## ABSTRACT

McCULLOCH, RYAN STERLING. The Effectiveness of Cerclage Wiring on Stabilizing Intra-Operative Femoral Fractures During Cementless Total Hip Arthroplasty in Canines. (Under the direction of Peter L. Mente and Simon C. Roe).

Force is required to prepare the bone and achieve the initial press fit for an uncemented hip implant during Total Hip Arthroplasty (THA) surgery. In some situations, this force may cause of an intra-operative femoral fracture resulting in an unstable implant, subsidence, and pain for the patient. Many of the less extensive fractures can be repaired with cerclage wire or cables. This study aimed to evaluate the ability of double loop cerclage wire(s) to restore the stability of the implant-bone interface after a simulated intra-operative fracture. Nine femora from euthanized canine were harvested for in vitro testing. The femora were prepared for implantation of an uncemented femoral stem (BFX™ series, BioMedtrix, Boonton, NJ). They were then potted and mounted in a materials testing machine (MTS 858 Mini Bionix II, Eden Prairie, MN). The implant was driven to a clinically appropriate height, struck with 3 impacts (simulating seating hammer blows), and then the stem loaded to failure. Once a fracture occurred, the implant was extracted, the femur was repaired with appropriate cerclage, re-broached, and re-implanted. The repaired specimen was then tested in the same fashion as the intact bone. During loading, the displacement of the implant relative to the bone was measured using a linearly variable differential transformer (LVDT). The force to initiate subsidence, the peak force at failure, and the peak subsidence distance were compared between intact (pre-fracture) and repaired (post-fracture) specimens using ANOVA with blocking by specimen. The wired specimens demonstrated a higher force to initiate subsidence than the intact specimens (2378.8N ±

656.9N *c.f.* 1705.1N ± 584.5N; p= 0.0019). The wired specimens also sustained a higher peak force at failure than the intact specimens (3309.0N ± 609.14N *c.f.* 2276.3N ± 855.6N; p 0.0022). Furthermore, the wired specimens did not subside a significantly greater amount than the intact specimens (Intact: 3.90mm, SD 2.09mm; Wired: 6.71mm, SD 3.66mm; p-value 0.0600). Cerclage wiring of intra-operative femoral fractures was able to restore the integrity of the femur and enable a stable implant-bone interface to be achieved.

# The Effectiveness of Cerclage Wiring on Stabilizing Intra-Operative Femoral Fractures During Cementless Total Hip Arthroplasty in Canines.

by
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## DEDICATION

*To my wife, Danielle, for your incredible love and support in this pursuit which otherwise would not have happened.*

## BIOGRAPHY

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## TABLE OF ABBREVIATIONS

**Table 1.** Abbreviations used in this paper.

| | |
|---|---|
| Contacting Neck | Failure by stem of implant contacting the medial edge of femoral neck cut |
| Force at failure | Peak force at failure |
| Force to initiate subsidence | The force sustained during loading prior to any subsidence occurring |
| OA | Osteoarthritis |
| LVDT | Linearly Variable Differential Transformer |
| MTS | Materials Testing Systerm (MTS 858 Mini Bionix II, Eden Prairie, MN) |
| Pre-cerclage | pre-cerclage trial (an intact specimen, before a fracture occurred and was repaired with cerclage wiring) |
| Post-cerclage | post-cerclage trial (specimen failed by fracture and cerclage wires were placed) |
| THA | Total Hip Arthroplasty |
| Strain difference | Difference of Cranial and Medial Strains (cranial minus medial) |

# 1. INTRODUCTION

## 1.1 Motivation

Osteoarthritis (OA) is a disease that has become very prevalent in both this country and the rest of the world. OA leads to the degradation of the cartilage at the joint surfaces and generates significant pain for the sufferers. While this disease is commonly thought to exclusively effect elderly individuals, this is not true. OA is prevalent in individuals as young as those in their twenties and thirties, hardly elderly individuals (Amstutz, 1991).

Additionally, canines suffer profoundly from OA. Commonly caused by hip dysplasia, many large breed dogs suffer from this affliction including the popular Labrador breed. The dog's hip joints slowly deteriorate until the gait becomes very painful and the animal begins to limp instead of walking.

Once the initial treatments of anti-inflammatory/analgesic medications and weight loss become unsuccessful at managing the pain, the best treatment for OA in the hip joint is the Total Hip Arthroplasty (THA) which has been developed and continuously improved over decades. THA involves removing the head of the femur, reaming a channel for the stem and placing an implant in the femur. The head of the implant articulates with a prosthetic acetabulum. Both cemented and non-cemented THAs are used in practice.

One potential complication when placing an uncemented hip implant is a peri-operative fissure or fracture of the femur. These fractures can result in significant subsidence (sinking in or settling in of an implant within the femur) and subsequent clinical failure of the implant if not corrected. One common method of stabilizing long oblique fractures adjacent to femoral stems involves the use of cerclage wire. This method involves using medical

grade stainless steel wire to form a double loop around the proximal end of the femur. More than one cerclage may be used and the tension generated when placing them helps to close the fracture and stabilize the femur to accept the implant. Currently, no work has been done to quantify the effectiveness of cerclage wires for stabilizing a post-fracture femur for implant in regard to load sustained and subsidence experienced. The current study aims to conduct this analysis.

### 1.2 Experimental Outline

Femora from euthanized canines (euthanized for purposes unrelated to this study) were obtained. These femora were reamed and broached in preparation for an uncemented femoral stem (BFX™ series, BioMedtrix, Boonton, NJ). Strain gauges were attached to the medial and cranial aspects. The bone was then supported in a hydraulic testing machine for experimental testing. The machine was used to press the implant into the femoral envelope until a clinically appropriate height was reached, then the implant was hammered three times to seat the implant with a load approximating that used by the surgeon, and then the implant was loaded to failure (defined as either the implant neck contacting the neck of the femur or a femoral fracture). Following this initial testing, the implant was extracted, and the bone prepared for the next size implant, if space was available, or with the same size implant. If failure occurred by contacting the neck, the specimen was tested again with a larger implant. If failure occurred via a fracture, the fracture was stabilized using double loop cerclage wire and the specimen was re-tested.

In all trials, the force, the cranial and medial proximal strains in the cortical bone, and the relative displacement of the implant to the femur were recorded continuously.

### 1.3 Hypothesis

It was hypothesized that femoral stems implanted in bones with a cerclage repaired fracture would be as stable as femoral stems in intact bones which had not experienced a fracture. There were three hypotheses tested: 1) The force required to initiate subsidence in a cerclage repaired specimen (post-fracture) would not be statistically lower than the force required to initiate subsidence in an intact specimen (pre-fracture). 2) The maximum force sustained prior to failure in a cerclage repaired specimen would not be statistically lower than the maximum force sustained in an intact specimen. 3) The maximum subsidence of an implant in a cerclage repaired specimen would not be statistically higher than the maximum subsidence measured in an intact specimen.

## 2. BACKGROUND

### 2.1 History of THA

Hip arthroplasty has developed mostly over the last two centuries. At times the progress has been rapid, and at others times it has been quite slow. Hip surgeries were performed as early as the 1700s. In some cases, when a joint became infected or severely arthritic, a surgeon would excise the joint to remove the effected tissue and to restore some joint mobility. This practice never gained a strong foothold in medicine, but is nonetheless the earliest known work in hip surgery (Gomez *et al.*, 2005).

In the mid 1800's surgeons in France began the use of interpositional arthroplasty (placement of a material between the bearing surfaces) in an attempt to improve the bearing surface. Dr. Verneuil attempted the use of adipose tissue. However, his attempts were ineffective. Following this, Dr. Chlumsky in Germany used many different interpositional materials: muscle, celluloid, silver, magnesium, zinc, glass, etc (Amstutz, 2000). These materials acted as a bearing surface for the joint, and none were very effective.

The first development of a hip implant that is recognizable as a predecessor to the modern implant occurred at the hands of a German professor, Dr. Gluck. He experimented with an ivory ball and socket joint in the late 1800s (Gomez *et al.*, 2005).

Many experimental attempts continued until 1923 when Dr. Smith-Petersen of Boston, Massachusetts first developed a mold prosthesis with synthetic interpositional material for hip arthroplasty. His early methods used a glass interpositional material that was placed between the femoral head and the acetabulum during surgery. The glass ended up breaking frequently during use, however he was heartened by the fact that a "membranous"

lining formed over the glass. In 1937 he began experimenting with Vitallium and obtained good results (Gomez *et al.*, 2005).

Also in the early 1900s the Judet brothers (France) attempted the use of an acrylic prosthetic. However, in use this material demonstrated an exceptionally high wear rate. In the 1940s Dr. Girdlestone popularized a method of resection of the femoral head. This procedure called for the removal of the head if the joint was infected or in some other way compromised (Gomez *et al.*, 2005).

In the 1940s, Dr Haboush and Dr. McKee developed a prosthetic and experimented with dental acrylic cement for fixation (Amstutz, 2000). Their designs had a high failure rate because of loosening of the components of the implant. Dr. Ring experimented with cementless components using metal-on-metal contact in the 1960s. These designs went out of vogue for many years, but have made a resurgence of late (Amstutz, 2000). The first design resembling a modern prosthetic hip originated in the 1950s. Dr. Thompson developed a Vitallium prosthetic with a flared collar below the head and a vertical intramedullary stem. The first such stem was implanted by Dr. Bohlman and Moore who later refined the model to have a fenestrated stem that allowed for bone ingrowth (Gomez *et al.*, 2005).

Gomez et al. (2005) covers the very interesting history of Dr. Charnley. The major advancement of the modern hip design occurred at the hands of Dr. John Charnley. Dr. Charnley was trained as a general surgeon and began to work in orthopedics during World War II. He began to specialize in the function and repair of the hip joint. He even conducted experiments upon himself, such as bone surgeries, to better understand the role and function of bone and joints. He noted that during the examination of a patient who was fitted with a

Judet prosthetic that the patient said that his implant squeaked when he leaned forward. With this observation, Charnley stumbled upon one of the major findings: namely, that a larger femoral head and associated acetabular cup generates larger frictional forces than that of a smaller head design. He therefore proceeded to design an implant with a femoral head size of 22mm.

Dr. Charnley also realized the need for low friction surfaces in the implant design. He experimented with, and ultimately developed and implanted a line of implants with polytetraflouroethylene (PTFE) bearing surfaces on both the cup and head sides of the implant. The *in vitro* testing was extremely promising. However, once implanted they generated excessive wear debris and even more importantly evoked a serious foreign-body reaction. Following this failure, he experimented with ultra high molecular weight polyethylene (UHMWP) which was first used in the textile industry. He implanted the first socket using UHMWP in 1962. UHMWP proved to be a success. At the same time, surgeons adapted dental cement for use as bone cement, polymethylmethacrylate (PMMA).

Charnley was the first to note that the bone cement achieved a mechanical bond with bone rather than a chemical adhesion. He was also the first to note the occurrence of bone resorption at points of high stress. Charnley performed more than 1,000 arthroplasties a year, and in the performance of all these procedures he observed occasional deep infections. He realized that the infections came from skin organisms and thus instituted the performance of THA under aseptic conditions using filtered air operating enclosures and special suits for the surgeons and assistants to wear (Ellis, 2006). He was truly a pioneer in THA.

Charnley went on to foster a new relationship with industry, developing implants with symbiotic work from surgeons and industry. He worked with Thackray Limited which still exists today as a subsidiary of DePuy Orthopedics. His pioneering efforts developed a novel cemented implant that was and still is used the world over. He never patented his design, so his basic ideas were used by many surgeons and companies everywhere to generate their own spinoff designs (Gomez, 2005).

In the late 1970s and the early 1980s, however, cemented stems were observed to frequently fail (Learmonth *et al.*, 2007). It was believed that observed bone resorption was due to wear debris of PMM and polyethylene, from the acetabular cup implant, accumulating in adjacent biological tissue. Additionally, the surgeon's techniques for using the cement can vary widely and the cement has to be mixed up at the time of surgery. Obviously, the use and mixing of the cement can be a source of quality control concerns. It was also noted that implants frequently failed in the younger patients who were much more mobile. Thus, surgeons generated the idea of utilizing a cementless stem. The stem would be stabilized by bony ingrowth occurring in the medullary canal. The surface of the implant was designed with pores, etched, beads, or other methods for providing a path for ingrowth (Learmonth *et al.*, 2007).

The first uncemented stem was implanted by Judet in France in 1971. The stem had a macrotextured surface of 1mm projections (Amstutz, 1991). The surface was extremely rough by today's standards. Other similar designs followed which all had the entire surface of the stem covered with a porous surface. However, with these stem designs the bone ingrowth primarily occurred at the distal portion which decreased the flexibility of the stem,

and resulted in thigh pain, proximal atrophy, and fatigue fracture of the stems. The next major advance was a stem that had pores made up of sintered beads on only the proximal surface. This stem was developed by Pillar and was the predecessor to the modern uncemented stem (Amstutz, 1991).

The use of THA to solve problems with the hip joint has become a relatively common procedure. It is estimated that there are approximately 200,000 replacements performed per year in the United States (JISRF, 2008). In fact, it is projected that the incidence of total hip arthroplasty will increase 175% over the coming years to a total of 572,000 implants per year by 2030 (Sanfilippo, 2006).

**2.2 Canine THA**

Many dogs have been the recipients of THA. Much work was done in the early 1980s and the number of procedures have continued to increase since that time based upon the increase in articles concerning canine THA at this time. Initially dogs were seen as a good model in which to study the finer points of the surgery, implant technique, design, and function before transferring the designs and procedures to use in humans. From the success of these procedures, it was seen that many dogs could benefit greatly from receiving a hip implant. These two needs insure that THA will be performed on dogs well into the future.

Dogs have been been used extensively in the study of the methods and details of using hip implants. Scientists and researchers found dogs to be a particularly well suited model for learning about THA in preparation for performing procedures or using new materials or designs on humans. There is a large amount of data on canine skeletal

dynamics, and they are known to develop OA in the hip at an early age (Bragdon *et al.*, 2004). There were multiple reasons to perform studies on dogs. Bragdon *et al.* used dogs for a host of implant studies including bone ingrowth, fixation, bone implant gap, micromotion, and many others. Dogs will certainly continue to be used for research. However, there has been some decrease in the usage of canines due to ethical concerns and because dog bone growth is better than osteoporotic human bone ingrowth, which makes canines a less relevant model. Both sheep and goats have been used in order to avoid ethical concerns, as dogs are much more frequently considered pets. Interestingly, Emus have been proposed as a biped animal model, based upon the experience of the surgeon involved in this study.

Canines suffer from a relatively high risk of hip dysplasia along with other joint ailments. For these reasons, hip implants have become much more common as a solution to joint problems in dogs. Like humans, cemented implants were first used in canines, but in an effort to escape problems with implant fixation and PMMA side effects, cementless implants began to see use in canines. A study of 50 dogs with a 6 year follow-up found that the clinical and radiographic long-term results of uncemented THA were excellent (Marcellin-Little, 1999). This study found bone ingrowth stabilizing the implants, very little subsidence, and a cumulative survival rate for the THA of 87% at 6 years.

One challenge with performing a hip replacement surgery in a dog is that there are numerous breeds and therefore a wide range of sizes of the femurs. One study set out to form a database of femur morphology for the use of the veterinarian performing a THA (Palierne *et al.*, 2006). They used 24 different internal and external features of the canine femur to classify it based upon the breed. Interestingly they found that although the size of

the femur varies greatly between breeds, the shape of the femur has less variance among dogs (no matter what breed) than it does in humans. A logical conclusion is that with implants made in different sizes, standardized shapes can be generated that will fit well among many breeds. Another interesting outcome of this classification of canine femurs was that the common technique of doing comparison studies on contralateral limbs is surprisingly valid. In fact, it was found that there was almost no bilateral variation in the canine femurs. Therefore, contralateral hips from the same animal are useful for controls. A very interesting finding of great use in research (Palierne *et al.*, 2006).

Hip arthroplasty is often very effective in providing dogs with a better quality of life. A survey of 145 pet owners whose dogs had undergone surgery a THA found that: 90.4% of owners thought that the surgery either decreased or completely eliminated their dog's source of pain; 92.4% said that the surgery either somewhat or substantially increased function of the joint; 73.1% rated the surgery as excellent; and 92.5% responded positively that the expense of the surgery was justifiable. The study showed that 34.5% reported that the dog's Quality of Life (QOL) was more improved following the surgery than they thought was possible, while 47.6% reported a great improvement, 9% moderate improvement, 2.8% slight improvement, 1.4% no improvement, and 0.7% reported worsening. Clearly, owners very strongly believe that total hip arthroplasty is very beneficial to their dogs. In fact, several dog owners believed that their dogs would have fared better had they undergone bilateral THA as opposed to unilateral. The owners felt so positive about the surgery that they would have preferred that their pet had both hips replaced instead of just one, a resounding success story (Skurla *et al.*, 2000).

In a study of dogs who had undergone THA (Olmstead *et al.*, 1997) and had the implants for up to almost 10 years, the authors firmly believed that THA was a beneficial procedure that could help the dog for many years. The authors believed that, based upon their experience, the prosthesis would last the lifetime of the canine. Since revision surgeries have a much higher incidence of complications and infections, this is a tremendous advantage, that the primary implant should last as long as the dog needs it.

### 2.3 Cemented vs. Uncemented Implants

The most commonly used fixation technique for total hip arthroplasties involves the use of polymethyl methacrylate to cement both the femoral stem and the acetabular cup in place. (Amstutz, 1991) This method was widely and exclusively utilized for a couple of decades until uncemented implants were popularized. However, there are a few concerns with using cement to stabilize a stem. The cement is mixed in the operating theatre. Unfortunately, this generates some slight differences in the quality of the cement that each surgeon mixes and introduces some variability in the quality of the interface properties. Also, there is some evidence that the cement causes stress shielding and subsequent bone resorption. Other concerns are tissue necrosis due to the exothermic curing of the cement and loosening of the implant within the cement bed over time. Finally, removal of the cement for revision surgery or when infection is present can be a difficult process (Parker, 2007).

There are a few advantages to cemented implants. They are immediately stable after the surgery. This results in less pain after surgery since the implant is constrained and unable

to move. Additionally the implant fit is not as critical or precise as that for an uncemented implant since the cement will fill in gaps between the bone and the implant. Thus, the surgeon has a bit more latitude in the formation of the canal for receiving the implant.

Uncemented implants have gained a large following. The reasons for this are numerous. First, the implants encourage bony ingrowth (osseointegration) into the implant for secure fixation, therefore becoming "one" with the bone. Two, they are more resistant to bone resorption. They generate no additional necrosis of the tissue during surgery and generate no PMMA wear debris. Finally, they tend to become more secure with time.

The disadvantages of uncemented hip implants are that they are harder to implant. They must have a very tight press fit for initial stability. The surgeon must create a very precise bone bed, which can be technically challenging. They also require that patient movement be restricted post-surgery to allow for bony ingrowth into the implant for stabilization and to prevent subsidence.

There is much debate about which style of implant is best and the result is far from decided. One study (Engesaeter, 2007) has shown that with normal cement, cemented hips tend to have a much higher infection rate than uncemented hips (1.8 times greater). In fact the study claimed that perioperative infection occurs in 30% of all operations. However, if antibiotic loaded cement is used then there is no difference in infection rate between cemented and uncemented THA.

A large study in Finland (Eskelinen, 2006) evaluated the rate of revisions for hip implants and found that there was very little difference between the two fixation methods. Both types had greater than 90% survival at 7 years, and at 15 years, the survival rate was

89% for porous uncemented implants and 84% for cemented. They determined that uncemented implants with a porous region for bony ingrowth at the proximal end had a lower risk of revision that cemented stems.

Another study (Sanfilippo *et al.*, 2006) found that the success for newer designs of cementless hip implants were significantly better than they used to be with loosening rates of only 0.7-5.9% and revision rates of 0.3-4%. It was found that the survival rates in younger patients were excellent with survival rates (8-12 yr) greater than 97%.

### 2.4 Materials

The implants used in this study are manufactured from cobalt-chromium. Another commonly used material for biomedical implants is titanium. Cobalt-Chromium is hard material that is resistant to wear and very stable in the body. It has a higher modulus of elasticity than Titanium, and at least one author found this beneficial, with the survival rate in regards to stem loosening after 5 years being significantly higher for Co-Cr than for Titanium and its alloys (Schweizer *et al.*, 2005). The authors hypothesized that the lower modulus of elasticity of Titanium implants, particularly in smaller sized, allowed for loosening of the implants. Cobalt-Chromium can be polished to a very smooth surface. Bischoff *et al.* showed that highly polished Cobalt Chrome implants have superior corrosion resistance to Titanium alloys (Bischoff *et al.*, 1994). Cobalt Chrome implants can be either cast or forged, with forged implants providing better strength and fatigue characteristics.

## 2.5 Bone Ingrowth

With uncemented implants, the fixation of the implant relies upon bone ingrowth into the implant to provide a stable and strong interface. This is opposed to the cemented implant where PMMA cement provides the mechanical bond to the bone. A key concern for the uncemented hip implant is the texture of the surface. The surface has to have the correct roughness to promote the ingrowth of bone into the implant. Initially, implants with a smooth surface and a pure press-fit application were used (Gomez *et al.*, 2005). However these implants tended to loosen over time. In one case, implants were used that had a right hand thread imprinted on the surface of the implant. This resulted in the left hip tightening and the right hip loosening when the patient walked up a flight of stairs! (Bauer *et al.*, 1999).

Bauer *et al.* also showed that multiple factors influence bone ingrowth into the implant: the type of loading, the bone-implant interface, the shape of implant and the surface texture, etc. Many different finishes have been used, and it has been shown that a pore size of approximately 50 μm to 400 μm can provide an optimum path for bone ingrowth. Interestingly, bone ingrowth is also affected by the proximity of the implant to the cortex. It has been shown that higher amounts of bone ingrowth occur in the anterior and medial locations of the implant. These areas are closer to the femoral endosteum, whereas the lateral and posterior regions are separated from the cortex by cancellous bone. More bony ingrowth helps to stabilize and strengthen the implant (Bauer *et al.*, 1991).

The implant generates varying stresses and strains within the bone. As explained in a paper by Leucht *et al.*., the bones that make up the skeleton are continuously under load and their tissues must be able to biologically respond to the mechanical stimuli to which they are

subjected (Leucht *et al.*, 2006). It was found that bone formation surrounded the implant after 14 days post-surgery and by 28 days post surgery a well organized layer of bone encapsulated the implant on all sides. Additionally, clinical studies have shown that when the implant is placed into bone, the periosteum proliferates and enhances bone formation in the days immediately following implant (Frenkel *et al.*, 2004). Amstutz (1991) reported that strains (.25-0.5microstrain) generated by micromotions cause bony encapsulation to occur. However, if the strain exceeds 0.5microstrain, fibrous tissue tends to form. In a strain-free and motion free environment, only a baseline level of osteogenesis occurs. The micromotion should be kept to under 30μm. If the motion exceeds this level, breaking of the bridging trebeculae can occur (Amstutz, 1991). Too much motion, and bone cannot form and fibrous tissue results; too little motion, and bone is not stimulated to grow.

The gap between the implant and the bone also determines the amount of ingrowth which can occur. It has been shown that gaps of up to 1 to 2mm can be bridged by bone, although surgeons aim for a tighter during an implant procedure. The bone bridging the gap is somewhat unstable, and a much stronger fixation can be achieved if the bone and implant are in close, tight contact (Amstutz, 1991).

Bone ingrowth is also influenced by numerous other factors out of the control of the surgeon. The bone quality, health of the patient, and patient age, all contribute to the development of a stable bony interface (Bauer *et al.*, 1999). Drug treatments for various conditions have also been found to negatively effect the amount and quality of bony ingrowth that occurs (Bauer *et al.*, 1999).

## 2.6 Fracture

Perioperative fractures (fractures that occur during or immediately following surgery) occur in approximately 1 percent of cases of cemented hips (Tsiridis *et al.*, 2002). The range for uncemented hips is considerably higher with a range of 3 to 18 percent. Causes of the fracture include: joint dislocation, implant preparation, stem impaction, or the final reduction of the joint reduction (Amstutz, 1991). The implantation of an uncemented stem requires a very tight press fit to obtain optimal fixation. This necessitates the use of a hammer with carefully judged blows to drive the broach in for preparation of the bed and for the actual placement of the implant. One study found the incidence of fracture during THR to be 2 to 6% of the total cases (Berend *et al.*, 2006), while another study found that the incidence is 3 to 18% for uncemented implants (Tsiridis *et al.*, 2002). Overall, the incidence of fracture is most likely somewhere well under 10% (Tsiridis *et al.*, 2002). This still a significant concern for surgeons as it represents a large number of patients.

In the preparation of the implant bed, there are numerous steps which depend upon the precise work of the surgeon. A pilot hole is drilled to establish the proper orientation of the rasps, reamers, and broaches. The surgeon must take special care to have the pilot hole follow the canal along the axis of the bone. Next, the reamers ( tools used to open the canal) must be correctly sized, oriented and have adequate cutting edges. The reamer must also be used to the correct depth. The broaches (tools used to cut the envelope for the implant) are used as the final step for preparation of the bed. These must have sharp cutting teeth and must be very precisely sized to match the geometry of the implant which is to follow. The appropriate amount of force must be utilized when driving the broach (Amstutz, 1991).

There has been some work done to determine what method for preparing the bed is best. A study by Kold *et al.*, evaluated the difference in fracture risk by performing a controlled experiment using a smooth tamp and a toothed broach to prepare the implant bed (Kold *et al.*, 2003). The toothed broach has cutting teeth that cut the canal of the bone to develop the properly sized bed for the implant. Both the tamp and the broach are hammered into place to form the bed. It was found that the smooth tamp had a significantly higher incidence of fracture development than did the toothed broach. It was believed that the higher fracture rate was due to significantly higher hoop stresses in the cortical wall formed by the driving of the smooth tamp.

An intraoperative fracture can occur during the reaming or broaching procedures. However the most common time when a femoral fracture occurs is during revision surgery for a loose implant (Tsiridis *et al.*, 2003). The implant has generated bone resorption, resulting in a thinner cortical wall. This wall is then subject to high stresses when large forces are used to remove the failed implant. This can commonly result in a fracture. For this reason, surgeons often cut or split the bone (a controlled fracture) to assist with removal and to ensure that the fracture occurs in a location that can easily be repaired.

Cementless hip implants are at a much higher fracture risk, as they require a tight press fit. The most likely steps for the development of a fracture are during the broaching phase, and the final impaction of the implant. There is an increased risk for a calcar fracture if the implant has a larger proximal portion. The proximal end of the femur can vary widely, and if the implant is oriented incorrectly, a calcar fracture can occur. Often, the broaches for an uncemented implant are significantly undersized to generate a tighter fit when the implant

is put into place. The surgeon is then much more likely to create a fracture when the implant is driven in for final seating (Amstutz, 1991). It has been observed that the hoop strains in the calcar region go up by 25% when the stem is inserted and by 400% when an oversized stem is used (Fishkin *et al.*, 1999).

The rate of femoral fractures goes up during a revision THA (Moroni, 2000). A study by Berend *et al.* (2004) noted multiple risk factors for a periprosthetic fracture which include: anterior approach to the hip, uncemented stems, and gender. However, cemented stems with fractures had a higher revision rate, and a lower survivorship than uncemented implants. The study concluded that uncemented implants with a proximal bony ingrowth surface performed very well, and were the best stem for surgeries in which a proximal fracture had occurred (Berend *et al.*, 2006). Therefore, the use of uncemented stems is well justified and will continue to increase, however the possibility of intraoperative fracture must still be a concern of the physician.

Fractures are classified according to their location on the femur in relation to the implant: If they occur at the proximal end of the femur, the distal end or below the implant. They are then further classified based upon the stability of the fracture. Fractures can occur at the distal end of the implant because of stress risers formed at there (Cameron *et al.*, 2004).

In dogs femoral fractures have been found to occur in 2.92% of THR surgeries (Liska *et al.*, 2004). These femoral fractures are more likely to occur in older dogs. However, there does not appear to be any pre-disposition to a fracture based upon gender, body weight or breed (Liska *et al.*, 2004).

