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Biomechanical Evaluation Of Periprosthetic Femoral Fracture Fixation

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**BIOMECHANICAL EVALUATION OF PERIPROSTHETIC FEMORAL FRACTURE
FIXATION**

by

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B.A.Sc. (Mechanical Engineering)
University of Toronto

A Thesis

Presented to Ryerson University
in partial fulfilment of the
requirements for the
Degree of Master of Applied Science
in the Program of
Mechanical Engineering

Toronto, Ontario, Canada, 2010

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Abstract

BIOMECHANICAL EVALUATION OF PERIPROSTHETIC FEMORAL FRACTURE FIXATION

Seung Yeon Robin Kim, B.A.Sc.

A thesis presented to Ryerson University in partial fulfilment of the requirements for the degree of
Master of Applied Science in the program of Mechanical Engineering

Toronto, Ontario, Canada, 2010

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This study proposes a bone plate fixation method to reduce the stress shielding effect on the fractured periprosthetic femur fixed with a metallic bone plate. The goal of this study is to design the finite element models of 5 bone plate attachment configurations applied to the periprosthetic femur fractured at 2 different levels (one with simple transverse fracture at mid-shaft with 1mm gap, and the other with 5mm gap at the fracture site simulating bone loss), and to validate the results by comparing with the experimental study. The average stiffness of the intact femur construct was 2502 N/mm which decreased to 1803N/mm and 801 N/mm for a 1mm and 5mm gap construct, respectively. The finite element model predicted the stiffness results of the experiments within 10% for the 1mm gap fracture case. The finite element model was less reliable when used to predict the stiffness values in the 5mm gap fracture case. The construct fixed only with cables in the proximal femur resulted in the least amount of stress shielding while maintaining a similar level of stiffness compared to the other configurations.

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List of Medical Terminology [145]

Abduction	moving of a body part away from the central axis of the body
Acetabulum	the cup-shaped cavity on the lateral surface of the hip bone, receiving the head of the femur
Adduction	moving of a body part toward the central axis of the body
Anteversion	abnormal forward tilting of a bodily organ
Arthritis	inflammation of a joint or joints characterized by pain and stiffness of the affected parts, caused by gout, rheumatic fever, etc.
Biocompatibility	the property of being biologically compatible by not producing a toxic, injurious, or immunological response in living tissue
Cancellous bone	sponge bone tissue contained in inner space of bone
Condyle	a rounded prominence at the end of a bone, most often for articulation with another bone
Contralateral	taking place or originating in a corresponding part on an opposite side
Cortical bone	the compact bone of the shaft of a bone that surrounds the marrow cavity
Diaphysis	the shaft of a long bone, between the epiphyses
Distal	situated farthest from the centre, median line, or point of attachment or origin
Epiphysis	the expanded articular end of a long bone, developed from a secondary ossification center, which during the period of growth is either entirely cartilaginous or is separated from the shaft by a cartilaginous disk
Femur	the longest thickest bone of the human skeleton, articulating with the pelvis above and the knee below
Intercondylar	between two condyles
Lateral	situated or extending away from the median plane of the body
Medial	situated toward the median plane or midline of the body or a structure
Metaphysis	the wider part at the end of a long bone, adjacent to the epiphyseal disk
Osteopenia	reduced bone mass due to a decrease in the rate of osteoid synthesis to a level insufficient to compensate for normal bone lysis
Osteoporosis	The word osteoporosis literally means "porous bones." It occurs when bones lose an excessive amount of their protein and mineral content, particularly calcium. Over time, bone mass, and therefore bone strength, is decreased. As a result, bones become fragile and break easily. Even a sneeze or a sudden movement may be enough to break a bone in someone with severe osteoporosis.

Patella	a triangular bone, about 5 cm in diameter, situated at the front of the knee in the tendon of insertion of the quadriceps muscle. Called also knee cap.
Prosthesis	an artificial substitute for a missing body part, such as an arm, leg, eye, or tooth; used for functional or cosmetic reasons or both
Proximal	nearest to a point of reference, as to a center or median line or to the point of attachment or origin
Resorption	the loss of substance or bone by physiologic or pathologic means, such as the reduction of the volume and size of the residual ridge of the mandible or maxillae
Sagittal	situated in the direction of the sagittal suture; said of an anteroposterior plane or section parallel to the median plane of the body
Supracondylar	above a condyle
Trochanter	a broad, flat process on the femur, at the upper end of its lateral surface, or a short conical process on the posterior border of the base of its neck

CHAPTER 1. INTRODUCTION

The study of biomechanics has been the interest of many researchers. By applying the laws and concepts of biomechanics, the mechanisms and structures of living organisms can be simulated and studied. In particular, the biomechanical study of femoral fractures has become important in the field of orthopaedics for two main reasons. One, as the average age of the general population is getting older, osteoporosis has become a serious issue for many patients. Osteoporosis is a serious disease that results in a weakening of a bone caused by the reduction in the bone mineral density (BMD) [1]. As a result of osteoporosis, many elderly patients suffer from bone fractures such as femoral fracture even from the simple event of falling [2, 3]. Two, increased reliance on motor vehicles has led to an increase in high-energy trauma that can often lead to femoral fractures [2]. Regardless of what caused a particular femur to fracture, the fracture often results in many serious symptoms such as severe pain and inability to move the leg [2].

Bone plate fixation is one of the treatment methods used to treat femoral fractures. Bone plate fixation, also known as plating, has four major benefits. First, it can be used for the patients with other implants such as artificial hips or knees [2, 3, 4]. Second, it can be used when the bone has been fragmented at the site of fracture [5, 6]. Third, the chances of shortening of the injured femur are smaller compared to other methods [5, 6]. Lastly, this method does not require reaming or cutting of the epiphyses and nearby growth plates [7]. This is particularly advantageous in pediatric patients [7].

Despite the benefits listed above, bone plate fixation can lead to an undesirable effect known as stress shielding. Stress shielding is a postoperative phenomenon that occurs in the fractured bone in which the metallic bone plate carries a disproportionately large percentage of the load [2, 8]. According to Wolff's law of stress related bone remodeling, stress shielding often reduces bone density and increases the porosity of the healing bone [2, 6, 8, 9, 10]. As a result, the plate fixation often requires longer healing time, and may even cause a re-fracture of the recovered bone when the plate is removed [8].

In the spirit of improvement, this study investigated several fixation plate designs with the goal of reducing stress shielding. Five large left Fourth Generation Composite Femurs were used (Model 3406, Pacific Research Laboratory, Vashon, WA, USA). First, a hip stem was implanted in each specimen in order to simulate a periprosthetic femur. The axial compression stiffness, bending stiffness and torsional stiffness of the five composite femurs were measured in this condition. Next, all specimens were cut transversely to simulate a simple mid-shaft fracture with a 1mm gap. Each specimen was immobilized using a different combination of screws and wires to attach a bone plate to the femur. These specimens

were subjected to axial loading and their stiffness and strain values were recorded. Lastly, all specimens were resected with a 5mm gap at the site of fracture.

The goal of this study was to apply the five different plate fixation constructs to the identically prepared periprosthetic femurs in order to investigate the effect of varying the combination of bone screws and cables used to attach the bone plate to the femur. By doing so, this study intended to provide an optimal solution that would minimize the stress shielding effect while maximizing overall stiffness or rigidity. The strain values were measured at eight locations along the specimens. Based on Hooke's law, strain is proportional to the localized stress in the material. Therefore, higher strain values are equated with large amounts of localized stress. A high strain value indicates that a minimal amount of stress shielding had taken place at the site of measurement.

The experimental study was then used to validate a finite element model of the periprosthetic femur and bone plate combination. The model was created with particular interest given to the predicted stiffness under various gap widths as well as the strain measured on the proximal side of the femur fracture.

This study covers an extensive range of disciplines between physiology and biomechanical engineering particularly in the area of long bone, bone fracture, and bone fracture fixation. This manuscript opens with the motivation for the study in *Chapter 2*. *Chapter 3* provides an introduction to the anatomy of the human limb, clinical aspects of femur fracture, biomechanics, biomechanical aspects of femur fracture, and material properties of bone. *Chapter 4* discusses both nonsurgical and surgical methods of fracture fixation with a focus of surgical treatment methods for femoral shaft fracture. *Chapter 5* lays out the problem statement, research objective and the primary goals of this study.

Chapter 6 explains the experimental study conducted. Specifically, it describes each component used, the specimen preparation process, and the mechanical and strain gauge tests conducted in the experiment. *Chapter 7* describes the development of the finite element model. *Chapter 8* provides the results from the experimental investigation and the finite element study. *Chapter 9* discusses the implications of the study, sources of error, and future research directions. *Chapter 10* concludes with the summary of findings regarding the optimal bone plate attachment method.

CHAPTER 2. MOTIVATION

The human femur is the longest and the strongest bone in the human body. It can be fractured by either a low-energy force applied to a patient with osteoporosis or a high-energy trauma occurrence to a healthy person [2, 3]. Patients with a fractured femur can often suffer severe damage at the injured limb and its related systems [2, 3].

According to the American Academy of Orthopaedic Surgeons, a fractured femur takes about 3 to 6 months to heal fully, however healing can begin to occur as early as 6 weeks [11, 12]. This is much longer than for most other human bones [2]. Such a long healing period leads to a high chance of misalignment [8]. Therefore the fractured femur requires an aid to enhance its healing process and to provide proper alignment.

Under normal loading conditions each femur handles up to twice one's own body weight [13, 14]. Based on the *Mean Body Weight, Height and Body Mass Index*, a femur in the average American male and female will be subjected to compressive loading of approximately 1703 and 1446 N, respectively [15]. Persons above the average weight will subject their femur to even higher loading conditions under regular activities of daily living [16].

An intramedullary nail is normally the method of choice for femur shaft fractures when there is no other surgical hardware present in the femur. However, because a nail is positioned to run through the middle of the femoral canal, it cannot be used in cases when there is already a total hip replacement in place. Therefore, bone plates become the device of choice, since they can be inserted on the lateral side of the bone so as not to physically interfere with a total hip stem while providing stabilization of the fracture.

Most of the commercially available bone plates are made of metallic materials such as titanium, titanium alloys, cobalt alloys or stainless steel [8]. An advantage of using metal alloys in biological applications is that they have been extensively studied and therefore their mechanical properties and bio-compatibility have been well documented.

Practical experience, however, has revealed that metallic bone fixation devices do not adequately match the stiffness properties of human bones. In fact, the elastic modulus of metal is about 7 to 12 times higher than that for human bones. The high rigidity of metal plates can result in an unbalanced load distribution between the bone and implants with the bone plate carrying most of the load. This phenomenon is called *stress shielding* or stress protection [8].

Stress shielding can cause the compressive stresses in the affected bone to be about 28-45% lower than they were pre-operatively [10]. Since compressive stress is required to maintain healthy bone density, stress-shielding often results in a lower bone density and higher porosity compared to the pre-operative bone [9]. The weakened bone now suffers an increased risk of re-fracture once the bone plate implant is removed [1, 9]. In one study, about 3% of patients re-fractured their femurs after the bone plate was removed following a visible re-union of the injured femur [17]. This carries a high societal cost both in terms of burdening the healthcare system as well as pain and suffering caused to the patient. Bone fixation methods must be mindfully selected in order to minimize the risk of re-fracture by optimizing the compressive stresses transferred to the femur in order to maintain healthy bone density.

CHAPTER 3. THE HUMAN FEMUR

3.1 Anatomy

3.1.1 Co-ordinate Planes for the Human Body

The human body is described in three major planes in order to specify their location and orientation in 3 dimensions (Figure 3.1.1). The *coronal plane*, also known as the frontal plane, passes through the body longitudinally from head to feet. This plane divides the body into front and back. The *sagittal plane* also passes through the body longitudinally but divides the body into left and right parts. The *transverse plane*, also known as the horizontal plane, is at a 90° angle to both coronal and sagittal planes. This plane runs through the body from left to right and divides it into upper and lower parts [18-20].

Figure 3.1.1 Anatomical planes of the human body [19]

There is one more commonly used co-ordinate plane called the *median plane*. The median plane is parallel to the sagittal plane, and it is used to describe the left and right halves of the body [18].

The *posterior* and *anterior* mean rear and front, respectively. The *superior* and *inferior* directions represent the directions toward the head and toward the feet, respectively. The *lateral* and *medial* directions indicate the directions away from the median plane and toward the median plane, respectively. The *proximal* and *distal* directions describe the directions toward and away from the torso of the human body, respectively [18, 20].

3.1.2 Human Femur

The femur, also known as the thigh bone, is the most proximal bone of the lower limb in human anatomy (Figure 3.1.2). There are two femurs, left and right and they are positioned in a mirror image with respect to the coronal plane. The femur is located inferior to the pelvis and superior to the tibia and fibula. At its proximal end, the femur forms a part of the hip joint. At the same time, the femur forms a part of the knee joint at its distal end. [21]

Figure 3.1.2 Human anatomy of lower limb [22]

The femur is the longest and the largest bone in the human body [21]. It is approximately 480mm in length and 23.4mm in diameter for an average adult male [21]. Each femur undergoes typical loading of up to 2 times the weight of an adult body [21].

The femur is composed of mainly 5 protuberances and a shaft. The 5 protuberances are the head, greater trochanter, lesser trochanter, lateral condyle and medial condyle [22, 23] (Figure 3.1.3). The head and the greater trochanter are located at the proximal end of the femur medially and laterally from the coronal view respectively. The lesser trochanter is inferior to both the head and the greater trochanter, and it is protruded anteriorly. Both the lateral condyle and the medial condyle are located at the distal end of the femur. The lateral and medial condyles are distinguished in the coronal view.

Figure 3.1.3 The human femur seen in 4 different views [23]

The femur is one of many long bones in the human body which is characterized by the long shaft, which is synonymous with the diaphysis [21]. Other examples of the long bone are the fingers, the toes and the arm bones including humerus, radius and ulna [24]. In the case of the femur, both ends are covered with articular cartilage where the hip joint and the knee joint are formed at proximal and distal ends

respectively [24]. The protuberances at both the proximal and distal end of the femur are called the epiphysis [24] (Figure 3.1.4). The femoral shaft is called the diaphysis [24]. The transitional zone between epiphysis and diaphysis is called the metaphysis [24]. The epiphyses are comprised of sponge bone in the interior of the femur [24]. The sponge bone, or cancellous bone, is softer, weaker, less dense and less stiff than the compact bone [24]. It is noted that the compact bone forms the structure of the bone, and it is exterior to the sponge bone [24]. The femoral shaft, or diaphysis, is comprised of compact bone, and contains the medullary cavity indicating the interior empty space [24].

Figure 3.1.4 General Bone Anatomy of (a) long bone [24] and (b) femur (posterior view) [25]

3.1.3 Hip Joint

The hip joint is anatomically referred to as the acetabulofemoral joint [26]. As its name describes, it is the joint where the femoral head and the acetabulum of the pelvis meet. There are two main functions of the hip joint. First, the hip joint supports the weight of one's body and, thus, allows static posture such as standing [26]. The other function is that the hip joint allows the rotation and articulation of the femoral head around the acetabulum. As such, the body is able to engage in dynamic motion such as walking or running [26].

Figure 3.1.5 Hip joint: (a) location of hip joint in coronal view [27], (b) detailed view [26]

Forming a part of the hip joint, the femoral head is oriented at an angle with respect to the median plane as shown in Figure 3.1.5. This angle is different from static posture to dynamic posture, as well as during dynamic motion. Such change in angle activates the change in the mode of load applied to the femur in a cyclic manner. This is called the gait cycle, and it will be further discussed in Section 3.2.

3.1.4 Knee Joint

The knee joint connects the distal end of the femur with the proximal end of the tibia and fibula. It is protected in the front by the patella, also known as the kneecap. It is the largest, strongest and heaviest joint in the human body [4]. Similar to the hip joint, the knee joint provide two major functions. First, the knee joint supports about half of the body weight [4]. This is important during static postures, such as standing. Secondly, the knee joint allows mobility of the human body. Working as a hinge, the knee joint allows the femur to rotate on the upper end of the tibia and patella [4]. Such capability allows one's lower leg to move back and forth.

