to be confirmed. Using the Instron 5544 mechanical testing device, four springs were tested in compression. Figure 35 shows the force displacement curve of the four springs up to 5mm of displacements. The tests were conducted until the springs became a solid piece and the coils came in contact with one another. This began occurring at 5mm compression. The data collected until 5mm compression is analyzed below. Mechanical testing was used in lieu of computer simulations because the springs were easily acquired and is extremely reliable.

The first analysis performed verified the spring's reported spring rate. Century Spring reported the spring rate to be 179 lb/in or 31 N/mm. The spring rate can be calculated using the geometric and material properties of the spring. This equation can be seen in Equation 1. The spring rate is "R", the shear modulus is "G", the wire diameter is "d", the number of active coils is "n", and the mean diameter is "D". These properties can be seen in both English and metric units in Table 6. Using this equation and the spring properties, the calculated spring rate was 30178 N/mm, or 30.178 N/mm. This correlates nicely with the reported 31 N/mm. Spring geometric measurements were confirmed using a caliper tool and were confirmed to be consistent with the reported values.

$$R = \frac{Gd^4}{8nD^3}$$

Equation 1: Spring Rate Equation

The average force applied at 5mm compression for the four springs was 140N. The maximum force exerted on any of the four springs was 625N. This spring was completely compressed and additional loading was still applied. None of the four springs broke, and all returned to their original length after compression. These springs can withstand the 200N desired load.

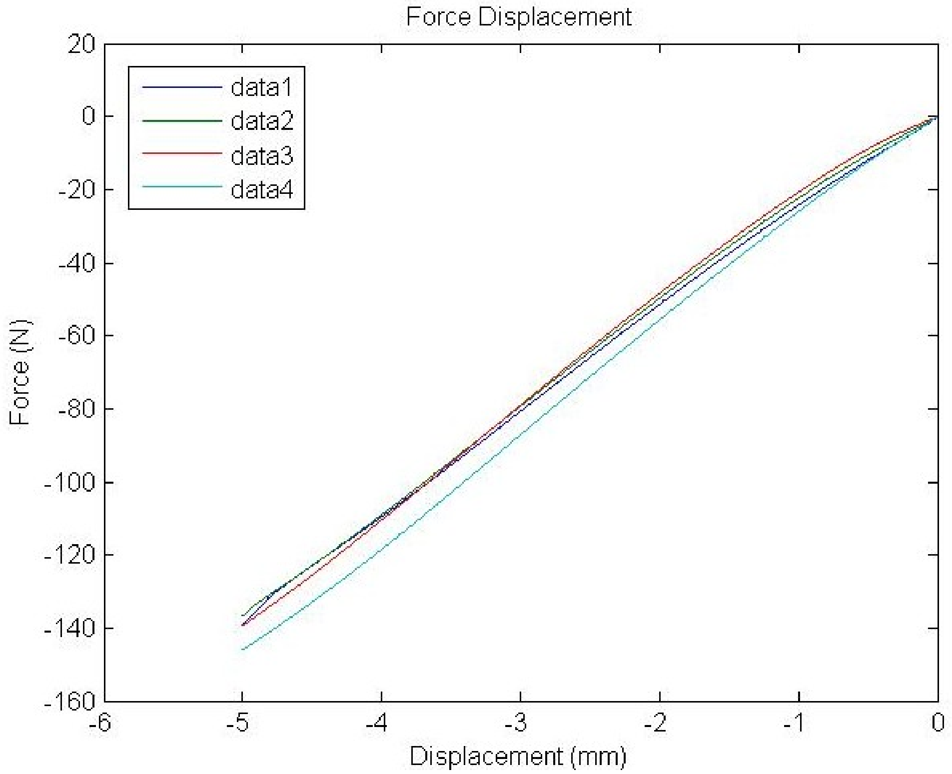


Figure 35: Force Displacement Curve of Spring Compression Testing

Using the force-displacement data collected by the Instron device, the stress in the wire may be calculated. In order to calculate the stress in a spring wire, the stress correction factor K must be determined. The stress correction factor is dependent on a geometric property of the spring, C, which is the ratio of the mean diameter to the spring diameter. This equation may be seen in Equation 2. The stress correction factor equation can be seen in Equation 3.