One study evaluating fracture generation in human cadaver femora found that fractures were generated at loads ranging between 1915 N to 9288 N (median 6351 N) (Carls *et al.*, 1999). The median force needed to generate a fracture in a human femur corresponded to 11 times the body weight of a person weighing 75 kg minus the weight of one leg (Carls *et al.*, 1999).

**2.7 Subsidence**

Subsidence is defined as the sinking or settling-in of the hip implant into the femur. This is an undesirable effect and results from poor stabilization of the implant. If the implant is properly stabilized in the femur then very little, if any, subsidence should occur. Subsidence is usually indicative of a problem with the implant procedure, either there is a fracture in the femur and the implant is subsiding, or there was improper preparation of the medullary bed in the femur prior to implant. Subsidence can also cause quite a bit of pain for the patient as a loose implant generates significant thigh pain. Also, subsidence can result in a different height for the two hip joints, therefore causing a non-anatomically correct position for the joint. This can result in uneven, and therefore, accelerated wear for the joints.

Subsidence sometimes can be noted in the post-operative radiograph. However, the implant normally has not experienced any, or only very little, loading at that point and therefore usually has not subsided by the time the post-operative radiograph is taken. Subsidence is most likely to occur in the period following the surgery, before bony ingrowth has occurred to securely stabilize the implant. In some cases, the subsidence can cause pain, in others, the implant may just "settle" and stabilize in the new position. The change in leg

length from subsidence can be a significant problem in biped humans, but is not as much of an issue for quadriped canines. If the canine continues to experience pain while walking, another radiograph is often performed. The small levels of subsidence often observed on radiographs require careful discernment to identify the problem (Figure 2.1).

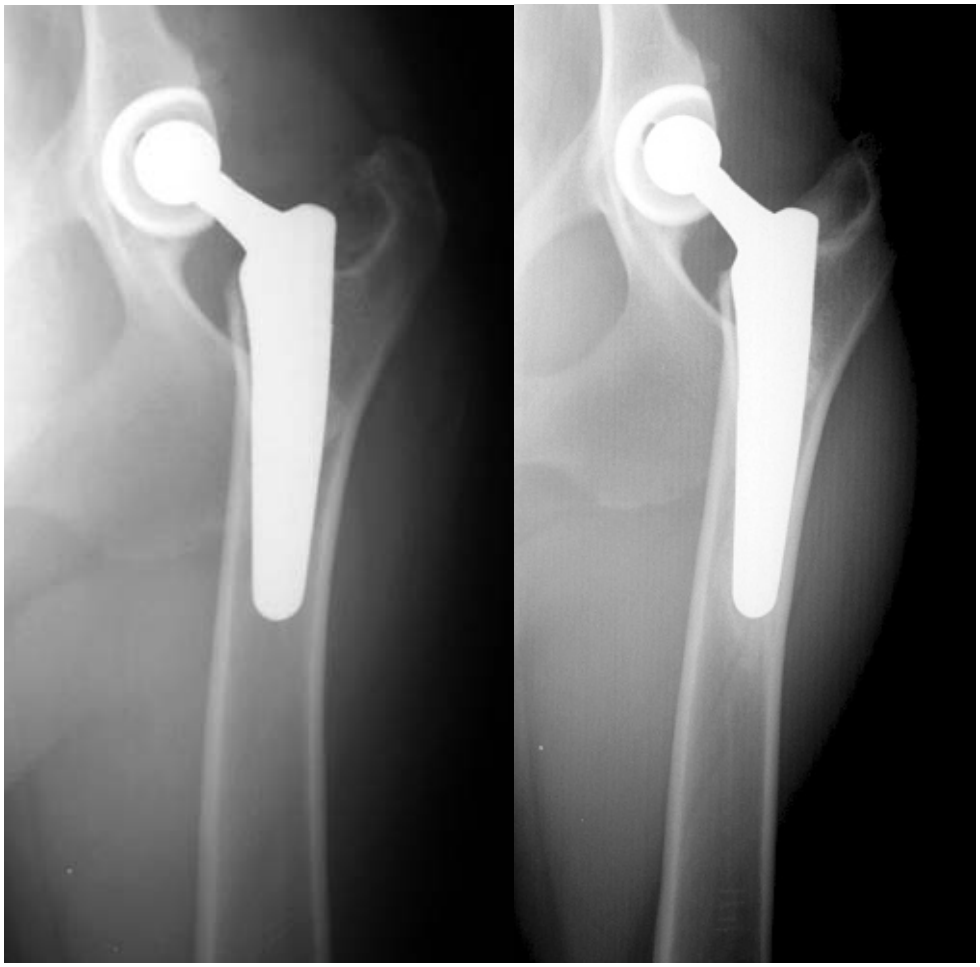


**Figure 2.1.** Subsidence Radiographs of BFX™ stem. The radiograph on the left is immediately post-operative and the radiograph on the right is 3 months post-operative (right). Careful observation of the neck cut in relation to the proximal end of the femur shows that the implant has subsided in the image on the right. Additionally, it can be seen that the distal end of the femur has moved laterally. Images are courtesy of the NCSU Veterinary School.

Subsidence of implants is a common side effect of femoral fractures. Once a fracture has occurred the implant is much more likely to subside as there is reduced capability of the bone to withstand the hoop stresses needed to maintain the position of the implant. That is, if the implant was implanted with relative ease, then it is much more likely to subside. It has been suggested that if the implant was easily positioned to the correct level, then it would be recommended to implant the next bigger implant (Rashmir-Raven *et al.*, 1992).

Some small amount of subsidence is expected and is not of great concern, however, if the implant moves by more than 1-2mm in the first year, or 3-5mm total then the implant has an increased risk for loosening (Sanfilippo, 2006). This small subsidence can result in more subsidence, pain for the patient and joint damage.

Subsidence can cause several problems for the patient; it can change leg length, making walking difficult; it can loosen the hip tension, allowing for luxation (dislocation of the hip joint); or it can be a sign of loosening of the implant within the femur which can be painful for the patient (Kim *et al.*, 1993). In following 19 patients who experienced subsidence of greater than 3mm following THA with an uncemented implant, 79% experienced thigh pain, with nine of those experiencing severe disabling pain (Kim *et al.*, 1993). Debilitating pain is often a reason that an implant is considered in the first place. If the implant results in the same or greater pain than was experienced previously, there is no advantage to the patient.

Another potential cause of subsidence is that during normal use, it has been seen that a hip implant can experience loads up to three times body weight, and this can cause the

supporting trabecular bone to collapse allowing for subsidence, especially among osteoporotic patients (Amstutz, 1991). This can clearly be seen by evaluating a statics model of the hip, where the distance of the femoral head to the stem acts as a lever arm which multiplies the weight of the body pushing down on the joint, therefore resulting in larger than expected forces. These forces are clearly magnified many times when the patient is walking, running, or climbing stairs. Therefore if the implant is not properly stabilized, subsidence can likely result.

Revision surgery, repairing a failed primary implant surgery, is commonly needed if loosening and subsidence occur. A study by Karrholm *et al.* evaluated 84 implants over a period of 4-7 years (Karrholm *et al.*, 1994). Their results showed that the probability of a patient requiring a revision surgery was higher than 50% if the stem subsided 1.2mm or more at the two year point. Clearly, a focus on preventing or minimizing subsidence as much as feasibly possible is advantageous for the patient.

Some question remains as to whether cemented implants have less risk of subsidence than uncemented implants. Cemented implants can loosen, but tend not to subside in the bone until there is significant change in the femoral shaft bone bed. There are not many comparison studies on this topic, however, in a study of younger patients who underwent hip arthroplasty with uncemented implants for osteonecrosis, no significant increase in subsidence of uncemented implants over cemented implants was found (Ince *et al.*, 2006). Of note, this study is particularly applicable, since young patients are the best candidates for uncemented implants. Thus, there is some evidence that uncemented implants are just as likely to resist subsidence as their cemented counterparts.

## 2.8 Cerclage Wiring

A fracture can occur intraoperatively during implantation of a cementless prosthetic. The wedge shape, the tight press fit, and the use of impacts to seat the implant all can contribute to the development of a fracture. Once a fracture has occurred, the implant becomes loose in the canal. The femur must be stabilized to properly secure the implant to avoid further loosening, pain and subsidence. The most common technique used is cerclage wiring where a loop of wire is placed around the femur to close the fracture and stabilize the femur. Cerclage wire is used because other methods such as intramedullary nailing and plate and screw fixation cannot be employed with an implant in the bone (Schmotzer *et al.*, 1996).

There are multiple treatments for peri-prosthetic (related to the time of the surgery) fractures. These include bone plates, screws, clamp plates, and cerclage wiring. However, of all the stabilization options, cerclage wire is the most cost effective and the simplest to use (Fishkin *et al.*, 1999).

In a study by Berend *et al.* (2004), 1320 hip implant procedures over 16 years were evaluated for incidence of intraoperative fractures. They found that fractures occurred in 4% of the cases. They found that a type I fracture (fracture occurring in the vicinity of the lesser trochanteric area but not extending past it) and a type II fracture (occurring in the lesser trochanteric area and extending up to 4 cm past it) could be adequately stabilized by the use of cerclage wire. They found the use of either multistrand or single filament cerclage wire would adequately stabilize the femur. No type III fractures (occurring in the lesser trochanteric area and extending greater than 4 cm distally) were found in their evaluation of the records. They found that uncemented implants with a proximal porous coating could

have excellent longevity if a fracture was repaired with cerclage wires. It was also found that the fractures most frequently occurred in patients with known developmental dysplasia, or other developmental hip disease. In fact, the prophylactic use of single or multiple cerclage wires in these cases was advocated. The cerclage wire increases the resistance of the femur to the hoop stresses generated by the implant, therefore aiding the avoidance of fracture development. Overall, they found no negative effects of the use of cerclage wire (Berend *et al.*, 2004). In fact, another author found that prophylactic use of cerclage may be recommended to strengthen the femur (Tsiridis *et al.*, 2003).

Fishkin *et al.* evaluated the crack fixation and propagation in human cadaver femora (Fishkin *et al.*, 1999). They utilized a single wrap of mono-filament stainless steel cerclage wire in up to four places. Their results showed that the cerclage wiring technique significantly reduced the propagation of the femoral fracture. Their recommendation was that for a human undergoing normal loads a fracture should be stabilized with at least two wraps of mono-filament wire cerclage, normal to the fracture line both superior and inferior to the lesser trochanter.

It has been recommended that a minimum of two double cerclages of 1.02mm diameter be used to adequately stabilize a fracture (Wagner *et al.*, 1996). This can result in relatively good stability. However this is still less than the stability of intact bone. The double cerclage involves one cerclage wire making two passes around the bone in one spot to increase the hoop stress resistance. Even with this, the patient must limit weight bearing on the limb as much as possible until the fracture has healed. Otherwise, the fixation of the implant could be compromised.

An *in-vitro* study was performed to compare cerclage techniques (Liu *et al.*, 1997). The researchers utilized simulated fracture with a load cell to measure compressive forces. Their results showed that there was no statistical difference in the compressive forces generated by a cable or a double cerclage wire. Thus, they concluded that a double cerclage was as capable as a cable.

The cost of using both wires and cables was evaluated in a retrospective study by Ritter *et al.* ( 2006). The investigators found that there was a significant difference in cost between the two systems. Surgeons use an average of 3.2 wires or cables to stabilize a fracture and the wire cost $29.79 per wire whereas the cables cost $275.40 per cable. They also found that clinically, double wires performed as well as cables. They concluded that cerclage wires may be preferable to cable since they are as effective and are less expensive.

In an evaluation of multiple different cerclage techniques, it was found that double-loop and double wrap/loop cerclage techniques can generate the highest tension. Each of these methods generates a significantly higher tension than that of any of the single loop methods (Roe, 1997). These methods also generate the highest yield point for cerclage fixation methods.

Cerclage wire, particularly double-loop, performs well as a stabilization method for femoral fractures. It can be used easily and is very inexpensive compared to other methods such as cables. Additionally, it can be used with the implant in place.

## 2.9 Summary of THA Procedure

The following is the summary of the procedure used to implant an uncemented hip implant in a canine subject at the NCSU veterinary school. After a canine subject is determined to be a candidate for a total hip arthroplasty, the surgeon takes x-rays of the hip to determine the if the animal's femur can accept an uncemented hip replacement. The surgeon bases this decision on experience related to quality of the bone, shape of the femur, adequacy of the acetabulum, among other factors.

The animal is then prepped for a sterile surgical procedure and access to the femoral head is established. The head of the femur is removed by making an appropriate neck cut (usually laid out with a neck cut template). The surgeon then introduces drills of successive sizes into the medullary canal to create the proper path for the reamers. Reamers of successive sizes, for the correspondingly sized implant, are used to establish an envelope for the broaches. Broaches of successive sizes are then used to further enlarge and shape the implant envelope, but more importantly to establish a precise fit for the implant once placed in the femur. The broach matching the size of the implant to be used is slightly smaller in all dimensions than the implant so that a press fit is established to stabilize the implant until bone ingrowth into the porous surface can be achieved.

Once the broaching is complete, the surgeon introduces the implant to the previously completed envelope in the femur. The implant is pressed firmly into place by hand. The drive distance (the amount of distance the implant has to be driven into the femur before it reaches a clinically appropriate height) is noted. If the drive distance is excessive, then the implant is removed and the femur is re-broached. In some cases, the surgeon uses his or her

judgment to overbroach the envelope with the next larger size broach to obtain the proper fit for the implant. This is often due to the specific anatomy of the bone, i.e. the shape and location of the cortical and trabecular bone. The broaches do not cut the cortical bone as well as the trabecular due to its increased hardness and therefore a larger broach may at times be required to cut the bone in the correct locations.

If the drive distance proves satisfactory, a hammer and impactor are used to drive the implant into the proper position. The impactor tip is placed in a recess on the top of the implant and the hammer is used to strike the other end of the impactor, and the implant is slowly driven into its proper location. The surgeon uses their extensive experience to judge the feedback they are receiving from the hammering. If they do not strike hard enough they will not be able to move the implant into position. However, if they strike too hard, the implant will cause a fracture of the bone. Therefore, the surgeon proceeds with caution and slowly hammers the implant down to a clinically appropriate height (usually with the top of the beaded surface being flush with the neck cut). The broaching method and tools are designed such that when the implant is at a clinically appropriate height the implant will be fully seated in the implant envelope. The surgeon verifies that the implant is seated by typically using two or three blows of the hammer with an equal level of applied force. These final blows of the hammer are at a force higher than that previously used in the implantation process. If the implant does not move, or only moves slightly, that indicates that the implant is appropriately and firmly seated. The surgeon then attaches the ball to the neck of the implant and manipulates the ball into the acetabular cup.

The wound is then closed and the surgery is complete. The animal is ideally restricted to conservative movements for a few weeks to allow for bony ingrowth to occur, and therefore firmly anchor the implant.

# 3. METHODS AND MATERIALS

## 3.1 Overview of Methods

One of the main aims of this study was the desire to mimic the clinical approach of the surgeon to a THA. While a surgeon has many variables that must constantly be changed based upon the specific case, only a finite number of variables can be evaluated in a scientific study. Therefore the goal was to attempt to recreate the clinical procedure as closely as possible in the laboratory (*in vitro*) setting. An overview of the process that was used is as follows: a femur from a canine was prepared *in vitro* to receive an appropriate implant. The femur was then loaded in an MTS hydraulic load frame and the implant was slowly driven to the appropriate clinical height. The implant was then hammered three times with a blow approximating the surgeon's. The implant was then loaded with a ramp displacement until failure occurred via a fracture or excessive subsidence. Once failure occurred, the implant was removed and the testing was repeated with clinically appropriate cerclage wires in place to stabilize the fracture. The subsidence of the implant and the force applied were captured during the test. Additionally, the hoop strains in the proximal femur on the cranial and medial aspects were collected with strain gauges. An in depth description of each step follows.

## 3.2 Hammer Testing

The first step of this investigation was to determine the hammering force used by the surgeon during the implant process. The orthopedic surgeon involved in this study has 29 years of experience as a veterinarian, 19 of which are as an orthopedic surgeon. He has been

involved in approximately 250 total hip arthroplasties and somewhere over 100 of those have used the uncemented BFX™ implant system (BFX™ system, BioMedtrix, Boonton, NJ). Therefore he has developed an excellent base of experience for hammering an implant into proper position. In order to re-create the surgeon's final three "seating" blows of the hammer with the MTS, the actual hammer blows needed to be accurately measured. This involved using a 3 axis piezo-electric load cell (15,000N Kistler 3 Component Force Sensor, Kistler Instrument Corp. Winterhur, Switzerland) to capture the force of a hammer blow. The load cell was mounted to an aluminum fixture, which was then fixed to a wood spring board. The mass of the set up was 1.6 kg, approximately the average weight of a canine hind leg. The attachment to the spring board was intended to approximate the feel of hammering an implant on a real dog during surgery. A tip for the load cell was manufactured that had a recess matching that of an implant so that the surgeon could use the normal impactor and impactor tip. A custom Labview (Labview ®, National Instruments Corporation, Austin, TX) program was written to capture the force output from the load cell at a high sampling rate of 60,000Hz. It was determined through experimentation that this high sampling rate was needed to correctly capture the peak force during the hammer blow. The user screen for the Hammer program is included ( Figure 3.1).

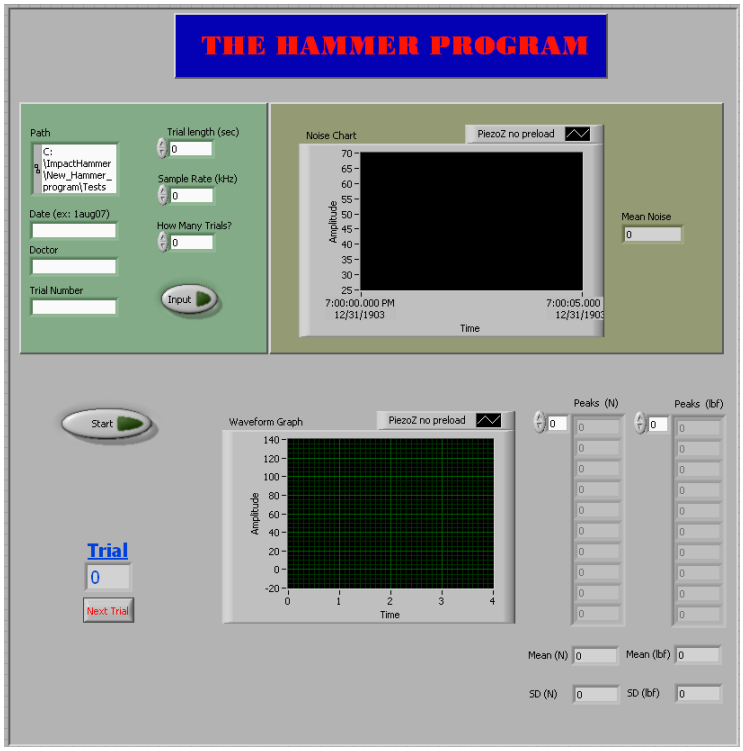



**Figure 3.1.** Front Panel of The Hammer Program. The program generated a graph for each hammer strike and displayed the peak force from each strike. Additionally all processed data was written to file for further analysis.

Thirty trials of the surgeon using the actual surgical hammer and the impactor with tip were conducted using the experimental set up. Once the hammer data was captured it was plotted in Excel and the mean and standard deviation of the peaks were calculated. The outcomes of the hammer trials are given in the results section.

The area under the force vs. time curve was calculated and set equal to the momentum of the hammer. Therefore:

$$Area\ under\ F\ vs.\ time\ curve = mass\ of\ \ hammer \times velocity$$

The mass of the hammer was measured to be 0.58 kg. Assuming that all of the momentum of the hammer is registered by the load cell (using the conservation of momentum) using the

impulse and the hammer mass, the velocity of the hammer was calculated. Subsequently, the energy of the hammer blow could be calculated, where:

$$E = \left(\frac{1}{2}\right)mv^2$$

This was the energy that would be recreated as closely as possible using the MTS machine during the *in vitro* testing.

### 3.3 Testing Set-up

#### 3.3.1 Fixtures

The normal impactor used during the surgical procedure could not be used as it had no way of being properly mounted in the MTS machine. Therefore a fixture had to be manufactured. An impactor was fabricated that used an aluminum rod to strike the top of the implant in a uniaxial fashion to load the implant vertically and induce no (or little) moment during the testing procedure. The impactor was attached to the actuator of the MTS machine. The aluminum rod of the impactor was left long enough to allow for striking the implant without the actuator getting in the way of any of the testing set up. The end of the impactor rod was turned to a smaller diameter to ensure that as it was loaded it contacted only the implant top and did not hit any part of the femur or the neck of the implant. As the tip of the impactor became slightly deformed by frequent testing, it was turned down again on a metal lathe to provide a new clean end for impacting.

The femurs were potted a two part resin for the testing. The femur then had to be held rigidly for the testing procedure. A femur grip fixture (Figure 3.2) was used that

consisted of an aluminum framework that securely gripped the potted portion of the femur. The femur grip allowed movement of the femur in two directions and rotation about one axis to compensate for potting inaccuracies and alignment of the implant with the impactor. Thus, the femur could be aligned perpendicularly in the testing machine to allow for axial loading of the implant.

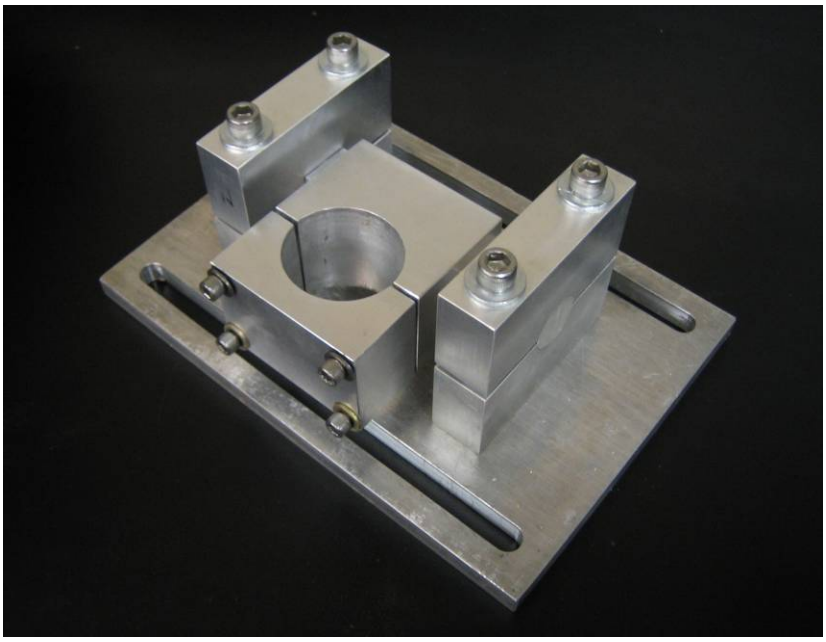


**Figure 3.2** Femur Grip. It can be seen that the two halves are tightened together to grip the potted end of the femur within the hole.

Measurement of the subsidence of the implant was the next challenge. The measurement desired was the amount of subsidence of the implant that occurred relative to the neck cut of the bone. The specimen was to be loaded axially through the impactor by the MTS machine. The MTS was capable of precisely measuring the displacement of the actuator (+/- 50mm). As the implant subsided, the crosshead would correspondingly move

lower and the displacement would be recorded. However, this measurement included the vertical compression of the entire bone specimen and any compression of the overall system. This measurement would not accurately assess the small measurements associated with the movement of the implant relative to the proximal end of the femur. Therefore a measurement method had to be developed which would take into account the variables of interest. After considering many options, and attempting set-ups of a few of the most viable, the best option was chosen. This option measured the relative displacement between the implant and the proximal end of the femur, the measurement of interest.

A linearly variable differential transformer (LVDT) was used to capture the relative displacement. An LVDT (Schaevitz ® PCA 375-500, Measurement Specialties, Inc, Hampton, VA) was chosen that had a linear range of 25.2mm which would more than encompass the maximum subsidence expected in the trials based upon clinical experience and literature reviews. The LVDT mount included multiple parts:

The measurement block started off with an attachment point at the greater trochanter of the femur. This anatomic position was chosen because of the mass of bone present here that provides a useful mechanical attachment site. Additionally this location is superior to the usual genesis site of a fracture and therefore would not be involved in the failure of the bone. The attachment consisted of a galvanized steel plate that was formed into a “C” shape to fit around the anatomic shape of the greater trochanter. Multiple holes were drilled into the curvature of the “C” shape to allow for attachment to the greater trochanter via bone screws. Two wings projected backwards from the C shape allowing for attachment to an aluminum block via 4 screws. The rear of the aluminum block was threaded to match a

threaded rod that was bent into two right angles to accommodate the measurement block. The threaded rod was threaded through the aluminum block to the proper position and then lock nuts on either side of the block could be tightened into position to prevent further movement. The measurement block was then threaded onto the opposite end of the threaded rod to provide a base for the spring loaded LVDT to press against to obtain a measurement. The measurement block was similarly locked into place via lock nuts on either side of the block (Figure 3.3).

The other side of the LVDT attachment anchored to the neck of the implant. Again, an aluminum block was used for this purpose which consisted of a hole matching the diameter of the neck of the implant. Two set screw holes were machined and tapped at right angles to the neck hole to allow for secure attachment to the implant. The opposite end of the aluminum block was threaded to receive a bolt. This bolt passed through a vertical height adjusting plate which consisted of an aluminum plate with a vertical slot milled through the width of it. The other end of the plate was then attached via a similar method (bolt into a threaded hole passing through the slot) to a second aluminum block. This block then had a hole matching the diameter of the LVDT through the other side of it, along with set screws to hold the LVDT in place.

Finally, everything was attached to a specimen and the displacement of the implant relative to the proximal end of the bone could be obtained with accuracy.

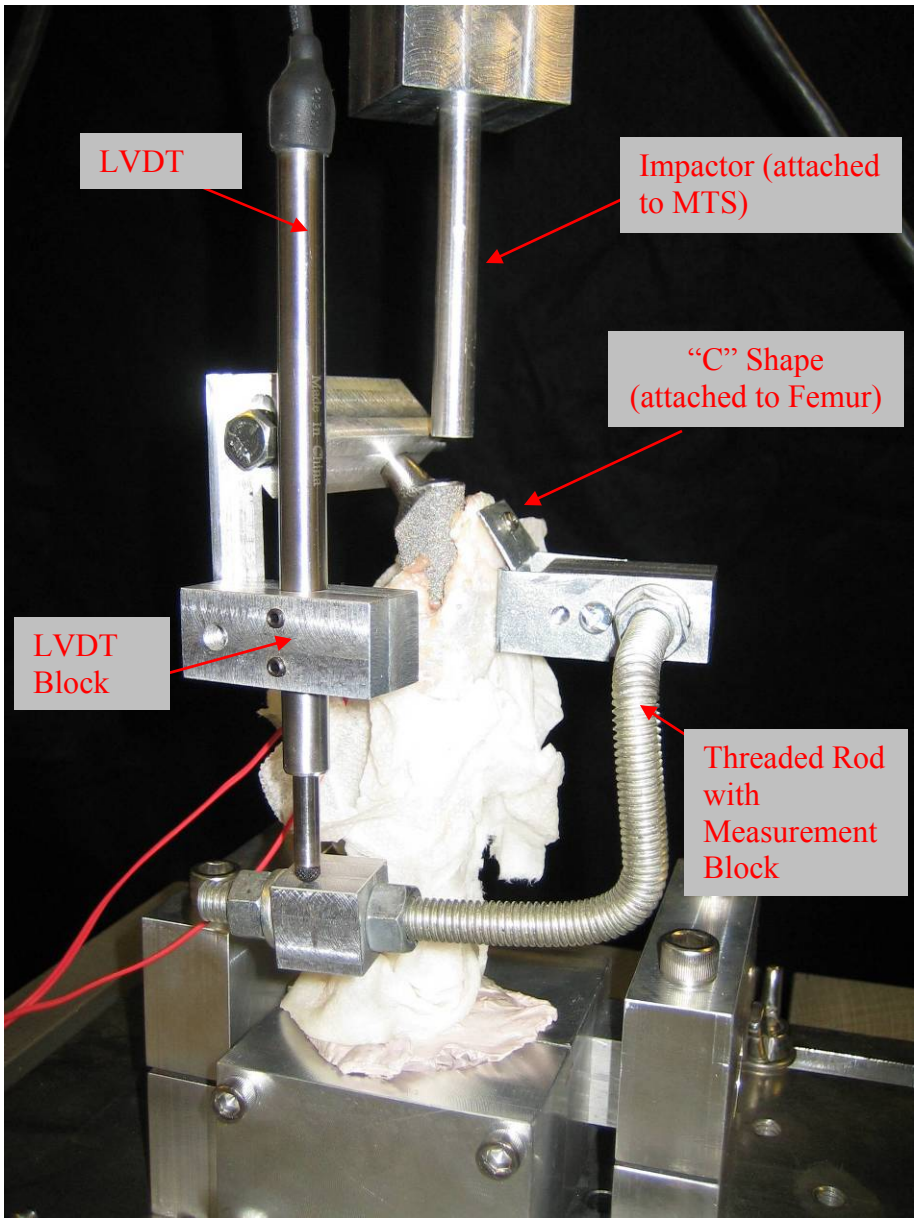



**Figure 3.3.** Equipment Set-up. The potted femur is gripped in the Femur grip which is mounted to the MTS. The Impactor is attached to the MTS actuator and aligned to strike the horizontal surface of the stem. The measurement block is attached via the "C" Shape to the greater trochanter and provides a bearing surface for the LVDT plunger. The LVDT Block is attached rigidly via the neck of the implant.