The ligaments, cartilage and menisci are the major tissues that form the knee joint as an assembly (Figure 3.1.6). The ligaments and the cartilage serve two important functions to the knee joint. First, the ligaments and cartilage enable a smooth movement of the lower extremities [10]. Second, they prevent the knee from moving too far from side to side such that femur, tibia and fibula are kept in place to allow for continuous motion [4]. Centering of the knee is ensured by ligaments essential to minimizing wear and tear on the cartilage [28]. The meniscus functions as a shock absorber and provides a cushion to the tibia and fibula [10]. It also minimizes the amount of stress carried by the femur on to the articular cartilage [28].

Figure 3.1.6 Anatomy of the human right knee [28]

3.2 Femur Fracture: Clinical Aspects

As the longest and the strongest bone in the human body, the femur will handle a large amount of compressive load before it fractures. Such a traumatic event is often associated with potentially life threatening injuries to its related systems [2]. In addition, the injured femur may disrupt the blood supply through the thigh muscle, i.e. quadriceps, and it may result in extensive bruising and loss of blood [2]. Therefore, patients with a fractured femur require immediate medical attention. Femur fractures often occur due to bone disease or a physical impact (trauma).

3.2.1 Bone Disease

Osteoporosis is one of the major bone diseases that can significantly increase the risk of bone fracture. Osteoporosis is developed when the bone mineral density (BMD) is reduced down to a critical level such that the microstructure of the bone is disrupted [1]. There are 6 major causes to osteoporosis recognized: aging, heredity, nutrition, lifestyle, medication and other illnesses.

Aging

According to the American Academy of Orthopaedic Surgeons (AAOS), osteoporosis affects approximately 28 million Americans and causes an estimated 1.5 million bone fractures per year [29]. Osteoporosis most commonly afflicts woman after menopause. The AAOS has estimated that one in two women and one in five men older than 65 years are at risk of fracturing a bone due to osteoporosis [29].

Heredity

Many researchers have found that a family history of osteoporosis and related bone fracture increased one's risk for osteoporosis [1, 29, 30]. In particular, a person with Caucasian and/or Asian ethnic ancestry, characterized with a small, slender body build with fair skin, is at an increased risk [1, 29, 30]. This explains some cases of young people afflicted with osteoporosis [29].

Nutrition and Lifestyle

Malnutrition may contribute to the reduction in BMD which can lead to osteoporosis. When the level of minerals, including calcium, phosphorus, magnesium, zinc and many others, is extensively low, osteoporosis may develop at any age [1]. Other factors such as smoking, excessive alcohol intake, being underweight and excessive physical activity may also contribute to developing osteoporosis [29].

Medications and Other Illness

Certain medications such as steroids have been linked to an increased risk of osteoporosis [29]. Illnesses such as some thyroid problems have also shown a link to osteoporosis [1, 29].

Even though osteoporosis leads to a weakened bone condition, the femur itself is generally strong enough to handle everyday loads. A traumatic event, such as a fall, is generally required in order to fracture the femur [29]. Only in extreme cases will a fracture result from simple household tasks [29].

3.2.2 Physical Impact

Physical impact is another cause of femur fracture. Falling from a high elevation or taking a hit during sports activities can cause a fracture to both healthy adults and children. Pediatric femur fractures, however, are most often due to physical abuse [7, 31]. Femur fractures in pediatric cases must be carefully diagnosed to avoid damaging or altering the growth plate located in between the femoral head and the neck of the femur [7].

3.2.3 Motor Vehicle Accident

Motor vehicle accidents are a source of high-energy trauma that can cause serious injuries to the bone. Different fracture patterns are based on the type of vehicle engagement, although the most common fracture is to the femoral head [3].

3.2.4 Symptoms

The fracture of the femur shows a number of relatively obvious symptoms such as severe pain, inability to move the leg, deformity and swelling. A fractured femur may also cause the injured thigh to become shorter than the healthy one due to the strong thigh muscles forcing the broken edges of the femur out of alignment [2].

3.3 Biomechanics

3.3.1 Human Gait Cycle

Human gait is defined as the type of locomotion carried out by limbs. Human gait is necessary to perform everyday physical tasks such as walking, running and jumping. Depending on the type of gait, the limbs experience different mechanisms including overall velocity, force, kinetic energy, and potential energy [32].

Walking, the simplest form of activity, is produced by repeating the gait cycles. According to the gait cycle developed by Perry, the gait cycle for walking can be divided into two phases, the *stance* phase and the *swing* phase [33]. The stance phase takes about 62% of the gait cycle while the swing phase takes about 38% of the gait cycle [33].

Figure 3.3.1 Phases of gait cycle for walking [33]

The stance phase is divided into 4 stages: the loading response, mid-stance, terminal stance and pre-swing [33]. For illustrative purposes, the various stages of the human gate will be described assuming that the subject stepped forward with their right foot as shown in Figure 3.3.1. In this case, the *loading response* starts when the right heel contacts the ground [34]. Once the rest of the right foot comes in contact with the ground and achieves a flat position, the left (contralateral) foot is able to stand on its toes. The loading response stage ends once the toes of the left foot leaves the ground [35]. During the loading response stage, the body experiences double limb stance [33].

The *mid-stance* follows the *loading response*. It begins with the toes of the left foot leaving the ground and ends when the centre of gravity is shifted directly over the right (standing) foot [35]. The *terminal stance* follows the *mid-stance* and ends when the left foot touches the ground [13]. Over 90% of the *mid-stance* and *terminal stance* is carried by a single limb stance [33, 35].

The *pre-swing* follows the *mid-stance* and is the last stage in the stance phase. The *pre-swing* begins when the left foot makes its initial contact with the ground. It ends when the right toes leave the ground. The pre-swing stage is performed with a double limb stance [33].

The swing phase is divided into 3 stages: the *initial swing*, *mid-swing* and *terminal swing* [33]. The *initial swing* begins when the right toes leave the ground and ends when the right knee reaches its maximum flexion of approximately 60° [35]. The *mid-swing* begins from the moment of maximum knee flexion and ends when the tibia is perpendicular to the ground [35]. Lastly, the *terminal swing* follows the *mid-swing* and ends when the right foot contacts the ground [35].

The single limb stances during the stance phase are carried out by the initially responding leg, which is the right leg in the example above. During the swing phase the weight is then transferred to the contralateral leg, or the left leg in the above example. The above explained gait cycle for walking is summarized in Table 3.3.1.

Table 3.3.1 Summary of stages in the gait cycle for walking [33, 34, 35]

			% of Gait Cycle	Weight Loaded by	
Gait Cycle	Stance Phase	Loading Response	0 – 10%	Double Limb Stance	
		Mid-stance	10 – 35%	Single Limb Stance	Initially responded leg
		Terminal Stance	35 – 52 %	Single Limb Stance	
		Pre-swing	52 – 62%	Double Limb Stance	
	Swing Phase	Initial Swing	62 – 100%	Single Limb Stance	Contralateral leg
		Mid-swing		Single Limb Stance	
		Terminal Swing		Single Limb Stance	

As shown in Figure 3.1.5, the femoral shaft is engaged to the hip joint at an angle with respect to the median plane. This angle is called the adduction angle and it changes throughout the gait cycle [25]. Researchers using computed tomography (CT) and stereophotogrammetry have measured this angle to be between 10° and 20° during the double limb stance of normal adults [36-41]. The angle of adduction increases to about 20° to 30° during the single limb stance [36-41].

3.3.2 Femur Fractures: Biomechanical Aspects

Femur fractures often occur as a result of either a high-energy trauma or a low-energy fall in patients with osteoporosis. Osteoporosis patients who have previously received orthopaedic implants such as a hip joint are at a significantly higher risk of fracturing their femur compared to the average person [42-44].

Femur fractures can be categorized into 3 broad categories: proximal femur fractures, femoral shaft fractures and distal femur fractures. Each of these fractures is described below.

Proximal Femur Fracture

A proximal femur fracture is one which occurs to the bulbous upper portion of the femur closest to the hip. The proximal femur fracture is generally accompanied by a hip fracture or hip joint failure and is most common in elderly patients with osteoporosis [3, 45]. Proximal femur fractures can be subdivided into 3 main types: femoral neck fracture, intertrochanteric femur fracture and subchanteric femur fracture.

A femoral neck fracture occurs when the femoral head, also known as the ball of the hip joint, is fractured off the femur [3, 45]. There are three types of femoral neck fracture: subcapital, transcervical, and basicervical neck fractures [46] (Figure 3.3.2).

Subcapital neck fracture occurs in the neck region just below the head and is generally caused by a relatively sharp reduction in cross-sectional area which acts as a stress rise in the bone.

The transcervical neck fracture generally occurs about mid-neck and where the cross-sectional area is the lowest resulting in high mechanical stresses.

The basicervical neck fracture generally occurs at the base of the neck and runs along a line joining the top of the greater trochanter to the top of the lesser trochanter.

The intertrochanteric fracture line cuts through the material of the greater and lesser trochanter.

Lastly, the subtrochanteric fracture occurs below the lesser trochanter and may even extend down the femoral shaft [3, 45]. This is the least common of the proximal femur fractures.

Figure 3.3.2 Four types of proximal femur fractures: (a) subcapital neck fracture [47], (b) transcervical neck fracture [47], (c) basicervical neck fracture [47], (d) intertrochanteric fracture [48], (e) subtrochanteric fracture [47]

Femoral Shaft Fracture

Femoral shaft fractures are generally caused by either high energy trauma or ill-fit orthopaedic implants which increase the stress carried by the femur [3, 42-44]. Considering the femoral shaft as a cylindrical bone structure, there are five main types of loading modes that may produce a fracture: tension, compression, torsion, bending and a combination of bending and compression [6, 31] (Figure 3.3.3).

When the tensile force is applied to the femoral shaft, a fracture pattern occurs normal to the direction of load assuming equal amount of forces being applied to both sides [31]. This type of fracture is called *simple transverse fracture* [26]. The fracture occurs along the planes where the tensile stresses are the highest. This type of fracture does not generate any small particles or bone debris [5].

High compressive loading can result in a fracture along a plane that is at an oblique angle with respect to the direction of the applied load [49]. Such a loading condition causes extensive shear stresses along the oblique plane [49]. In other words, the compressive force produces a fracture along the planes of high shear stresses.

Torsional forces generally result in a spiral type fracture. In these cases, a small crack on the surface of the shaft initiates a fracture which continues through the bone in a spiraling manner [49]. The point of initiation occurs parallel to the axis of the specimen in a plane where the highest shear stresses are observed [49]. The remainder of the fracture pattern occurs within planes where the tensile stresses exist [5]. This type of the fracture pattern is called an oblique spiral fracture [49].

Bending forces cause half of the femur to go into tension and the other half to go into compression [49]. This results in a fracture pattern which is consistent with tensile and compressive forces. In other words, a simple transverse fracture will be present on the tension side of the femur whereas an oblique fracture will be seen on the compression side. Typically 2 oblique fracture patterns are observed on the compression side which causes comminution [5, 49]. This type of fracture is called a *butterfly fracture*, and the comminution is called the *butterfly fragment* [5].

A femoral shaft subjected to a combination of bending and compressive forces demonstrates a similar fracture pattern to that of bending force only. In this mode of loading, however, the butterfly fragment will involve more than 50% of the cortex [5]. Thus the cortical contact between the proximal and distal fragments will be less than 50% [5]. As the amount of the applied compressive force gets greater, the butterfly fragment consists of more than one piece [5].

Figure 3.3.3 Five modes of force that fracture femoral shaft: (a) tensile force, (b) compressive force, (c) torsional force, (d) bending force, (e) combination of bending and compressive forces [6].

Distal Femur Fracture

Distal femur fractures occur within the distal (bottom) 15cm of the femur [3]. Distal fractures are generally caused by either high-energy trauma or low-energy injuries for patients with osteoporosis [3]. These types of fractures most commonly occur in patients with ill-fitting total knee prostheses [3]. On the other hand, high-energy trauma can be transmitted to the flexed knee and will create fractures at the distal femur [3].

The distal femur fractures are mainly divided into 4 categories: supracondylar fracture, intercondylar fracture, condylar fracture and distal femoral epiphyseal fracture [50] (Figure 3.3.4). Supracondylar fractures occur on the plane normal to the axis of the femur around the edges of the epiphysis where the stresses are concentrated due to the change in cross-sectional area. The supracondylar fracture breaks off the distal femur from the rest of the femur in a transverse direction. The intercondylar fracture runs between the lateral condyle and the medial condyle. This fracture segments the femur into at least three parts if not more depending on the severity of the event of injury. The condylar fracture produces an oblique fracture pattern across the epiphysis. This results in a femur with one of the condyles intact and an oblique fracture of the other condyle. The distal femoral epiphyseal fracture occurs across the epiphysis. In other words, parts of epiphysis are intact with the femoral shaft while the rest of the epiphysis is fractured in a transverse direction with respect to the axis of the femur.

Figure 3.3.4 Four types of distal femur fractures: (a) supracondylar fracture, (b) intercondylar fracture, (c) condylar fracture, (d) distal femoral epiphyseal fracture [50].

3.4 Material Properties of Bone

Bones have anisotropic material properties [31]. They behave differently depending on the orientation of the load. In the case of the femur, the anisotropic characteristics are accentuated by its cylindrical shape. As shown in Table 3.4.1, the femoral shaft has much greater strength in the longitudinal direction than the transverse direction [31]. For example, the ultimate compressive strength is approximately 6 times greater in the longitudinal direction than in the transverse direction [31] (Table 3.4.1). The femur can also handle about 31% higher compressive loads in the longitudinal direction compared to tensile loads. The

femur is, however, weaker in transverse compression compared to transverse tension [31]. This means that the femur will endure high longitudinal compressive loads but is weak when subjected to transverse loading.

Table 3.4.1 Mean values of material properties of the human femur [8, 31]

Type of Bone	Direction and Type of Load	Density (g/cm ³)	Ultimate Strength (MPa)	Modulus of Elasticity (GPa)
Cortical (Femoral shaft)	Longitudinal Tension	1.85	133	17.7
	Longitudinal Compression	1.85	193	17.7
	Longitudinal Shear	1.85	68	3
	Transverse Tension	1.85	51	12.8
	Transverse Compression	1.85	33	12.8
Cancellous	Compression	0.31	6	0.76

As mentioned in Section 3.1.2, the femur consists of cortical and cancellous bones. The cortical bone is high in strength and modulus of elasticity, thus keeping the bone structure in place. In comparison, the cancellous bone is low in both strength and modulus of elasticity. The cancellous bone is also much lower in density due to its sponge-like structure. Since the femurs are usually loaded longitudinally during everyday activities, the combination of the strong cortical bone in the longitudinal direction and the cancellous bone working as a shock absorber allows the body to carry one's body weight and greater loads produced from aggressive activities such as jumping and running.

CHAPTER 4. METHODS OF FEMUR FRACTURE FIXATION

The broken femur may be supported by either nonsurgical or surgical treatment. Such a decision can be made based on various factors including the patient's degree of skeletal maturity, the amount of fracture displacement, the type of fracture and the presence of associated injuries [2]. In this chapter various methods of femur fracture fixation are discussed with a focus on surgical treatment methods for femoral shaft fracture.

4.1 Nonsurgical Methods of Fracture Fixation

4.1.1 Traction

Traction is the traditional fixation method for the fracture of femur. Traction is done by first placing the leg in a cast then inserting a metal pin through the cast all the way into the fractured femur [2]. The free end of the metal pin is attached with a series of strings that connect to weights [2] (Figure 4.1.1). The healing progress must be closely monitored by X-ray such that appropriate adjustments can be made as frequently as required [2].

Figure 4.1.1 Illustration of skeletal traction [51]

Although traction is effective for most simple fractures, it is a lengthy process. Research has shown that early mobility reduces the probability of complications and increases the speed of recovery time [2]. As a result, most practitioners favour other methods of fixation.