$$C = \frac{D}{d} = 3.1930$$

Equation 2: Calculation of C

$$K = \frac{4C - 1}{4C - 4} + \frac{0.615}{C} = 1.5346$$

Equation 3: Stress Correction Factor K

There are two methods for determining the wire stress of a spring. One method uses the displacement of the spring in question (Equation 4), and the other method uses the applied load (Equation 5). Using the displacement or load data acquired by the Instron device, stress curves may be produced. These curves may be seen in Figure 36 (displacement) and Figure 37 (load).

The displacement stress plot only shows one curve because it was calculated using the displacement and there was little variation. The springs were all compressed to 5mm and all showed similar stresses throughout the test. The average maximum stress calculated by displacement was 14884 MPa. The wire stress calculated by the applied load showed much more variation and four distinct, yet very similar, curves may be seen in Figure 37. The average maximum stress calculated using this method was 13454 MPa.

$$S_{displacement} = \frac{8RDK\Delta}{\pi d^3}$$

Equation 4: Wire Stress Using Displacement

$$S_{load} = \frac{8PDK}{\pi d^3}$$

Equation 5: Wire Stress Using Applied Load

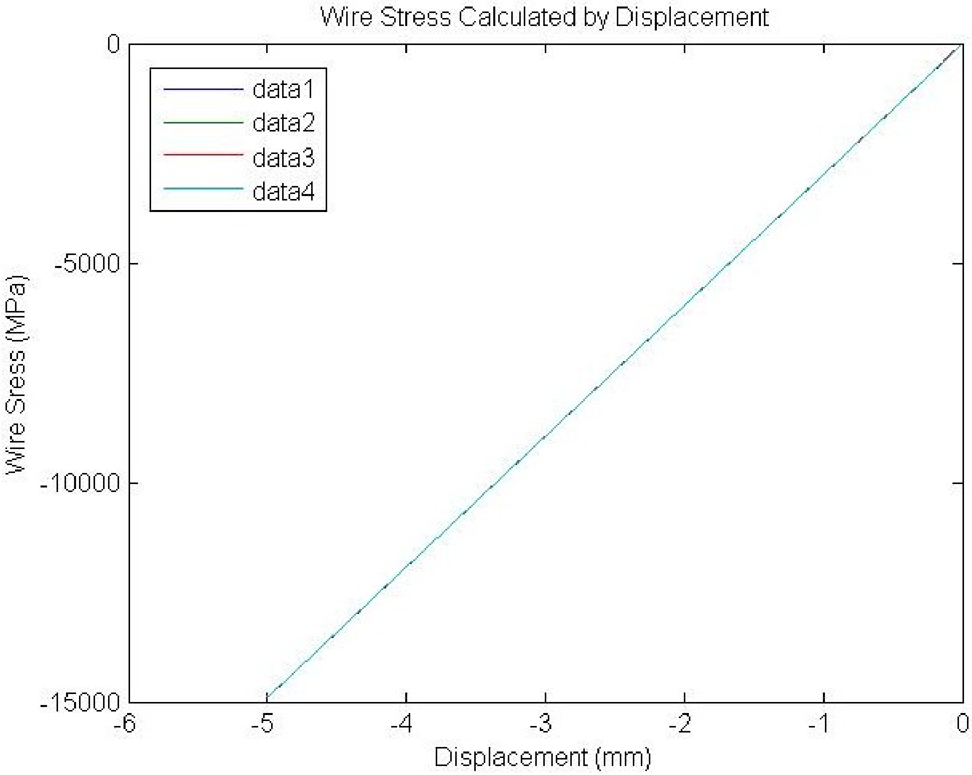


Figure 36: Wire Stress Calculated Using Displacement Data

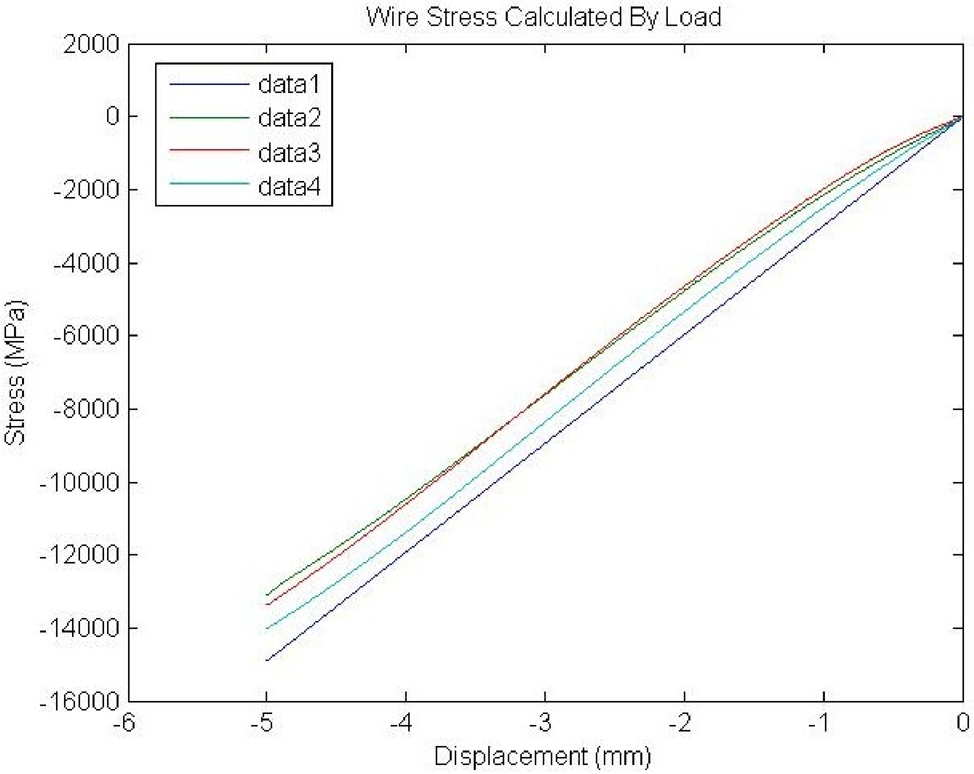


Figure 37: Wire Stress Calculated Using Load Data

5.2 Assembly FEA Modeling

Like the design alternatives presented in Chapter 4, the final design was modeled using Solidworks Simulation. The assembly was modeled as a unit. The two plates were placed in the assembly in the correct positions relative to each other. Then a spring connection