### 3.3.2 Strain Measurement

It was desired to obtain the hoop strain in the bone on the cranial and medial proximal surfaces of the femur. The strain could provide a useful indication of where the hoop stress was the greatest and subsequently, where the fracture would be most likely to occur. Based upon clinical experience with most fractures originating on the cranial and medial aspects of the femur during intra-operative fractures, these locations were chosen for strain gauge (Type KFG-3-120-C1-11L1M2R Omega Engineering, Inc, Stamford, CT) attachment sites. The target location was approximately 1cm distal to the neck cut and oriented perpendicular to the long axis of the bone. This site was variable based upon the availability of a suitably large and relatively flat attachment location on the surface of the femur. The gauges used had attached lead wires to eliminate the need to solder the gauges after they were attached to the bone and therefore minimize the risk of potential de-lamination of the gauge from the surface of the bone.

The strain gauge lead wires were connected to a bridge board (NI 2043 board National Instruments Corporation, Austin, TX) which was supplied by a power board (National Instruments SC 2071) which in turn was powered by a constant 5V power supply. A quarter-bridge set-up was used on the bridge board and the output was sent to a BNC board (National Instruments BNC 2081 board) to allow for use of BNC connectors to interface with the Labview® data processing board. The excitation voltage for these gauges was 2.5 V, and the strain was calculated according to the following formula for a quarter-bridge setup:

$$\varepsilon = \frac{4 \cdot V_0}{V_{Ex} \cdot GF}$$

$\varepsilon = strain$

$V_0 = output\ voltage$

$V_{Ex} = excitation\ voltage$

$GF = Gauge\ \ factor$

### 3.3.3 Testing Protocol and MTS Program

The protocol for the actual testing was developed with a goal of clinical relevance. In summary, the femur is broached to the correct depth and the implant is inserted by hand. The surgeon then slowly and with minimal force taps the implant into place until it is at a clinically relevant height, with the top medial edge of the beaded surface flush with the proximal medial edge of the neck cut. The surgeon then uses three firm hammer blows to verify that there is little movement of the implant, and the stem implantation portion of the surgery is complete.

In order to keep the testing as relevant as possible, the MTS program set up was desired to be as similar as possible to the an actual implant procedure utilized in the operating room. For trials 1 through 4, the MTS was used to slowly press the implant into place by manually guiding the displacement of the actuator until the implant was at clinical height. For trial 5 and subsequent testing the MTS was programmed to automatically press the implant into place at a constant rate of 0.1mm/sec. Once the implant was at the clinically relevant height, the operator pressed a stop button to stop the progress of the actuator and the MTS then retracted the actuator from the implant. For all trials; to mimic the hammering done by the surgeon during an actual THA, the MTS was then programmed to impact the

implant three times. Based upon the practice impacts and the impacting performed during trial 1, the MTS was started with the tip of the impactor separated from the proximal surface of the implant by 10mm. The MTS was operated in displacement control which ensured that the MTS could accurately control its rate of speed. The crosshead was then advanced at a speed of 75mm/sec until the impactor struck the implant end. A force detection threshold was set at 120N. This detection threshold would retract the crosshead once the set force was exceeded. Due to the high speed of the actuator, significant overshoot occurred (expected) and the maximum force seen was substantially higher than 120N. The goal was to have the imparted energy match the energy calculated from the hammer trials. After the first four trials the procedure was re-evaluated and the force detection threshold was lowered to 80N to more closely replicate the imparted energy to the implant. The load cell used on the MTS machine had a range of +/- 15,000N.

Once the three impacts were completed, the next step was to drive the implant into the femur until failure. The MTS actuator with the impactor tip was driven into the implant at a constant rate of advance (0.1mm/sec) until failure occurred. Failure was defined as a fracture occurring or the stem of the implant contacting the neck cut. Once the failure point was reached, the operator would hit a stop button and the MTS actuator would retract.

After the failure occurred, the implant was removed, the fracture was stabilized with cerclage, the femur re-broached for the next larger implant, and the same procedure was repeated for the post-cerclage specimen.

### 3.4.4 Labview Program

For actual testing of specimens a method of accurately collecting data had to be developed. The MTS machine and its associated operational software is capable of collecting force and actuator displacement data. However, for this testing LVDT and strain gauge data had to be collected simultaneously. Furthermore the data needed to be linked to the same time stamp to be able to accurately assess relationships between the MTS force data and the measured strains and LVDT displacement readings.

Labview® software (Labview ®, National Instruments Corporation, Austin, TX) provided the most efficient means of collecting this data in the fashion desired. Labview® is essentially a programming language geared towards data collection and processing needs. The inputs had already been identified (LVDT, two strain gauges, MTS force, MTS displacement). The program was designed to take the inputs and sample them at appropriate rates, depending on the portion of the testing to be done. The Labview® program was developed to accept and output digital signals to the MTS operational software so that the program was able to remotely control the MTS machine.

The design of the program involved the user entering the name of the trial, with any other identifying information needed, such as date, and right/left limb. The ranges for the control parameters could also be manipulated by the user. When the user initiated the trial, the program would send a signal to the MTS to begin driving the implant into the clinically relevant height. When the clinical height was reached, the stop button was pressed. Meanwhile, all of the data from the various inputs was collected. Once the stop button was pressed the data was written to a file and on-screen graphs of the collected information were

shown to the user. The "next" button caused the program to begin the impacts of the implant with operational control by the user required to begin each subsequent impact. Again, data was written to a file and displayed after each impact. Finally, the user directed the program to drive the implant in until failure via another button. The same data collection and display occurred once failure was reached.

The impact portions of the program occurred at a high speed (75mm/sec) therefore the program recorded the data at a high frequency (1000Hz). The initial drive to clinical height and the loading until failure occurred at a much lower speed (0.1mm/sec) and therefore the data was collected at correspondingly lower frequency of 100Hz. The settings for the data collection rates were determined through pilot testing.

The program output to excel files with header information and in a columnar format. Excel was used for all further data processing. The utility of collecting sequenced data along with precise timed control of the MTS machine proved to be very beneficial while running the trials.

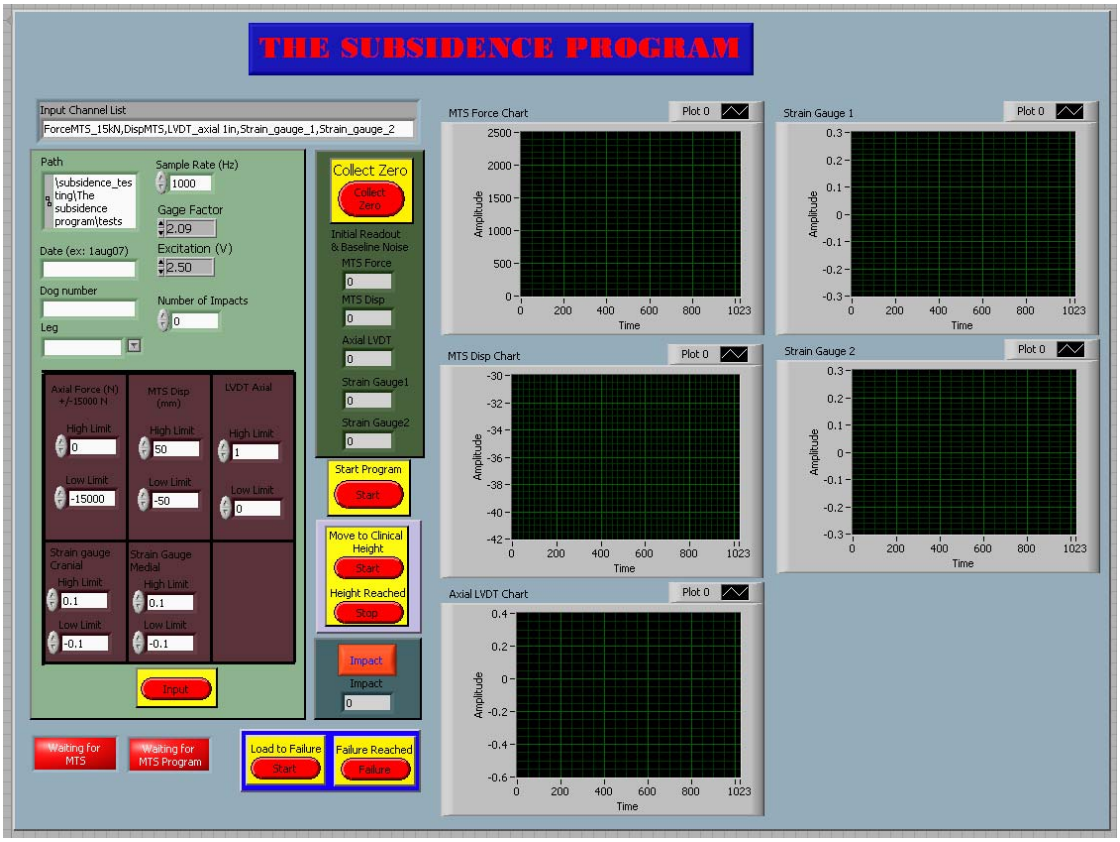



**Figure 3.4.** Front panel of The Subsidence Program. This is the user interface screen for the operation of the program. The program collects zero points for all data streams, initiates clinical height positioning, impacts, and final load to failure.

## 3.4 Specimen Preparation

Femora from euthanized canines were obtained for the study. The canines included in this study were large breed dogs which are those that more often suffer from hip dysplasia and the resultant OA.

**Table 3.1.** Anthropometric Data. The table lists the breed information for the canine specimens used in the trials along with body mass (where known).

| **Anthropometric Data** | |
|---|---|
| *Breed* | *Body Mass (kg)* |
| Pointer | 30 |
| Rottweiler | 36.7 |
| Husky | 28.12 |
| Unknown | Unknown |
| Labrador | 29.03 |
| Pitbull | 23.13 |
| Pitbull | 24.04 |
| Husky | 28.13 |
| German Shepard | 26 |
| Mean | 28.14 |
| SD | 4.21 |

The animals were euthanized at a humane animal shelter for purposes of population control. The femurs were isolated from each hind leg and all soft tissue was removed. The femurs were kept bathed in saline to prevent the bone from drying out. Before preparation for the testing, the bones were wrapped in gauze or absorbent towels and then soaked with saline and wrapped tightly in a re-sealable plastic bag. They were then frozen until trial preparations were to be performed.

The femur specimen was held in a specially designed vice. The vice set-up involved drilling a hole through the condyles of the femur. A rod was then placed through the hole and the femur was gripped for the subsequent preparations (Figure 3.6).

### 3.5 Implant Preparation

The surgeon used an implant template provided by Biomedtrix to determine the precise location and orientation of the neck cut. A saw was then used to cut off the proximal end of the femur, removing the ball and neck of the femur (Figure 3.5). The surgeon then used a 3.2mm drill bit followed by a 5mm drill bit to drill a channel down the center of the bone. The drill was started in the inter-trochanteric notch and aligned with the long axis of the proximal femur.

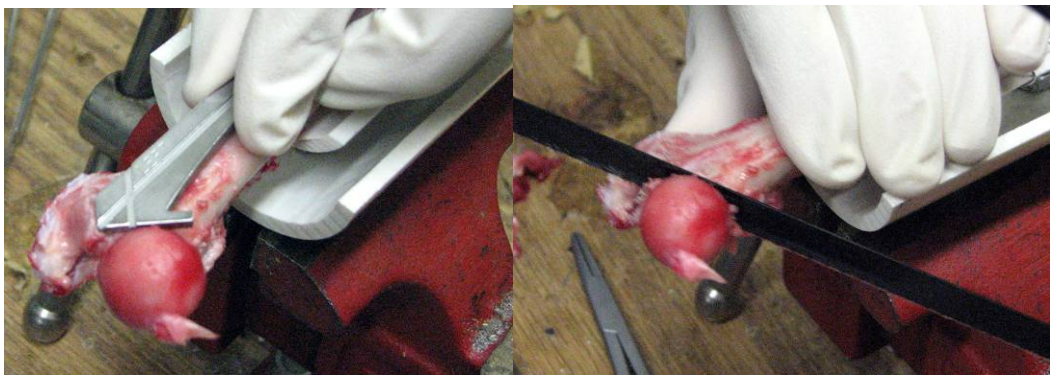


**Figure 3.5.** Marking and Cutting Neck. In preparation for creating the implant bed, the surgeon marks the neck cut (left) and then makes the cut (right).

For trials 1-4 the initial drills were followed by successively larger drills until a broach could be introduced. For trial 5 and subsequent trials, reamers were used prior to the broaching step. Again these were supplied by Biomedtrix. The reamers mount to a drill and quickly remove a conical section of the internal portion of the femur and aid greatly in beginning broaching.

**Figure 3.6.** Drilling and Broaching. The figure on the left shows drilling the hole for the implant envelope. The figure on the right shows broaching for the implant.

Once the initial prep was done, the broaches were used. The broaches are similar to a precisely shaped file. The end of the broach is shaped precisely like the implant, and the size of the broach corresponds to the sizes of the implants. The broaches have cutting edges around their circumference. The cutting edges remove both trabecular and cortical bone in the proper location to prepare the implant envelope within the femur. The procedure involves hammering the broach in partially, removing, cleaning off the bone and other tissue fouling the cutting edges, and then repeating. The process continues until the broach is fully in the femur at a clinically appropriate height. The broach creates an envelope that is slightly smaller than the size of the implant. This creates a tight press-fit of the bone within the femur to allow for a strong fixation until bone ingrowth can provide a mechanical bond at the beaded surface.

The implant was then put into the envelope and evaluated for drive distance. The drive distance is the distance from the neck cut of the femur to the top of the beaded implant surface on the medial aspects. An excessively long drive distance (usually a distance greater than 10-15mm) will result in the implant not being able to be driven down to a clinically

appropriate height (top of beaded surface flush with neck cut). Although the correct broach for the implant was used, the envelope may be surrounded by more cortical than trabecular bone due to the particular anatomy of the specimen. As cortical bone is much less compressible than trabecular bone, the press-fit becomes too tight and the implant ends up having a much larger drive distance. In this case the surgeon would partially over-broach with the next sized broach. For example, a number 9 broach would be used for a number 8 implant. The broach was partially introduced so that some cortical bone would be removed and the implant would be replaced. The fit would be re-evaluated and the process would continue in a progressive manner until the drive distance was appropriate.

### 3.6 Potting

Once the femurs were prepared for the implant they were then ready for potting. The fixture to hold the femurs vertical for testing utilized two aluminum blocks with a cut out 50.8mm hole. The two halves were then tightened via bolts to fix the femur. Thus, for the femur grip, the end of the femur had to have a 50.8mm diameter base.

The condyles of the femur were removed with a saw to aid in potting. A drill was used to create two transverse holes at the distal end of the femur. Two approximately 38mm screws were then screwed through the distal end of the femur. The screws were oriented at 90 degrees to each other and the head protruded from one surface of the femur and the tip of the screw protruded from the other surface. The screws provided a bonding surface for mechanical fixation of the femur within the potting material.

The potting material used was Bondo (Bondo Co, Atlanta, GA) a plastic two part filler that hardens to a strong material. This material was chosen due to its ready availability and success in using it previously. An appropriate amount of potting material with its hardener were mixed for use and placed in a plastic wrap lined 50.8mm inch mold. The distal end of the femur was then pressed into the potting material and held vertically until the potting material hardened. Once hard, the femur in the potting material was removed from the mold and the plastic wrap was removed from the potting material. The reaction was exothermic and the potting material was allowed to fully cool until proceeding with preparation.

During this preparation process, the femur was kept moistened with saline to prevent the bone from drying.

### 3.7 Strain Gauge Attachment

The procedure used for attaching the strain gauges was partially adapted from the procedure discussed in Chapter 20 of "Mechanical Testing of Bone and the Bone-Implant Interface." (An *et al. (*Chapter authors Szivek, J.A, and Gharpuray, V.M.), pg 314, 2000). Strain gauges were to be attached to the medial and cranial aspects of the proximal end of the femur. The aim was to place the gauges approximately 1cm distal to the neck cut oriented transversely to measure the hoop strain. The position had to be slightly adjusted trial by trial to accommodate the particular anatomy of the individual specimen.

A scalpel was used to scrape the periosteum and any remaining soft tissue off of the chosen sites for the strain gauge attachment. The scraping was done lightly in order to not

remove actual cortical bone. Once the tissue was removed a piece of 400 grit aluminum oxide sandpaper was used to abrade the site of attachment. A gauze pad with some acetone was then used to wipe the appropriate sites to remove residual oils on the surface that would affect strain gauge bonding.

Once the acetone evaporated from the surface, M-Bond adhesive (Vishay Intertechnology Inc., Malvern, PA) was used to prepare the site. A few drops of adhesive were spread thinly on both sites and allowed to dry for a few minutes. Once dry to the touch, a new piece of 400 grit paper was used to lightly abrade the adhesive surface. A 70 percent ethanol soaked wipe was used to clean the bonding surface and allowed to evaporate.

The strain gauge was removed from its protective plastic and carefully handled to keep the gauge scrupulously clean. The gauge was picked up using a piece of cellophane tape attached to the top, or exposed side, of the gauge. A thin layer of catalyst was applied to the bonding surface of the gauge and allowed to dry for one to two minutes. One to two drops of adhesive were then placed on the bonding site and the gauge was applied to the site by careful positioning using the cellophane tape. Firm pressure was applied to the top of the gauge for one to two minutes. The cellophane tape was then very carefully removed so as not to pull up the strain gauge. The lead wires of the strain gauge were lightly tugged to check the bonding of the strain gauge to the surface of the femur.

The strain gauges chosen for this experiment were ones with lead wires attached. Near the actual gauge the insulation of the lead wires was not present. To prevent contact of the exposed un-insulated portion of the lead wires during testing, a piece of tape was applied to the lead wires to keep them separated. This completed the attachment of the strain gauges.

The wires were carefully wrapped around the femur and the saline soaked cloth was wrapped over the entire bone. The bone was then re-frozen if necessary prior to testing.

For the first few specimens, wiping with acetone was not performed as part of the gauge installation procedure. However, some intermittent difficulty was experienced in adhering the strain gauges to the bone surface. In these cases, an oily film could be observed on the prepared surface of the bone even after cleaning with ethyl alcohol. The gauges were unable to adhere with oils present on the surface. Many fewer problems were encountered after the bone surface was cleaned with acetone.

### 3.8 Testing Procedure

#### 3.8.1 Preparation

Prior to each trial the equipment was set up for testing. The strain gauge boards and power supply were connected and tested to ensure functionality. A test strain gauge was used to verify the outputs. The MTS procedure was opened and tested on a practice wooden specimen to verify its proper operation. The LVDT was connected to a signal amplifier and conditioner (LVDT Signal Conditioner ATA 2001, Schaevitz Hampton, VA) and allowed to "warm-up" for approximately a half hour prior to the testing to ensure proper readout. (incorrect performance was observed if the warm-up period was not observed). The Labview® program was also opened and tested to insure its proper operation.

The potted specimen was thawed for approximately an hour before the testing to allow it to warm to room temperature prior to the procedure. The specimen was kept moistened with saline to prevent drying. The potted end of the femur was then mounted in

the femur fixture on the MTS. The implant was firmly pressed by hand into the envelope created in the femur. The LVDT mount and the measurement block was then adjusted and mounted to the femur. (Figure 3.4) The cross head of the MTS with the impactor tip was positioned just above the top of the implant and the femur fixture was rigidly fixed on the MTS table.

The strain gauge lead wires were connected to the 2043 board. The potentiometers on the board were used to adjust the output from the gauges to the zero point prior to the beginning of the test. The drive distance for the implant was also recorded at this point.

### 3.8.2 Testing

The Labview® program was started and the MTS machine drove the implant in until it reached clinical height. The impactor tip then raised off of the implant surface and was used to impact the implant three times, all the while recording the inputs. The final load to failure portion of the procedure was then conducted with the implant being driven in at 0.1mm/sec until the stem contacted the neck cut or a fracture occurred. Fractures were usually detected audibly prior to visually. The bone generally failed very suddenly and a load "pop" was heard as a result of the break in the cortical bone. The procedure was then stopped and the final data was written to the file. Many pictures of the process were taken to document the performance of the specimens.

### 3.8.3 Implant Removal

At this point, the potted femur was completely removed from the testing set-up. The femur was gripped in a vice by the potted end and a Biomedtrix vise-grip stem extractor was used to remove the implant from the femur. The implant was then cleaned of all the remaining soft tissue and dried for the next test.

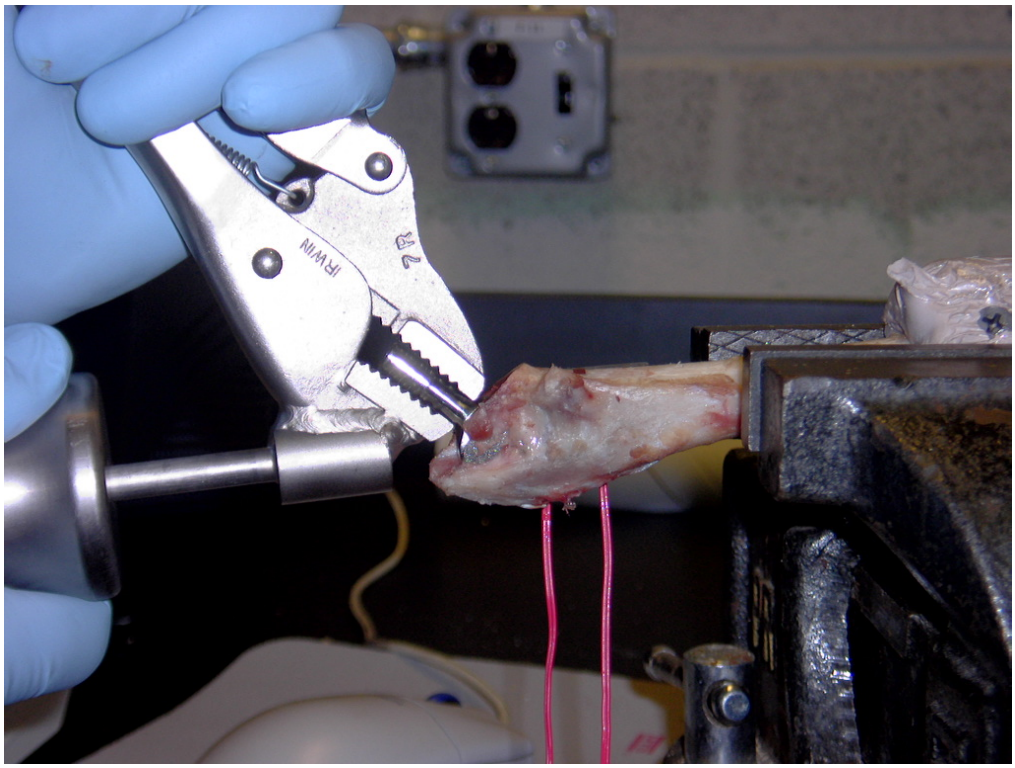


**Figure 3.7.** Extracting implant. The extracting tool is attached to the neck of the implant and used to pull the implant out of the femur.

If the failure mode involved the stem contacting the neck cut, then the surgeon broached the femur for the next larger size implant to repeat the testing.

### 3.8.4 Post-Test

However, if the implant failed via a fracture, then cerclage wire was used to close the fracture to repair the bone. The surgeon used a cerclage tying tool with 1.02mm (commonly referred to as 18 gauge) stainless steel wire to tie double loop cerclage wires. Based upon a clinical evaluation of the bone and its associated fracture either two, or three double loop cerclage were used. Generally, the longer, or more distal the fracture, the more cerclage that were used. The cerclage were approximately evenly spaced starting at the proximal femoral end and working down to the middle of the diaphysis of the bone.

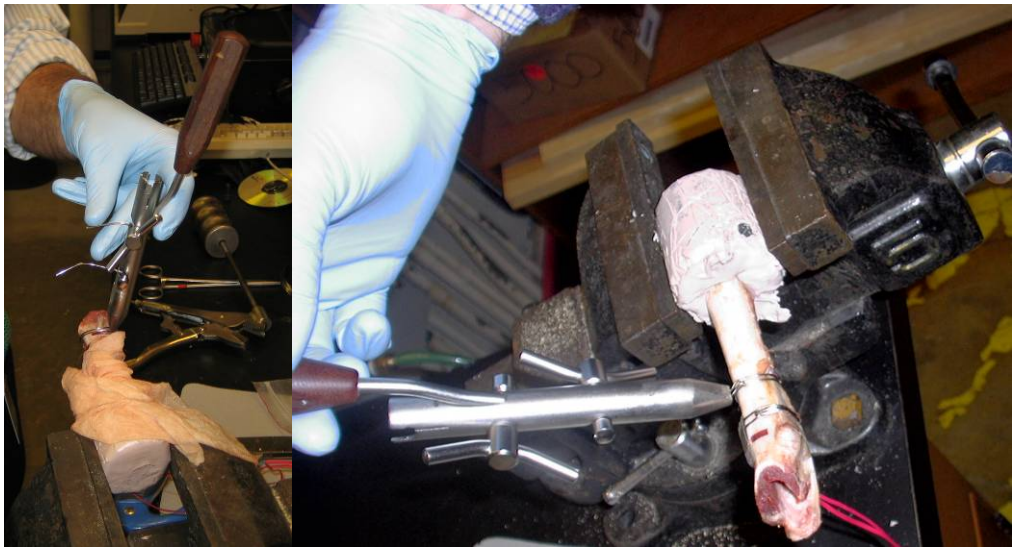


**Figure 3.8.** Tying Cerclage Wires. On the left the surgeon is using the cerclage wiring tool to wrap the cerclage around the femur. After tension has been created in the wire by winding the spools, the knot is created by folding the wire over itself (right).

After tying the cerclage was complete, the surgeon evaluated the bone envelope. If the anatomy of the particular specimen could support the next larger sized implant, then the bone was broached to accommodate it. In some cases, the envelope was surrounded by a thin

layer of cortical bone and could not support the next larger size, as the broach would remove too much of the cortical bone and would substantially weaken the bone. In this case the same size implant was replaced in the femur. Clinical experience on the part of the surgeon was used to make the determination of the proper course of action on a case by case basis.

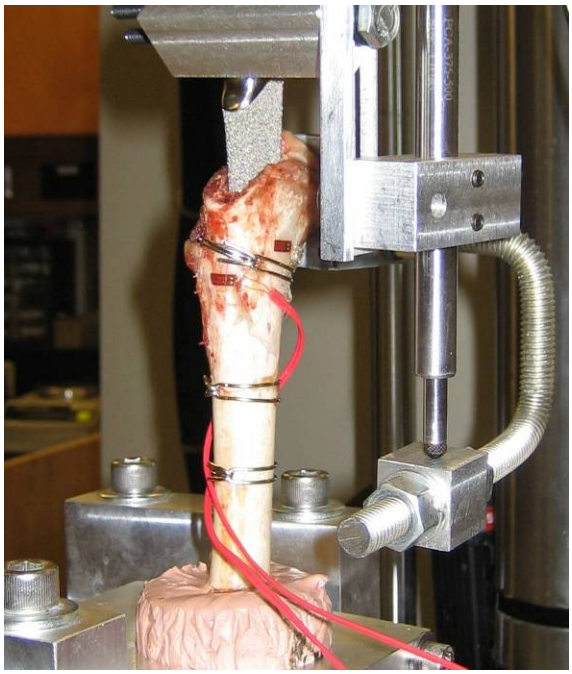


**Figure 3.9.** Wired specimen ready for testing. Three double loop cerclage wires were placed to secure the fracture. Note the drive distance present before the implant is pushed in.