4.1.2 Casting

Casting is another type of nonsurgical treatment that can be used for the fracture of the femur. There are 2 important requirements to meet in order to choose casting as a method of treatment. First, the patient should be about 50-60 lb in body weight [52]. This weight generally restricts the age of patients to be treated to about 8 years or younger [2]. Heavier weights are not feasible since the cast does not support any of the body's weight. This type of treatment method is only applicable to simple fractures [2]. If the fracture is accompanied by any fragments or comminution, casting will not work since it is not able to remove the fragments or maintain proper alignment. The remaining fragments or comminution may also cause further complications such as infection at the injured area [2].

4.2 Surgical Methods of Fracture Fixation

A number of surgical fixation methods have been designed to provide a stable and secure means of healing fractured femurs. The most popular applications are external fixation, intramedullary nailing and plating. Unless the patient is in non-ambulatory status or expected to have a serious complication during operation, intramedullary fixation and plating are preferred [2, 3].

4.2.1 External Fixation

External fixation is a surgical treatment performed by placing the pins through the lateral thigh muscles to place the fractured segments of femur in proper locations as shown in Figure 4.2.1[3, 5, 8]. By doing so, the segments of femur can be compressed without losing their original dimensions and fixed into a correct alignment [53]. The lateral ring-shaped frames are used to adjust the location of the pins [5, 53]. This method of treatment stabilizes the fractured femur without introducing additional damage to the exterior wound [5]. It is an option for patients with severe soft tissue damage or contamination along with the fracture of the femur [2, 5]. It is also used when serious complications are expected during an operation [3].

Figure 4.2.1 External fixation: (a) illustration demonstrating application [53], (b) x-ray picture showing fracture of femur fixed with external fixator [54]

There are a number of disadvantages associated with external fixation. First, a full recovery cannot occur with this treatment alone and therefore other procedures must take place as soon as the patient's condition improves [5]. Second, about 30% of patients experience infection around the site of pin insertion. Therefore, meticulous pin preparation prior to the operation, careful infection preventions and appropriate antibiotics must be ensured [53]. Third, the restriction of muscles may also limit the motion of knee, and its design is relatively bulky. Thus normal physical activities cannot be conducted while the external fixation methods are being used [5]. Lastly, the rigid pins are inserted in between neurovascular systems, muscles and tendons which may rupture if moved [53]. Thus any replacement of pins must be closely monitored and the patient must be mindful of their motion [3, 5].

4.2.2 Intramedullary Fixation

Intramedullary (IM) fixation, also known as the intramedullary nailing, is currently the most popular method used to treat femur fractures [3, 5]. This fixation is most commonly used with femoral diaphysis fractures [5]. In this method of treatment, the proximal or distal end of femur is carefully reamed until an adequately sized canal is obtained [5]. A guidewire is passed across the site of fracture and then a rod is

inserted inside the femur and locked into place by lateral screws [5] (Figure 4.2.2). Since the interior of the femur consists of spongy bone of the epiphysis and the medullary cavity, the rod can be placed without removing material from the core of the bone. This method is considered to be minimally invasive and avoids further soft tissue injury while providing appropriate alignment [5]. Early movement is also possible since the nail can bear weight. Upon full healing of the fracture, the nail is usually removed [2].

Figure 4.2.2 Illustration of retrograde nailing operation [55]

Depending on the type and location of fracture different insertion techniques can be used [3]. There are two main insertion techniques, retrograde nailing and antegrade nailing. The retrograde nailing starts from the medial femoral condyle and proceeds in the proximal direction [3, 5] (Figure 4.2.3). This technique is ideal for patients with proximal femur and femoral shaft fractures [3]. Relatively easy access to the distal femur makes this technique desirable for patients who are obese, pregnant or in spine trauma [3].

Figure 4.2.3 Retrograde nailing: (a) illustration demonstrating completed implant, (b) X-ray picture of retrograde nailing [55].

The antegrade nailing is done by inserting a nail through either the piriformis fossa or the greater trochanter in a distal direction as shown in Figure 4.2.4 [3]. This technique can be used for a wide range of fractures located from just below the lesser trochanter to about 7cm above the knee joint [5]. Compared to retrograde nailing, antegrade nailing is difficult to access at the starting point especially in muscular and obese patients [3]. However, it is reported that the rate of healing and infection can be expected to be similar between different insertion starting points [3].

Figure 4.2.4 X-ray pictures of antegrade nailing done by (a) piriformis fossa entry, (b) greater trochanter entry [56]

Intramedullary fixation has a high healing rate between 90% and 95% [3]. Due to the nature of the operation, this method may damage the growth plate of the femur. Thus it is usually recommended for patients who have attained skeletal maturity [2].

There are 4 major disadvantages of using the intramedullary fixation method. First, the intramedullary fixation may result in a rotational deformity [2]. This fixation uses a nail that passes across the fractured bone such that the fractured ends of the femur come in contact with each other and thus reunite in time. However, it is not guided to control the rotational alignment. As a result, an additional operation may become necessary to correct such a complication. Second, the intramedullary fixation cannot be used in the case where many segments and comminutions are at the site of fracture [2, 3, 5]. More severe injuries often accompany many segments of fractured bone. As the number of fractured segments increases, the operation becomes more difficult and it becomes impossible to gather all segments into alignment [3, 5]. In addition, the clean-up of an internal wound area is difficult due to small and distant incision points. Third, a shortening of overall length of the femur upon union may be observed [5]. The shortening of the femur on one side may result in an unequal length of legs making it difficult to perform physical activities. This side effect can be corrected surgically by either lengthening the shortened femur or shortening the contralateral femur [5]. However, such an extra procedure is costly and brings added risk and recovery

time. Fourth, reaming of either the epiphysis up to an appropriate canal diameter may cause additional risk and damage to the injury [3]. Especially the antegrade nailing requires the reaming of piriformis fossa or greater trochanter which is extremely close to the femoral neck. The fracture of the femoral neck is generally considered to be the most serious complication experienced during intramedullary nailing [3]. Fifth, due to the nature of the intramedullary nailing the nutrient artery is damaged following the implantation [6]. Revascularization may be recovered by the small vessels in approximately six weeks, however the regeneration of the nutrient artery may take up to six months [6]. In addition, there exists further possibility of delay or even permanent damage in the regeneration of the artery when reaming is used as a part of nailing [6].

The medullary cavity is not uniform in its radius. As a result when a nail is inserted through the medullary cavity it will make contact only at the narrowest segment thus bending at either end will occur [6]. By reaming, contact area can be increased, and the stability of the fixation also increases [6]. However, reaming may cause excessive damage to the periosteal supply which can result in the permanent failure of revascularization [6]. Some patients complain about occasional pain in the thigh, trochanteric or knee as well as in the area of incision [5]. More importantly, such pain is not always relieved by removing the nail [5]. Further study is required to diagnose the cause of such pain and to provide better pain control.

4.2.3 Plating

Bone plate fixation, also known as plating, is another popular method to repair the fractured femur. This method requires opening the injured area and placing a bone plate over the fractured bone. The bone plate can be secured by using a combination of screws and/or cables. Locking bone plates comes with threaded screw holes which provide tighter engagement between the bone plate and bone screws compared to the non-threaded style of non-locking bone plates.

Bone plates are generally categorized into four main types: neutralization plate, compression plate, buttress plate and condylar plate [6].

Neutralization Plate

The neutralization plate, also known as protection plate, is used as a bridge between the healthy segments of bone that are located above and below the fracture [6]. It is secured to the healthy segments using bone screws. This type of plate does not pre-load the site of fracture which is generally located near the middle

of the plate [6]. This plate is not meant to be loaded under torsional, bending and shearing forces [6]. It is usually applied for short oblique fractures, butterfly fractures or fractures with mild fragments [6].

To provide inter-fragmentary compression and stability the neutralization plate may be used in conjunction with lag screws [6] (Figure 4.2.5). Early mobilization is generally possible with the use of a neutralization plate [6]. Figure 4.2.5 depicts an application using a neutralization plate to bridge between two healthy bone segments along with two lag screws to secure a single bone fragment.

Figure 4.2.5 Neutralization plate secured with regular bone screws along with two lag screws [6]

Compression Plate

A compression plate is used to introduce a compressive pre-load to the system. This is accomplished by first securing the plate to one side of a fractured bone. The plate is then put into tension by pulling the free end of the plate away from the fixed end (Figure 4.2.6). The bone plate is then attached to the other side of the bone fracture and the external pulling force is removed. Once the pulling force is removed the plate tries to contract back to its initial (unloaded) dimensions, squeezing the two bone halves together [6]. The compressive pre-load helps prevent the fracture surface from opening up and can be particularly helpful in preventing inter-fragmentary fractures under torsional or shear loading condition. This also helps protect the blood supply system and can decrease the required healing time [6]. Figure 4.2.6 shows the pre-loading process before the second bone segment is fixed.

Figure 4.2.6 Compression plate secured with bone screws and pulled by tensioner [6]

Buttress Plate

A buttress plate is commonly used to treat epiphyseal and metaphyseal fractures which are accompanied by weakened bone cortex [6]. It is designed with a larger surface area which facilitates a wider distribution of the load [6] (Figure 4.2.7(a)). This plate is contoured accurately to reflect the profile of the fractured epiphyses. The plate is firmly secured to the larger fragment of the bone using bone screws but snugly fitted to the underlying bone cortex [6] (Figure 4.2.7 (b)). When the plate is secured too tightly to the weakened bone cortex it will often cause bone deformity [6]. Cancellous lag screws are also used to produce compression forces across the fragments [6]. This plate applies a force to the bone in a direction perpendicular to the surface of the plate [6].

(a)

(b)

Figure 4.2.7 Buttress plate: (a) buttress plate side view [57], (b) Buttress plate plan view [58]

Condylar Plate

A condylar plate is commonly used to treat the intra-articular distal femoral fractures with metaphyseal comminutions [6]. The proximal femoral osteotomy and intercondylar femur fracture are the two most frequent fracture types fixed using a condylar plate. In these types of fractures there is usually a major breakage around the metaphysis either laterally or obliquely. This fracture results in a long working femoral shaft with short segments of distal epiphyses and metaphyseal comminutions [6]. The condylar plate has a similar design to the buttress plate but is used when restoration of the knee joint is required [6] (Figure 4.2.8). In order to accomplish this, the plate fixes to the metaphysis and to the femoral shaft and combines the functions of a neutralization plate and a buttress plate [6]. When used with a tensioner, this also acts as a compression plate [6].

Figure 4.2.8 Condylar plate: (a) sample of condylar plate [59], (b) X-ray picture of metaphyseal fracture of femur fixed with condylar plate [60]

4.2.4 Benefits of Plate Fixation

Bone plates can be used in several applications where intramedullary nailing is not possible. For example, femur fractures to the proximal end of the femur are relatively common following total hip or hip stem replacements. In these cases retrograde nailing cannot be used to fixate the fracture surface and antegrade

nailing is generally considered to be too risky to be used in practice. In these cases practitioners generally use bone plates to fixate the fracture surface.

Unlike IM nailing, bone plates can be used when there are too many segments or a large amount of comminutions at the site of fracture. The ability of plating to apply a compressive pre-load to force the fractured bone segments closely together is particularly helpful in these cases [6].

When compared to IM nailing, bone plates are less likely to cause shortening of the injured femur in the cases where there are multiple bone fragments [5]. This is because unlike IM nailing, bone plates can maintain an appropriate distance between segments [6]. Upon full recovery, the length of femur is generally expected to be approximately equal to the contralateral femur [5,6].

Plate fixation eliminates the lateral rotation which can lead to misalignment and deformity. Since the bone plate is applied directly across the segments of a fractured bone, the alignment prevents rotation.

Plate fixation methods also avoid reaming and cutting of the epiphyses and nearby growth plates. This is particularly advantageous in pediatric patients [7].

4.2.5 Limitations of Plate Fixation

Most commercial bone plates are manufactured from metals such as titanium, titanium alloys, cobalt alloys or stainless steels [8]. These metals are popular since their material characteristics are well known and their extensive manufacturing methods have already been developed to produce highly precise geometries. The high stiffness of metallic bone plates does, however, lead to the bone plate carrying a large percentage of the load. This is commonly referred to as stress shielding and it has a negative effect on the bone density and overall health of the affected bone. Table 4.1.1 presents a comparison of the mechanical properties of the femoral shaft compared to commonly used bone plate materials.

Table 4.1.1 Mechanical properties of human femur and metallic materials commonly used in orthopedic applications [8, 31, 61-63]

	Type of Load	Density (g/cm ³)	Ultimate Strength (MPa)	Modulus of Elasticity (GPa)
Human Bone (Femoral Shaft)	Longitudinal Tension	1.85	133	17.7
	Longitudinal Compression	1.85	193	17.7
Titanium Alloy	Longitudinal Tension	4.50	220	116
Cobalt Alloy	Longitudinal Tension	8.80	225 (yield)	211
Stainless Steel	Longitudinal Tension	7.81 (average)	870	190
	Longitudinal Compression		1080 (yield, average)	196 (average)

According to Wolff's law of stress related bone remodeling, lower bone density and higher porosity in the healing bone is often observed when stress shielding has occurred [2, 6, 8, 9, 10]. Thus, the bone will remain weak and less dense even after the full union of the fracture site [2, 6, 8, 9]. This phenomenon is called bone resorption [8, 9]. As a result of bone resorption, a longer duration of bone plate fixation is required until the healing bone gains a sufficient amount of stiffness [5, 8]. The weakened bone is more prone to refracturing once the bone plate is removed [2, 6, 8, 9]. Therefore, the ideal bone plate must transfer a sufficiently large load to the femur in order to maintain healthy functionality, however it must also be stiff enough to maintain proper alignment of the fracture surface [8, 9].

The bone plate fixation has several other major disadvantages. First, plating has a higher risk of infection compared to intramedullary nailing [5]. This is due to the large amount of hardware such as screws and cables used in this method. Therefore an extremely careful sanitization process is required during preparation prior to the operation, and the appropriate antibiotics must be prescribed in order to prevent serious illness due to infection.

Plating also has a high risk of nonunion due to hardware malfunction [5]. The screws and cables used to fix the plate to the bone are more prone to failure compared to IM nailing. If the hardware fails to maintain proper alignment at the fracture surface then immediate corrective action (usually surgery) is required [5].

CHAPTER 5. CURRENT STUDY

This study was conducted to determine the optimal combination of screws and cables that could be used to fix a bone plate to a fractured femur while minimizing the amount of stress shielding caused by the bone plate. This study examined the biomechanics of surgical repair methods for femoral shaft fracture in the presence of a total hip replacement, which is a real-world challenge for clinical management. Five synthetic femurs were used as the experimental specimens. In order to make a design recommendation with proven success, this study unfolded its analysis in two parts. First, 5 physical models were built to test the current titanium femur fixation plate and to observe their mechanical characteristics under various types of load. These results were then analyzed to determine the effect that various configurations had on the stress shielding effect. Second, finite element analyses were performed by modeling the femur fracture fixations using a titanium bone plate. The models were simulated to identically resemble the specimens used in the experimental study and validated by comparing with the experimental results.

5.1 Problem Statement

The high elastic modulus of metallic bone fixation plates causes an uneven load distribution between the plate and the fractured bone. This phenomenon often has negative consequences such as bone resorption or re-fracturing of the bone.

5.2 Research Objective

The objective of this study was to evaluate the effect that various bone plate fixation designs have on the overall system stiffness and stress shielding effects. This study focused on the fixation of a simple transverse femoral shaft fracture. A hip stem was also incorporated at the proximal end of the femur to reflect the frequency of fractures occurring after hip replacement surgery.