was simulated between the two parallel vertical portions. SolidWorks Simulation allows the modeling of many different connection joint types such as pins, welds, and springs. To model a spring, the normal and tangential stiffness of a spring are required. The normal stiffness was modeled using the 31000 N/m spring rate provided by Century Spring and confirmed through mechanical testing. The tangential stiffness property was assigned to be an extremely high value, 1000000 N/m to ensure that the only motion during the simulation was compressive. Like the simulations for the other devices, this test was completed with a 200 N compressive load. The plates were modeled as 316L Stainless Steel.

The results of the assembly simulation may be seen in Figure 38 and Figure 39. As shown from the displacement model, the device displaces approximately 6.4mm, and surpasses the 2mm design specification. The 6.4mm displacement also surpasses the coil interaction threshold of the spring, where the spring begins to behave like a solid cylinder instead of a spring. The actual displacement should be between 5mm and 6mm. The stress graph shows stresses up to 293 MPa. This is a cause for concern because the yield strength of 316L Stainless Steel is 170 MPa. Of all the devices that have failed to hold the 200N force, the maximum stress in these plates is the closest to the yield strength of the material. Because this is also the only design that produced the required deformation, it was selected as the final design despite the stress issues. Mechanical testing will be performed to confirm these simulated results, but it is likely that future work to refine the plate design will be necessary.