Once the cerclage repair and re-broaching (if necessary) were completed, the femur and new implant were tested. The testing procedure post-cerclage followed the same procedure as the pre-cerclage testing. The implant was pushed in until it reached clinical height, three impacts were performed, and then the implant was loaded until failure. This completed the testing of a specimen.

### 3.9 Processing Results

The Labview® program was designed to output tab delimited files containing the data from the MTS actuator (force and displacement), LVDT displacement, and cranial and medial strain gauges. The data for the three impacts was collected at 1000Hz due to the high speed of the impact; and the data taken while positioning to clinical height and loading to failure were collected at 100Hz due to the slower speed of advance of the actuator. The files were then imported into Excel for post processing.

A spreadsheet was set up for each trial to determine the peak force at failure (ForceFail), peak displacement (both MTS actuator displacement and LVDT displacement), and peak strain gauge values for each impact and for the clinical height and load to failure parts of the trial. Graphs were plotted of the strain gauge data over time for the load to failure trials. Graphs were also generated for force versus displacement for the load to failure trials. In some cases the failure occurred during the initial impacts and the graphs were plotted for these portions of the trials. The subsidence measurement was calculated as the LVDT displacement from the starting value (at the clinically relevant height) to the final value at fracture. The force to initiate subsidence was determined from the graph of force versus displacement. The force versus displacement graphs consistently displayed a vertical portion which followed the y-axis until the trace diverged to the right along the positive x-axis. The vertical portion represented a rise in force with no movement of the implant. The inflection point of the force at which the trace began to deviate from the y-axis, indicating subsidence, was designated as the force to initiate subsidence (ForceInit). The final value that was compared between the pre-cerclage and post-cerclage specimens was that of relative

subsidence. The peak subsidence in the pre-cerclage specimens that failed by fracture was compared to the post-cerclage subsidence that occurred at a force equivalent to 10N less than the force at failure of the pre-cerclage specimens (relative subsidence).

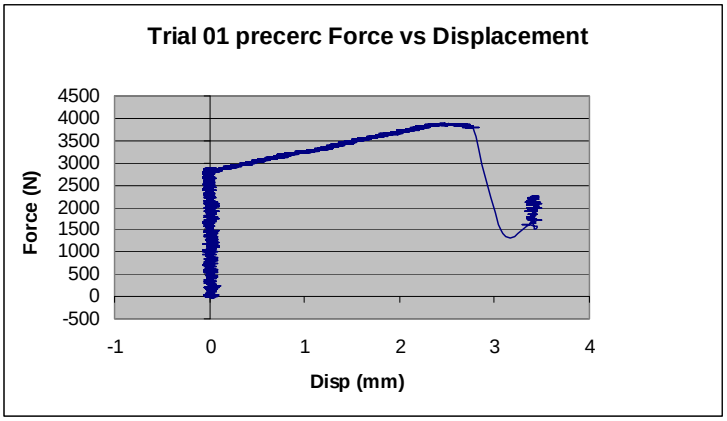



**Figure 3.10.** Example Force vs. Displacement (LVDT) graph for testing. Note how the force rises along the positive y axis with no displacement until the inflection point at approximately 2800N. This point is the Force to Initiate subsidence (ForceInit).

The strain gauge data was processed using a moving window average to eliminate some of the extreme peaks and valleys which were caused by noise in the data collection equipment. The moving average took an average of 50 data points.

### 3.10 Statistical Analysis

The variables analyzed for significance were the peak subsidence in each trial (Sub), the peak force sustained by the specimen before failure (ForceFail), the force to initiate subsidence (ForceInit), the peak cranial and medial strain, and the difference between cranial and medial strain. The last value, the difference between cranial and medial strain was

evaluated in an attempt to capture any significant difference between the strains experienced in the cranial and medial cortical walls of the femora during testing.

The intact pre-cerclage (pre-failure) specimens were compared to the wired, post-cerclage (post-failure), specimens. Additionally the trials that used reamers (4,6,7,8,9) were compared to the trials that did not use reamers (1,2,3) and evaluated for any significant differences. All of the variables were evaluated for the normality of their distribution using a Shapiro –Wilk test. If the distribution was normal then the variables were compared between the two groups using an ANOVA test, with blocking by specimen. The blocking reduced the inter-specimen variability associated with the testing. If the distribution of the variable was not normal, then a Wilcoxon-Mann-Whitney test was used to evaluate any significant differences. A p-value of 0.05 was used to determine significance. The results of the trials were analyzed using SAS software (SAS v9.1.3 Service pack 4, SAS Institute Inc., Cary, NC).

# 4. RESULTS

## 4.1 Hammer Trials

Before the trials could begin the hammer force used by the surgeon was collected in order to determine the settings of the MTS machine. After conducting 30 trials of hammer blows, the data was processed to yield an average peak force of 5518.94N (SD=622.57N). (Table 4.1).

**Table 4.1.** Mean and standard deviation for the force and impulse obtained from the hammer trials

| Number of trials=30 | |
|---|---|
| **Avg Pk Force (N)** | 5518.94 |
| **SD** | 622.57 |
| **Area under curve (Impulse Ns)** | 1.6934 |
| **SD** | 0.2951 |

Considering that the surgeon was controlling the force of his hammer blows by "feel," the results proved to be very consistent, with a relatively small standard deviation. This offered evidence that mimicking the "seating" hammer blows with a consistent energy input on the hydraulic load frame during the specimen testing would be relevant. The consistency of the peaks can be observed in a plot of the trials (Figure 4.1).

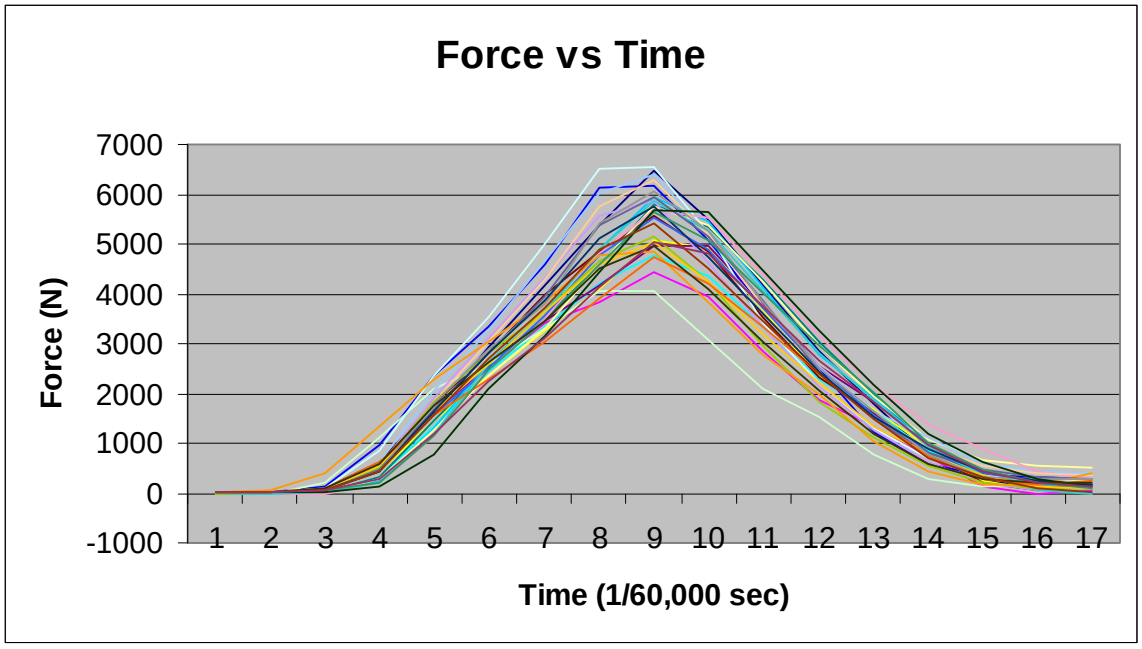



**Figure 4.1.** Plot of Force vs. Time for Hammer Blow trials. This plot shows the peak forces reached during the trials.

The mass of the hammer was measured to be 0.58 kg, the velocity of the hammer was calculated to be 2.92 m/sec. Subsequently, the energy of the hammer blow was calculated to be 1.236 J. This was the energy that would be recreated as closely as possible using the MTS machine during the *in vitro* testing.

## 4.2 Specimen Testing

Nine trials were conducted. The first three trials were prepared without the use of reamers, whereas the subsequent six trials used reamers for preparation. Failure modes were noted, either a fracture (Fx) or contact of the neck (neck of implant contacting neck cut) (CN). (Table 4.2) Trials 4, 6, 7, and 8 had two pre-cerclage trials since the initial test ended

with a neck contact mode of failure. Therefore, a second trial was conducted in each case and a fracture of the femur occurred.

**Table 4.2.** Trial Testing Summary. The table lists the failure mode for each test and the size of implant used in the test. Additionally the Fracture Description section provides a description of the femoral fracture which occurred during that test. In the case where the failure mode was via contacting the neck, there was no fracture, therefore no fracture Method given.

**Failure Summary**

| Trial | Test | Failure Mode | Implant Size | Fracture Description |
|---|---|---|---|---|
| 1 | pre-cerclage1 | Fx | 9 | lateral cortex |
| | post-cerclage | Fx | 9 | distal tip of implant |
| 2 | pre-cerclage1 | Fx | 10 | distal cranial |
| | post-cerclage | Fx | 10 | opening of same fracture |
| 3 | pre-cerclage1 | Fx | 7 | Proximal Cranial (but not at neck) |
| | post-cerclage | Fx | 7 | Distal extension of same fracture |
| 4 | pre-cerclage1 | CN | 7 | N/A |
| | pre-cerclage2 | Fx | 8 | Originated at medial neck cut |
| | post-cerclage | Fx | 9 | Cranial Surface originated distally |
| 5 | pre-cerclage | Fx | 8 | Originated at medial neck cut |
| | post-cerclage | Fx | 9 | Originated distal cranial side |
| 6 | pre-cerclage1 | CN | 6 | N/A |
| | pre-cerclage2 | Fx | 7 | Cranio-Medial full-length Fx origin neck cut |
| | post-cerclage | Fx | 8 | Extension of same Fx |
| 7 | pre-cerclage1 | CN | 6 | N/A |
| | pre-cerclage2 | Fx | 7 | Caudal-medial Fx originated distally |
| | post-cerclage | Fx | 7 | Fx opened distally |
| 8 | pre-cerclage1 | CN | 6 | N/A |
| | pre-cerclage2 | Fx | 7 | Cranial face at neck on first impact |
| | post-cerclage | Fx | 7 | Original fracture opened |
| 9 | pre-cerclage | Fx | 8 | Medial Fx originated at neck |
| | post-cerclage | Fx | 9 | Fx extended distally |

*note: CN = contacted neck, Fx = fracture*

**Table 4.3.** Number of double-loop cerclage used in each trial.

| **Double Loop cerclages** | |
|---|---|
| Trial | Number of Cerclages |
| 1 | 3 |
| 2 | 3 |
| 3 | 2 |
| 4 | 3 |
| 6 | 3 |
| 7 | 3 |
| 8 | 3 |
| 9 | 3 |

It is worthy of note that many of the fractures (trials: 1 post-cerclage, 2 pre-cerclage1, 4 post-cerclage, 5 post-cerclage, 7 pre-cerclage2) originated distally. In trials where fractures occurred, the fracture occurred suddenly with little to no visible deformation of the cortical bone. As the bone is a very hard material, the failure was via brittle fracture of the material. The fracture was usually accompanied by a loud noise that alerted the observers to the development of the fracture. A small hairline fracture that was not immediately visible could result in a sudden drop in the sustained load, and therefore failure of the specimen. Given that, the observers of the trial had to frequently listen for the fracture to develop in order to stop the test at the appropriate time. For the post-cerclage trials the original fracture generally extended to cause failure of the specimen. This was frequently accompanied by failure of the cerclage wires, defined as the opening of the cerclage knot on the most proximal cerclage.

Trial 5 was excluded from the statistical analysis because the post-cerclage specimen fractured before the implant reached an appropriate clinical height (top of beaded surface of implant adjacent to top edge of neck cut on the medial aspect). Three of the pre-cerclage specimens failed during the impact portion of the testing. The implants had been positioned at a clinical height. Trial 2 pre-cerclage1 failed on the first impact. Trial 7 pre-cerclage2 failed on the second impact. Trial 8 pre-cerclage2 failed on the first impact. Because of the rapid loading rate, the accuracy of the measurement of the peak load from these tests may not be as accurate as those obtained during slower load application.

The peak force that occurred at failure for all trials was 2092.3 N (SD 905.1 N) for the pre-cerclage1 trials, 2644.4 N (SD 708.2 N) for the pre-cerclage2 trials, and 3309.0 N (SD 609.1 N) for the post-cerclage trials. The average subsidence for the pre-cerclage1 trials was 3.5mm (SD 1.6mm), 4.7mm (SD 2.9mm) for the pre-cerclage2 trials, and 6.7mm (SD 3.7mm) for the post-cerclage trials. Finally the relative subsidence (the subsidence that occurred at a post-cerclage force equivalent to 10N less than the pre-cerclage force at failure) was 1.8mm (SD 3.0mm) (Table 4.4)

**Table 4.4.** Force at failure and Subsidence Results. List of trials conducted with the peak force (N) reached before failure and the peak subsidence (mm) reached before failure. Mean and standard deviations are also listed for each category.

| **Overview of Trials – Force at Failure, Subsidence** | | | | | | | |
|---|---|---|---|---|---|---|---|
| | *Force at Failure (N)* | | | *Subsidence (mm)* | | | |
| Trial | *Pre-cerclage1* | *Pre-cerclage2* | *Post-cerclage* | *Pre-cerclage1* | *Pre-cerclage2* | *Post-cerclage* | *Relative Subsidence* |
| 1 | 3880.5 | | 4193.4 | 3.50 | | 3.23 | 0.5323 |
| 2 | 1340.3 | | 3058.9 | 1.07 | | 14.01 | 0.0303 |
| 3 | 1939.6 | | 2972.3 | 1.97 | | 4.81 | 0.5340 |
| 4 | 1480.2 | 2917.0 | 2690.7 | 3.04 | 7.56 | 3.97 | 3.97 |
| 6 | 1871.7 | 3302.6 | 3332.5 | 4.23 | 4.84 | 8.91 | 8.4700 |
| 7 | 2947.0 | 2710.0 | 3712.7 | 4.12 | 0.68 | 3.47 | 0.3673 |
| 8 | 2078.1 | 1647.9 | 3993.0 | 3.47 | 5.76 | 7.61 | 0.3395 |
| 9 | 1201.2 | | 2518.2 | 6.56 | | 7.69 | 0.1040 |
| Mean | 2092.3 | 2644.4 | 3309.0 | 3.5 | 4.7 | 6.7 | 1.8 |
| SD | 905.1 | 708.2 | 609.1 | 1.6 | 2.9 | 3.7 | 3.0 |

The force to initiate subsidence was determined from interpretation of the Force vs Displacement graphs for each trial. This force was the inflection point of the graph as the curve deviated from the positive y-axis. The average force to initiate subsidence was 1556.7N (SD 615.3N) for the pre-cerclage1 trials, 2001.7N (SD 439.5) for the pre-cerclage2 trials, and 2378.8N (SD 656.9N) for the post-cerclage trials.

**Table 4.5.** Force to Initiate Subsidence Results. List of the force (N) to initiate subsidence for each trial.

| **Overview of Trials – Force to Initiate Subsidence** | | | |
|---|---|---|---|
| | *Force to Initiate Subsidence(N)* | | |
| Trial | *Pre-cerclage1* | *Pre-cerclage2* | *Post-cerclage* |
| 1 | 2862.44 | | 3768.64 |
| 2 | 1127.93 | | 2077.42 |
| 3 | 1536.75 | | 1837.05 |
| 4 | 1443.54 | 1781.78 | 2661.35 |
| 6 | 1241.79 | 2636.05 | 2263.18 |
| 7 | 2038.80 | 1940.92 | 2643.38 |
| 8 | 1133.26 | 1647.95 | 2066.76 |
| 9 | 1069.34 | | 1712.54 |
| Mean | 1556.7 | 2001.7 | 2378.8 |
| SD | 615.3 | 439.5 | 656.9 |

Strain data was collected for each test for each trial on both the medial and cranial aspects of the femur. In trial 2 pre-cerclage1, no strain information was collected, likely due to equipment malfunction, as the same strain gauges collected information for the post-cerclage trial. In the post-cerclage trials 4 and 5, no medial strain gauge information was collected due to the strain gauge being damaged by the fracture in the previous test. For the pre-cerclage1 trials, the mean value for cranial strain was 0.0144 (SD 0.0157) and 0.0128 (SD 0.0171). The mean for the pre-cerclage2 trials was 0.0272 (SD 0.0108) for the cranial gauges and 0.0228 (SD 0.0199) for the medial gauges. The post-cerclage strain mean values were 0.0133 (SD 0.0157) for the cranial strain gauges and 0.0185 (SD 0.0162) for the medial strain gauges. (Table 4.6)

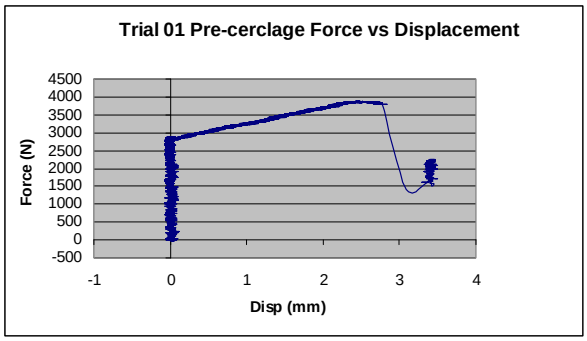
**Table 4.6.** Strain Results. Cranial and Medial Strain for each trial. If no strain information was collected or the linear range was exceeded, the cell is left empty.

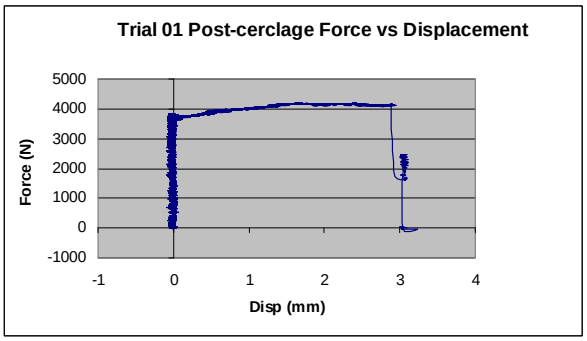
| **Overview of Trials - Strain** | | | | | | |
|---|---|---|---|---|---|---|
| | *Strain Pre-cerclage1* | | *Strain Pre-cerclage2* | | *Strain Post-cerclage* | |
| Trial | *Cranial* | *Medial* | *Cranial* | *Medial* | *Cranial* | *Medial* |
| 1 | 0.0030 | 0.0015 | | | 0.0013 | 0.0124 |
| 2 | | | | | 0.0500 | 0.0500 |
| 3 | 0.0418 | 0.0081 | | | 0.0500 | 0.0180 |
| 4 | 0.0033 | 0.0031 | 0.0432 | 0.0500 | 0.0146 | |
| 6 | 0.0032 | 0.0048 | 0.0195 | 0.0254 | 0.0042 | 0.0165 |
| 7 | 0.0084 | 0.0162 | 0.0230 | 0.0080 | 0.0067 | 0.0046 |
| 8 | 0.0096 | 0.0061 | 0.0230 | 0.0080 | 0.0034 | 0.0092 |
| 9 | 0.0313 | 0.0500 | | | 0.0129 | |
| Mean | 0.0144 | 0.0128 | 0.0272 | 0.0228 | 0.0133 | 0.0185 |
| SD | 0.0157 | 0.0171 | 0.0108 | 0.0199 | 0.0157 | 0.0162 |

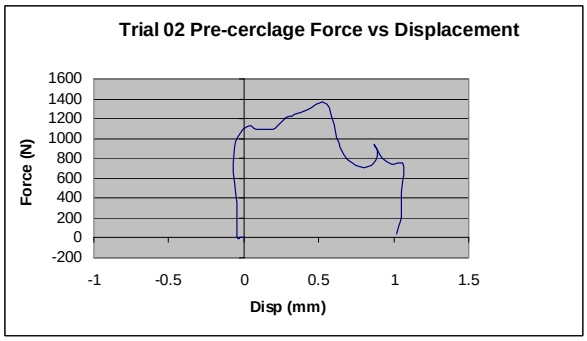
The force for each trial was collected with sequenced displacement data as measured by the LVDT. The graphs of force vs. displacement (Figure 4.2) were plotted for each trial. The trace typically demonstrates a vertical rise, indicating no displacement as the force rises. As the force climbs, the trace diverges from the vertical axis as some displacement occurs. This point is the force to initiate subsidence. The trace then typically exhibits a steady rise in force with displacement. The failure typically occurred suddenly resulting in a prompt, precipitous drop in force. Trial 02 pre-cerclage, trial 07 pre-cerclage2, and trial08 pre-cerclage2 failed during the impaction portion of the testing. Therefore, since the failure occurred when the MTS actuator was moving at a high rate of speed (75mm/sec) the graph displays an unusual shape based upon having very few data points. Interestingly, Trial 04 pre-cerclage1 and post-cerclage demonstrated plateaus where the force remained nearly

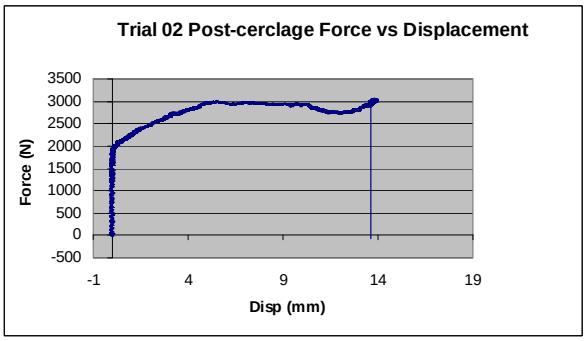
constant after movement of the implant began. This force stayed relatively constant until failure occurred.

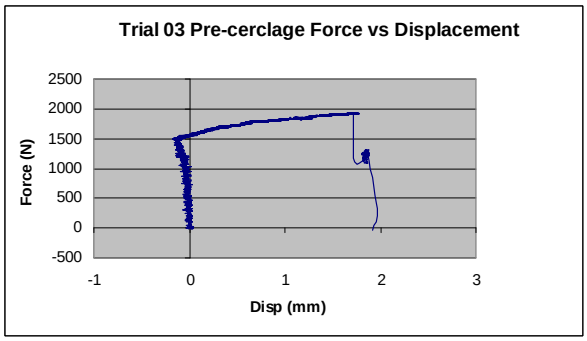
**Figure 4.2.** Force vs. Displacement for all trials. This figure includes graphs of the Force vs. Displacement for the Pre-cerclage1, Pre-cerclage2, and Post-cerclage tests for all trials.

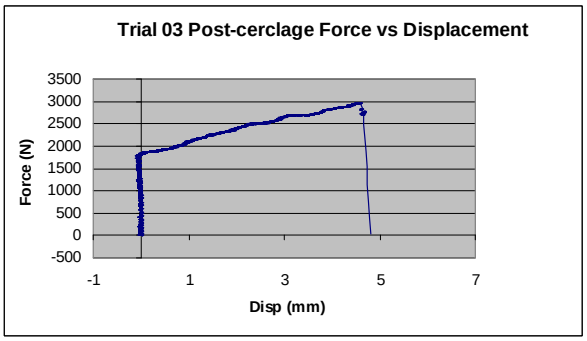

Trial 01 Pre-cerclage Force vs Displacement
Force (N)
4500
4000
3500
3000
2500
2000
1500
1000
500
0
-500
-1
0
1
2
3
4
Disp (mm)

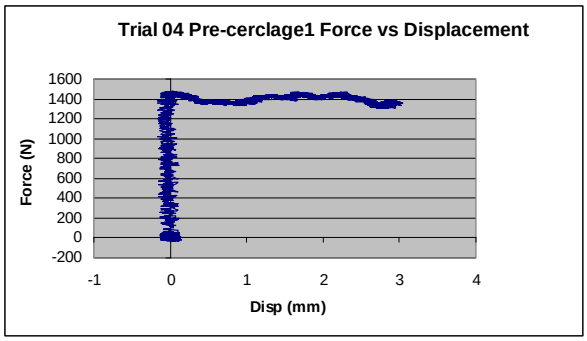

Trial 01 Post-cerclage Force vs Displacement
Force (N)
5000
4000
3000
2000
1000
0
-1000
-1
0
1
2
3
4
Disp (mm)

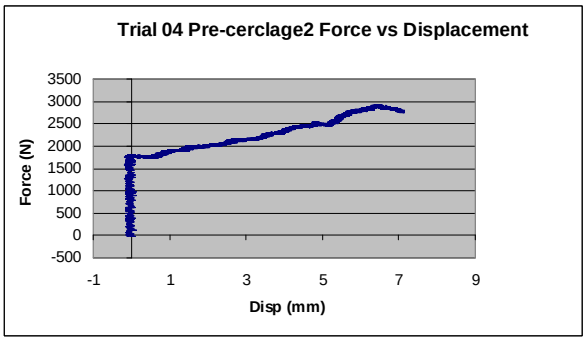

Trial 02 Pre-cerclage Force vs Displacement
Force (N)
1600
1400
1200
1000
800
600
400
200
0
-200
-1
-0.5
0
0.5
1
1.5
Disp (mm)

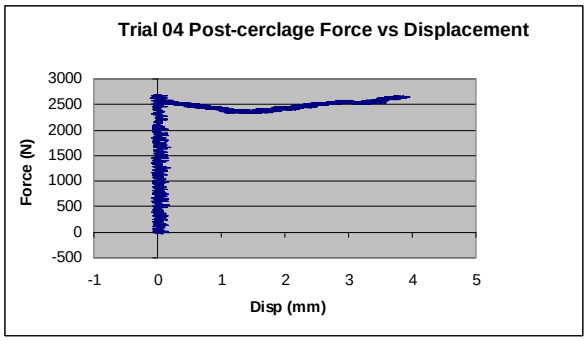

Trial 02 Post-cerclage Force vs Displacement
Force (N)
3500
3000
2500
2000
1500
1000
500
0
-500
-1
4
9
14
19
Disp (mm)

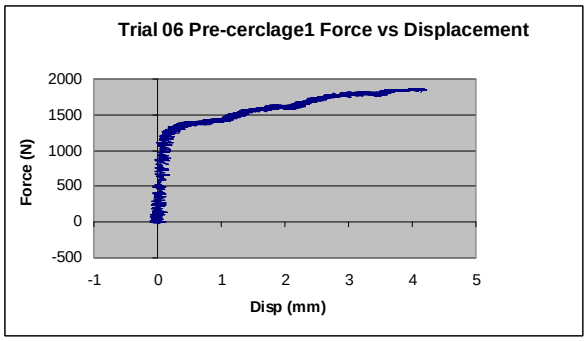

Trial 03 Pre-cerclage Force vs Displacement
Force (N)
2500
2000
1500
1000
500
0
-500
-1
0
1
2
3
Disp (mm)

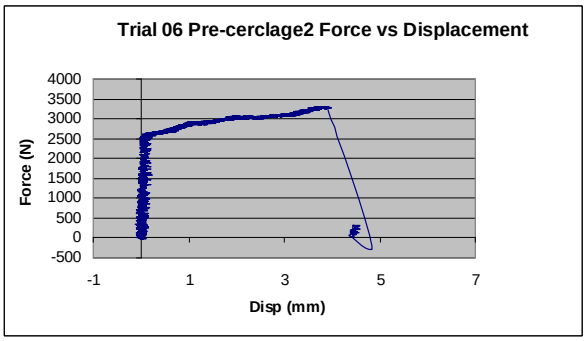

Trial 03 Post-cerclage Force vs Displacement
Force (N)
3500
3000
2500
2000
1500
1000
500
0
-500
-1
1
3
5
7
Disp (mm)