5.3 Primary Goals of this Study

The main goals of this study were to:

1. Research relevant literature on the anatomy of the femur, biomechanics of the lower limbs, causes of femoral failure as well as various femur fixation methods and procedures. Literature was also reviewed on the topic of stress shielding and its prevention, particularly with respect to *in vivo* and *in vitro* experimental studies in long bone/femur fixation. Lastly, finite element studies on stress distribution in lower limbs were reviewed.
2. Conduct an experimental study of the load transfer characteristics of 5 different metallic bone fixation constructs used to fix a simple mid-shaft femur fracture. The applied loads were kept within the elastic region such that no permanent damage was done to the specimens.
3. Develop a 3D geometry of the femur-bone plate systems using a CAD model, and to generate finite element analysis (FEA) of the 5 femur-metallic bone plate systems used in the experimental study. The results from the FEA model would then be validated by comparing with the experimental results.

CHAPTER 6. EXPERIMENTAL STUDY

In this chapter, the experiments performed to study the mechanical behaviour of the femur are explained. The experiments were performed using the following three test conditions; (1) an intact femur, (2) a femur with simple mid-fracture with a 1mm gap and (3) femur with 5mm gap in the mid-fracture. These experiments were conducted at the Martin Orthopedic Biomechanics Laboratory located within St. Michael's Hospital, Toronto, Canada.

6.1 Material Selection

6.1.1 Composite Femur

Five large left Fourth Generation Composite Femurs (Model 3406, Pacific Research Laboratory, Vashon, WA, USA) were used. Cortical and cancellous bone density, respectively, were 1.64 and 0.20 g/cm³ (Table 6.1.1).

Table 6.1.1 Material properties of composite femur specimens [64]

	Material Properties		
	Density [g/cm ³]	Compressive Strength [MPa]	Compressive Modulus [GPa]
Cortical Bone	1.64	157	16.7
Cancellous Bone (Solid)	0.20	6.0	0.155

The Fourth Generation Composite Femur specimens were specially designed with a larger canal diameter of 16mm, rather than the 13mm option. This was done to more closely simulate osteoporotic cortices. This modification also limits the number of screws that can be applied to the femoral shaft and is meant to simulate a worst-case clinical scenario. The detailed geometry of the specimen is shown in Figure 6.1.1.

Dimension	
a	485mm
b	52mm
c	37mm
d	120°
e	32mm
f	93mm
g	16mm canal

Figure 6.1.1 Large left Fourth Generation Composite Femur [65]

6.1.2 Bone Plate and Cable

Five identical Zimmer Cable-Ready Grip Systems (Zimmer, Warsaw, IN, USA) were used in this study. Each system came with a bone plate consisting of 8 non-locking holes (i.e. non-threaded screw holes). Either a unicortical or a bicortical screw could be threaded through the screw hole depending on the biological condition of the bone. When the immediate area of the bone underneath the bone plate has a large diameter and is free of fractures and crack initiation, a bicortical screw can be used. Otherwise, a unicortical screw should be used as long as it does not penetrate through the bone or too close to the fracture. The screw holes were oblong in appearance so that minor position adjustments could be made during an operation.

As its name implies, the bone plate came with a cable ready design. This allowed a cable to be attached to the plate and then wrapped around the bone in order to secure it in place. All cables used in the current study were inserted in the same direction to maintain consistency as shown in Figure 6.1.2. Once the cable was threaded through the plate, it was tensioned and then secured by a set screw. Finally, the loose end of the cable was cut close to the plate.

Figure 6.1.2 Zimmer Cable-Ready Bone Plate: (a) 8 non-locking hole bone plate (b) detail view of screw hole and cable insertion.

Since every femur has its own unique profile, it is common practice for a surgeon to modify the bone plate prior to installing it during an operation. This is done so that the bone plate profile matches the profile of the injured femur as closely as possible. This is an important step since appropriately adjusted bone plates will minimize the local stresses imposed onto the bone by the plate and screws. In this study, a manual bone plate bender was used to adjust the profile of each bone plate using standard surgical procedures (Figure 6.1.3).

Figure 6.1.3 Bone plate bender with an inserted bone plate

6.1.3 Bone Screws

In this study, both unicortical and bicortical pin head bone screws were used. All screws were made of 316L medical grade stainless steel (Synthes, Paoli, PA, USA). The unicortical screws were 4.5mm in diameter and 14mm in length. The bicortical screws were 4.5mm in diameter and 50mm in length.

For consistency, 4 holes in the distal fracture fragment were engaged with the bicortical screws on all 5 specimens. The bone plate was then fixed to the proximal portion of the femur using a variety of screw and cable arrangements. In all cases where unicortical screws and cables were used, the cable was installed immediate to the screw as per common medical practices [66, 67].

6.1.4 Hip Stem

Five Exeter™ Total Hip Systems (Stryker, Mahwah, NJ, USA) were used in this study (Figure 6.1.4). Each system consisted of an Exeter™ Femoral Stem and an Orthinox™ Head which were made of cobalt-28 chromium-6 molybdenum alloy. The Orthinox Head consisted of a spherical head placed on the tip of the hip stem to permit simulation of the human ball-and-socket hip joint. The installation procedure of the hip stem is explained in Section 6.2.1.

Figure 6.1.4 Five Exeter™ Total Hip Systems (hip stems) used in this experiment.

6.1.5 Strain Gauges

The strain gauges were used to measure the surface strain of the femur and the metallic fixation plates, and thus, the surface stress during axial compression. The following factors were considered while selecting the strain gauges used in this experiment [68]:

- amount of strain gradient
- type of load tested
- level of required accuracy
- amount of maximum elongation
- cyclic endurance
- ease of installation and heat dissipation

The Vishay® general purpose linear-pattern strain gauge with a resistance of 350 Ω was selected as the strain gauge of choice for this study. The specified strain range of $\pm 5\%$ for this gauge was well within the anticipated strain range of $< 0.1\%$ based on the required loading conditions. The operating temperature range, overall dimensions and gauge factor/gauge factor sensitivity were all appropriate for this the intended use. The specifications of the selected strain gauge are shown in Table 6.1.2.

Figure 6.1.5 Vishay® general purpose – linear-pattern strain gauge (Model No. CEA-06-125UW-350, Vishay Intertechnology, Inc., Malvern, PA, USA) [69]

Resistance	350Ω ± 0.3%
Gauge Length	3.18mm
Overall Dimension	8.26mm X 4.57mm
Strain Range	± 5%
Temperature Range	-75°C to +175°C
Gauge Factor (GF) at 24°C	2.120 ± 0.5%
GF Sensitivity	(1.2 ± 0.2)% / 100°C
Transverse Sensitivity	(0.7 ± 0.2)%

Table 6.1.2 Product specifications for Vishay® general purpose – linear-pattern strain gauge (Model No. CEA-06-125UW-350, Vishay Intertechnology, Inc., Malvern, PA, USA) [69]

The strain gauge mounting surfaces were ground down to produce a flat surface prior to installation. After unloading a particular test specimen, the entire construct was allowed to sit for at least 10 minutes before any loading was reapplied. This was done to ensure that the specimen returned to its initial shape and was free of residual strain.

6.2 Specimen Preparation

6.2.1 Femur Preparation

To incorporate specimens into the mechanical testing system, it was necessary to anchor the distal femurs. This was done by cutting off their condyles and then potting the remaining femur in 88mm X 88mm X 75mm steel chamber using anchoring cement (Figure 6.2.1).

Figure 6.2.1 Distal femur anchoring procedure: (a) Fourth Generation Composite Femur, (b) cut-out dimension on distal femur, (c) potted femur specimen using anchoring cement.

Once potted, the femurs had hip stems installed at the proximal end. This was done in 3 steps. First, the proximal end of the each femur was removed using an industrial band saw by cutting along a line that was 66mm down from the tip of the femoral head and approximately 35° with respect to the femoral shaft in the coronal plane. Second, the cancellous bone was removed from the incision area using a rasper such that appropriate volume of empty space was attained for hip stem insertion. Third, each hip stem was inserted and the bone cement (Simplex P, Stryker, Mahwah, NJ, USA) was mixed and poured into the prepared end of the femur. The specimens were left for about 15 minutes until the cement was completely solidified. Figure 6.2.2 illustrates the hip stem implantation procedure.

Figure 6.2.2 Exeter hip stem implantation procedure (Images are extracted from Exeter Total Hip System product brochure, 2001 [70])

6.2.2 Three Levels of Specimen Conditions

The following 3 femur conditions were prepared in this study (Figure 6.2.3 and 6.2.4).

Level I: Intact Femur with Hip Stem

The intact femurs were implanted with hip stem

Level II: Fractured Femur – 1mm Gap

Once the intact femurs were tested, a transverse cut was made to the mid-shaft of each femur using a band saw. The fractured surfaces of the femur were placed to have a 1mm gap between them. Each femur was then fixed using a Zimmer Cable-Ready Grip System.

Level III: Fractured Femur - 5mm Gap

The initial fracture site was widened using a band saw to 5mm to simulate a comminuted fracture. The bone plates were not moved or modified between the level II and level III tests.

Figure 6.2.3 Three conditions of testing specimens: (a) Level I: intact femur with hip stem, (b) Level II: transverse mid-shaft fracture (1mm gap) of femur repaired with plate, (c) Level III: femur with 5mm gap at the site of fracture.

6.2.3 Five Types of Construct Design

Five types of constructs were used in this study (Figure 6.2.4). All 5 specimens were prepared identically at the distal half of the femur below the fracture line by applying 4 bicortical screws on the bone plate. On the proximal portion of the femur, cables and/or unicortical screws were used to install the bone plate. The method of hardware attachment was differently designed for each specimen based on the combination and the sequence of the hardware.

Figure 6.2.4 Design of 5 constructs: (a) Construct 1 (4 unicortical screws and 2 cables), (b) Construct 2 (4 unicortical screws and 4 cables), (c) Construct 3 (4 cables), (d) Construct 4 (2 unicortical screws and 2 cables at 1-3 positions), (e) Construct 5 (2 unicortical screws and 2 cables at 1-4 positions). Note all constructs are fixed at the distal end using 4 bicortical screws.

6.3 Mechanical Testing

The Instron® 8874 mechanical tester (Instron, Canton, MA, USA) was used to perform the testing in 3 modes: axial compression, lateral compression and torsion (Figure 6.3.1). The system was operated by a hydraulic power supply with biaxial actuator controllability. All measurements were made directly from the load cell actuator. Load cell characteristics included a capacity of +/-25 kN, a resolution of 0.1 N, and an accuracy of +/- 0.5% [71].

All tests were performed within the linearly elastic region of the synthetic femur. Thus, it was assumed that no permanent deformation occurred during the tests. This was verified a visual inspection for fracture/damage and through an examination of the load-displacement graph to ensure that the loading and unloading curve maintained linearity with a Pearson linear correlation coefficient $R^2 > 0.8$.

Each type of test was performed and measured 3 times for each specimen. An average value of 3 measurements was recorded and used for the analysis.

Figure 6.3.1 Instron® FastTrack™ 8874 [71]

6.3.1 Axial Stiffness Test

For axial compression testing, each femur was secured at its potted distal end by an industrial swivel vice (Figure 6.3.2). To simulate the proximal anatomical orientation of the femurs with the hip stem implantation, the femoral balls were inserted into a cup cut-out of an obliquely sectioned stainless steel cylinder with 15° of adduction [72]. The femoral balls were permitted to rotate inside the cup in order to simulate natural hip articulation [72]. The cup and ball of the hip stem were assumed to be frictionless. Due to the anatomical orientation of the femur, the axial load was applied away from the axis of the femoral shaft. Because of this, axial loading was in fact a combination of axial compression and bending [72].

Vertical loads were applied to the top of the femoral head at a load rate of 5mm/min with a preload of 50N. The Instron was programmed to reach a maximum displacement of 1mm. Stiffness was defined as the slope of the load-vs-displacement curve. The same procedure was used for Level I, II and III specimens.

Figure 6.3.2 Axial compression test: (a) experimental set-up of the femur with 15° incline simulating adduction, (b) detailed view of femoral ball and acetabular cup

6.3.2 Lateral Stiffness Test

The specimens were placed in the coronal plane and held horizontally in a vice. A support was placed immediately under where the site of fracture would be created. This set-up was intended to promote lateral bending of the femoral shaft (Figure 6.3.3).

Once the femur was properly positioned, a 50N preload was applied to the specimen to ensure proper engagement. Lastly, a load was applied to the tip of the femoral ball at a loading rate of 5mm/min. The Instron was programmed to reach a maximum displacement of 2mm. Stiffness was defined as the slope of the load-vs-displacement curve.

Figure 6.3.3 Lateral compression testing experimental set-up

6.3.3 Torsional Stiffness Test

A torsion tester was not available at the testing facilities used to perform this series of experiments. In order to simulate the torsional load, the hip step was oriented parallel to the floor and the Instron mechanical tester was used to apply a downwards force to the femoral ball. In this configuration, the applied force was offset from the axis of the femoral shaft creating a twisting moment thereby simulating a torsion test.

To minimize the bending load experienced by the fracture site, a support was placed under the femur as close to the proximal end as possible. In this case, each femur was placed horizontally in a vice with a support placed under the subtrochanteric region 105mm away from the site of fracture (Figure 6.3.4). Previous studies have shown that the bending had a minimal effect on the measured stiffness values when this set-up was used [72].

The torsion test was performed by first preloading each specimen at 50N. A load was then applied to each specimen at a rate of 5mm/min. The Instron was programmed to reach a maximum displacement of 2mm. Stiffness was defined as the slope of the load-vs-displacement curve.

(a)

(b)

Figure 6.3.4 Torsional stiffness testing experimental set-up: (a) top view, (b) side view

6.3.4 Strain Gauge Set-up

The installation of strain gauges requires a strict protocol for 3 main reasons. First, the maximum strain measurement is restricted to the range of $\pm 1300\mu\epsilon$ [68]. This requires high precision in the installation procedure such that the gauges do not go beyond the specified strain endurance requirement. Second, the surface finish must be kept within the range of 1.6 – 3.2 μm in order to allow for proper bonding of the strain gauges to the installation surface [73]. Poor adherence of the strain gauges may result in inaccurate measurements. Lastly, the contamination of the installation sites may prevent the gauges from making direct contact. The contaminants can include oil, grease, organic contaminants, and chemical residues [73]. Such contaminants may form an extra layer over the sites of measurement, thus the measured strain will not accurately reflect the actual behaviour of the tested specimen.

In order to achieve results that accurately reflect the surface strain of the specimen, the following strain gauge installation procedure was followed in accordance with the manufacturer's instructions:

1. Degreasing

The aerosol type spray can of CSM-2 Degreaser was used to remove oils, greases, organic contaminants and chemical residues [73]. The aerosol application method was chosen since the dissolved contaminants would not be traced back into the parent solvent [73]. In order to prevent recontamination, the surfaces were wiped with sterilized cotton in one direction only.

2. Surface Finishing

320-grit silicon carbide paper was used to remove any debris sticking to the surface as well as to flatten the surface curvature. Even surfaces with minimal curvature are needed to produce accurate strain gauge measurements.

3. Strain Gauge Positioning

A permanent marker was used to accurately locate the site of the strain gauges. A “+” was used to locate the horizontal and vertical orientation of the gauges such that they are lined up properly. This also allowed the strain gauges to be installed uniformly on all the sample structures.

4. Conditioning

The M-Prep Conditioner A from Vishay was used to clean up all surfaces as well as to remove any residues remaining from the step 1 and 2. The M-Prep Conditioner was repeatedly applied, and the cotton tipped applicator was used to scrub the surfaces until no discolouration was smeared on the

applicator. Once the surface was cleaned, the surface was dried by wiping the cleaned area with a sterilized cotton ball in a slow stroke motion to prevent re-contamination.

5. Neutralizing

The optimal surface condition of alkalinity for the adhesive strain gauge systems is in the range between 7.0 and 7.5pH as per the manufacturer's instruction [73]. This was accomplished after the removal of the residue from the M-Prep Conditioner applied in step 4. Once the surface was neutralized, a fresh cotton ball was used to dry the area in a single slow stroke. Another fresh cotton ball was used to wipe the area in the opposite direction such that no contamination would remain on the cleaned boundary [73].