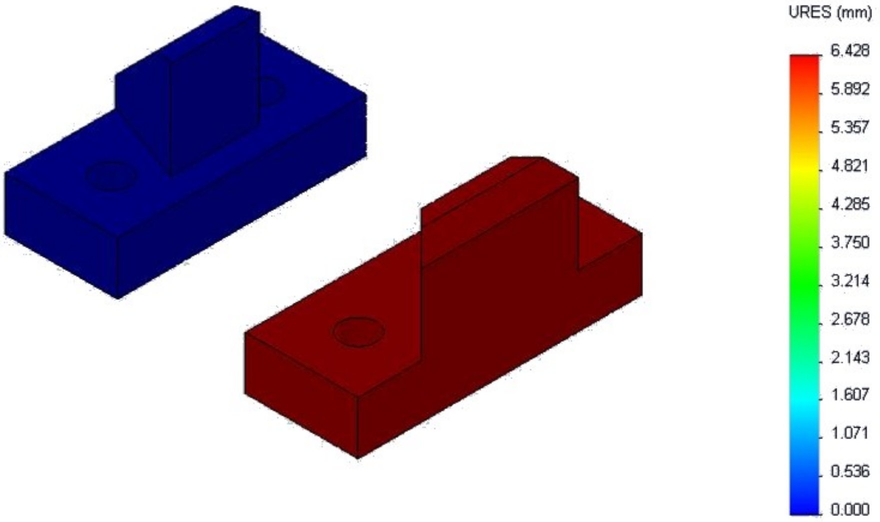


Figure 38: Device Assembly Displacement Model

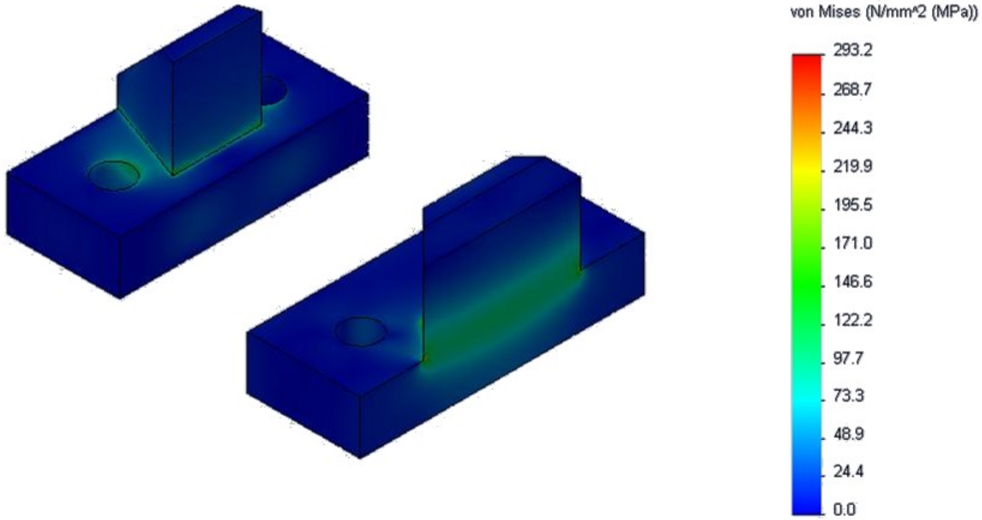


Figure 39: Device Assembly Stress Model

5.3 Assembly Mechanical Testing

Three device assemblies were constructed and tested using WPI's Instron 5544 mechanical testing device. Compression testing was performed on the device assembly. The original intention was to test the device as it would be connected in the canine. That is, using cortical screws to mount the device to a material such as PVC, wood, or bone analog. Then the mounting material would be placed between the grips for the testing. This would load and fix the device using the screw holes, as it is intended to be used. Because of manufacturing delays and equipment availability, however, countersinks were not drilled onto the plates. The 8mm self-tapping cortical screws that we had acquired could no longer reliably hold the device in place. Additionally, proper drilling equipment to insert the screws was not available.