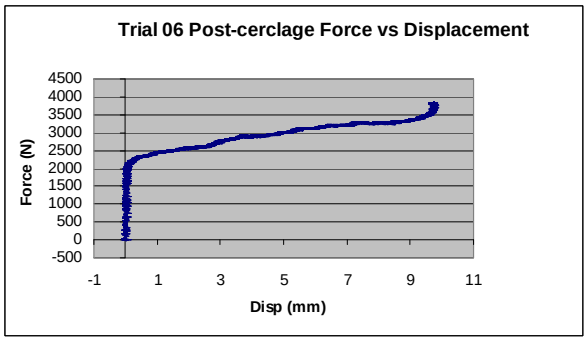

Trial 04 Pre-cerclage1 Force vs Displacement
Force (N)
1600
1400
1200
1000
800
600
400
200
0
-200
-1
0
1
2
3
4
Disp (mm)

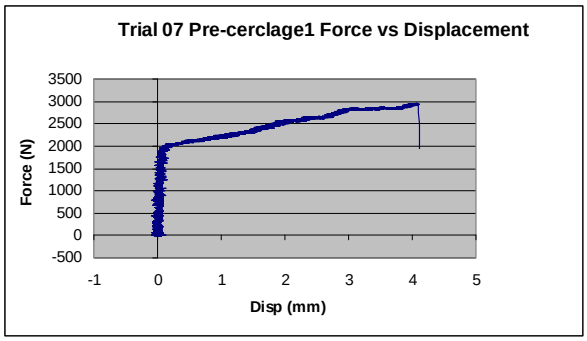

Trial 04 Pre-cerclage2 Force vs Displacement
Force (N)
3500
3000
2500
2000
1500
1000
500
0
-500
-1
1
3
5
7
9
Disp (mm)

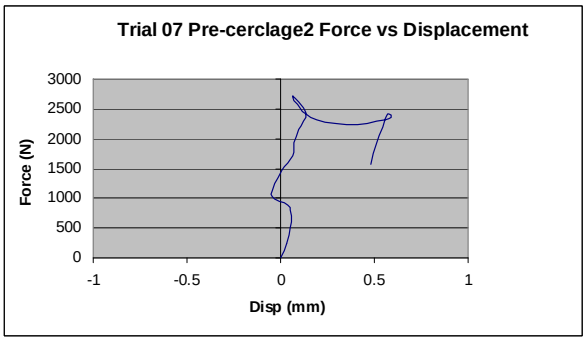

Trial 04 Post-cerclage Force vs Displacement
Force (N)
3000
2500
2000
1500
1000
500
0
-500
-1
0
1
2
3
4
5
Disp (mm)

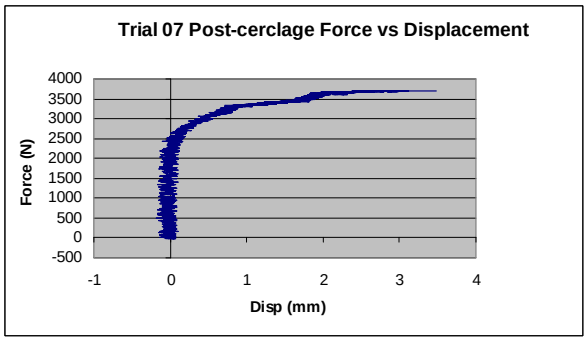

Trial 06 Pre-cerclage1 Force vs Displacement
Force (N)
2000
1500
1000
500
0
-500
-1
0
1
2
3
4
5
Disp (mm)

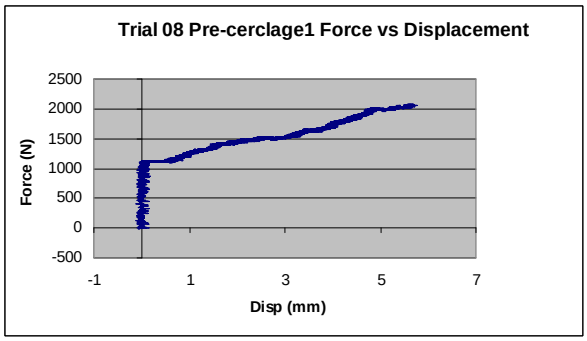

Trial 06 Pre-cerclage2 Force vs Displacement
Force (N)
4000
3500
3000
2500
2000
1500
1000
500
0
-500
-1
1
3
5
7
Disp (mm)

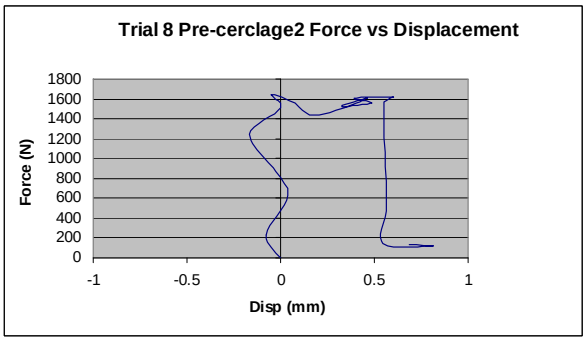

Trial 06 Post-cerclage Force vs Displacement
Force (N)
4500
4000
3500
3000
2500
2000
1500
1000
500
0
-500
-1
1
3
5
7
9
11
Disp (mm)

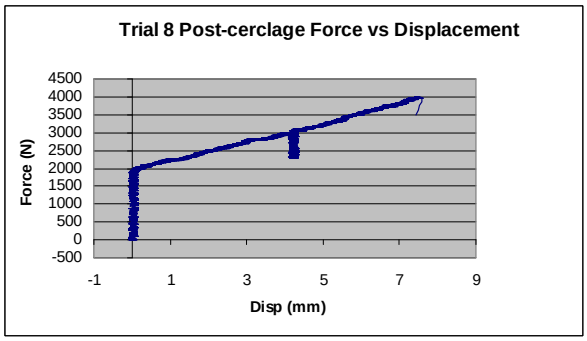

Trial 07 Pre-cerclage1 Force vs Displacement
Force (N)
3500
3000
2500
2000
1500
1000
500
0
-500
-1
0
1
2
3
4
5
Disp (mm)

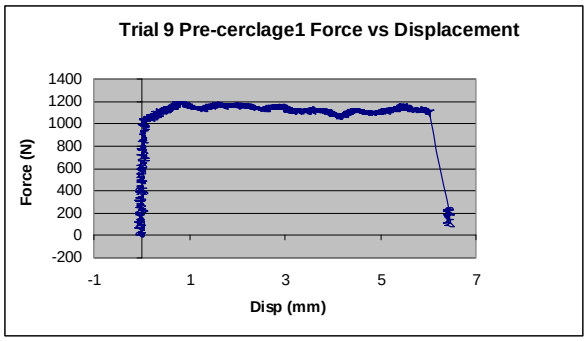

Trial 07 Pre-cerclage2 Force vs Displacement
Force (N)
3000
2500
2000
1500
1000
500
0
-1
-0.5
0
0.5
1
Disp (mm)

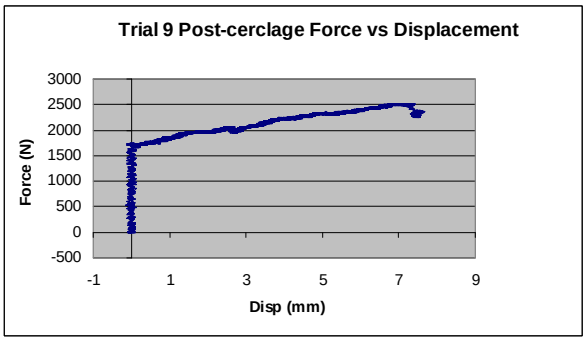

Trial 07 Post-cerclage Force vs Displacement
Force (N)
4000
3500
3000
2500
2000
1500
1000
500
0
-500
-1
0
1
2
3
4
Disp (mm)


Trial 08 Pre-cerclage1 Force vs Displacement
Force (N)
2500
2000
1500
1000
500
0
-500
-1
1
3
5
7
Disp (mm)


Trial 8 Pre-cerclage2 Force vs Displacement
Force (N)
1800
1600
1400
1200
1000
800
600
400
200
0
-1
-0.5
0
0.5
1
Disp (mm)

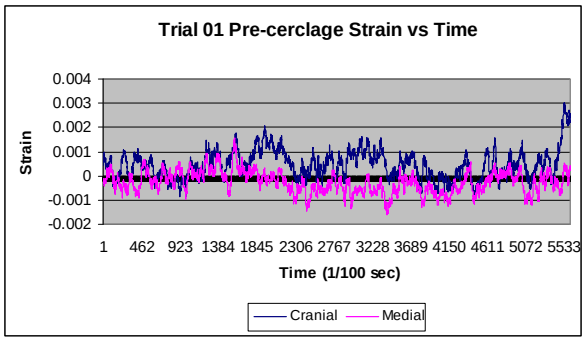

Trial 8 Post-cerclage Force vs Displacement
Force (N)
4500
4000
3500
3000
2500
2000
1500
1000
500
0
-500
-1
1
3
5
7
9
Disp (mm)

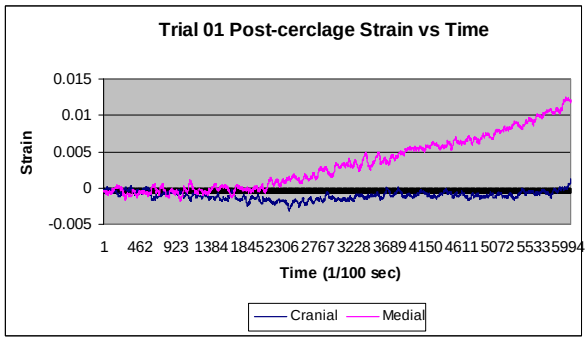

Trial 9 Pre-cerclage1 Force vs Displacement
Force (N)
1400
1200
1000
800
600
400
200
0
-200
-1
1
3
5
7
Disp (mm)

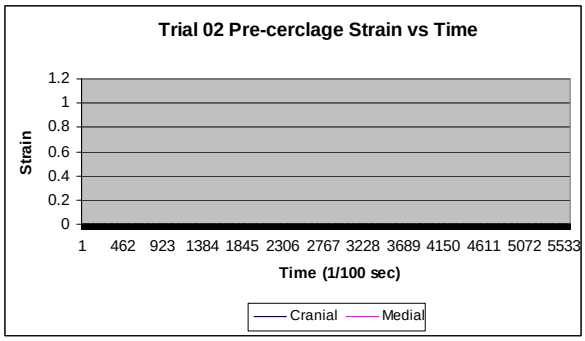

Trial 9 Post-cerclage Force vs Displacement
Force (N)
3000
2500
2000
1500
1000
500
0
-500
-1
1
3
5
7
9
Disp (mm)

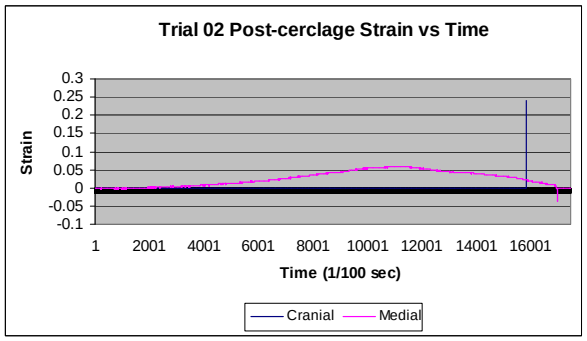
Strain data for the cranial and medial aspects of the femurs was collected for all trials (Figure 4.3). Graphs of strain vs. time were plotted for all trials. The linear range of the strain gauges was +/- 0.05 strain, therefore the graphs were plotted only within the linear range for the gauges. No strain data was collected in trial 02 pre-cerclage, likely due to equipment error. In the post-cerclage trials 4 and 5, no medial strain gauge information was collected due to the strain gauge being damaged by the fracture in the previous test. Two kinds of behavior were noted for the strain data. In trials(trial 01 post-cerclage, trial 03 post-cerclage, medial gauge for trail 04 precerclage2 and post-cerclage, trial 06 post-cerclage, trial 07 precerclage1 and post-cerclage, trial 08 pre-cerclage1, and trial 09 post-cerclage cranial) demonstrated a continuous rise in strain until fracture occurred. Alternatively, other trials demonstrated relatively constant strain before a sudden rise in strain as failure occurred (trial 01 pre-cerclage, trial 02 post-cerclage, trial 03 pre-cerclage, trail 04 pre-cerclage2, trial 06 precerclage2, trial 08 pre-cerclage2, and trial 09 pre-cerclage1).

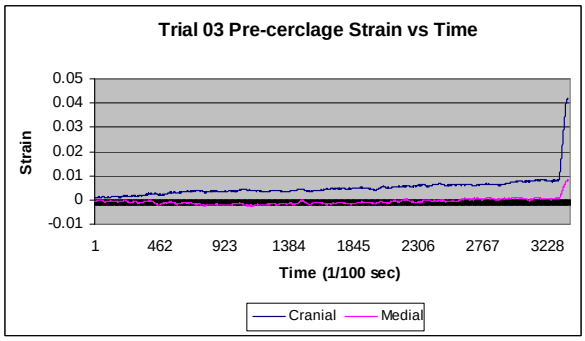
F**igure 4.3.** Strain vs. Time for all trials. This figure includes graphs of Strain vs. Time for the Pre-cerclage1, Pre-cerclage2, and Post-cerclage tests for all specimens. Both Medial and Cranial strains are given where acquired.

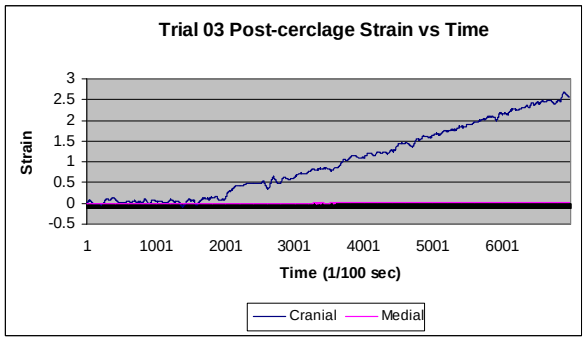

Trial 01 Pre-cerclage Strain vs Time
Strain
0.004
0.003
0.002
0.001
0
-0.001
-0.002
1 462 923 1384 1845 2306 2767 3228 3689 4150 4611 5072 5533
Time (1/100 sec)
Cranial
Medial

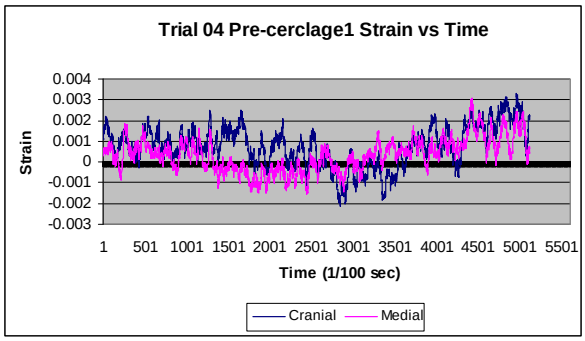

Trial 01 Post-cerclage Strain vs Time
Strain
0.015
0.01
0.005
0
-0.005
1 462 923 1384 1845 2306 2767 3228 3689 4150 4611 5072 5533 5994
Time (1/100 sec)
Cranial
Medial

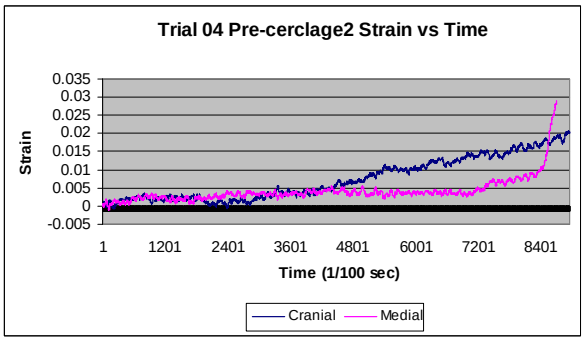

Trial 02 Pre-cerclage Strain vs Time
Strain
1.2
1
0.8
0.6
0.4
0.2
0
1 462 923 1384 1845 2306 2767 3228 3689 4150 4611 5072 5533
Time (1/100 sec)
Cranial
Medial

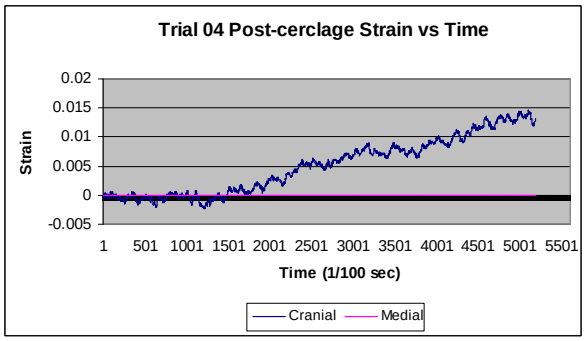

Trial 02 Post-cerclage Strain vs Time
Strain
0.3
0.25
0.2
0.15
0.1
0.05
0
-0.05
-0.1
1 2001 4001 6001 8001 10001 12001 14001 16001
Time (1/100 sec)
Cranial
Medial

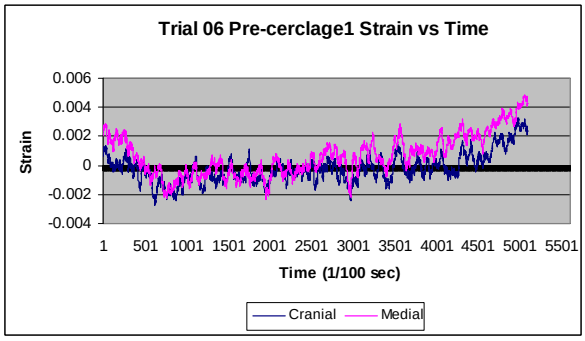

Trial 03 Pre-cerclage Strain vs Time
Strain
0.05
0.04
0.03
0.02
0.01
0
-0.01
1 462 923 1384 1845 2306 2767 3228
Time (1/100 sec)
Cranial
Medial

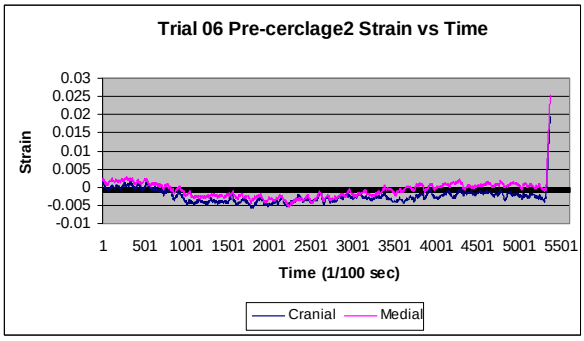

Trial 03 Post-cerclage Strain vs Time
Strain
3
2.5
2
1.5
1
0.5
0
-0.5
1 1001 2001 3001 4001 5001 6001
Time (1/100 sec)
Cranial
Medial

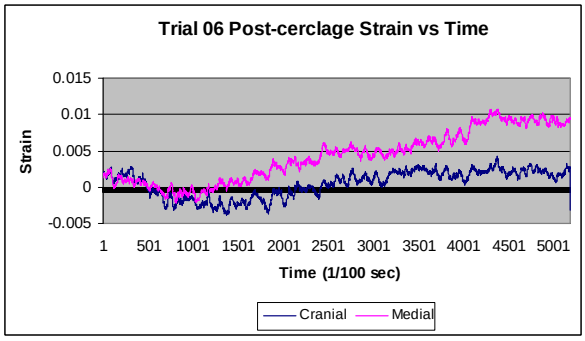

Trial 04 Pre-cerclage1 Strain vs Time
Strain
0.004
0.003
0.002
0.001
0
-0.001
-0.002
-0.003
1 501 1001 1501 2001 2501 3001 3501 4001 4501 5001 5501
Time (1/100 sec)
Cranial
Medial

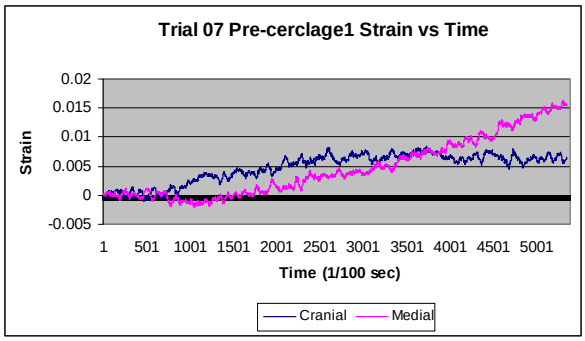

Trial 04 Pre-cerclage2 Strain vs Time
Strain
0.035
0.03
0.025
0.02
0.015
0.01
0.005
0
-0.005
1 1201 2401 3601 4801 6001 7201 8401
Time (1/100 sec)
Cranial
Medial

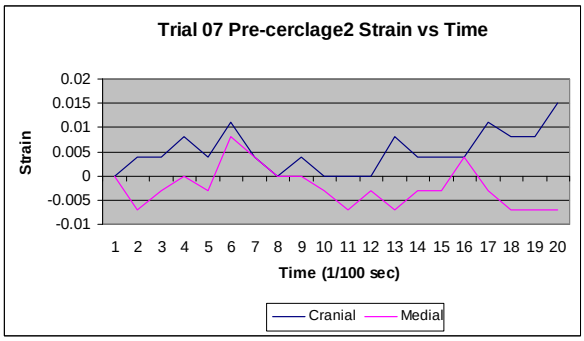

Trial 04 Post-cerclage Strain vs Time
Strain
0.02
0.015
0.01
0.005
0
-0.005
1 501 1001 1501 2001 2501 3001 3501 4001 4501 5001 5501
Time (1/100 sec)
Cranial
Medial

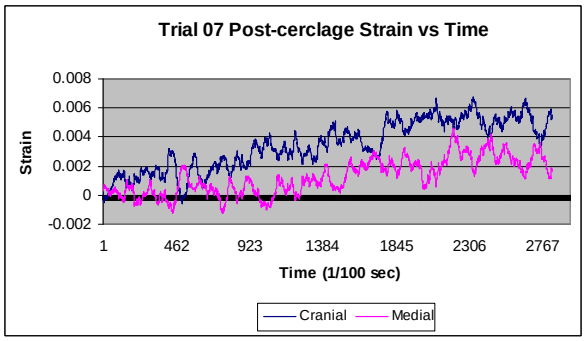

Trial 06 Pre-cerclage1 Strain vs Time
Strain
0.006
0.004
0.002
0
-0.002
-0.004
1 501 1001 1501 2001 2501 3001 3501 4001 4501 5001 5501
Time (1/100 sec)
Cranial
Medial

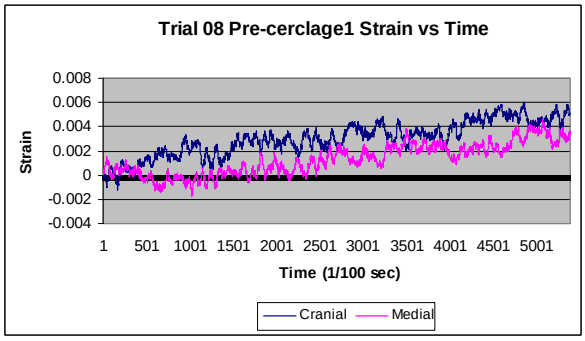

Trial 06 Pre-cerclage2 Strain vs Time
Strain
0.03
0.025
0.02
0.015
0.01
0.005
0
-0.005
-0.01
1 501 1001 1501 2001 2501 3001 3501 4001 4501 5001 5501
Time (1/100 sec)
Cranial
Medial

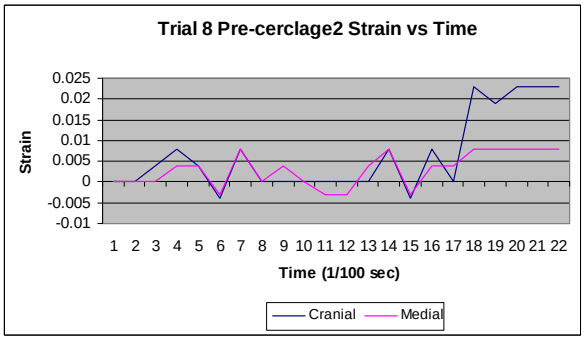

Trial 06 Post-cerclage Strain vs Time
Strain
0.015
0.01
0.005
0
-0.005
1 501 1001 1501 2001 2501 3001 3501 4001 4501 5001
Time (1/100 sec)
Cranial
Medial

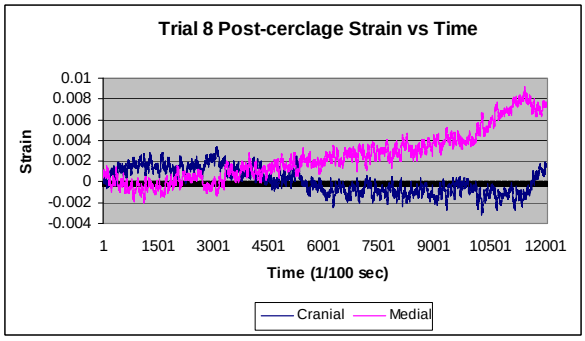

Trial 07 Pre-cerclage1 Strain vs Time
Strain
0.02
0.015
0.01
0.005
0
-0.005
1 501 1001 1501 2001 2501 3001 3501 4001 4501 5001
Time (1/100 sec)
Cranial
Medial

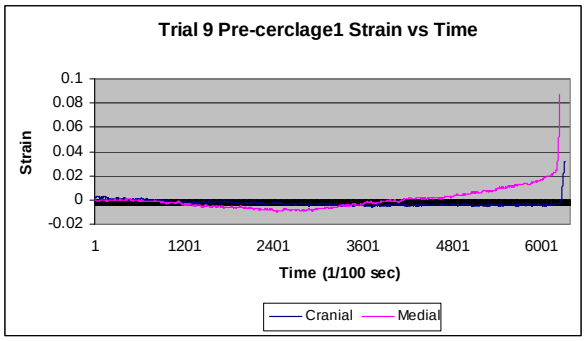

Trial 07 Pre-cerclage2 Strain vs Time
Strain
0.02
0.015
0.01
0.005
0
-0.005
-0.01
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20
Time (1/100 sec)
Cranial
Medial

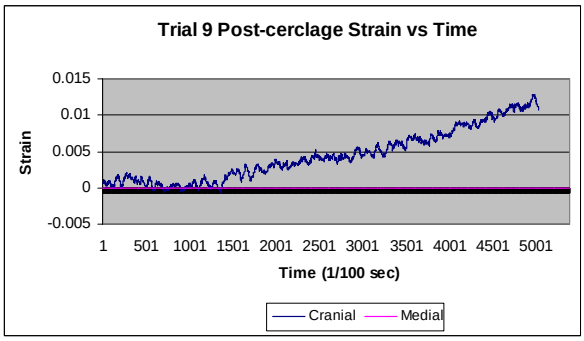

Trial 07 Post-cerclage Strain vs Time
Strain
0.008
0.006
0.004
0.002
0
-0.002
1 462 923 1384 1845 2306 2767
Time (1/100 sec)
Cranial
Medial


Trial 08 Pre-cerclage1 Strain vs Time
Strain
0.008
0.006
0.004
0.002
0
-0.002
-0.004
1 501 1001 1501 2001 2501 3001 3501 4001 4501 5001
Time (1/100 sec)
Cranial
Medial


Trial 8 Pre-cerclage2 Strain vs Time
Strain
0.025
0.02
0.015
0.01
0.005
0
-0.005
-0.01
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22
Time (1/100 sec)
Cranial
Medial


Trial 8 Post-cerclage Strain vs Time
Strain
0.01
0.008
0.006
0.004
0.002
0
-0.002
-0.004
1 1501 3001 4501 6001 7501 9001 10501 12001
Time (1/100 sec)
Cranial
Medial


Trial 9 Pre-cerclage1 Strain vs Time
Strain
0.1
0.08
0.06
0.04
0.02
0
-0.02
1
1201
2401
3601
4801
6001
Time (1/100 sec)
Cranial
Medial


Trial 9 Post-cerclage Strain vs Time
Strain
0.015
0.01
0.005
0
-0.005
1
501
1001
1501
2001
2501
3001
3501
4001
4501
5001
Time (1/100 sec)
Cranial
Medial

As previously stated, the max linear range of the strain gauges was 5 percent for the model of strain gauges used in this study. Therefore the scatterplots below as well as the following statistical analysis of the results uses a value of 0.05 strain when the range of the strain gauge was exceeded. The following Figures show scatterplots of the results grouped by trial.