6. Strain Gauge Preparation

The gauge was carefully removed from the packaging. The gauge was centered on the PCT-2A cellophane tape, and the outside, soldering/wiring side, of the gauge was then adhered to the tape. The inside of the gauge that would come in contact with the specimen, was applied with the M-Bond 200 Catalyst. The catalyst was left to dry for at least 30 seconds.

7. Strain Gauge Bonding

A few drops of the M-Bond 200 were dropped on the bonding side of the gauge. The cellophane tape was flipped, and the gauge was carefully located and adhered over the "+" mark from step 3. Air bubble was removed using a firm stroke applied over the cellophane tape covered with sterilized cotton. The tape was left on the gauge until wiring was performed. Steps through 6 to 7 were repeated for each of the 8 strain gauges used installed on the 5 constructs used in this study.

8. Wiring

Colour-coded (red, black and white) lead wires were used in this study to connect the strain gauges to the CRONOS-PL Data Acquisition Unit. Once these conductor wires were separated slightly at both ends, about half of insulation was stripped off and the black and white wires were inter-twined and soldered onto the left terminal of the strain gauge. The red wires were then soldered on the right terminal of the strain gauge. The wiring procedure was performed in accordance to the manufacturer's instruction for a three-wire quarter-bridge circuit (Figure 6.3.5).

Figure 6.3.5 Lead wire wiring: (a) three-wire quarter-bridge circuit [74], (b) soldering illustration [75]

6.3.5 Strain Gauge Positions

A total of 8 strain gauges were installed on each specimen as shown in Figure 6.3.6. One of the strain gauges was installed on the neck of the hip stem, one on the greater trochanter, two on the bone plate and four on the medial side of the femur (Figure 6.3.7). All these positions were measured with respect to the potting line within a tolerance of $\pm 2\text{mm}$.

Figure 6.3.6 Positions of the 8 strain gauges

Figure 6.3.7 Detailed view of strain gauges: (a) detailed medial view for strain gauge positions 5-8, (b) detailed proximal view for strain gauge positions 1-2, (c) detailed lateral view for strain gauge positions 2-4

6.3.6 Strain Gauge Test

Each strain gauge test was conducted in 5 steps. First, the red, black and white wires were connected to the +VB1, I1_1/4B1 and +IN1 slots, respectively. A small piece of free wire was also intertwined with the white wire and connected to the +IN1 slot. The other end of the free wire was inserted into the SENSE1 slot. This step completes the quarter bridge of the strain gauge (Figure 6.3.8(a)). This step was repeated for the second strain gauge except the red wire was connected to the +VB2 slot this time. A total of 4 DSub-15-pin connectors were required to properly wire all 8 strain gages.

After the DSub connectors were wired, the connectors were then plugged into a UNI2-8 all purpose 8-channel amplifier installed in the CRONOS-PL unit (Figure 6.3.8(b)).

After plugging the DSub connectors into the CRONO-PL unit, the CRONO-PL unit was connected to a computer via a LAN line (Figure 6.4.8(c)). Each specimen was set up under the loading cell for a

compression load while strain values were recorded. A 50N preload was applied to prevent any slippage between the femoral ball and the loading cell fixture and to allow for “settling” of any interfacial micromotion in the specimen. The Instron was programmed to apply and maintain a maximum compression load of 1000N for 90 seconds. The imc Devices V2.6 software was used to record the strain values during the loading period from 30 second to 60 second such that all specimens were bound under the loading cell with minimal fluctuation in the collected data. Lastly, the recorded signals were reviewed and analyzed using the Famos 5.0 software.

(a)

The positions of the strain gauges are indicated in a numbering system from 1 to 8. Each DSub-15 connector is pair for 2 strain gauges.

(b)

(c)

Figure 6.3.8 Strain gauge test set-up: (a) 2-channel Dsub-15-pin connector wired from 2 strain gauges [67], (b) UNI2-8 for CRONOS-PL unit [68], (c) compression test set-up for strain measurement

CHAPTER 7. FINITE ELEMENT MODELING AND ANALYSIS

A 3D model of the Fourth Generation Composite Femur was prepared in a previous study of knee implants conducted by Mahboob [76] using SolidWorks. Mahboob's model was then modified to simulate the periprosthetic femur anchored in a cement block such that the model was designed identical to the specimens used in the experimental study. The model was then exported to ANSYS Workbench version 12(ANSYS Inc., Canonsburg, USA) for the finite element analysis conducted in this study. The detailed information was entered to simulate the model which resembled the testing procedure followed in the experimental study.

7.1 Femur

The Fourth Generation Composite Femur 3-D model created by Mahboob [76] was modified with a cement block at the distal end as shown in Figure 7.1.1. The femur model was resected at its condyles to model the anchoring chamber used in the physical set of experiments as discussed in Chapter 6.

Figure 7.1.1 Femur CAD model anchored with chamber at distal end

The geometry of Exeter™ hip stem was modeled using SolidWorks and attached to the proximal end of the femur in a similar configuration to that described in Section 6 (Figure 7.1.2).

Figure 7.1.2 CAD model of femur implanted with hip stem assembly: (a) Orthinox Head (ball head), (b) Exeter™ Femoral Stem (hip stem), (c) Surgical Simplex P Bone Cement

7.2 Bone Plate and Hardware

SolidWorks was used to model the Zimmer Cable-Ready Grip System used in the experimental study. The bone plate was attached to the simulated femur shown in Figure 7.1.2. Five distinct combinations of bone screws and cables were then applied to secure the bone plate on to the femur model (Figure 7.2.1). The combinations of screws and cables were identical to that of the experimental study.

Upon the completion of bone plate assembly, a fracture at the femoral mid-shaft was created. This was to ensure the alignment of the femur during simulation. The femur models were considered for two fracture conditions: simple transverse fracture and transverse fracture with 5mm gap. To simulate the simple transverse fracture, a 1 mm gap was created at the site of fracture such that clearance was ensured between fragments.

Figure 7.2.1 Five bone plate fixation simulations with 5mm fracture gap: (a) Construct 1 (4 unicortical screws and 2 cables) , (b) Construct 2 (4 unicortical screws and 4 cables), (c) Construct 3 (4 cables), (d) Construct 4 (2 unicortical screws and 2 cables at 1-3 positions), (e) Construct 5 (2 unicortical screws and 2 cables at 1-4 positions). Note that all constructs have identical fixation designs distal to the fracture gap by employing 4 bicortical screws.

7.3 Material Properties

Many researchers [77-81] have measured the strain values in order to investigate the effect of plate stiffness as well as the stress shielding effect of the bone-implant system. Strain values are commonly used since it is much easier to directly measure the strain in comparison to the stress. Strain is defined as:

$$\epsilon = \frac{\Delta L}{L} \quad \text{Equation 7.3.1}$$

where ϵ represents the normal strain, ΔL represents a change in length and L represents the original length. Stress, on the other hand, is related to strain through Hooke's Law:

$$\sigma = E\epsilon \quad \text{Equation 7.3.2}$$

where σ represents the stress, and E represents Young's Modulus. Given a fixed Young's Modulus for a material, the increase in strain infers a proportional increase in stress. Equation 7.3.2 is valid as long as the stress and strain are kept within the elastic region. The equation of stress is expressed as:

$$\sigma = \frac{F}{A} \quad \text{Equation 7.3.3}$$

where F represents the applied force, and A represents the cross-sectional area. Combining Equation 7.3.1 and 7.3.3 into Equation 7.3.2, the axial stiffness can be expressed as:

$$\frac{F}{\Delta L} = \frac{AE}{L} \quad \text{Equation 7.3.4}$$

The 3D model of a periprosthetic femur fixed with bone plate consisted of various components made with different materials. Material specifications for the same material can vary depending on the source referenced. The material properties used in the finite element model are discussed in this section.

7.3.1 Synthetic Bone Model

The Fourth Generation Composite Femur was simulated with the mechanical properties provided by the manufacturer (Pacific Research Laboratories, Vashon, WA, USA). Many previous studies have considered synthetic femurs as linearly elastic homogeneous materials when comparing FE (finite element) and experimental results [72, 82-85]. Since the goal of the present study was to understand the mechanical performance of the femur-bone plate system as opposed to the biological study of bone tissue, the same assumption was considered.

Considering the composite femur as a homogeneous isotropic linear elastic material, the shear modulus, G , can be calculated as:

$$G = \frac{E}{2(1 + \nu)} \quad \text{Equation 7.3.3}$$

where E is Young's Modulus and ν is Poisson's ratio. Using Equation 7.3.3, the shear modulus for cortical bone and cancellous bone were calculated to be 5.72 GPa and 0.06 GPa respectively. The material properties of synthetic bone are listed in Table 7.3.1.

Table 7.3.1 Material property of synthetic bone

	Cortical Bone	Cancellous Bone
Density [64]	1.64 g/cm ³	0.20 g/cm ³
Young's Modulus [64]	16.7 GPa	0.155 GPa
Ultimate Compressive Strength [64]	157 MPa	6.0 MPa
Poisson's Ratio [85, 86]	0.46	0.3
Shear Modulus	5.72 GPa	0.06 GPa
Elasticity Model	Linear elastic	Linear elastic
Isotropy	Isotropic	Isotropic

7.3.2 Bone Plate, Bone Screw and Cable

As a part of the Zimmer Cable-Ready Grip System, the bone plate, bone screws (both unicortical and bicortical screws) and cables were all made of 316L medical grade stainless steel. The material properties of the 316L stainless steel were obtained from the standardized values provided by the American Iron and

Steel Institute (AISI). The Poisson's ratio ranged between 0.220 and 0.346 for the stainless steel in general [61]. In this study, 0.3 was chosen as the approximate average value. The mechanical properties of 316L stainless steel are listed in Table 7.3.2.

Table 7.3.2 Material property of 316L stainless steel

Density [87]	8.0 g/cm ³
Tensile Ultimate Strength [87]	560 MPa
Tensile Yield Strength [87]	235 MPa
Young's Modulus [87]	193 GPa
Poisson's Ratio [61]	0.3
Elasticity Model	Linear elastic
Isotropy	Isotropic

7.3.3 Hip Stem and Femoral Ball

In this study, the periprosthetic femur was constructed by implanting the Exeter™ Total Hip System into the proximal end of the synthetic femur. This consisted of a hip stem called the Exeter™ Femoral Stem and a femoral ball called the Orthinox™ Head. Both the hip stem and the femoral ball were made of cobalt-chromium-molybdenum (CoCrMo) alloy as per the manufacturer's manual [70]. CoCrMo alloy is commonly used in total hip joint implants due to its relatively high strength and corrosion resistance [88-89].

While the detailed material properties for the hip stem and femoral ball were not available from the manufacturer, this study assumed that they were made from wrought CoCrMo. This material and condition was chosen since it was popular in the fabrication of hip implants due to its grain refinement and elimination of macro-defects [89]. Wrought CoCrMo alloy follows the ASTM F-1537 standard [88, 90]. The material is also known as Cobalt-28 Chromium-6 Molybdenum alloy since it contains 28% chromium and 6% molybdenum [88, 90]. The density of this alloy was determined to be 8.28 g/cm³ based on the commercially available BioDur® CCM Plus® alloy manufactured by Carpenter Technology Corporation [90]. The Young's Modulus and Poisson's ratio were set at 210 GPa and 0.31 respectively based on the previous study conducted by Medley et al. [91]. The yield strength, ultimate tensile strength and elongation to fracture were available from the study of structural properties of CoCrMo alloys conducted by Varano [89]. Table 7.3.3 lists the material properties used in the FE simulation.

Table 7.3.3 Material property of cobalt-chromium-molybdenum alloy

Density [90]	8.28 g/cm ³
Young's Modulus [91]	210 GPa
Poisson's Ratio [91]	0.31
Yield Strength [89]	872 MPa
Ultimate Tensile Strength [89]	1.172 GPa
Elongation to Fracture [89]	12%
Elasticity Model	Linear elastic
Isotropy	Isotropic

7.3.4 Bone Cement for Hip Stem Implantation

Surgical Simplex P bone cement (Stryker, Mahwah, NJ, USA) was used during the experimental study in order to implant the hip stem and, thus, to permit the creation of a periprosthetic femur fracture. The bone cement is polymethylmethacrylate (PMMA) [92]. Mechanical properties of PMMA were obtained from various sources in the literature (Table 7.3.4).

Table 7.3.4 Material Properties of PMMA

Density [92]	1.19 g/cm ³
Young's Modulus [92, 93]	2.45 GPa
Poisson's Ratio [92]	0.38
Ultimate Tensile Strength [92, 93]	62 MPa
Elasticity Model	Linear elastic
Isotropy	Isotropic

7.3.5 Anchoring Block

In the experimental study, all test specimens were rigidly fixed at their distal end by using a square steel tube chamber filled with anchoring cement (Flow-stone, King Packaged Materials Company, Burlington, ON, Canada). In order to generate a model which mimicked the experimental conditions as closely as possible, the material property of concrete was applied to the anchoring block component of the model. The stiffness behaviour of the anchoring block was set to be flexible in the ANSYS Workbench. The material property of cement was provided by the material library that came in the ANSYS software (Table 7.3.5).

Table 7.3.5 Material properties of anchoring concrete

Density	2.30 g/cm ³
Young's Modulus	30.0 GPa
Poisson's Ratio	0.18
Compressive Ultimate Strength	41.0 MPa
Tensile Ultimate Strength	5.0 MPa
Elasticity Model	Linear elastic
Isotropy	Isotropic

7.4 Finite Elements and Nodes

7.4.1 SOLID187

All solid bodies in this study were automatically modeled with the SOLID187 elements by default (Figure 7.4.1(a)). SOLID187 creates high-order tetrahedral elements that have 10 nodes with 3 degrees of freedom at each node [94]. It has quadratic displacement behaviour and is ideal for modeling irregular meshes [94]. The SOLID187 elements have various capabilities including stress stiffening, large deflection and large strain capability that are useful to simulate deformation [94]. In addition, orthotropic and anisotropic material properties can be entered into the elements as input data [94]. Since the material directions correspond to the element coordinate direction, the linear elasticity of the materials listed in Section 7.3 can be utilized [94]. The SOLID187 outputs data by presenting the element stress directions parallel to the element coordinate system [94]. As shown in Figure 7.4.1 (b) and (c), the surface stress outputs follow the surface coordinate system (x-y axis) and they can be allocated for any surface [94].

Figure 7.4.1 SOLID187: (a) elements employed to solid bodies of the 3D model , (b) input element geometry [124], (c) output element geometry [94]

7.4.2 CONTA174

CONTA174 is a 3D 8-node element that is automatically generated for the rigid-flexible and flexible-flexible contact analysis [95] (Figure 7.4.2). The CONTA174 contact element is associated with the 3D target segment element, TARGE170 [95]. It is applicable to 3D geometries that are either solid or shell elements [95]. In CONTA174, the contact pair is defined by taking one body as a contact surface and the

other as a target surface [95]. In this study, CONTA174 was applied to the contact surfaces between the femur and cable and between the femur and screw. All contact elements in this study were set to be bonded except for the contact surface between the cortical bone of the femur and the bone plate which was simulated with no separation.

Figure 7.4.2 CONTA174 contact element description [95]

7.4.3 TARGE170

TARGE170 is a type of 3D target surface element that is automatically generated to associate with contact surface elements such as CONTA174 [96]. When the contact elements overlay the elements describing the boundary of a deformable body must come in contact with the target surface [96]. TARGE170 defines such boundaries for a set of target segment elements as shown in Figure 7.4.3. The target surface is paired with its associated contact surfaces via a shared real constant set [96].

In the case where the target surface is defined to be rigid, the TARGE170 target elements can be modified to model more complex shapes [96]. On the other hand, when the target surface is flexible, the target elements will overlay the solid, shell or line elements to describe such a deformable target body [96].