A new test method was developed to evaluate the device assemblies. The devices were placed into the grips as shown in Figure 40. Leather strips were used to increase friction and provide a better grip on the assembly. This grip orientation was selected because it did not add support to the vertical spring attachment of the vertebral plates. The FEA simulations showed that the device would fail along the line where the vertical piece meets the rest of the plate. The devices were loaded at a rate of 20 N/min up to 225 N.

The results of the device mechanical testing may be seen in Figure 41. These data show that coil interactions began in the spring before 5mm of compression, unlike the spring alone where coil interactions began after 5mm. This was caused by bending of the spring, and could be seen during testing. This bending was expected because the axis of the spring is not along the axis of loading between the two plates. The spring offset cause a bending moment in the spring, compressive on the side of the spring near the plates. Because of this, the coils facing the plates began interfering with each other before the remainder of the coils.

The mechanical testing of the devices to 225N showed the devices ability to withstand the 200N design specification. Additionally, no signs of failure were observed. Future testing should be conducted to determine the fatigue properties of the device, and whether the device would remain functional over time.

Figure 40: Final Device Mechanical Testing Setup

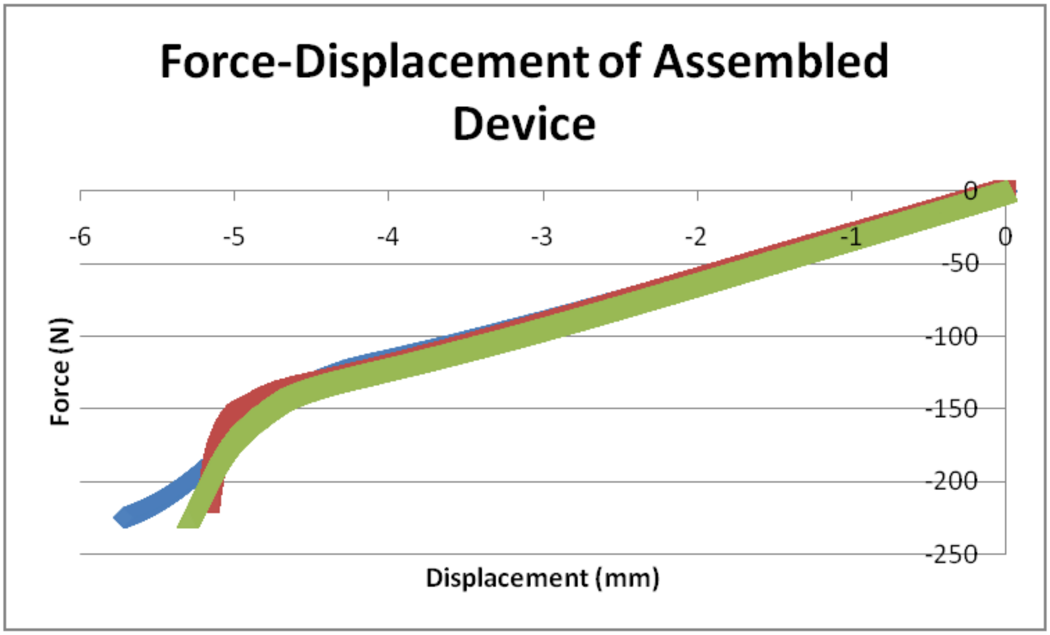


Figure 41: Final Device Mechanical Testing Results

6 Discussion

The goal of this project was to produce a canine orthopedic device to alleviate back pain in military working dogs caused by lumbosacral stenosis. To achieve this goal, four primary-level objectives were established. The device had to be safe, easily implanted, effective, and easily manufactured.

The safety objective was met by designing the device entirely of biocompatible materials. The only materials considered for the plates were Ti-6Al-4V, Nitinol, and 316L Stainless Steel. Stainless steel cortical screws were selected for fixation to reduce galvanizing corrosion. Additionally, the device was designed to reduce wear by containing minimal contacting parts.