The force to initiate subsidence values vs. trial were plotted to provide a visual interpretation of the data (Figure 4.4). The post-cerclage values of force to initiate subsidence were typically higher than the pre-cerclage values (trials: 1, 2, 3, 4, 7, 8, 9). The pre-cerclage2 values are higher than the pre-cerclage1 values for all trials except 7.

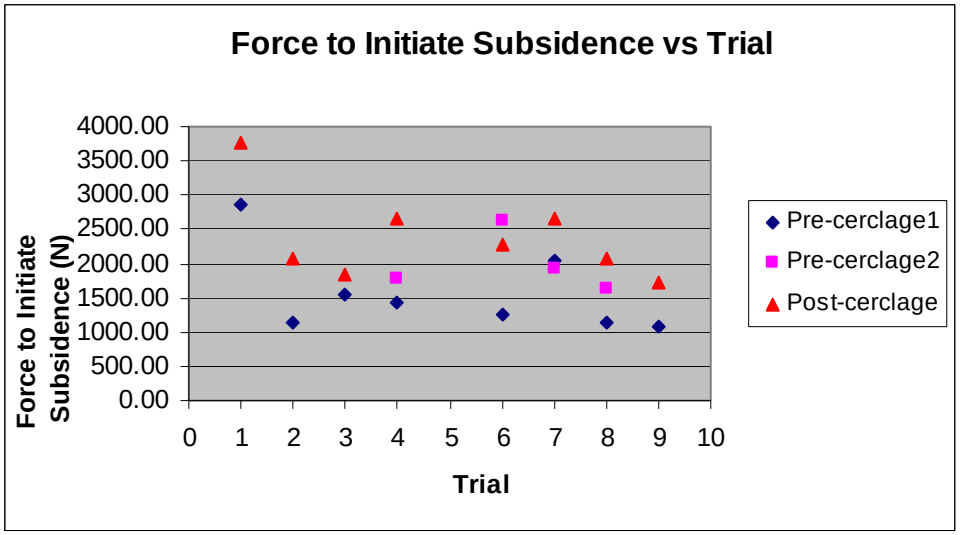



**Figure 4.4.** Force to Initiate Subsidence vs. Trial. Scatterplot of the Force to Initiate Subsidence by trial for Pre-cerclage1, Pre-cerclage2 and Post-cerclage.

It can be observed that the peak force at failure is highest in the post-cerclage trials for trials 1, 2, 3, 7, 8, and 9 (Figure 4.5). The pre-cerclage2 values of force at failure are higher than the pre-cerclage1 values for trials 4 and 6 (but not trials 7 and 8).

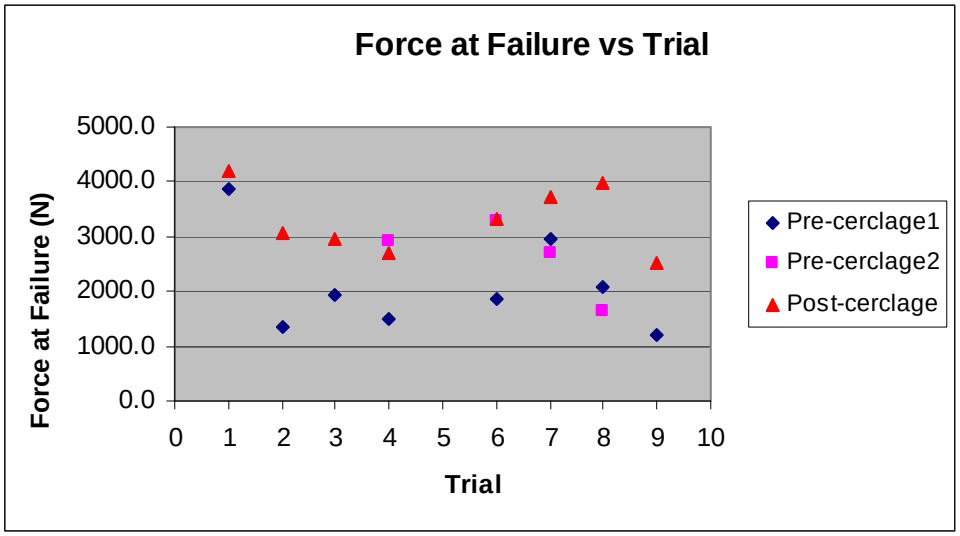



**Figure 4.5.** Force at Failure vs. Trial. Scatterplot of the Force at Failure by trial for Pre-cerclage1, Pre-cerclage2 and Post-cerclage.

The subsidence values measured were highest for the post-cerclage trials in 5 of the 8 trials (trials 2, 3, 6, 8, and 9) (Figure 4.6). The pre-cerclage2 trials had higher values than the pre-cerclage1 trials except for trial 7.

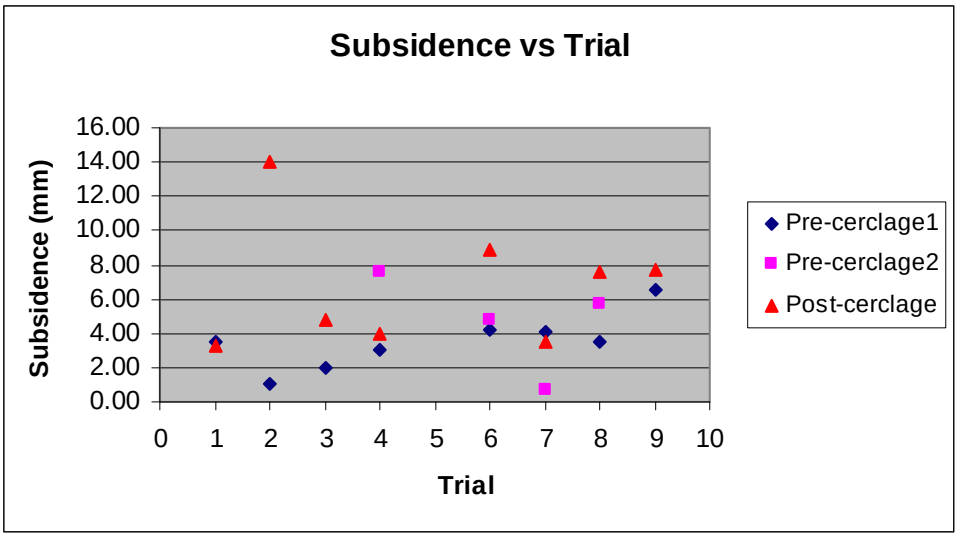



**Figure 4.6.** Subsidence vs. Trial. Scatterplot of the Subsidence by trial for Pre-cerclage1, Pre-cerclage2 and Post-cerclage.

The cranial gauges reached their maximum linear range of 0.05 in post-cerclage trials 2 and 3 (Figure 4.7). In all cases the post-cerclage cranial strain is lower than the pre-cerclage2. Also, in all trials with two pre-cerclage tests the second trial demonstrated a higher peak cranial strain.

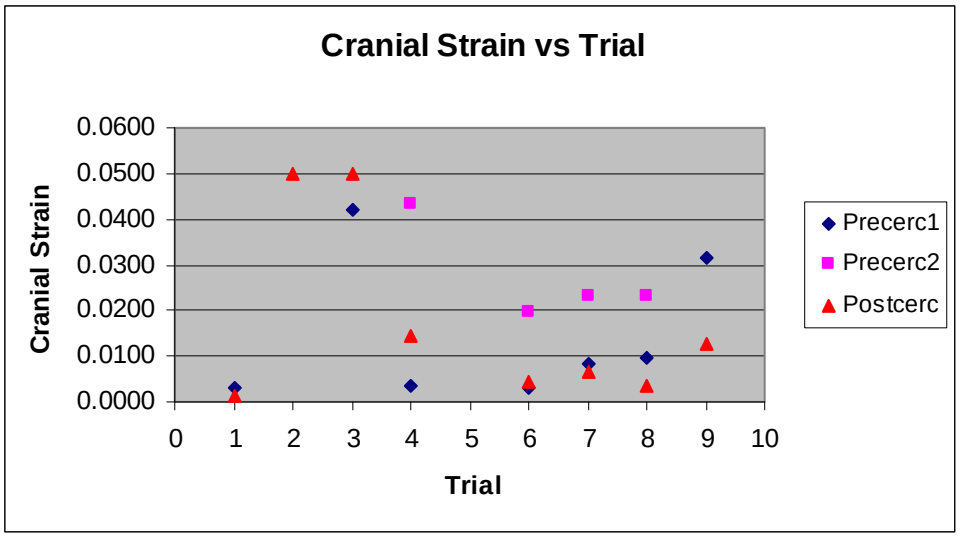



**Figure 4.7.** Cranial Strain vs. Trial. Scatterplot of the Cranial Strain by trial for Pre-cerclage1, Pre-cerclage2 and Post-cerclage.

In trials 1, 2, 3, 6, and 8 the post-cerclage medial strain exceeded the strain of the pre-cerclage1 trial (Figure 4.8). The pre-cerclage2 strain exceeded the pre-cerclage1 medial strain in all trials except trial 8.

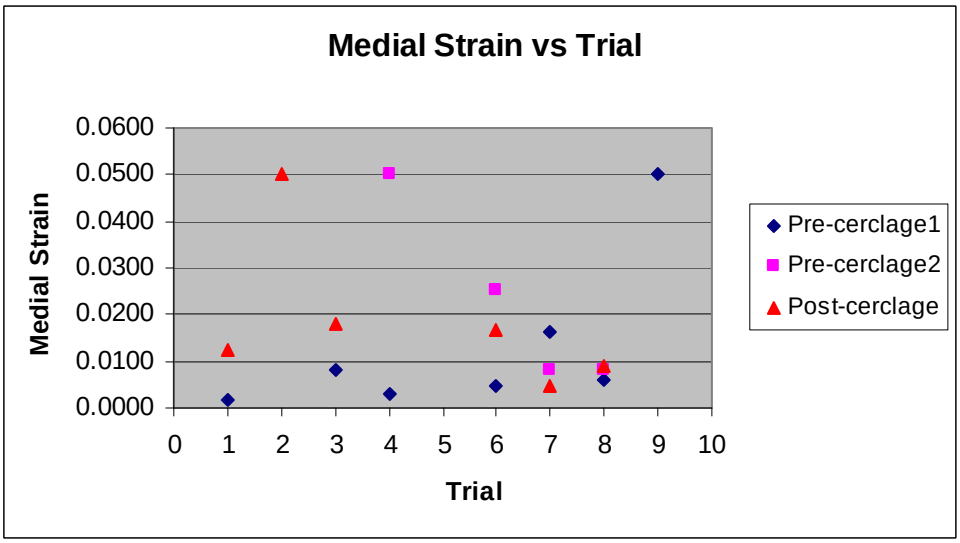



**Figure 4.8.** Medial Strain vs. Trial. Scatterplot of the Medial Strain by trial for Pre-cerclage1, Pre-cerclage2 and Post-cerclage.

The difference in strain values (cranial strain value minus the medial strain value) was calculated to evaluate any consistency in the difference in strains experienced between the medial and cranial aspects of the femur specimens during testing. Interestingly, there seems to be little consistency in the difference between the recorded peak strain values (Figure 4.9). In two post-cerclage trials the difference is positive (trials 3 and 7) and in four cases the difference is negative (trials 1, 2, 6, and 8). In the pre-cerclage1 trials the difference in strain values was positive in four cases (1, 3, 4, and 8) and negative in three cases (6, 7, and 9). In the pre-cerclage2 trials the strain difference was negative in two cases (trials 4 and 6) and positive in two (trials 7 and 8).

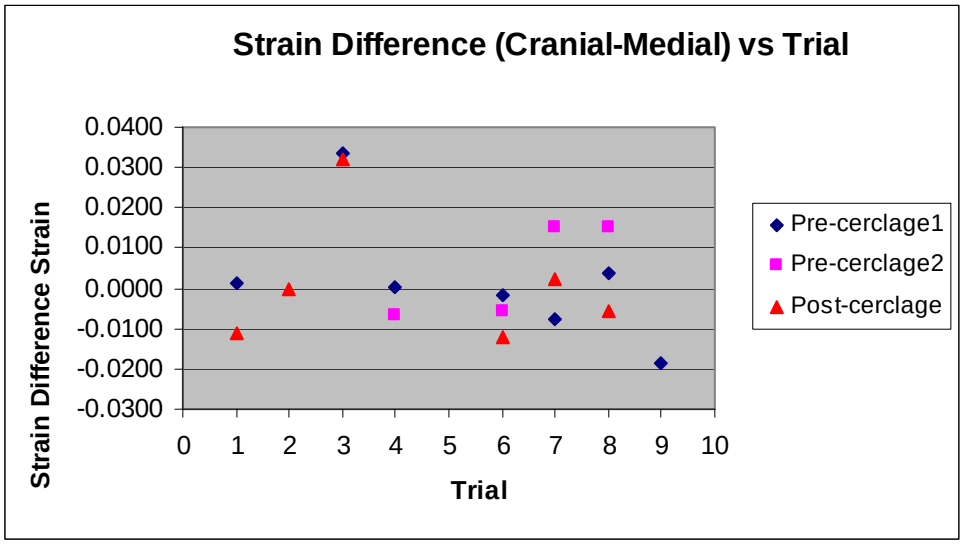



**Figure 4.9.** Strain Difference vs. Trial. Scatterplot of the Strain Difference by trial for Pre-cerclage1, Pre-cerclage2 and Post-cerclage. Note: Strain Diff = Cranial Strain – Medial Strain.

The statistical analysis used a type I error rate of 0.05 in all cases, therefore a p-value of less than 0.05 indicates evidence of a statistically significant difference between compared values.

Intact vs. Wired specimens were compared (Table 4.7). Intact specimens included both pre-cerclage trials. Wired specimens are post-cerclage specimens with cerclage wiring. The Shapiro-Wilk test was used to evaluate the normality of each variable and the force to initiate subsidence, force at failure and the subsidence were found to have normal distributions and therefore they were evaluated using an ANOVA test. However, the strain variables were found to not be normally distributed and they were evaluated using a Wilcoxon-Mann-Whitney test. The force to initiate subsidence was compared between the pre-cerclage specimens (mean 1705.05N, SD 584.49N) and the post-cerclage specimens (mean 2378.79N, SD 656.88N). The p-value was found to be significant with a value of 0.0019, indicating that there is a significant difference between the pre-cerclage and post-cerclage trials. The pre-cerclage values of force at failure were compared for pre-cerclage (mean 2276.33N, SD 855.58N) and post-cerclage (mean 3308.97N, SD 609.14) trials. Again, the p-value was found to be significant with a value of 0.0022, indicating a difference between pre-cerclage and post-cerclage trials. The trials were compared on the basis of subsidence with the pre-cerclage trials (mean 3.90mm, SD 2.09mm) demonstrating more subsidence than the post-cerclage trials (mean 6.71, SD 3.66mm). However, the p-value was 0.0600 indicating no significant difference. The pre-cerclage cranial strain (mean 0.190, SD 0.0150) was compared to the post-cerclage values (mean 0.0179, SD 0.0203). In this case the p-value was not significant (p-value 0.4685. The medial strain was also evaluated with

pre-cerclage values (mean 0.0165, SD 0.0179) compared to post-cerclage values (mean 0.0185, SD 0.0162) and was found to have a non-significant p-value of 0.4507. Finally the difference in strain values (cranial strain – medial strain) was compared between pre-cerclage trials (mean 0.0026, SD 0.142) and post-cerclage trials (mean 0.0008, SD 0.0163) and was also found to be non-significant with a p-value of 0.9097.

Therefore, in comparison of the pre-cerclage trials to the post-cerclage trials, there was a significant difference in the force at failure and the force to initiate subsidence, with the post-cerclage trials having higher values in both cases. No significant differences were obtained for subsidence or for strain comparisons between the pre-cerclage and post-cerclage trials.

**Table 4.7.** Intact Specimens (pre-cerclage) vs. Wired Specimens (post-cerclage). Intact specimens includes both Pre-cerclage1 and Pre-cerclage2 trials. The mean, standard deviation (SD) and p-values are given. A p-value less than 0.05 is significant. Trial 5 is excluded from the analysis.

| ***Pre-Cerclage*** | | | | | | |
|---|---|---|---|---|---|---|
| | Force to Initiate Subsidence (N) | Force at Failure (N) | Subsidence (mm) | Cranial | Medial | Strain Difference |
| Mean | 1705.05 | 2276.33 | 3.90 | 0.0190 | 0.0165 | 0.0026 |
| SD | 584.49 | 855.58 | 2.09 | 0.0150 | 0.0179 | 0.0142 |
| *N = 12* | | | | | | |
| ***Wired*** | | | | | | |
| | Force to Initiate Subsidence (N) | Force at Failure (N) | Subsidence (mm) | Cranial | Medial | Strain Difference |
| Mean | 2378.79 | 3308.97 | 6.71 | 0.0179 | 0.0185 | 0.0008 |
| SD | 656.88 | 609.14 | 3.66 | 0.0203 | 0.0162 | 0.0163 |
| *N = 8* | | | | | | |
| P-values | **0.0019** | **0.0022** | **0.0600** | **0.4685** | **0.4507** | **0.9097** |

The pre-cerclage trials that failed by fracture were compared to the post-cerclage trials (which all failed by fracture) thereby removing all specimens that failed by contacting the neck. The same variables as before were evaluated for comparison. Again, the Shapiro-Wilk test was used to evaluate the normality of each variable and the force to initiate subsidence, force at failure and the subsidence were found to have normal distributions (therefore they were evaluated using an ANOVA test), however the strain variables were found to not be normally distributed (therefore they were evaluated using a Wilcoxon-Mann-Whitney test). The force to initiate subsidence in the pre-cerclage fracture trials (mean

1825.40N, SD 645.95N) was compared to post-cerclage trials (mean 2378.79N, SD 656.88N). In this comparison the p-value was found to be significant at 0.0093. The force at failure was also evaluated with pre-cerclage fracture trials (mean 2367.39N, SD 978.27N) compared to post-cerclage trials (mean 3308.97N, 609.14N). The difference was found to be significant with a p-value of 0.0184. The subsidence of the pre-cerclage fracture specimens (3.99mm, SD 2.59mm) was matched against the post-cerclage specimens (mean 6.71mm, SD 3.66mm) and yielded a non-significant p-value of 0.1499. The pre-cerclage fracture trials cranial strain (mean 0.0264, SD 0.0139) was compared to the post-cerclage specimens (mean 0.0179, SD 0.0203). The p-value was not significant at 0.1248. The medial strain pre-cerclage fracture values (mean 0.0216, SD 0.0207) were compared to the post-cerclage values (mean 0.0185, SD 0.0162) and the p-value was non-significant at 0.9430 Finally, the strain difference for pre-cerclage fracture trials (mean 0.0048, SD 0.0176) was compared to that of the post-cerclage trials (mean 0.0008, SD 0.0163) and was found to have no significance at a p-value of 1.0000.

As in the comparison of pre-cerclage and post-cerclage, the comparison of pre-cerclage fracture trials with post-cerclage fracture trials yielded a significant difference between the force to initiate subsidence values and the force at failure values. In both cases the post-cerclage trials demonstrated higher forces. There were no significant differences found for the comparisons of subsidence or strain values.

**Table 4.8.** Pre-cerclage Fracture failures vs. Post-cerclage Fracture failures. Analysis of only those specimens that failed by fracture (fx), and not CN (contacting the neck). The mean, standard deviation (SD) and p-values are given. A p-value less than 0.05 is significant. Trial 5 is excluded from the analysis.

***Pre-Fracture***

| | Force to Initiate Subsidence (N) | Force at Failure (N) | Subsidence (mm) | Cranial | Medial | Strain Difference |
|---|---|---|---|---|---|---|
| Mean | 1825.40 | 2367.39 | 3.99 | 0.0264 | 0.0216 | 0.0048 |
| SD | 645.95 | 978.27 | 2.59 | 0.0139 | 0.0207 | 0.0176 |

***Post-Fracture***

| | Force to Initiate Subsidence (N) | Force at Failure (N) | Subsidence (mm) | Cranial | Medial | Strain Difference |
|---|---|---|---|---|---|---|
| Mean | 2378.79 | 3308.97 | 6.71 | 0.0179 | 0.0185 | 0.0008 |
| SD | 656.88 | 609.14 | 3.66 | 0.0203 | 0.0162 | 0.0163 |
| P-values | **0.0093** | **0.0184** | **0.1499** | **0.1248** | **0.9430** | **1.0000** |

The initial three trials did not use reamers for the implantation procedure, however the subsequent 5 trials did employ reamers. A statistical analysis was conducted to evaluate the differences between reamer preparation and non-reamer preparation in both the pre-cerclage trials and the post-cerclage trials. No statistical difference was found for any of the variables based upon the use of the reamers (Table 4.9).

For the pre-cerclage specimens, the force to initiate subsidence in the pre-reamer specimens (mean 1842.37N, SD 906.74N) was compared to the post-reamer specimens (mean 2378.79N, SD 656.88N) and no significance was found at a p-value of 0.8105. The

force at failure for the pre-reamer specimens (mean 2386.81N, SD 1327.83N) was compared to the post-reamer specimens (mean 2369.30, SD 682.87) and again was non-significant at a p-value of 0.9797. The subsidence of the pre-reamer specimens (mean 2.18mm, SD 1.23mm) was compared to the post-reamer specimens (mean 4.21mm, SD 2.01mm) and was not significant (p-value 0.1166). The cranial pre-reamer strain (mean 0.0224, SD 0.0274) was compared to post-reamer strain (mean 0.0166, SD 0.0135) and was non-significant at p-value 0.8958. The medial strain pre-reamer (mean 0.0048, SD 0.0047) was compared to post-reamer medial strain (mean 0.9681, SD 0.5126) and was found to have a non-significant p-value of 0.5126. Finally the strain difference pre-reamer (mean 0.0176, SD 0.0228) was compared to the post-reamer strain difference (mean -0.9514, SD 2.6984) and did not have a significant difference (p-value 0.2386).

**Table 4.9.** Pre-cerclage Pre-Reamer specimens vs. Pre-cerclage Post-Reamer specimens. Evaluation of the effect of reamers on the outcome of the trials. The mean, standard deviation (SD) and p-values are given. A p-value less than 0.05 is significant. Trial 5 is excluded from the analysis.

| ***Pre-cerclage specimens*** | | | | | | |
|---|---|---|---|---|---|---|
| ***Pre-Reamer*** | | | | | | |
| | Force to Initiate Subsidence (N) | Force at Failure (N) | Subsidence (mm) | Cranial | Medial | Strain Difference |
| Mean | 1842.37 | 2386.81 | 2.18 | 0.0224 | 0.0048 | 0.0176 |
| SD | 906.74 | 1327.83 | 1.23 | 0.0274 | 0.0047 | 0.0228 |
| ***Post-Reamer*** | | | | | | |
| | Force to Initiate Subsidence (N) | Force at Failure (N) | Subsidence (mm) | Cranial | Medial | Strain Difference |
| Mean | 1733.01 | 2369.30 | 4.21 | 0.0166 | 0.9681 | -0.9514 |
| SD | 485.01 | 682.87 | 2.01 | 0.0135 | 2.7092 | 2.6984 |
| P-values | **0.8105** | **0.9797** | **0.1166** | **0.8958** | **0.5126** | **0.2386** |

Next the post-cerclage specimens were evaluated for any difference between the pre-reamer and post-reamer specimens (Table 4.10). The force to initiate subsidence in the pre-reamer specimens (mean 2561.04N, SD 1052.70N) was compared to the post-reamer specimens (mean 1733.01N, SD 485.01N) and no significance was found at a p-value of 0.5841. The force at failure for the pre-reamer specimens (mean 3408.20N, SD 681.42N) was compared to the post-reamer specimens (mean 3249.42N, SD 636.67N) and again was non-significant at a p-value of 0.7501. The subsidence of the pre-reamer specimens (mean

7.35mm, SD 5.82mm) was compared to the post-reamer specimens (mean 6.33mm, SD 2.44mm) and was not significant (p-value 0.7332). The cranial pre-reamer strain (mean 1.3405, SD 1.8938) was compared to post-reamer strain (mean 0.0084, SD 0.0051) and was non-significant at p-value 1.0000. The medial strain pre-reamer (mean 0.0298, SD 0.0255) was compared to post-reamer medial strain (mean 0.0101, SD 0.0060) and was found to have a non-significant p-value of 0.1904. Finally the strain difference pre-reamer (mean 1.3252, SD 1.8899) was compared to the post-reamer strain difference (mean -0.0053, SD 0.0072) and did not have a significant difference (p-value 0.7728). (Table 4.10)

**Table 4.10.** Post-cerclage Pre-Reamer specimens vs. Post-cerclage Post-Reamer specimens. Evaluation of the effect of reamers on the outcome of the trials. The mean, standard deviation (SD) and p-values are given. A p-value less than 0.05 is significant. Trial 5 is excluded from the analysis.

| ***Post-cerclage specimens*** | | | | | | |
|---|---|---|---|---|---|---|
| ***Pre-Reamer*** | | | | | | |
| | Force to Initiate Subsidence | Force at Failure | Subsidence | Cranial | Medial | Strain Difference |
| Mean | 2561.04 | 3408.20 | 7.35 | 1.3405 | 0.0298 | 1.3252 |
| SD | 1052.70 | 681.42 | 5.82 | 1.8938 | 0.0255 | 1.8899 |
| ***Post-Reamer*** | | | | | | |
| | Force to Initiate Subsidence | Force at Failure | Subsidence | Cranial | Medial | Strain Difference |
| Mean | 2269.44 | 3249.42 | 6.33 | 0.0084 | 0.0101 | -0.0053 |
| SD | 401.46 | 636.67 | 2.44 | 0.0051 | 0.0060 | 0.0072 |
| P-values | **0.5841** | **0.7501** | **0.7332** | **1.0000** | **0.1904** | **0.7728** |

The final analysis which was conducted compared the relative subsidence (Table 4.4) of the post-cerclage specimens compared to the subsidence of the pre-cerclage fracture specimens. The post-cerclage trials sustained higher forces before failure than did the pre-cerclage trials. Therefore it was important to compare how much subsidence (relative subsidence) occurred in both specimens at a force approximately 10N less than the force that caused failure in the pre-cerclage trials. Interestingly, it was found that the relative subsidence in the post cerclage trials (mean 1.79mm, SD 2.99mm) was less than that of the pre-cerclage fracture trials (mean 3.99mm, SD 2.59mm). The values were not normally distributed based upon a Shapiro-Wilk test, therefore a Wilcoxon-Mann-Whitney test was conducted and no-significant difference was found between the amount of subsidence (p-value 0.0907).

Different modes of fracture failure in pre-cerclage specimens are shown in the following images (Figure 4.10). In some cases, the fracture extended through the strain gauge, rendering it useless for the subsequent post-cerclage trial (image on right in Figure 4.10).