Figure 7.4.3 TARGE170 target element geometry [96]

7.5 Boundary Conditions

The anchoring cement block provided a fixed support to the periprosthetic-bone plate system as shown in Figure 7.5. This fixed support was constrained at 5 faces. A 1000N force was applied to the tip of femoral ball at a 15° angle to replicate the adduction angle used in the experimental study.

Figure 7.5 Boundary conditions applied to the Construct 5 with a 5mm gap at the site of fracture

7.6 Contact

All contacting surfaces were modeled to be bonded except the contact surfaces between the proximal half of the femur and the bone plate and between the distal half of the femur and the bone plate which were set with *no separation* (Figure 7.6).

Figure 7.6 Sample locations of contact shown in Construct 4 with 1mm transverse fracture gap

7.7 Mesh Sensitivity and Convergence

Using the SOLID187 elements, a 10-node tetrahedral mesh was generated to the periprosthetic femur-bone plate system. Papini et al. verified that a high level of accuracy can be produced from the tetrahedral mesh used on the femur model [72]. Since the specimens constituted of mainly femur bone material, it was fair to expect a sufficient level of accuracy from tetrahedral meshing. The ANSYS Workbench meshing utility automatically rearranged the elements such that the Jacobian element would measure the deviation from an ideally shaped element to be above 0.7 for all meshes.

For each test trial, an axial load of 1000N was applied at a 15° angle, and the normal elastic strains were recorded at the 8 different locations shown in Figure 6.3.6 (a). The results were refined using the *Relevance* setting in the ANSYS Workbench. The *Relevance* can be set in a range between -100 and +100 to modify the mesh between a high speed mesh and a high accuracy mesh, respectively. The *Relevance* setting was changed for each test specimen until a convergence was achieved in the result. Figure 7.7.1 and Figure 7.7.2 show the meshing results for the Level II and III respectively.

Figure 7.7.1 Mesh applied to simulation models at the level II fracture condition (1mm gap): (a) Construct 1 (4 unicortical screws and 2 cables), (b) Construct 2 (4 unicortical screws and 4 cables), (c) Construct 3 (4 cables), (d) Construct 4 (2 unicortical screws and 2 cables at 1-3 positions), (e) Construct 5 (2 unicortical screws and 2 cables at 1-4 positions). Note that all constructs have identical fixation designs at the distal end using 4 bicortical screws.

The Table 7.7.1 and Table 7.7.2 summarize the total number of nodes, total number of elements and the relevance used for the constructs at Level II and III respectively at their best convergences.

Table 7.7.1 Meshing set-up applied to simulation models at Level II fracture condition (1mm gap)

	Construct Number				
	1	2	3	4	5
Number of Nodes	170,127	209,588	487,604	162,778	204,824
Total Number of Elements	98,673	121,558	299,635	94,323	115,299
Relevance	86%	89%	89%	86%	100%

Figure 7.7.2 Mesh applied to simulation models at Level III fracture condition (5mm gap): (a) Construct 1, (b) Construct 2. (c) Construct 3, (d) Construct 4, (e) Construct 5

Table 7.7.2 Meshing set-up applied to simulation models at Level III fracture condition (5mm gap)

	Construct Number				
	1	2	3	4	5
Number of Nodes	167,005	200,575	481,628	160,034	148,087
Total Number of Elements	96,782	116,326	295,459	92,713	84,885
Relevance	85%	85%	85%	85%	85%

CHAPTER 8. RESULTS

8.1 Experimental Results

Results from the experimental study are summarized in this section. The results from the Level I constructs were collected and analyzed to be used as a reference for the Level II and III testing results. In the strain gauge tests, the specimens were divided into 3 sections, top, middle and bottom, by assigning the strain gauge positions 1 and 2 (top), 3/5/6 (middle), and 4/7/8 (bottom). Recall that the femoral head of each specimen was replaced with a hip stem to simulate the periprosthetic femur fracture repair. Also recall that the distal half of the femurs were fixed to the bone plate in an identical manner such that the differences in fixation existed in only the proximal portion of the specimens.

8.1.1 Three Modes of Loading on Level I Constructs

The intact femurs with hip stems alone were tested under 3 modes of load; axial compression, lateral compression and torsion. This testing was done prior to the creation of a simple mid-shaft fracture or the addition of the bone plate. Based on the relatively small standard deviation between samples at the Level I condition as shown in Table 8.1.1, the absolute stiffness values measured in the Level II and Level III tests will be used later in this paper. This is because the stiffness values at Level II and Level III are affected primarily by the bone plate and not material/geometric differences in the femurs themselves.

Table 8.1.1 Stiffness of the intact periprosthetic femurs (Level I). Stiffness expressed as N/mm.

Mode of Load	Construct					Average	Standard Deviation
	1	2	3	4	5		
Axial Compression	2275.3	2517.4	2722.9	2464.6	2528.0	2501.6	160.1
Lateral Bending	106.6	104.7	111.3	96.7	102.7	104.4	5.4
Torsion	187.9	214.3	223.0	198.9	207.3	206.3	13.6

: Highest stiffness

: Lowest stiffness

8.1.2 Experimental Test on Constructs in Level II Fracture Condition (1mm Gap)

Axial Compression Test

The axial compression stiffnesses were tested on the femur-metallic bone plate systems with the Level II fracture condition where mid-shaft transverse fractures were fixed by 5 different fixation methods as explained in Section 6.2.4. Although a preload of 50N was applied to each specimen, the slippage between the femoral ball and the loading cell fixture was not completely eliminated for all specimens. Occasional cracking sounds were heard from the hip stem cements while the load was applied to the specimens, yet no visible cracks were observed. An insignificant amount of powder debris from the cement was observed around the distal femoral shafts at the edge of the cement block.

All Level II constructs showed a reduction in the stiffness to various degrees compared to the intact femurs (Level I constructs). For instance, Construct 1 (4 unicortical screws and 2 cables at the proximal end) showed a 12.2% of reduction in axial stiffness compared to its condition in Level I. Construct 4 (2 unicortical screws and 2 cables at 1-3 positions on the proximal half of femur) exhibited the highest reduction in the stiffness of 60.8%. Results of the stiffness tests are shown in Table 8.1.2 and Figure 8.1.1.

Table 8.1.2 Axial compression stiffness of constructs in Level II fracture condition

	Construct Number				
	1	2	3	4	5
Axial Compressive Stiffness [N/mm]	1998.9	1199.9	1844.4	966.4	1803.0
% Reduction (Level I – Level II)	12.2%	52.3%	32.3%	60.8%	28.7%
% Difference Compared to the Stiffest Construct	Stiffest Construct	39.9%	7.7%	51.7%	9.8%
$\% \text{ Difference} = \frac{(\text{Stiffness of Construct 1} - \text{Stiffness of Construct \#})}{\text{Stiffness of Construct 1}}$

Figure 8.1.1 Axial compression stiffness of constructs in Level II fracture condition

Strain Gauge Test

All 5 specimens were instrumented to measure their strain values along 8 different surface positions. These measurements were collected 3 times for each specimen, and the average values of each are shown in Table 8.1.3. The sign of the recorded strain values at each strain gauge position was the same for all the configurations except at position 7, which took on both positive and negative values.

Table 8.1.3 Strain measurements on constructs in Level II fracture condition (1mm gap)

Strain Gauge Position		Strain ($\mu\epsilon$)				
		Construct 1	Construct 2	Construct 3	Construct 4	Construct 5
Top	1	452.4	482.3	486.0	485.6	464.5
	2	2.9	40.7	43.4	35.7	15.4
Middle	3	53.8	24.2	32.6	43.4	52.2
	5	-499.8	-425.7	-639.0	-507.3	-491.0
	6	-479.1	-476.8	-674.5	-502.9	-421.9
Bottom	4	-66.4	-125.34	-38.6	-125.5	-44.9
	7	-5.6	114.0	-110.2	234.2	-37.4
	8	128.2	360.3	53.9	436.1	80.6

Note: + represents tension, - represents compression

8.1.3 Test on Constructs at Level III Fracture Condition (5mm Gap)

Axial Compression Test

All 5 specimens from the Level II testing were resected with a 5mm gap at the site of fracture to produce the Level III constructs. Among all Level III constructs, Construct 3 had the highest axial compressive stiffness followed by Construct 1, Construct 2, Construct 4 and Construct 5. However, their stiffnesses were relatively close to one another with all measured values being within 14% of the mean stiffness. The results of the axial compression tests are shown in Table 8.1.4.

Table 8.1.4 Axial compression stiffness of Level III constructs

	Construct Number				
	1	2	3	4	5
Axial Compression [N/mm]	886.7	868.0	999.8	836.0	801.2
% Difference from Mean	0.95%	-1.18%	13.83%	-4.82%	-8.78%
Mean Stiffness = 878.3 N/mm, % Difference from Mean = $\frac{\text{Measured Stiffness} - \text{Mean Stiffness}}{\text{Mean Stiffness}}$					

With an increase in the length of the fracture gap to 5mm, all constructs showed significant reductions in their axial compressive stiffness. In detail, the stiffnesses the constructs at the Level III condition were decreased by 61 to 68% compared to Level I. Compared to the constructs with a simple transverse fracture (Level II), the Level III constructs showed an average reduction in their axial stiffness of approximately 40%. Table 8.1.5 presents a comparison of the percent reduction in axial compression stiffness from Level III to Level I and Level II.

Table 8.1.5 Comparison of the axial compression stiffnesses

	Construct Number				
	1	2	3	4	5
% Reduction (Level I – Level III)	61.0%	65.5%	63.3%	66.1%	68.3%
% Reduction (Level II – Level III)	55.6%	27.7%	45.8%	13.5%	55.6%

Figure 8.1.2 Axial compressive stiffness of 5 constructs comparing the intact femurs (Level I) to femurs with simple 1mm transverse fracture gap (Level II) and femurs with 5mm gap at the site of fracture (Level III)

During the experiment, it was noticed that the Level III constructs experienced much larger slippage during the pre-load. This led to several adjustments in placing each specimen. Some cracking sounds were heard from all Level III specimens.

Strain Gauge Test

The Level III constructs were instrumented to measure the strain values at the same positions as the Level II constructs. The strain measurements are shown in Table 8.1.6.

Table 8.1.6 Strain measurements on specimens at Level III fracture condition (5mm gap)

Strain Gauge Position		Strain ($\mu\epsilon$)				
		Construct 1	Construct 2	Construct 3	Construct 4	Construct 5
Top	1	422.9	487.0	436.1	464.5	429.6
	2	2.9	38.4	38.2	47.6	17.1
Middle	3	24.2	19.8	11.9	24.6	-4.6
	5	-432.6	-425.7	-505.2	-487.0	-477.2
	6	-442.8	-482.2	-520.0	-514.0	-452.2
Bottom	4	1.2	-130.3	-126.3	-130.9	-139.7
	7	227.8	164.9	124.2	256.2	349.9
	8	433.8	416.9	411.0	487.5	612.1

Note: + represents tension, - represents compression.

8.2 Finite Element Analysis Results

8.2.1 Axial Compression Stiffnesses for Level II Constructs

Five FE constructs were designed to match the experimental test specimens. Each FE model was loaded under 1000N at a 15° ramp mimicking the adduction of femur at double limb stance. The axial compressive stiffnesses were calculated in 2 steps. First, using the ANSYS Workbench, the maximum and the minimum *directional displacements* were measured in the direction where the 1000N force was applied. The average value of the two displacements was taken. Since the applied force was 1000N, the axial compression was then calculated by taking 1000N divided by the average displacement of the femoral ball. The calculated axial compression stiffness values are shown in Table 8.2.1.

Table 8.2.1 Calculated axial compressive stiffness for Level II constructs using FE model

Construct Number	Axial Compressive Stiffness [N/mm]
1	1926
2	1324
3	1775
4	1889
5	1813

8.2.2 Strain Values Calculated for Level II Constructs Using FE Model

The normal elastic strain was determined using ANSYS for the same positions measured in the experimental study. Figure 8.2.1 shows the sample strain values measured at 8 positions on Construct 2. The final results from all constructs under the Level II conditions are tabulated in Table 8.2.2.

(a) Strain 1

(b) Strain 2

(c) Strain 3

(d) Strain 4

(e) Strain 5

(f) Strain 6

(g) Strain 7

(h) Strain 8

Figure 8.2.1 FE model measuring normal strain at 8 different positions for Construct 2 at Level II fracture condition (1mm gap)

Table 8.2.2 Strain values for Level II constructs from FE model

Strain Gauge Position		Strain ($\mu\epsilon$)				
		Construct 1	Construct 2	Construct 3	Construct 4	Construct 5
Top	1	416.6	448.4	414.4	424.1	460.5
	2	9.1	19.0	11.1	19.6	14.3
Middle	3	53.0	25.7	36.7	49.6	45.3
	5	-395.0	-396.1	-409.7	-405.1	-414.4
	6	-386.3	-404.1	-424.1	-413.0	-416.3
Bottom	4	-68.1	-110.0	-66.1	-99.1	-10.2
	7	231.1	233.9	302.9	253.2	29.8
	8	586.4	620.5	659.0	638.8	73.0

Note: + represents tension, - represents compression

8.2.3 Axial Compressive Stiffnesses for Level III Constructs

Using the FE model, the axial compressive stiffnesses for the fractured periprosthetic femur models with 5mm gap were calculated. The axial compressive stiffnesses were calculated based on the directional displacements of the femoral ball for a constant applied load of 1000N (Table 8.2.3).

Table 8.2.3 Calculated axial compressive stiffness for Level III constructs using FE model

Construct Number	Axial Compressive Stiffness [N/mm]
1	1359.0
2	1101.9
3	768.2
4	849.1
5	1262.0

8.2.4 Strain Values Calculated for Level III Constructs Using FE Model

The normal elastic strain was determined using ANSYS for the same positions measured in the experimental study. The final results from all constructs under the Level III conditions are tabulated in Table 8.2.4.

Table 8.2.4 Calculated strain values for Level III construct

Strain Gauge Position		Strain ($\mu\epsilon$)				
		Construct 1	Construct 2	Construct 3	Construct 4	Construct 5
Top	1	411.8	453.3	412.1	413.0	414.4
	2	8.4	34.1	11.4	40.8	15.9
Middle	3	46.1	20.1	69.3	-31.1	17.2
	5	-373.8	-363.7	-417.1	-335.1	-416.4
	6	-380.7	-426.1	-489.7	-395.6	-429.2
Bottom	4	-102.2	-139.9	-94.8	-116.6	-126.3
	7	231.5	185.3	290.4	281.1	329.7
	8	637.2	465.8	721.3	763.6	661.4

Note: + represents tension, - represents compression

8.3 Comparative Analysis Results

The data analysis was performed in 3 steps. First a comparison of the data between the finite element and the experimental results was conducted. Next, an examination of the stiffness properties of the various constructs was examined. Finally the strain and stress shielding effects of the constructs were examined. An in-depth discussion of the causal factors for the various tendencies observed in this section is reserved for the Discussion (chapter 9).

8.3.1 Validation of the Finite Element Model

Evaluation of Axial Stiffness Values

The axial stiffness values predicted by the finite element program were compared to the experimental results to determine whether the finite element model could be used to predict the axial stiffness of a particular construct. Results are shown in Table 8.3.1.

Table 8.3.1 - Comparison of predicted and measured axial stiffness values

		Axial Stiffness (N/mm)				
		Construct 1	Construct 2	Construct 3	Construct 4	Construct 5
Level II	Experiment	1998.9	1199.9	1844.4	966.4	1803
	FE	1926	1324	1775	1889	1813
	Difference	-3.6%	10.3%	-3.8%	95.5%	0.6%
Level III	Experiment	886.7	868	999.8	836	801.2
	FE	1359	1101.9	768.2	849.1	1262
	Difference	53.3%	26.9%	-23.2%	1.6%	57.5%
		$\text{Difference} = \frac{\text{FE Stiffness} - \text{Experimental Stiffness}}{\text{FE Stiffness}}$				

With the exception of Construct 4, the finite element program predicted the axial stiffness of each construct to within 10.3% of the observed results for the Level II (1mm gap) condition. The correlation of the stiffness values between the finite element model and the experimental results for the Level II condition is plotted in Figure 8.3.1 without Construct 4. With the y-intercept set to 0, the correlation plot indicates that although the finite element program has a slight overall tendency to underestimate the axial stiffness, there is a reasonably strong correlation between the data as exhibited by the R^2 value of 0.882. Across all constructs, except Construct 4, the finite element model underestimated the observed Level II stiffness by 2 N/mm.