The easily implanted objective was satisfied by ensuring that the device was implantable using current surgical techniques. To do this, we observed a cadaver dissection by Dr. Julien Cabassu, where Dr. Cabassu demonstrated the different surgical approaches to the lumbosacral joint. Our design utilizes the most common surgical approach for implantation. Additionally, it is designed to fit into the current locations used for spinal rod fixation. There is some concern that variations in dog size could lead to variations in fixation location distances. More investigation is necessary to determine the appropriateness of this fixation method. Current literature made no indication, and there was not ample enough time nor cadavers to perform our own investigation.

The effectiveness objective was satisfied by ensuring that the device met the design specifications outlined by the team. The 2mm displacement and 200N loading conditions were both satisfied by the final device.

Finally, the easily manufactured objective was met through our selection of materials and a design for manufacturing mindset. The material selection of the only manufactured parts, the plates, was made with manufacturability in mind. Type 316L Stainless was selected because it was the easiest metal to machine. Additionally, the device is made up of three separate pieces microwelded together, which is a much simpler process than a unibody device. Such a unibody device would require much more advanced and expensive manufacturing techniques.

Each year, the US Military spends hundreds of thousands of dollars on medical costs for surgeries and revision surgeries to correct lumbosacral stenosis in MWD. Additionally, dogs must be retired and newer dogs purchased and trained. This is a large monetary commitment. With a device such as this, dogs could be free of lumbosacral pain much longer, and therefore require less maintenance or new training costs.

The impact of this device on the environment would be minimal. There are no toxic, radiological, or other pollutant materials used in the device. Without knowing being an expert on the production methods of stainless steel, it is difficult to make a full account of the environmental impact of the device. Considering only the assembly and implantation steps, however, there is minimal impact on the environment.

The societal impact of this device is directly related to the ethical impact as well. The purpose of the device is to prolong the usefulness of MWD to the military. This reduces the instances of retirement. As discussed, retirement can result in either adoption or the dog being euthanized. While a successful device design will reduce the retirement rate, and therefore the adoption rate, it will also reduce the rate of dogs being euthanized. The reduced adoption rate will result in decrease of MWD being owned by private individuals, therefore reducing their presence in society. However, it will also alleviate the ethical concerns of euthanasia. The societal and ethical impacts are essentially opposite, but feed off of each other.

The political ramifications of this device could vary. By reducing the amount of retirements, the amount of trainee canines could be reduced as well. This could reduce the need for training. Without a need for as much training, resources such as personnel and facilities would not be necessary. This could lead to a loss of jobs in some areas, which can produce political ramifications.

There are no known health and safety issues for humans as a result of this device. The device is simple in its operation and does not produce any radiation or other dangerous side effects for surgeons or dog handlers. The only foreseeable safety consideration is in the manufacturing process. As with any manufacturing process, skilled and aware machinists are needed to safely operate the manufacturing equipment.

This device is very manufacturable and reproducible. The spring component is commercially available. The endplates are constructed of easily machines stainless steel. Additionally, the welding of the device is possible using current microwelding techniques.

This device has no direct sustainability effects. The only incorporation of sustainable technologies could be the power sources of the manufacturing equipment. The manufacturing was performed using computer-assisted machining devices. These devices require a large amount of power, and powering these devices using renewable energy could improve the ecological impact of the device.

7 Final Design and Validation

The final design of this device was derived by the accumulation of background knowledge, the pursuit of our project objectives, and the results of experimental testing. Through the preliminary literature review, we were able to determine a design specification of withstanding 200N of force on the device. By participating in a canine cadaver dissection, the team was able to determine the displacement in the joint to be approximately 2mm. This was established as the project's other numeric design specification. The other design specifications were more abstract. The device had to be safe, that is biocompatible with the dog. To achieve this objective, Type 316L Stainless Steel was used in the design of the device. This material is known to be biocompatible and is currently used in numerous implants. Additionally, during the design process alternative designs that included the minimal amount of contacting or moving parts were considered to reduce the possibility of wear. The device had to be shown effective by meeting the 20N and 2mm design specifications outlined earlier. The device was ensured to meet the sizing specifications by taking measurements of the lumbosacral joint during a cadaver dissection. The surgical techniques used for implantation as also determined during the cadaver dissection. This ensured that current surgical practices would be used to implant the device. Finally, the device had to be easily manufactured. The final design of this device was manufactured using endmills cutting the pieces from a stock piece of 316L stainless steel. The device was assembled using current microwelding techniques.