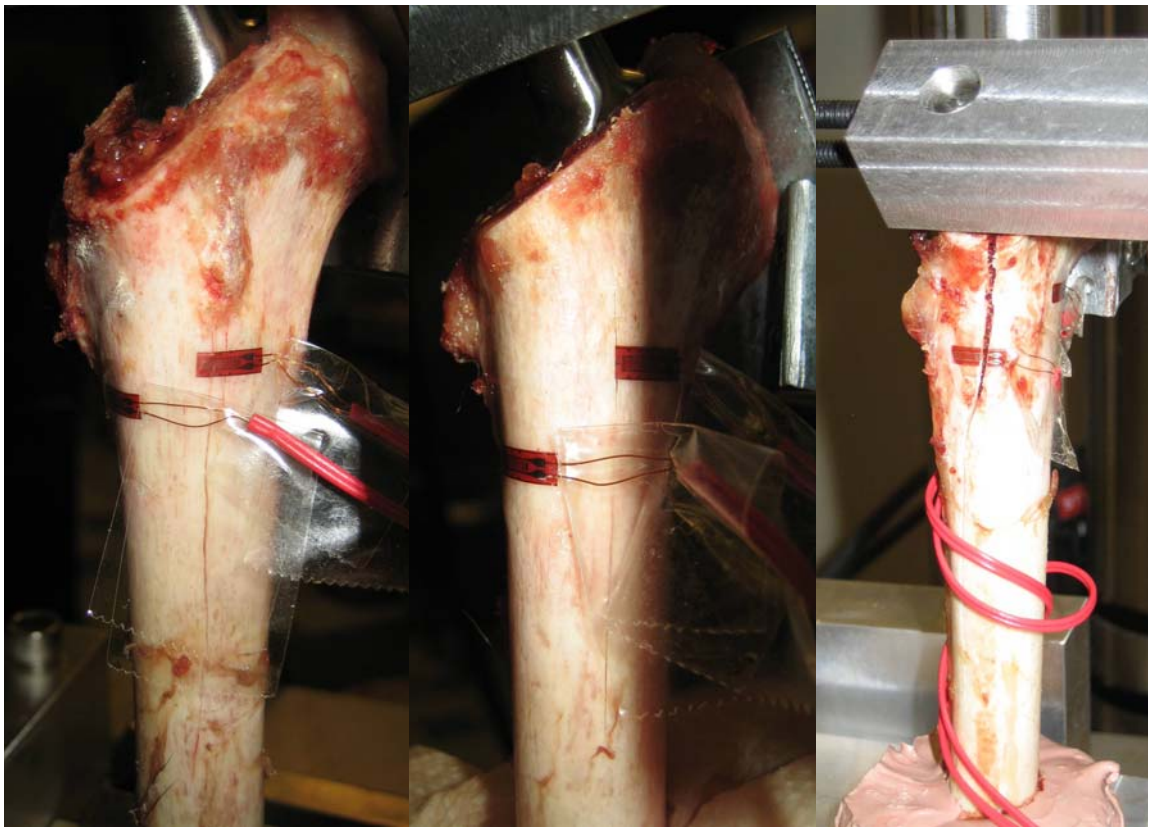


**Figure 4.10.** Pre-cerclage fractures. In the picture on the left, the fracture originated distally. The middle image shows a fracture that originated proximally, though not at the neck. The fracture is a hairline vertical fracture that is difficult to see. The picture on the right shows a fracture that originated at the proximal medial neck cut.

Other images are shown of the fractures that occurred in the post-cerclage trials (Figure 4.11). The post-cerclage specimens generally failed by spread of the pre-existing fracture. When the fracture opened further, the double-loop cerclage knots began to open as they absorbed the hoop stress present in the wall of the femur.

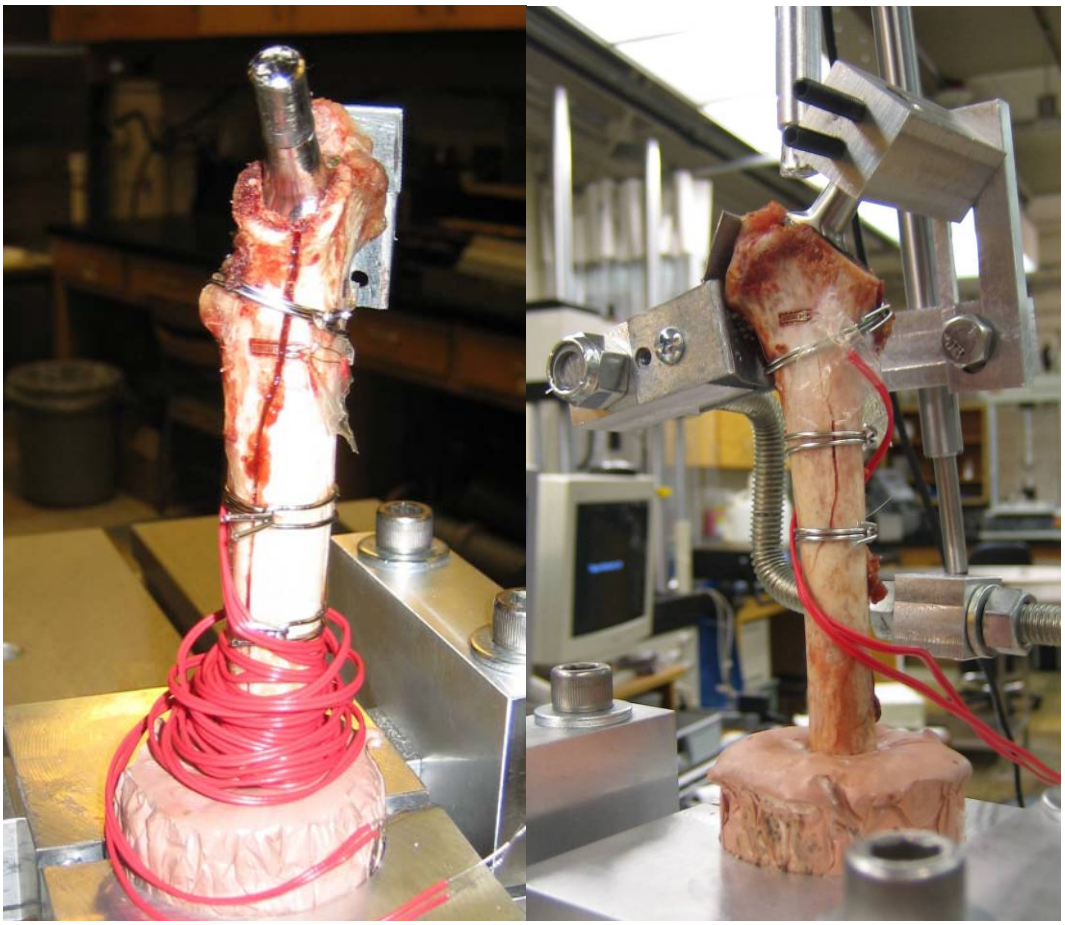


**Figure 4.11.** Post-cerclage failure specimens. The image on the left shows a fracture that extended distally. Note the opening of the cerclage knots. The image on the right also shows a fracture that opened distally.

## 5. DISCUSSION

The chief objective of this study was to determine the suitability of cerclage wiring as a method for stabilizing fractures and preventing significant subsidence in canines. There were three hypothesis for this study: 1) The force required to initiate subsidence in a cerclage repaired specimen (post fracture) would not be statistically lower than the force required to initiate subsidence in an intact specimen. 2) The maximum force sustained prior to failure in a cerclage repaired specimen would not be statistically lower than the maximum force sustained in an intact specimen. 3) The maximum subsidence of an implant in a cerclage repaired specimen would not be statistically higher than the maximum subsidence measured in an intact specimen.

The first hypothesis was supported by the data from the trials. The force to initiate subsidence was significantly higher in the post-cerclage specimens than in the pre-cerclage specimens. When intact specimens were compared to wired specimens the p-value obtained was 0.0019. When pre-cerclage specimens that failed by fracture were compared to post-cerclage specimens a significant p-value was again obtained, 0.0184. The second hypothesis was also supported by the trials. The maximum force sustained prior to failure was higher in the wired specimens in each analysis. In the comparison of the intact and wired specimens, the wired specimens failed at a significantly higher force (p-value: 0.0022). Between the pre-cerclage and post-cerclage fracture failure specimens, wired specimens again sustained a significantly higher force (p-value: 0.0184). The third hypothesis was also supported in the analysis of the trials. While the subsidence was higher for the post-cerclage specimens (3.90mm vs. 6.71mm), there was no statistically significant difference in the subsidence

between the specimens. When intact specimens were compared to wired specimens no significant difference was found (p-value: 0.0600). Again, when pre-cerclage fracture specimens were compared to post-cerclage fracture specimens no significant difference was found for subsidence (p-value: 0.1499).

It was hypothesized that the force to initiate subsidence would be no lower in the cerclage treated specimens. However the cerclage treated specimens actually sustained higher forces than the intact un-fractured specimens, a very striking result. The cerclage treated specimens sustained a higher force than the intact specimens. As the implant is pushed or hammered into the femur, the implant ideally contacts the bone envelope evenly around its circumference. The implant effectively acts as a wedge in the femur, which is desired to achieve a tight press fit. However, pushing the implant into place generates hoop stress in the cortical bone of the femur. This hoop stress that can be supported by the bone wall serves to hold the implant in place within the bone, preventing further movement. If a smaller implant was used, then more of the contact of the implant-bone interface occurred with cancellous bone, which is significantly less rigid than cortical bone. This would allow for movement of the implant to occur at a lower applied force. After the initial testing generated a fracture, the bone was repaired with double loop cerclage wires. These wires have a significant ability to resist hoop stress and can sustain a tension load in the range of 400N prior to failure. (Roe, 1997) The force applied in the post-cerclage testing therefore generated hoop stresses that were transferred to the double loop cerclage wires. In many of the trials, this involved 3 double loop cerclage wires. The ability of the cerclage to reinforce the bone as the implant was loaded likely prevented movement of the implant. Another

possible reason for the increased force to initiate subsidence in the post-cerclage specimens was the size of the implant used. In the subsequent trials, larger implants were used by default. In other words, the initial test was done with an appropriately sized implant, however, once it failed the testing was repeated with the next size larger implant. This was necessary because the initial test enlarged the bone bed. The larger implant has a higher surface area and more exposed beads. The beaded surface was significantly rougher than the other areas of the implant and would generate higher frictional forces at the implant-bone interface. This might allow the large implant to sustain a higher load before subsidence begins. Additionally, with the larger implant there is likely a higher percent canal fill which allows for the load to be distributed to a higher proportion of cortical bone, which is significantly stronger than the trabecular bone (Rashmir-Raven *et al.*, 1992). The more dense cortical bone can support a higher load than the trabecular bone which likely collapses/compresses under load. Additionally, the bone bed of the specimen was compacted/compressed by the earlier trials so that the implants in the post-cerclage trials rested in a much firmer bed. This likely helped to prevent initial movement until the force had risen to a high value.

Similarly, the cerclage treated specimens exhibited a higher force at failure than the intact specimens. As in the force to initiate subsidence results, the cerclage wires proved beneficial to the performance of the femur under load as the double loop cerclage wires can sustain a high tensile load prior to failure. As the wedging effect of the implant was produced during the loading, the force was transmitted to the cerclage wires. Rather than the cortical bone sustaining all of the load as in the intact specimens, the cerclage likely resisted

most of the hoop stress loading. Therefore the force at failure value was higher in the post-cerclage specimens due to the high failure strength of the cerclage wires. Also, as discussed earlier, the post-cerclage test involved larger implants. The larger surface area of the larger implant resulted in the load being distributed over a larger area which likely helped reduce the load experienced at any one point in the bone for an equivalent loading to the intact tests.

Subsidence was not statistically different between the intact specimens and the cerclage treated specimens. However there did appear to be a trend towards more total movement in the post-cerclage specimens at failure, however this movement occurred at significantly higher loads. Again, the cerclage wires helped resist the hoop stress in the bone to prevent the existing fracture from opening and allowing subsidence to occur. The larger implant in the post-cerclage trials also resulted in higher frictional forces which helped to prevent movement of the implant. However, the trend toward more movement in the post-cerclage specimens could have been due to a slight ability of the fracture to open before the load was absorbed by the cerclage wires. Additionally, the cerclage wires failed in a plastic fashion, with the knots slowly opening as the bending strength of the wire was exceeded. This slow plastic failure likely allowed the implant to subside some as the existing fracture opened. The observed trend toward more subsidence in the post-cerclage trials is not clinically significant, though. This subsidence did not occur until the force to initiate subsidence was exceeded, and that value occurred at a force that would be unlikely to occur clinically.

Another comparison was conducted to evaluate the relative subsidence in the post-cerclage specimens (relative to the force at failure of the pre-cerclage specimens). This

analysis, although finding no-significant difference (p-value 0.0907), showed that at similar loads, the cerclage repaired specimens actually demonstrated less subsidence than the pre-cerclage specimens. This is an interesting finding which shows that at similar loading, cerclage repaired specimens will demonstrate no more subsidence than intact specimens.

There were some limitations associated with this study. Any *in vitro* study is an approximation and attempt at a recreation of the *in vivo* situation. While the loading to the implant was replicated as closely as possible to that encountered during surgery, there are some differences. The position of the femur, the associated soft tissue, and the difficult access of the real surgery sum to make for very different situations than in the laboratory. The hammer blows recreated with the MTS machine were designed to replicate the surgeons hammer blows. However, the surgeon has a highly developed sense of "feel" for the feedback he receives from hammering an implant into place. This sense of feedback can only be approximated with the MTS machine. In order to more adequately assess the surgery, radiographs should have been taken at each step to assess implant alignment, canal fill, and the state of the bone walls. However, radiographs were only taken during some of these trials and only after testing was complete to assess the implant position and fracture extent.

Finally, strain gauges proved to be difficult to use in this testing. There was some difficulty with adhering the gauges to the bone surface, however this was overcome. Initially acetone was not used to clean the bone surface of oils, but after acetone was used, there was very little problem with gauge bonding. However, they were very unpredictable for the post-cerclage trials. Often the fracture of the pre-cerclage trial would loosen the gauge or would

literally split the gauge. In some cases the cerclage wire had to be placed over a strain gauge, rendering the gauge useless. The position of the gauges had to be varied between specimens due to the particular morphology of the bone. A smooth, flat spot of sufficient size was required for the gauge to properly adhere. It would be beneficial to use smaller gauges to minimize some of the difficulties experienced, though this would make application of the gauges more difficult. In some cases fractures occurred distally, and it would be beneficial to have gauges in the isthmus area of the femur.

Trial 5 was removed from the analysis, because, in the post-cerclage specimen, the bone failed prior to the implant reaching a clinically appropriate height. The implant could not be pushed into the bone deep enough for the beads to be flush with the neck cut because the implant was contacting cortical bone around its circumference at the distal end of the implant. Therefore, this trial and its associated failure were not clinically relevant and were not included in the results. In the surgical setting, the surgeon would have noted the difficulty in getting the implant to the proper position. The surgeon would have then extracted the stem and over-broached with the next larger size broach. He or she would have then re-introduced the implant. If the broach would not fit because of the size of the femur, he or she would have had to utilize a cemented stem. Because the mechanism of failure of this specimen was not clinically relevant, it was removed from consideration of the results.

Interestingly, the first three trials (those prepared without reamers) failed distally. This indicated that the distal end of the implant was contacting cortical bone and caused the highest stresses at that location. These failures are of particular concern because this region of the femur is not visible during the intra-operative *in vivo* approach used in surgery.

However, once reamers were used for preparation, there was only one distal failure in the subsequent 5 trials. Though there was no significant difference between the reamer and non-reamer prepared trials, it appears that it is important to use the reamers for proper preparation of the implant bed. The reamers helped open the hard cortical bone of the caudal femoral neck and allow the broach to work in the more central region of the femur. Without the reamer, the broach is driven more laterally by the caudal cortical bone. This created an implant envelope which was more in contact with the cortical wall at the lateral distal end.

The mean body mass of the canines utilized in this study was 28.14kg (SD 4.21 kg). That translates to an average weight of 275.8 N. The average force to initiate subsidence in the post cerclage trials was 2378.8 N. Therefore, the force to initiate subsidence for the cerclage specimens was 8.6 times the weight of the canine. This result, is made even more impressive by the fact that this was for just one femur. In fact with a canine performing a trot (a very fast walk, just slower than running) the peak force experienced in a hind leg is approximately 70% of body weight. (Budsberg, 2001). With the canines used in this study that would have translated to a peak hind leg force of approximately 193 N. With the force to initiate subsidence sustained by the specimens, this would yield a factor of safety of 12.3, a very substantial margin. Another study by Page *et al.* (1993) found that the *in vivo* peak load experienced in a hip joint is 165% of body weight, higher than that measured by Budsberg. However, even with this larger value the peak load for the canines used in these trials would have been 455N. Therefore at the peak force to initiate subsidence, as measured in these trials, the safety margin would be 5.2, still a large margin. Cerclage treatment is a very useful treatment for femoral fractures. The torsion forces on a hip joint are also worthy

of consideration. The mid-gait position of the canine stance has the femur flexed at 20°, and this can generate a moment of up to 1.6Nm. It would be beneficial to evaluate cerclage treatment in regards to torsion forces in the canine femur.

With the high force necessary to initiate subsidence, very little movement should occur at the implant/bone interface. This is important because a stable interface is necessary for bone ingrowth to occur and for the implant to become stabilized in the bone. With little movement, the bond should be stronger, last longer, and be less likely to need a revision. (Karrholm *et al.*, 1994) However, some amount of movement at the bone-implant interface is desirable to cause mechano-induction of osteogenesis for bony ingrowth (Clark et al., 2005).

The number of cerclage used is of importance. The surgeon commonly tries to bracket the fracture with cerclage. It has been recommended that cerclages be placed proximally, in the middle of, and distal to the fracture (Fishkin *et al.*, 1999). In this study the cerclage was used in that fashion. A proximal cerclage was employed in all cases, along with a cerclage in the middle of the fracture, and finally a cerclage just past the distal end of the fracture. If the fracture was very small and there was limited room for the placement of cerclage wires, then fewer would be used. However all trials used 3 cerclage with the exception of trial 3 where only 2 cerclage were used. While several cerclage have been shown to be very beneficial, intra-operatively the surgeon's experience was that frequently just one proximal cerclage would be placed. This is most likely due to the small incision used for performing a THA. The surgeon, when noting a fracture, may only be able to see a very small portion of the fracture and therefore, incorrectly, assume that it is shorter than its

actual length. Based upon the extent of the fractures in this *in vitro* study, a surgeon may find it beneficial to fully explore an intra-operative fracture. While this study did not examine the efficacy of single vs. multiple cerclage, more cerclage wires may be needed than initially assumed. Likely, one proximal cerclage may not provide the necessary support needed for the implant. As discovered in these trials, fractures can occur distally in the femur. This is particularly troublesome, as the surgeon would not be able to detect these fractures visually in during an operation. An experienced surgeon may be able to feel a decrease in resistance to movement during his hammer blows which could indicate a fracture has occurred. However, the implant will most likely still feel very secure when manipulated by hand. At this point the surgeon could elect to open the incision further to explore the femoral wall for a fracture. If the fracture extends distally beyond the implant the surgeon may be able to detect the fracture on a radiograph. However, if the fracture does not extend past the implant, the radiograph will be of little use since the radio-opaque implant will obscure the fracture.

In humans, cables are more frequently used than cerclage wires. One study claimed that cables provide superior performance in fatigue compared to monofilament cerclage (Weiss *et al.*, 1996). However a retrospective study found that both cerclage and cables result in more than adequate stabilization of the fracture (Berend *et al.*, 2004). Two other *in vitro* studies generate slightly different results, one found that cables were stronger than wire (Carls *et al.*, 1997) and another found that doubled wires were similar in performance to cables (Liu *et al.*,1997). One benefit of cerclage is that they plastically fail as opposed to the strand breakage that is seen in the failure of a cable. Thus, a cerclage failure occurs over a

range of force, with the cerclage knot slowly opening as the force goes up. It would be expected that cables would generate similar results if used in the same manner as the cerclage wire in this study. In veterinary surgery, the cost difference dictates that wire be used.

## 6. CONCLUSION

This was an *in vitro* study used to analyze the repair of intra-operative femoral fractures associated with using an uncemented hip implant (Biomedtrix BFX™ system). Double loop cerclage of 1.02mm (18 gauge) stainless steel wire were used to repair the fractures. The study showed the value of the cerclage wire as a treatment for a femoral fracture. When an implant is loaded axially, cerclage treated specimens were able to achieve a statistically higher force to initiate subsidence and a higher peak force prior to failure than the intact specimens. There was no statistical difference in the subsidence of the implant at failure between the intact and cerclage treated specimens. Cerclage treatment allows a fractured femur to sustain higher loads prior to the initiation of subsidence and substantially higher peak loads prior to failure. Along with this proven performance, and the ease of use (Fishkin *et al.*, 1999) and low cost of cerclage (Ritter *et al.*, 2006), cerclage wiring should be a commonly used tool for the surgeon repairing a proximal femoral fracture that develops during the implantation of an uncemented stem.

## 7. AREAS OF FURTHER STUDY

Based upon the experience of conducting these trials and the ultimate findings of the study, some areas would benefit from further investigation. In future trials, more extensive use of radiographs would be beneficial for quantifying the results. Radiographs could be used to assess percent canal fill, implant alignment, and severity and extent of the facture. Radiographs could be taken both before and after implanting, after fracture, and after implant removal for each test.

More strain gauges would help to determine the location and extent of the strain in the cortical wall. The gauges would ideally be smaller than those used in this trial to allow for easier positioning. If more gauges were used, or if they were used in duplicate at each location, the damage of a gauge by a fracture or cerclage placement could be overcome.

For comparative purposes, and to relate these trials to procedures used in humans, cerclage cables (as opposed to wire) could be used in the repair of the femoral fractures. To further relate these results to humans, it would be beneficial to conduct the trials in human cadaver femora fitted with uncemented implants for humans.

This study showed the benefits of a cerclage treatment for femoral fractures, after the fracture occurred. It is possible that the prophylactic placement of a proximal cerclage, or two, before hammering the implant into place may help prevent a fracture occurring in the first place. This prophylactic use may also result in better loading performance of the femur after the surgery is complete. However, a full study is required to explore the utility of prophylactic cerclage.

It would also be beneficial to explore the performance of other implant systems and loading methods. This study focused on axial loading only to mimic the forces experienced in surgery. Post-operatively, the hip joint experiences torsion forces that would be of interest to study in regards to cerclage stabilization. Also, this study focused on one implant type, the BFX™ series. It would be useful to categorize the performance of a wide range of uncemented implants from many manufacturers after the cerclage repair of a femoral fracture.

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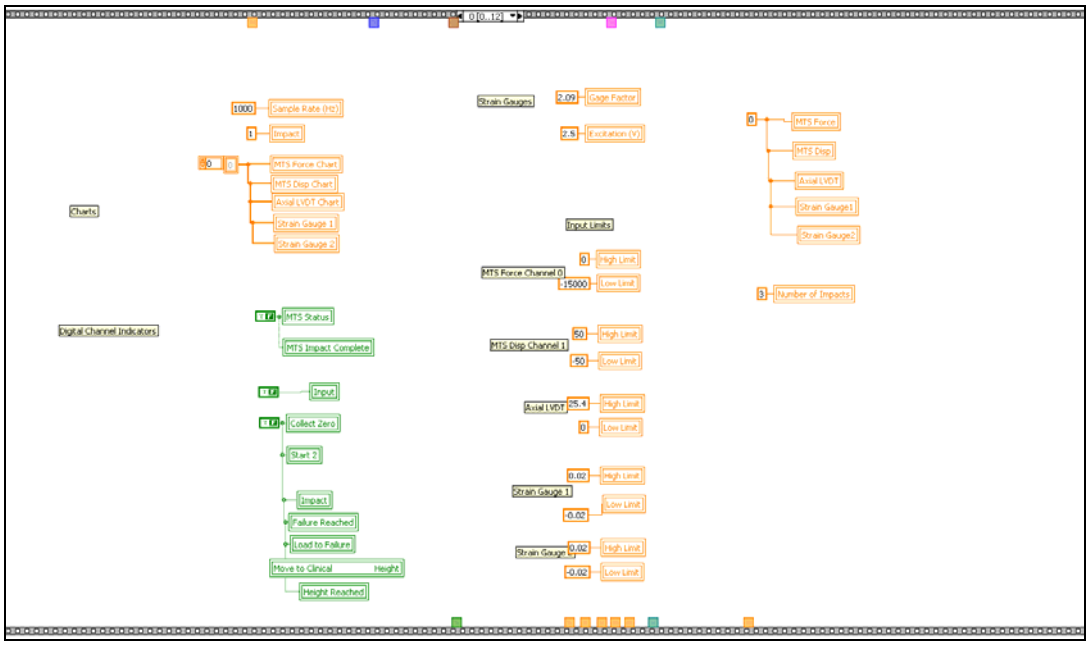
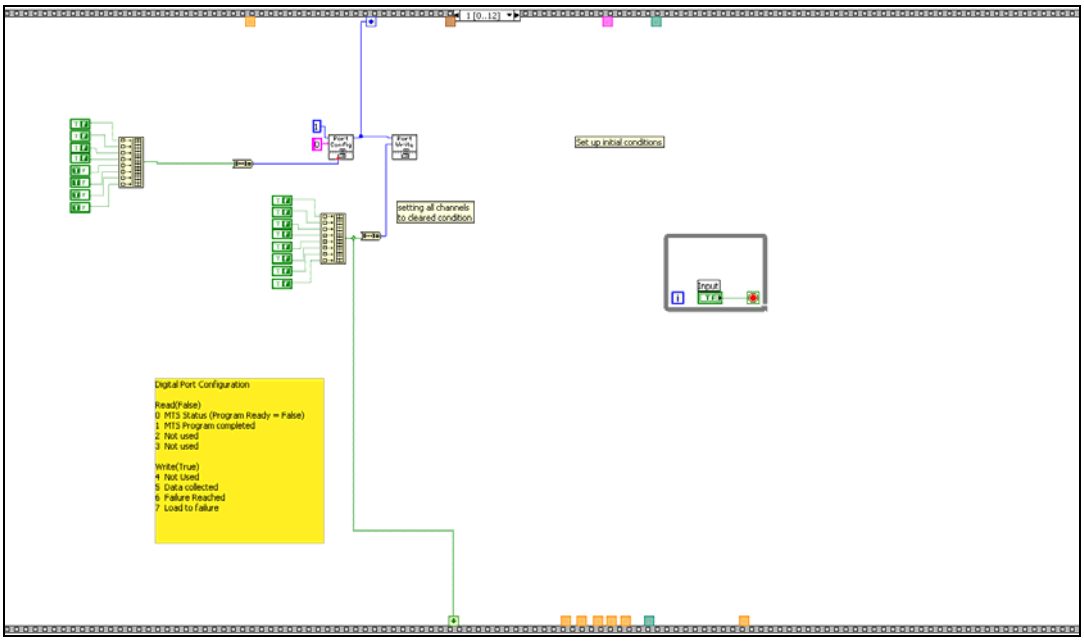
# APPENDICES

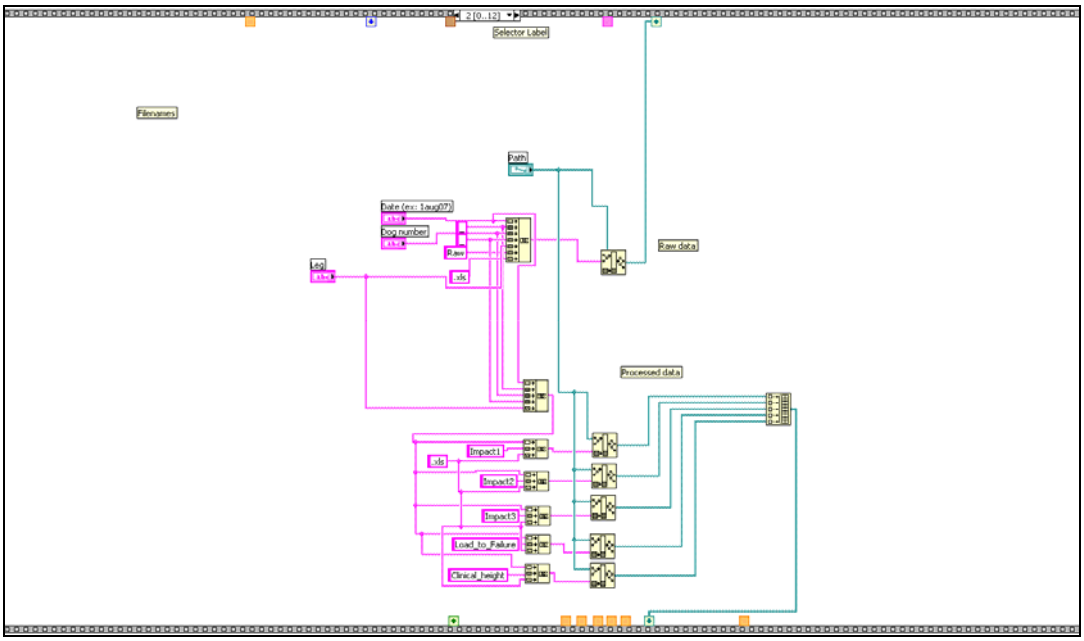
## Appendix 1. The Subsidence Program Code

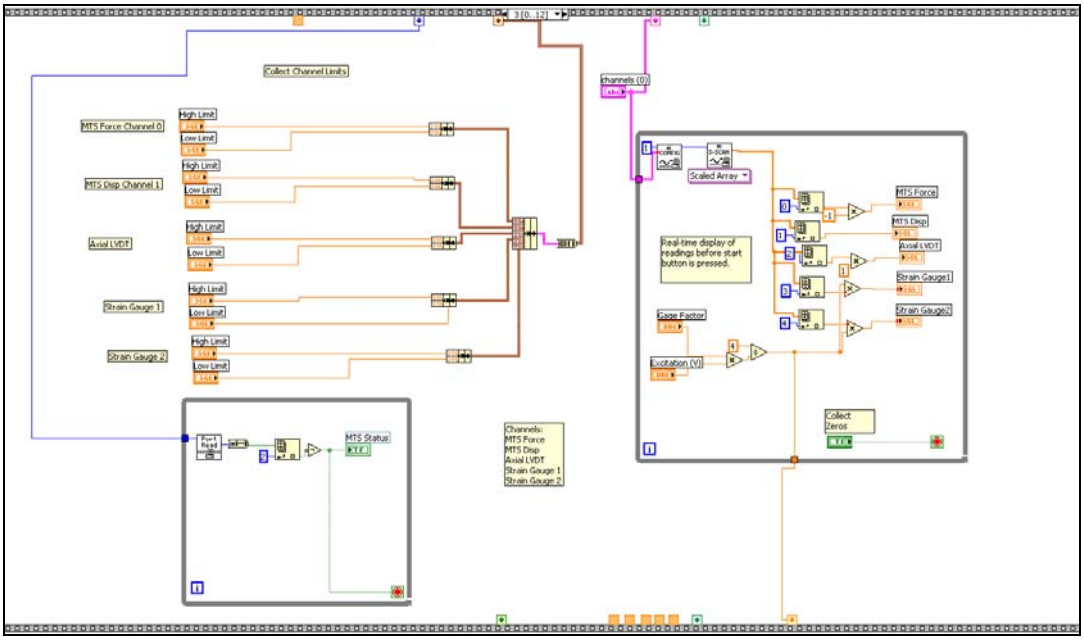
The Labview program used in this research is a graphical programming language geared towards the development of data capture and analysis. The Subsidence Program discussed in the Methods section was built for the conduct of this study. The program captures the input of force and displacement from the MTS load cell, the LVDT displacement, and the data from the medial and cranial strain gauges. All of this data is sequenced so that the data can be compared at a specific point in time. Additionally, the program utilized digital inputs and outputs to precisely control the operation of the MTS machine. In other words, the specific operations of the MTS machine (positioning to clinical height, impactions, and load to failure) were all initiated and stopped by the operation of the Labview code. The complete code is included in the appendix (Figure A.1).