Figure 8.3.1 Plot of the axial stiffness results from the FE analysis and experimental study for Level II (excluding construct 4)

The observed results for Construct 4 are significantly below that of Construct 5 (Table 8.3.2). This is unexpected since Construct 4 and 5 only vary by the position of the bottom screw and cable on the proximal half of the bone plate. In light of the other experimental results from the Level II loading condition, the measured stiffness of Construct 4 appears to be significantly lower than expected. This is especially true when comparing between the stiffness of the Level II and Level III loading conditions in which the stiffness of Construct 4 only decreased by 13%, compared to an average of 46% across the other constructs. Based on the experimental data from the other constructs, the experimental results from Construct 4 appear to be artificially low. In fact, the stiffness of 1889 N/mm predicted by the finite element model appears to be in better agreement with the majority of the observed experimental data. Therefore the finite element model appears to have been successful in predicting the stiffness of the constructs in the Level II. Possible explanations for the low measured stiffness in Construct 4 are examined later in the discussion section.

Table 8.3.2 - Observed and calculated stiffness values for Level II configuration

		Construct Number				
		1	2	3	4	5
Experimental (Mean = 1562N/mm)	Stiffness (N/mm)	1999	1200	1844	966	1803
	Difference from Mean (%)	27.9%	-23.2%	18.0%	-38.2%	15.4%
Finite Element (Mean = 1745N/mm)	Stiffness (N/mm)	1926	1324	1775	1889	1813
	Difference from Mean (%)	10.35%	-24.14%	1.70%	8.23%	3.87%
$\% \text{ Difference from Mean} = \frac{(\text{Measured Stiffness} - \text{Mean Stiffness Value})}{\text{Mean Stiffness Value}}$						

The average stiffness observed in the mechanical tests performed at the Level III condition (5mm gap) was 878.3 N/mm whereas the finite element model predicted an average stiffness of 1068.0 N/mm. Thus the finite element program tended to overestimate the stiffness of the constructs by an average of 22% at the Level III condition.

Based on the results of the Level III experimental study, all of the observed stiffness values were between -9 and 14% of the average observed stiffness (Table 8.3.3). This indicates that the method of fixing the proximal end of the bone plate to the femur had a relatively small effect on the overall stiffness of the femur/bone-plate combination. A larger number of samples are required to determine whether the observed differences in measured stiffness value are statistically significant.

In contrast to the observed results for the Level III testing condition, the stiffness values calculated using the finite element model predicted the stiffnesses ranging from -28 to 27% of the average predicted stiffness (Table 8.3.3). The finite element results indicated that the stiffness of the system would be largely dependent on the method used to attach the proximal part of the bone plate to the femur. This discrepancy between the finite element analysis and the test results is examined further in the Discussion section (chapter 9).

Table 8.3.3 - Observed and calculated stiffness values for Level III configuration

		Construct Number				
		1	2	3	4	5
Experimental (Mean = 878N/mm)	Stiffness (N/mm)	886.7	868.0	999.8	836.0	801.2
	Difference from Mean (%)	1.0%	-1.2%	13.8%	-4.8%	-8.8%
Finite Element (Mean = 1068N/mm)	Stiffness (N/mm)	1359.0	1101.9	768.2	849.1	1262.0
	Difference from Mean (%)	27.2%	3.2%	-28.1%	-20.5%	18.2%
$\% \text{ Difference from Mean} = \frac{(\text{Measured Stiffness} - \text{Mean Stiffness Value})}{\text{Mean Stiffness Value}}$						

Evaluation of Strain Values

In order to determine whether the ANSYS finite element model accurately predicted the strain in the fixated femur, the result of the finite element model and the experimental test were plotted along separate axes. A linear best fit line with a y-intercept of 0 was then passed through the data cloud and the slope and R^2 values were recorded as shown in Figure 8.3.2. This process was repeated for all constructs at both the Level II and III conditions. Table 8.3.4 summarizes the slope and R^2 values recorded for all experimental conditions. Please see Appendix C for the detail. A slope of greater than 1 indicates that the finite element analysis had a tendency to overestimate the strain, whereas a slope of less than 1 indicates that the finite element analysis tended to underestimate the strain when compared to the experimental results. The R^2 values are an indication of the deviation (or spread) in the data. A linear best fit line with a slope of 1 and an R^2 value of 1 would represent the case where the strain results predicted by the finite element analysis exactly matched the experimental results.

Figure 8.3.2 Plot of the results from FE analysis and experimental study for Construct 5 in Level II condition

Table 8.3.4 Correlation coefficient between experimental strains and FE strains

		Construct Number				
		1	2	3	4	5
Level II	Slope	0.92	1.05	0.68	0.96	0.93
	R ²	0.67	0.91	0.47	0.93	0.99
Level III	Slope	1.04	0.95	1.08	0.98	0.98
	R ²	0.93	0.99	0.89	0.89	0.99

The R² values for the Level II condition varied between 0.47 and 0.99 whereas the values for the Level III condition varied between 0.89 and 0.99. Based on these results, the finite element model appeared to be much better at predicting strain at the Level III condition (5mm gap) compared to the Level II condition (1mm gap).

In general, the slope of the Level II best fit line was less than 1. This indicated that the finite element program had an overall tendency to underestimate the strain in the Level II condition. The slope in the best fit line for the Level III condition varied between 0.95 and 1.08. This indicated that there was no overall tendency to either overestimate or underestimate the strain in the Level III condition.

It was observed that the finite element analysis grossly underestimated the strain at position 6, and overestimated the strain at positions 7 and 8. Possible reasons for these are examined later in the Discussion section (chapter 9). If these 3 strain gauge sensors are not considered in the correlation

coefficient analysis, the slope and R^2 values improve dramatically. Table 8.3.5 shows the correlation coefficients for the case where strain at positions 6 through 8 are not considered.

Table 8.3.5 Correlation coefficient between experimental strains and FE strains for positions 1-5 only

		Construct Number				
		1	2	3	4	5
Level II	Slope	0.85	0.93	0.72	0.83	0.91
	R^2	0.99	1.00	0.97	1.00	0.99
Level III	Slope	0.92	0.90	0.87	0.79	0.91
	R^2	0.96	1.00	0.98	0.98	1.00

In general, the finite element model was able to accurately predict the observed strains in the Level III configuration. When used to predict the strains in the Level II configuration, the finite element program was able to accurately predict the strain in the gauge positions 1 through 5 although it had trouble predicting the observed strain at positions 6 through 8.

8.4 Compressive Strain & Stress Shielding

In order to analyze the amount of stress shielding caused by the various bone plate fixation methods, this study examined the strain measured on the medial surface of the femur below the trochanter (strain gauges 5 and 6). Since stress is proportional to strain, a larger strain is measured when the material is more heavily stressed. Compressive stresses are required to maintain healthy levels of bone density and are, therefore, desirable.

A comparison of the experimental results and the finite element analysis showed that the finite element analysis was not able to accurately model the strain at position 6 (medial surface on the proximal side of the fracture closest to the fracture surface). This could have been caused by several reasons including premature/improper load transfer from the femur to the bone plate and incorrect modeling of the contact plane between the fracture surfaces. These explanations are further investigated in the Discussion section (chapter 9). In this section, the strain values measured during the experiments are focused rather than the finite element results.

Based on the experimental results for gauge positions 5 and 6, the highest amount of compressive strains were measured in Construct 3 for both the Level II (no gap) and Level III (5mm gap) conditions (Tables 8.4.1 and 8.4.2). The strains at these positions were higher by between 8 and 32% than the average strain

measured across all constructs. Based on these results, the attachment method used for Construct 3 led to the least amount of stress shielding in the proximal portion of the femur. The reasons for this are examined later in the Discussion section (chapter 9).

Table 8.4.1 - Experimental strain values for positions 5 and 6 - Level II (1mm gap)

		Construct Number				
		1	2	3	4	5
Gauge Position 5 (Mean = -512µε)	Strain (µε)	-499.8	-425.7	-639.0	-507.3	-491.0
	Difference from the mean (%)	-2.4%	-16.9%	24.8%	-0.92%	-4.1%
Gauge Position 6 (Mean = -511µε)	Strain (µε)	-479.1	-476.8	-674.5	-502.9	-421.9
	Difference from the mean (%)	-6.3%	-6.7%	31.9%	-1.6%	-17.4%
$\text{Difference from the mean (\%)} = \frac{\text{Measured Strain} - \text{Mean Value of Strain}}{\text{Mean Value of Strain}}$						

Table 8.4.2 - Experimental strain values for positions 5 and 6 - Level III (5mm gap)

		Construct Number				
		1	2	3	4	5
Gauge Position 5 (Mean = -465µε)	Strain (µε)	-432.6	-425.7	-505.2	-487.0	-477.2
	Difference from the mean (%)	-7.1%	-8.6%	8.5%	4.6%	2.5%
Gauge Position 6 (Mean = -482µε)	Strain (µε)	-442.8	-482.2	-520.0	-514.0	-452.2
	Difference from the mean (%)	-8.2%	0.0%	7.8%	6.6%	-6.2%
$\text{Difference from the mean (\%)} = \frac{\text{Measured Strain} - \text{Mean Value of Strain}}{\text{Mean Value of Strain}}$						

CHAPTER 9. DISCUSSION

9.1 Summary of Important Findings from Present Study

The different bone plate attachment methods studied in this research all exhibited similar levels of axial compressive stiffness under the same fracture conditions. It was hypothesized that this may have been because the uppermost attachment point of the proximal portion of the bone plate was nearly identical in all cases with the exception of Construct 2 which exhibited a lower stiffness in the 1mm gap condition. In any event, the average stiffness of the femur construct decreased from 2502 N/mm, to 1803 N/mm, and to 801 N/mm as the femur went from being completely intact, to having a simple transverse fracture with a 1mm gap, and to having a simple transverse fracture with a 5mm gap respectively. This demonstrated the need to maintain the smallest practicable gap between fracture surfaces when installing the bone plate. While Constructs 1 and 3 exhibited the highest stiffness levels in the 1mm gap and 5mm gap cases, respectively, the results did not strongly favour one configuration over the others. More testing would likely be required to determine the statistical significance of the observed results.

In general, the FE model tended to under predict the strain values at strain gauge positions 1 through 5. This was shown in the slope of the best fit line from Table 8.3.5 which had values of 0.72 to 0.93. Recall that if the slope of the best fit line is less than zero, the model tended to under predict the observed results. The FE model, however, had a very strong correlation with the observed data as exhibited by R^2 values ranging from 0.96 to 1.00 (Table 8.3.5). This was an indication that although the FE model underestimated the strain values at the various positions by a constant amount that could likely be rectified by applying a correction factor. Thus, based on the observed results, the finite element model could be used to reliably predict the strain along the hip stem (Position 1), greater trochanter (Position 2), bone plate (Position 3 and 4) and the medial side of the femur below the lesser trochanter (Position 5) provided that an appropriate correction factor was applied.

One of the primary focuses of this research was to examine the effect of various bone plate attachment methods on the effect of stress shielding. The experiment was designed with the intent of observing the stress shielding effects on the proximal portion of the femur. In order to do so, the distal portions of the femurs were set up in the same manner for each construct. The distal end of the femurs were also potted and rigidly fixed during the experiment and the finite element analyses. As a result, the boundary conditions imposed on the distal end of the femur did not accurately mimic those occurring within a human body. Therefore, the strain gauge measurements from positions 7 and 8 were not of any particular interest to this study. If the strain in the distal portion were to become a particular interest to future

researchers more time must be spent to refine the finite element model. It may also become necessary to redesign the experiment so that more realistic forces are applied to the distal end of the femur.

9.2 Comparison of Present Experiments with Previous Studies on Fracture Fixation

Although intramedullary nailing has gained popularity among medical practitioners today, many researchers have proven bone plate fixation is a better method of fixation. Wingerter et al. conducted an in-vivo experiment on 10 rats identically prepared for a lateral resection of femoral shaft [97]. The rats were divided into 2 groups: one group of rats was treated by the intramedullary nailing and the other group was treated by the plate fixation method. After 4 weeks post-implantation, the rats with plate fixation showed much faster growth of new bone at both proximally and distally resected areas compared to the ones fixed with nailing. Cusick et al. compared 3 fixation methods, intramedullary nailing, condylar buttress plate, and condylar bone plate fixation with a lag screw, to treat the supracondylar fracture mimicked on 20 synthetic human femur samples [98]. Under bending stiffness testing performed in various orientations, the bone plate fixation with a lag screw showed the best results.

An increasing number of researchers have shown interest in implementing the allograft strut fixation to treat femur fracture. However, the allograft strut alone has not shown promising results. Dennis et al. used cadaveric human femurs to mimic periprosthetic femoral shaft fracture [99]. Six samples were fixed by the bone plate fixation, the other 6 samples were fixed with 2 allograft struts placed on the anterior and lateral cortices of the femur and fastened with cables. Under a cyclic axial compression loading, the bone plate fixation showed less than 2% reduction in overall rigidity whereas the allograft strut fixation showed a reduction in rigidity by nearly 12% [99]. Similarly, the bone plate fixation performed better in both lateral bending and torsion tests compared to the allograft strut fixation.

When bone plate fixation is combined with the allograft strut fixation, many researchers have observed significant improvement in load support and rotational deformity compared to the bone plate fixation alone [100-102]. Wilson et al. compared three different methods: the bone plate fixation, bone plate fixation combined with strut allograft and strut allograft fixation [102]. Based on an investigation conducted using 6 cadaveric femurs with supracondylar fracture, the bone plate combined with allograft strut minimized interfragmentary rotation [102]. Similarly, Talbot et al. compared the locking bone plate fixation, the non-locking bone plate fixation combined with medially placed allograft strut and the non-locking bone plate combined with intramedullary nailing fixation [100] (Figure 4.3). Their study found that non-locking plate fixation combined with allograft strut demonstrated the highest stiffness under

various loading conditions including axial compression, bending and torsion [100]. The bone plate fixation with an intramedullary nail resulted in an intermediate level of stiffness, the locking bone plate alone showed the least stiffness [100].

Figure 9.2 Three constructs designed by Talbot et al. for axial compression, bending and torsion tests [100]: (a) locking bone plate fixation, (b) non-locking bone plate fixation with intramedullary nailing, (c) non-locking bone plate fixation with allograft strut

Zdero et al. tested the benefits of adding an allograft strut to treat the femur fracture [101]. They tested 4 construct designs:

- a) the locking bone plate fixation with locking screws,
- b) the locking bone plate fixation with locking screws and cables,
- c) the non-locking bone plate with non-locking screws and cables, and
- d) the non-locking bone plate with a cadaveric femoral allograft strut, non-locking screws and cables.

Among these fixation methods, the combination of a non-locking plate with an allograft strut secured with screws and cables resulted in the highest stiffness [101]. In summary, it was commonly found that the implementation of an allograft strut to a non-locking plate provides a higher stiffness than the implantation of bone plate alone. It was also concluded that the use of locking plate provided no stronger support to the injured femur compared to the non-locking plate. In fact, the use of an allograft strut played a more important role in providing stronger support [100-102].

Many researchers have considered the periprosthetic femoral shaft fracture as the subject of their experimental studies [99, 101-104]. This reflects the clinical relevance of an increasing number of femoral shaft fractures that result from hip arthroplasty [15]. As discussed in Section 4.2.3, the bone plate fixation is the only option that allows the surgeons to fix the fractured femur around other implants such as hip stem.