After design and assembly, the device was tested in computer simulations using SolidWorks Simulation. The spring component was tested independently to determine its ability to withstand the 200N load and displace the required 2mm. Then, the assembled device was mechanically tested to determine if the plates could meet the same specifications. By showing that the assembled device could meet these criteria, and remembering the other objectives that were considered during the design process, the final design is a device that fully meets the goal outlined by the project.

8 Conclusions and Recommendations

The device developed as a result of this project met all the design specifications and completed the project objectives. The device withstands the loading present in the lumbosacral facet joint and is capable of displacing enough to preserve range of motion in the canine. If implanted, this device should provide a reduction in pain for the dog while maintaining range of motion. These results are an improvement over current spinal rod fixation of vertebrae fusion techniques which relieve pain but reduce mobility. The reduction of pain in preserved range of motion should allow canines affected by degenerative lumbosacral stenosis to return to active military service. This will result in a decrease in the rate of premature retirement of these highly-trained animals.

The results of this study are of course preliminary. No in vivo testing has occurred, which is necessary before making any claims of a successful device. Additionally, investigation should occur into the variability of spinal rod fixation locations among these animals. Slight changes in dog size could alter the locations of safe drilling areas on the vertebrae, which is problematic for any device designed with a plate. This project did not have the time nor the resources to conduct such a study. This study showed the device's ability to withstand the desired load for one cycle. More experimentation is necessary to determine the effects of fatigue on the device's lifetime. Finally, a biomechanical study should be conducted to determine the effects of stress shielding in the area, and how this phenomena could alter the structure of the spine.

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Appendix A: MWD Mission-to-Type Matrix

Adapted From (Riley, 2005)

Mission	***MWD Type***		
	PEDD	**PNDD**	**PD**
A. Area Security Operations			
(1) Area and reconnaissance	X	X	X
(2) Screening and surveillance	X	X	X
(3) Base/air-base defense	X	X	X
(4) Cordon and search	X		
(5) Checkpoints	X	X	X
(6) Roadblocks	X	X	X
(7) Response force	X	X	X
(8) Critical site, asset, HRP security	X[1]	X	X
B. Maneuver and Mobility Support Operations			
(1) Maneuver support	X	X	X
(2) Mobility support	X	X	X
C. I/R Operations			
(1) EPW and CI	X[2]	X[2]	X[2]
(2) Evacuation	X	X	X
D. Law and Order Operations			
(1) Force protection	X	X	X
(2) Military Police Investigations		X	
(3) Customs support	X	X	
(4) Redeployment operations	X	X	
(5) Suspicious/unattended packages	X[3]		
(6) Health and welfare inspections	X	X	
(7) Crowd control	X[4]	X[4]	X[4]
(8) Alarm responses	X	X	X
(9) Bomb threats	X		
(10) Public MWD demonstrations	X	X	X
E. PIO	X	X	X

[1] PEDDs will not be used to provide security in ASPs, as the ammunition and explosives contained at the ASP will detract from the MWD's detection ability and may distract the MWD from his patrol function.

[2] MWDs will not be used in a correction/detention facility to ensure custody of prisoners.

[3] PEDDs can be used to search the area around a suspicious/unattended package for secondary devices. At no time will a PEDD or handler be used to search the package itself.

[4] Direct confrontation with demonstrators is not recommended, but is authorized with the commander's approval when lesser means of force have been unsuccessful.