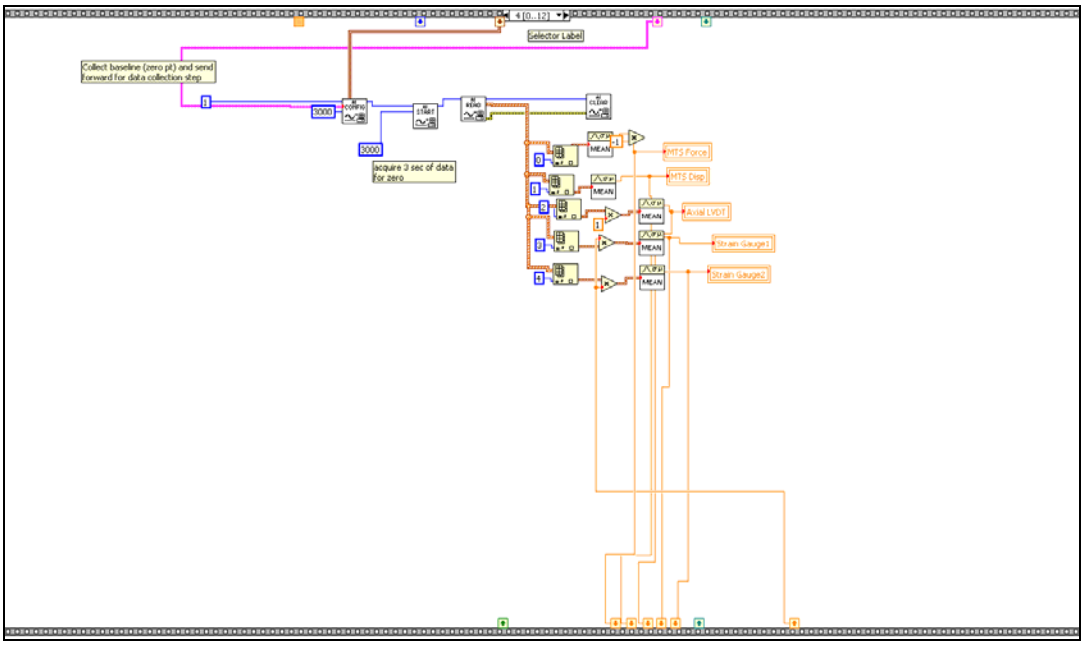
**Figure A.1.** Labview Block Diagram Code. The following figures show the graphical code of The Subsidence Program. The code sets the initial values for all variables, establishes inputs and outputs for the MTS machine, creates files for writing data, initiates trials while collecting data, and writes the data to file. The program also collects zero points for all variables and uses those to correct the input streams.

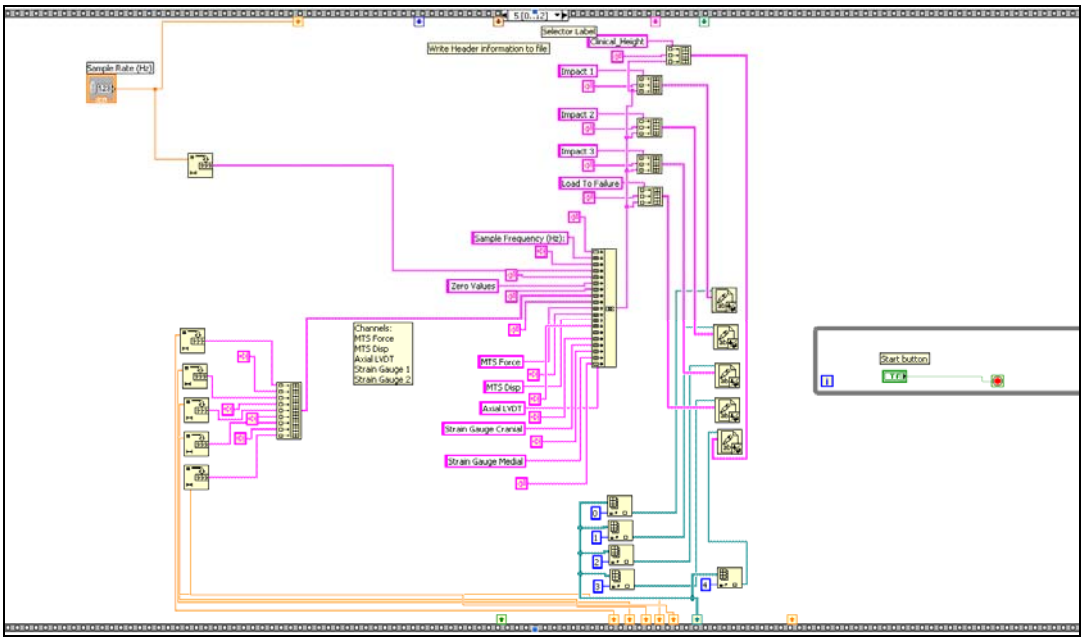

0 [0..12]
1000
Sample Rate (Hz)
1
Impact
MTS Force Chart
MTS Disp Chart
Axial LVDT Chart
Strain Gauge 1
Strain Gauge 2
Charts
Strain Gauges
2.09
Gage Factor
2.5
Excitation (V)
MTS Force
MTS Disp
Axial LVDT
Strain Gauge1
Strain Gauge2
Input Limits
MTS Force Channel 0
High Limit
-15000
Low Limit
Number of Impacts
Digital Channel Indicators
MTS Status
MTS Impact Complete
MTS Disp Channel 1
50
-50
Input
Collect Zero
Start 2
Impact
Failure Reached
Load to Failure
Move to Clinical
Height
Height Reached
Axial LVDT
25.4
Strain Gauge 1
0.02
-0.02

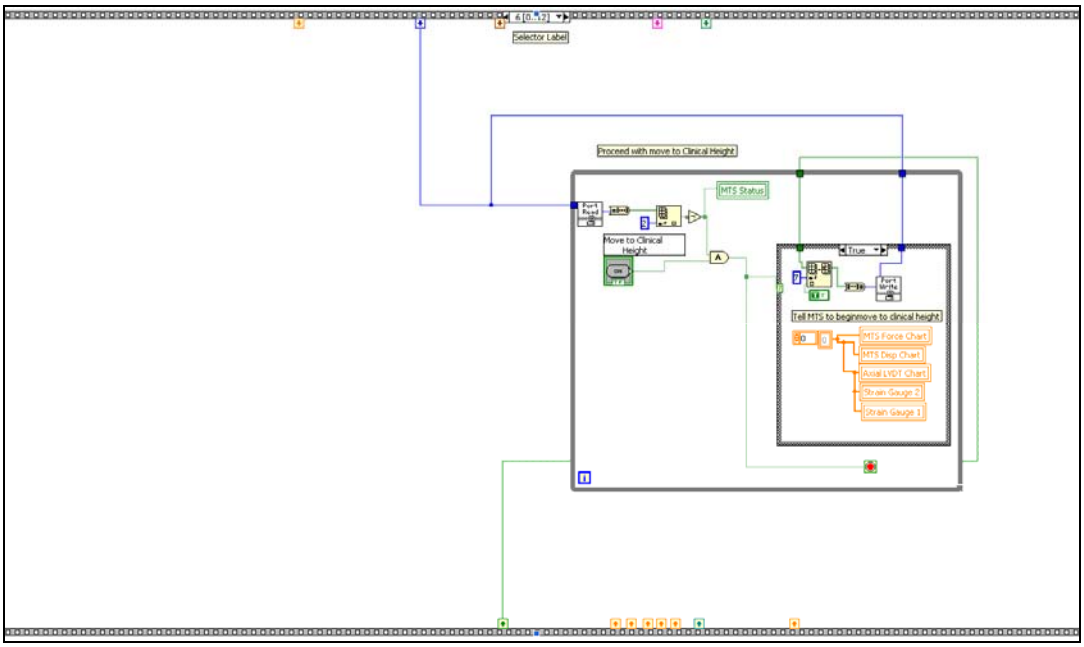

1 [0..12]
Set up initial conditions
setting all channels to cleared condition
Input
Digital Port Configuration
Read(False)
0 MTS Status (Program Ready = False)
1 MTS Program completed
2 Not used
3 Not used
Write(True)
4 Not Used
5 Data collected
6 Failure Reached
7 Load to Failure

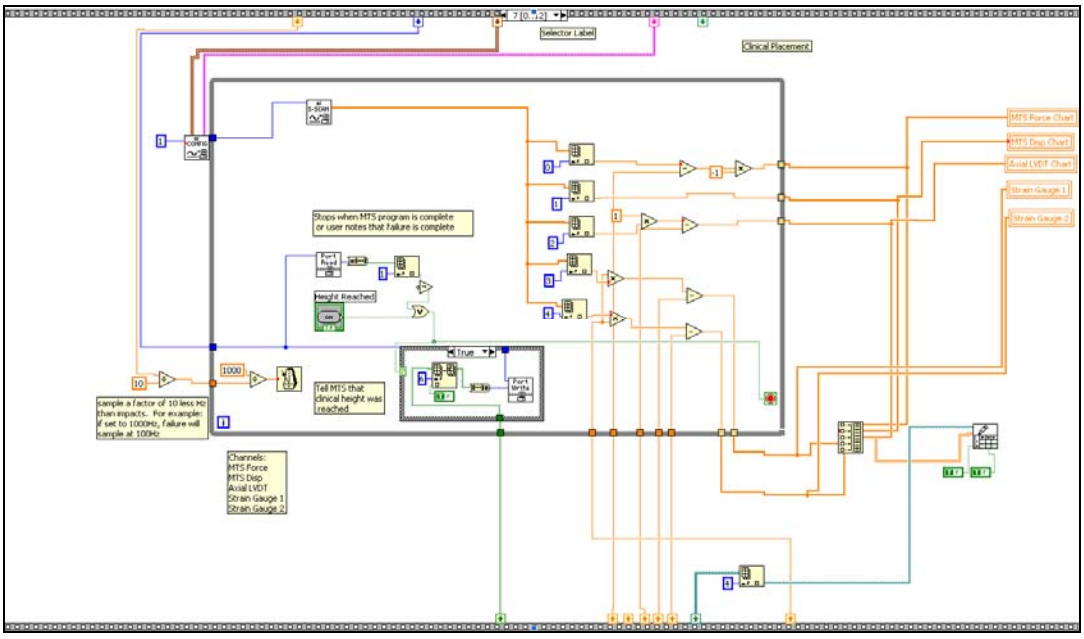

2 [0..12]
Selector Label
Filenames
Path
Date (ex: 1aug07)
Dog number
Raw
.xls
Leg
Raw data
Processed data
Impact1
.xls
Impact2
Impact3
Load_to_Failure
Clinical_height2

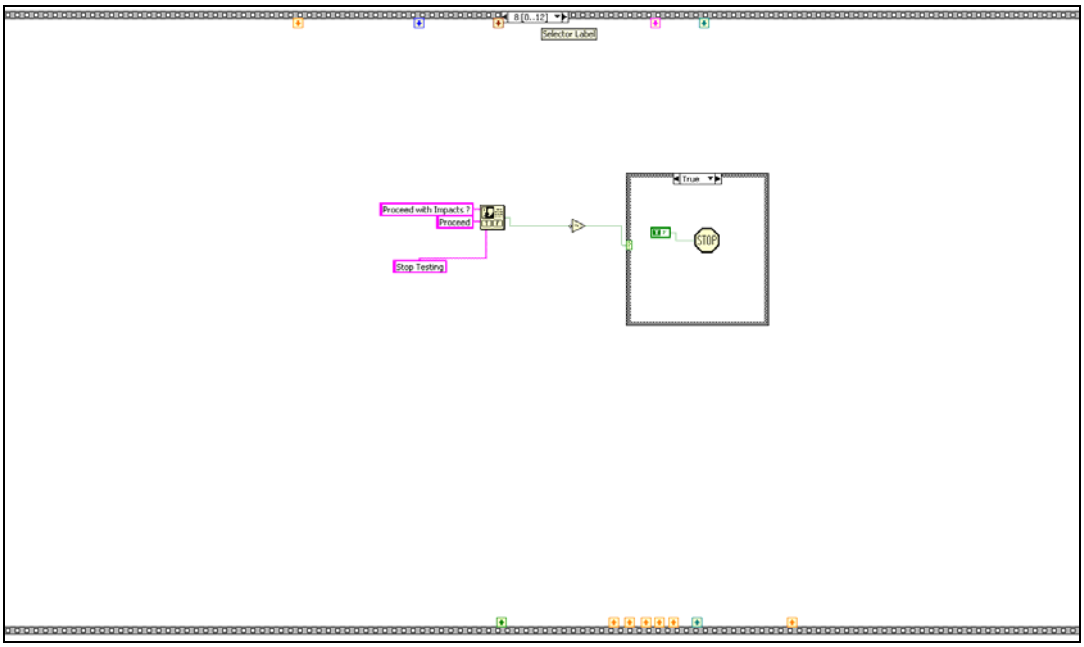

3 [0..12]
Collect Channel Limits
channels (0)
MTS Force Channel 0
MTS Disp Channel 1
Axial LVDT
Strain Gauge 1
Strain Gauge 2
High Limit
Low Limit
Scaled Array
Real-time display of readings before start button is pressed.
Gage Factor
Excitation (V)
MTS Force
MTS Disp
Axial LVDT
Strain Gauge1
Strain Gauge2
Collect Zeros
MTS Status
Channels:
MTS Force
MTS Disp
Axial LVDT
Strain Gauge 1
Strain Gauge 2

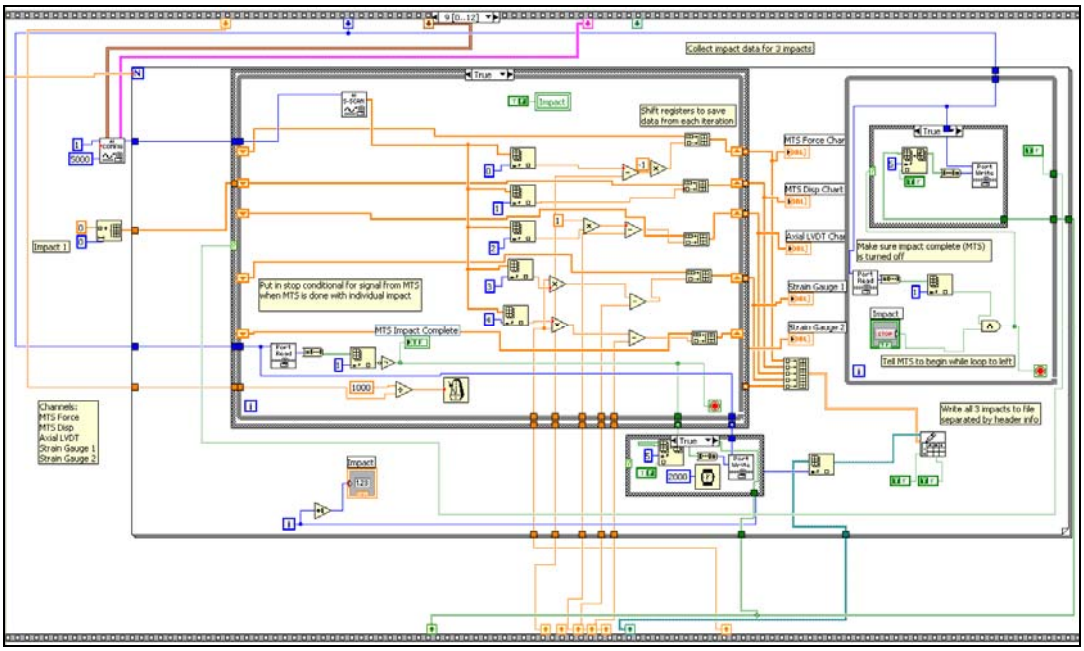

Selector Label
Collect baseline (zero pt) and send forward for data collection step
5000
acquire 3 sec of data for zero
MEAN
MTS Force
MTS Disp
Axial LVDT
Strain Gauge1
Strain Gauge2

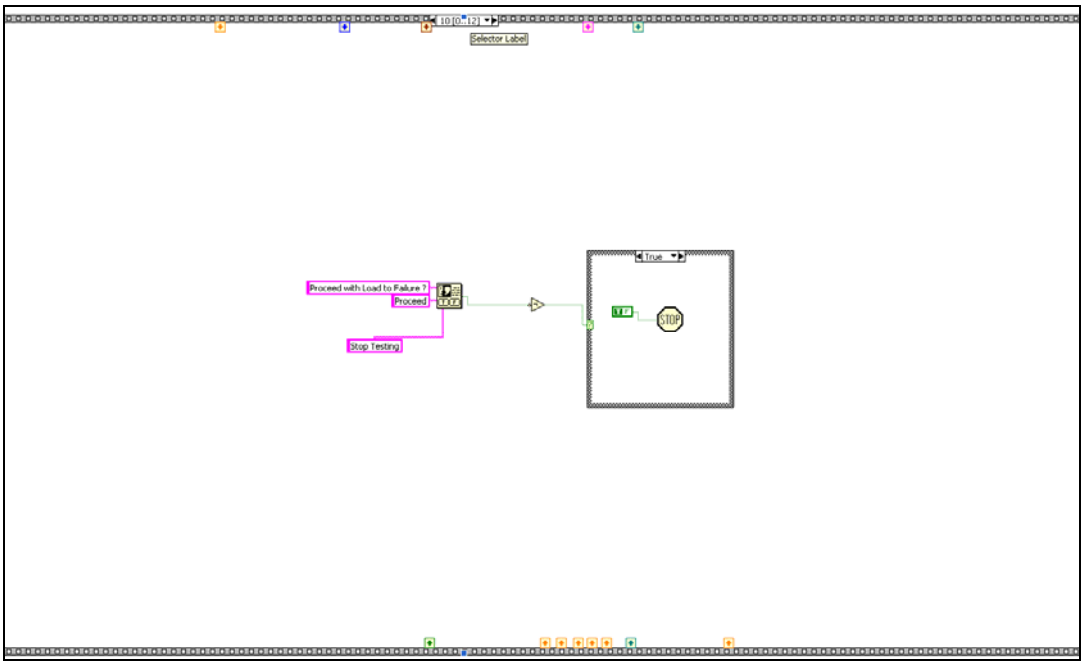

Selector Label
Write Header information to file
Sample Rate (Hz)
Clinical_Height
Impact 1
Impact 2
Impact 3
Load To Failure
Sample Frequency (Hz)
Zero Values
Channels:
MTS Force
MTS Disp
Axial LVDT
Strain Gauge 1
Strain Gauge 2
MTS Force
MTS Disp
Axial LVDT
Strain Gauge Cranial
Strain Gauge Medial
Start button

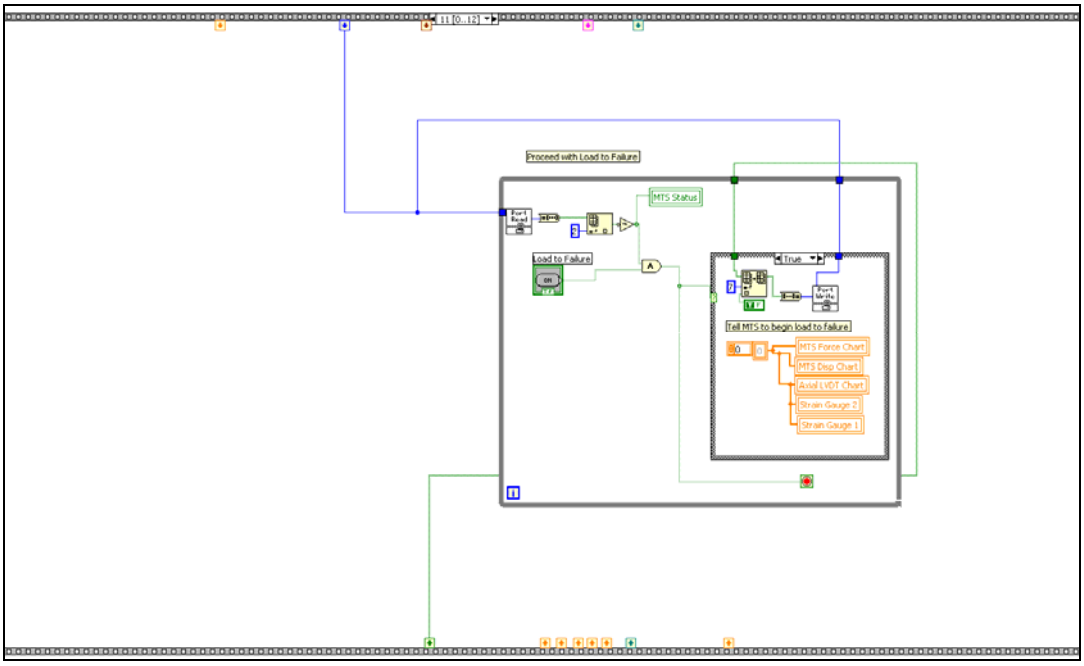

Selector Label
Proceed with move to Clinical Height
MTS Status
Move to Clinical Height
True
Tell MTS to beginmove to clinical height
MTS Force Chart
MTS Disp Chart
Axial LVDT Chart
Strain Gauge 2
Strain Gauge 1

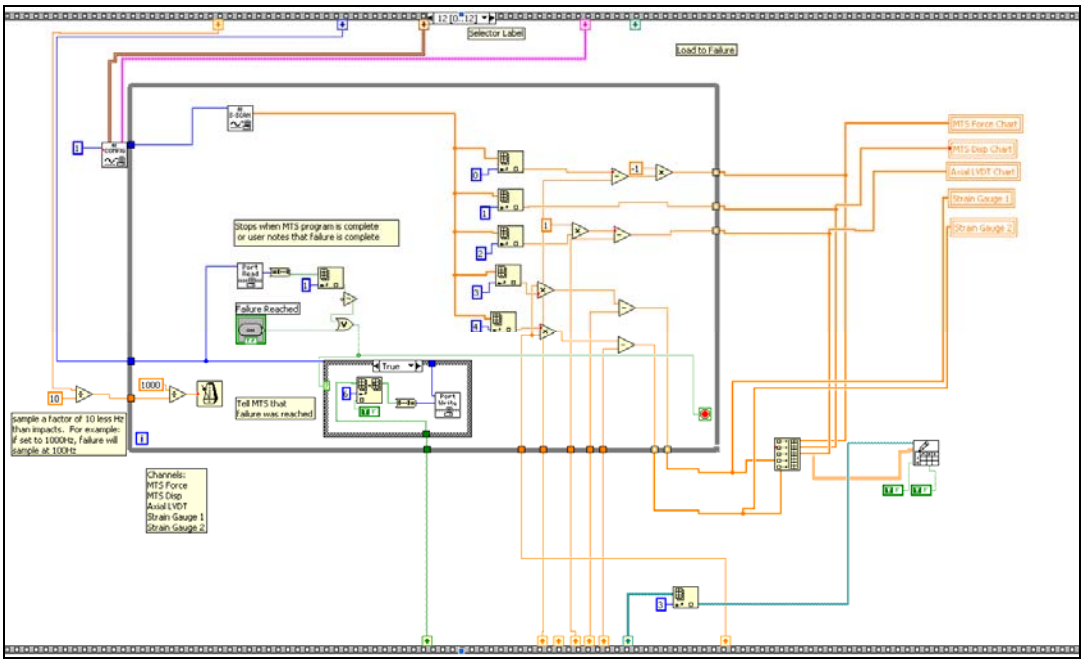

Selector Label
Clinical Placement
Stops when MTS program is complete or user notes that failure is complete
Height Reached
True
Tell MTS that clinical height was reached
1000
10
Sample a factor of 10 less Hz than impacts. For example: if set to 1000Hz, failure will sample at 100Hz
Channels:
MTS Force
MTS Disp
Axial LVDT
Strain Gauge 1
Strain Gauge 2
MTS Force Chart
MTS Disp Chart
Axial LVDT Chart
Strain Gauge 1
Strain Gauge 2


Selector Label
Proceed with Impacts ?
Proceed
Stop Testing
True
STOP


Collect impact data for 3 impacts
Impact
Shift registers to save data from each iteration
Impact 1
Put in stop conditional for signal from MTS when MTS is done with individual impact
MTS Impact Complete
Channels:
MTS Force
MTS Disp
Axial LVDT
Strain Gauge 1
Strain Gauge 2
Make sure impact complete (MTS) is turned off
Tell MTS to begin while loop to left
Write all 3 impacts to file separated by header info


Selector Label
Proceed with Load to Failure ?
Proceed
Stop Testing
True
STOP


Proceed with Load to Failure
MTS Status
Load to Failure
True
Tell MTS to begin load to Failure
MTS Force Chart
MTS Disp Chart
Axial LVDT Chart
Strain Gauge 2
Strain Gauge 1


Selector Label
Load to Failure
MTS Force Chart
MTS Disp Chart
Axial LVDT Chart
Strain Gauge 1
Strain Gauge 2
Stops when MTS program is complete
or user notes that failure is complete
Failure Reached
True
1000
10
Tell MTS that
Failure was reached
sample a factor of 10 less Hz
than impacts. For example:
if set to 1000Hz, failure will
sample at 100Hz
Channels:
MTS Force
MTS Disp
Axial LVDT
Strain Gauge 1
Strain Gauge 2