PEDD: Patrol Explosive Detector Dogs
PNDD: Patrol Narcotic Detector Dogs
PD: Patrol Dogs

Appendix B: Table of Lumbosacral Stenosis Statistics in 29 Military Working Dogs

Adapted from (Linn, Bartels, Rochat, Payton, & Moore, 2003)

Variable	All Dogs	Return to Normal Function	Improved Function	No Change
Breed	Total = 29	Total = 12 (41.4%)	Total = 11 (37.9%)	Total = 6 (20.7%)
Belgian Malinois	18	6 (33.3%)	8 (44.4%)	4 (22.2%)
German Shepherd	9	4 (44.4%)	3 (33.3%)	2 (22.2%)
Dutch Shepherd	1	1 (100%)	0	0
Labrador Retriever	1	1 (100%)	0	0
Gender	Total = 29	Total = 12 (41.4%)	Total = 11 (37.9%)	Total = 6 (20.7%)
Male	18	8 (44.4%)	5 (27.8%)	4 (22.2%)
Male (castrated)	6	1 (16.7%)	5 (83.3%)	1 (16.7%)
Female (spayed)	5	3 (60%)	1 (20%)	1 (20%)
Mean Age (Months)				
At first clinical signs	73	62	78	90
At diagnosis	86	71	91	108
At surgery	89	74	93	112
At death	113	109, n = 3	111, n = 5	116, n = 6
Surgery to death	15	33, n = 3	17, n = 5	4, n = 6

Variable	All Dogs	Return to Normal Function	Improved Function	No Change
Clinical Sign	Total = 29	Total = 12 (41.4%)	Total = 11 (37.9%)	Total = 6 (20.7%)
Lameness	21	8 (38.1%)	8 (38.1%)	5 (23.8%)
Pain	21	7 (33.3%)	10 (47.6%)	4 (19%)
Lethargy	5	1 (20%)	4 (80%)	0 (0%)
Slow to Rise	2	0 (0%)	1 (50%)	1 (50%)
Reluctance to jump	11	5 (45.5%)	5 (45.5%)	1 (9.1%)
Reluctance to search high				
Muscle tremors	4	2 (50%)	1 (25%)	1 (25%)
Paresis	4	3 (75%)	0 (0%)	1 (25%)
Atrophy	12	2 (16.7%)	6 (50%)	4 (33.3%)
Dragging Toes	9	1 (11.1%)	3 (33.3%)	5 (55.6%)
CP deficits	5	1 (20%)	2 (40%)	2 (40%)
Ataxic/abnormal gait	16	4 (25%)	7 (43.8%)	5 (31.3%)
Urinary incontinence	9	4 (44.4%)	3 (33.3%)	2 (22.2%)
Fecal incontinence	2	0 (0%)	1 (50%)	1 (50%)
	2	0 (0%)	1 (50%)	1 (50%)
Surgical Procedures	Total = 26	Total = 11 (42.3%)	Total = 9 (34.6%)	Total = 6 (23.1%)
Dorsal Laminectomy	7	2 (28.6%)	2 (28.6%)	3 (42.9%)
Facetectomy	3	1 (33.3%)	2 (66.7%)	0 (0%)
Foraminotomy	8	4 (50%)	4 (50%)	0 (0%)
Discectomy	11	6 (54.5%)	2 (18.2%)	3 (27.3%)
Traction-fusion	1	0 (0%)	1 (100%)	0 (0%)
Surgical findings				
Subluxation of L7	12	3 (25%)	6 (50%)	3 (25%)
Hypertrophic ligamentum flavum	15	8 (53.3%)	4 (26.7%)	3 (20%)
Hypertrophic articular facets				
Hypertrophic interarcuate ligament	5	0 (0%)	4 (80%)	1 (20%)
Bulging disc	2	0 (0%)	1 (50%)	1 (50%)
Nerve root entrapment	13	6 (46.2%)	4 (30.8%)	3 (23.1%)
Thickened lamina	14	6 (42.9%)	6 (42.9%)	2 (14.3%)
Natural fusion of L-S components	2	1(50%)	1 (40%)	0 (0%)
	3	1 (33.3%)	2 (66.7%)	0 (0%)

Appendix C: Final Design Drawings