The present axial stiffnesses of the 5 constructs for Level II (range, 966.4 - 1998.9 N/mm) overlapped with the periprosthetic femoral shaft fracture constructs used to repair the simple fractures of Zdero et al. (range, 1576 – 1925 N/mm) [101]. The present axial stiffnesses of the 5 constructs for Level III (range, 801.2 - 999.8 N/mm) were mostly lower than the periprosthetic femoral shaft fracture constructs used to repair the comminuted fractures of Zdero et al. (range, 951 – 1526 N/mm) [101], but overlapped substantially with those of Talbot et al. (range, 803 – 934 N/mm) [103].

9.3 Comparison of Present FEA with Previous Studies on Fracture Fixation

Finite element (FE) modeling has become a popular practice to design and develop new products and to improve existing applications. Compared to clinical research, FE modeling is inexpensive and can be done in a short period of time. It also provides consistency between different specimens, thus it is ideal for comparison studies where identical testing conditions are required for all specimens. Given detailed information of the material properties of the components, a relatively high level of accuracy and repeatability can be achieved from FE modeling. Other information such as accurate direction of the applied load, realistic stiffness behaviour of the components and reference temperature can improve the results even further to reflect the physical condition where the application is used.

Since intramedullary nailing has been the most popular method used to treat femur fractures, there have been many research studies conducted using the FE model to investigate the stress distribution within the nail and the femur. For example, Cheung et al. [78] used the Third Generation Composite Femurs implanted with an intramedullary nail to analyze the stress loading during walking gait. The surface strain values were measured during their experiment and then compared with the FE model. The FE model was used to predict the load sharing patterns between the implant and the femur as well as the areas of stress concentration while modifying the number of screws used in the implant. Using the FE model, they were also able to predict the load bearing capabilities of the nail when the material was changed from titanium to steel. Cheung et al. have not only verified that the experimental results were in

good agreement with the FE model, but they also demonstrated the versatility of the FE model in terms of evaluating different types of materials.

Wang et al. [105] used a FE model to investigate the stresses in the Gamma nail under different types of femur fracture. The Gamma nail is an implant used for the treatment of subtrochanteric femoral fractures [105]. It is a popular nail that is clinically proven to work [105]. Using the Gamma nail model, Wang et al. determined that the Gamma nail would permit higher stresses around screw holes when used for subtrochanteric fractures as opposed to the femoral neck fracture. Their study was also able to support the clinical argument of omitting one of the distal screws in simple fractures.

Chen et al. performed compressive and torsional experiments on synthetic femurs, one with a transverse fracture and the other with an oblique fracture, restored with a retrograde intramedullary nail [106]. FE models were then created to evaluate the results from the mechanical test with a focus on the stiffness variations in the areas around the screw holes. Based on the FE simulations, Chen et al. determined that the alteration of the boundary conditions does not affect the stiffness and stress values of the implant. Instead they determined that the stress values of the implant were most greatly affected by 1) the number of screws used at both proximal and distal ends of the nail, 2) the locations of the screws, 3) the material properties of the screws, and 4) the geometry of the screws.

As more advantages of the bone plate fixations have been recognized by clinical practitioners, many researchers have developed FE models of the fractured femur fixed with the bone plates. Cheal et al. [77, 79, 80] modeled a 3D intact plexiglass tube representing a long bone fixed with a 6-hole plate and screws. A transversely fractured tube model was also generated. The models were then loaded under a static tensile load with and without preloads to analyze the stress distribution of the compression plate fixation. The models were validated by measuring the surface strains of the plated tubes from the mechanical tests. With a higher mesh density with greater than 80% “relevance”, they were able to determine that the static tensile preload in the plate and screws would induce stress in the adjacent bone, and that the overall diameter of the bone upon full recovery would be reduced compare to the contralateral bone.

Papini et al. performed mechanical tests on synthetic femurs as well as 25 cadaveric femur specimens under various modes of loading including axial compression and torsion to validate the FE models of the synthetic femurs [72]. The FE model was calibrated with different Young's Moduli to mimic a range of cadaveric femurs' bone quality. Using FE, the composite femurs of 2 different sizes were modeled. This test examined the effect of a change in bone size. The researchers concluded that the smaller femur was less rigid than the larger femur for the same elastic modulus. Comparing the results from the cadaveric femurs with the results from the synthetic femurs, it was concluded that the synthetic femurs were

representative of the healthy bone with good quality bone stock, thus it would provide an upper bound. The value of elastic modulus could be calibrated to simulate osteoporotic femur which provided a lower bound. Nevertheless, the FE model provided a good estimation of the behavior of human femurs subjected to axial compression and torsion.

Mihalko et al. developed the two-dimensional finite element models of fractured periprosthetic femur fixed by 3 different methods: a revision long stem prosthesis, a lateral plate combined with allograft strut secured by cables, and a custom plate with 5 proximal cables [107]. It was noted that the cables were simplified and modeled as 2 truss-shaped components such that the supportive forces were located only in the axial direction [107]. The plate model combined with allograft showed stress transfer near the proximal end of the femur and that the highest tensile stress occurred at the mid-shaft fracture site. They were able to confirm that the stress shielding effect was greater at the proximal femur segment compared to the distal femur segment. The model revised with a long prosthesis showed an increase of stress shielding around the site of fracture and that the transfer of stress occurred more distally as the length of the stem increased.

In order to reduce the stress shielding effect of the bone plate, many recent studies have investigated the possibility of using a composite bone plate with low elastic modulus compared to the metal plates. Veerabagu et al. [81] produced a FE model of a diaphyseal long bone fixed with a braided carbon-epoxy composite plate. The FE model used a 4-point bending test conducted within the orthotropic linear elastic region. The authors found that the longitudinal strain was increased in both the bone and bone plate when a composite plate was used instead of metal. Since a higher strain is beneficial for the bone growth, the composite plate demonstrated a promising potential for further research and development

Beaupre et al. used an FE model to study the influence of the factors related to the bone plate such as screw tightness, sliding friction, and magnitude of load [108]. The FE model was employed with frictional interface elements between the bone plate and the bone while the screw head was separated from the surrounding surfaces such that it would not participate in any stress loading. The authors concluded that the factors contributing to the stress shielding effect were the material properties of the bone plate as well as the placement of the plate, rather than the amount of slippage between the plate and the bone.

While most of these studies used the intramedullary nailing as the femoral fracture fixation method, Mihalko et al. modeled the bone plate fixation that was relatively similar to the present study. However, Mihalko et al. stated no measured values of axial stiffness or strain. Thus no direct comparison of the results was possible.

9.4 Inter-comparison of Five Constructs

The stiffness of Construct 4 under Level II (1mm gap) condition measured during the experiment was about half of that for Construct 5 despite the fact that both were attached to the proximal portion of the femur using 2 unicortical screws and 2 cables. In fact, only the location of the bottom most screw and cable were different between the 2 configurations. Based on the relatively minor difference in configuration, such a large difference in the measured strain was questionable. Furthermore, the finite element analysis predicted the stiffness of Constructs 1, 2, 3 and 5 within 10% of their observed stiffnesses, but overestimated the observed stiffness of Construct 4 by about 96%.

Since the femoral ball was only displaced by 2mm in the axial compression tests, the fracture surfaces (initially 5mm apart) never touched one another during the Level III tests. In this case, 100% of the applied load was carried across the gap by the bone plate. The large lateral distance between the femoral ball and the bone plate led to a relatively large bending moment being applied to the plate. Thus, the stiffness of the Level III axial tests was generally limited by the resistance of the bone plate to bending.

Since the distal end of the plate was attached in an identical manner for all the constructs, the bending moment applied to the bone plate was only affected by the method of attachment used for the proximal portion of the plate. The method used to attach the topmost portion of the bone plate to the proximal side of the femur likely had the greatest effect on the bending load applied to the plate. Since most of the constructs used the identical methods to attach the uppermost portion of the bone plate to the femur (one unicortical screw and one wire), the stiffnesses of all structures were expected to be approximately the same in response to axial loading at the Level III condition. This was reflected in the results in which the experimentally measured stiffness of all constructs except for Construct 3 were within about 9% of the average measured stiffness. Unlike the other configurations, Construct 3 was attached at the proximalmost position of the plate using only the wire (no unicortical screw). This type of connection was less rigid when compared to the other constructs, and therefore transferred a smaller bending moment being applied to the bone plate. In turn, this led to the stiffness of Construct 3 being about 18% higher than that of the other constructs.

9.5 Clinical and Biomechanical Implications

9.5.1 Strain Distribution Due to Geometrical Characteristic of Femur

In this study, the strain values were measured while applying an axial compression at the tip of the femoral ball. Remembering the femur was similar to an inversed L-shape, the load was applied away from the femoral shaft. As a result, the applied force was delivered to the femur-plate system as a combination of axial compression and bending. In other words, the strains at Position 1, 2, 3 and 4 were expected to be in tension since they were located on the lateral surface whereas the strains at Position 5, 6, 7 and 8 were expected to be in compression since they were located on the medial surface. However, the femur-plate systems were placed at a 15° angle during tests to mimic the adduction of the femur at double leg stance. This leads to a transition in the femoral shaft from tension to compression and vice versa, starting at about the point where the line of action of the applied axial force vector intersects with the femoral shaft axis. Assuming the transition occurs at the mid-shaft, the strain at Position 3 was expected to remain in tension while the strain at Position 4 would be in compression. Similarly, the strains at Positions 5 and 6 were expected to remain in compression while the strains at Positions 7 and 8 would now be in tension. Such expectation in the strain pattern was accurately matched with the results from both experimental and finite element analysis.

9.5.2 Selection Based on Compressive Stiffness

Based on the results of the experimental study, the stiffnesses of all constructs were generally similar. In other words, the various bone plate attachment methods studied did not have a large affect on the stiffness of the system. It was possible that the discrepancies that were observed in the results could have been caused by unintended differences in the individual test setups such as different screw torques, differences in the simulated fracture surface and/or geometric differences caused while using the plate bender. In the future, more tests are required to determine whether the relatively small differences observed in this current study are statistically significant.

Based on the observed data only, Construct 1 had the highest stiffness under the fracture with 1mm gap (Level II) conditions while Construct 3 had the highest stiffness under the 5mm gap (Level III) conditions. That being said, all of the constructs exhibited similar stiffness values under axial compressive loading and therefore one configuration could easily be substituted for another without greatly sacrificing stiffness or rigidity.

9.5.3 Selection Based on Stress Shielding

In order to promote healthy bone density and minimize porosity, the femur must be subjected to compressive loading. As previously mentioned, bone plates commonly handle too much of the applied loads thereby reducing the compressive loads transferred through sections of the bone itself.

The experimental study made use of strain gauges located on the medial side of the femur below the lesser trochanter in order to evaluate which fixation method transferred the maximum amount of compressive stress through the bone rather than the plate. The experimental results from the most proximal sensor (Position 5) were validated through an FE analysis of the structure. The measured results from the sensor closest to the fracture surface (Position 6), however, could not be independently verified through the FE model. Nevertheless, the results measured at gauge position 5 were similar to those measured at gauge position 6, therefore deemed to be valid if only in a relative sense.

Based on the measured strain values at gauge positions 5 and 6, Construct 3 provided the maximum level of stress transfer and therefore the lowest level of stress shielding. However, recall that if cables are used as an exclusive attachment method, the healing bone will have a high risk of rotational deformity and poor alignment.

9.6 Sources of Error and Limitation

The Level II configuration was intended to test the situation where the 2 fracture surfaces were held with 1mm gap. If the gap between the fracture surfaces was large enough then the pre-load might not have been high enough to completely close the gap prior to the loading. In this case, the initial load application would have simply been used to close the gap rather than loading the specimen. Given the relatively high consistency between the finite element analysis and the experimental results for the other constructs, the experimental results for Construct 4 appear to be erroneous. If Construct 4 had a larger than average gap between the fracture surfaces, or if the surfaces were restricted from achieving close contact due to geometric constraints, then the stiffness measured during the experiment would be lower than an idealized theoretical case.

A limited amount of slippage at the femoral ball was also observed during some of the trials. Although the force-displacement curve was analyzed to check for the force inconsistencies and slippage, a minor to moderate level of slippage might have occurred without detection. Depending on the extent of the slippage, this would have caused underreporting in the measured stiffness in the affected test. This could

also have been a factor in the apparent underreporting of the experimentally measured stiffness of Construct 4 in Level II condition.

During the preparation of the specimens, the screws and cables were applied to the femur through the bone plate by subjective “feel”, as done typically by surgeons during operation. This resulted in some screws inserted in the femur at an angle, and slightly different tensions applied to the cables. Such variations in installation of the screws and cables might have caused variation between specimens. Some specimens might have been less restricted by the bone plate fixation whereas others might have been more tightly restricted by the bone plate. In turn, this could have affected the stiffness and strain measurements made experimentally.

The error associated with FE results would be likely related to problems encountered in modeling the cable connections used to attach the proximal portion of the femur to the bone plate. The cables were modeled as a solid without incorporating its tension characteristics. If a model can be created to better simulate the interaction between the cables, the calculated strain values would likely be reduced as well. The anchoring block was modeled as a cement block instead of a steel chamber filled with cement which was how it was prepared in the experiment. If the model were to be modeled with a steel chamber filled with cement at the distal end of the femur, the strain values of the femurs would be reduced due to stiffer support provided by the steel chamber which would allow less bending near distal end.

The bonding of the strain gauges carried a few challenges. The strain gauges were fragile, thus extremely careful handling was required while peeling from the package and bonding on to the femoral surfaces. Bonding the strain gauges was difficult when it was positioned close to the bone plate, screws and cables. The gauges bonded near stress risers such as bicortical screws in the distal femurs could prevent accurate measurements.

The human femur consists of 2 main structures, cortical and cancellous bone. According to Reily et al., the cortical bone possesses transverse isotropic properties [86]. Many other researchers have found that cancellous bone has orthotropically symmetric structures [109-112]. However, Cristofolini et al. have observed that when artificial composite femurs were assessed using various mechanical tests including axial loading, 4 point bending and torsion, their results fell well within the range for that of human cadaveric specimens [113]. In fact, the variability between different composite femurs was reduced by 20-200 times compared to the cadaveric specimens [113]. For that reason, composite femurs have provided better consistency in many previous studies [72, 82-85].

The purpose of this study was to examine the properties of different bone plate fixation methods. As a result, it is desirable for the mechanical properties of the bones used in this study to possess as little variance as possible. This allows the properties of the individual bone samples to be eliminated as an independent variable when examining the stress shielding effects. Therefore, this study used composite femurs which could be manufactured with consistent mechanical properties and dimensions under controlled tolerances. In contrast, cadaveric specimens would have had a large variation in mechanical properties and dimensional structures [72, 100, 103].

This study considered only the static load scenario. In reality, the femurs experience cyclic dynamic load, thus one may argue that the dynamic loading would be more clinically relevant. However, the goal of this study was to establish an initial investigation on the effect of varying the methods of the bone plate fixation applied to the femur rather than to achieve absolute measurements.

Destructive load-to-failure tests were beyond the present study's scope. However, the stiffness, strain, and stress results of the 5 constructs were similar in range to those of prior experimental and finite element studies. Thus, it would be expected that load-to-failure results of the current repair constructs would likely also have been in a similar range to those measured by other investigators like Talbot et al. [103] and Zdero et al [101].

9.7 Future Work

This study shall be extended in the future by increasing the number of specimens. In this study, each specimen was fixed with different plate attachment methods. Thus the results from this study would be difficult to be generalized and used as an absolute measure. By increasing the number of specimens, the results will allow for statistical comparisons.

Another suggestion is to use cadaveric femurs in mechanical tests. As discussed earlier, the synthetic femurs are isotropic in their cortical bone while the cadaveric femurs are anisotropic. Although the synthetic femurs provide a good representation of the human femur, their characteristics cannot be replicated perfectly.

Lastly, further research is recommended to involve a composite bone plate. A composite bone plate can be fabricated to sustain an appropriate amount of stiffness that can be matched to that of bone. With composite materials it is possible to produce an absorbable or degradable bone plate such that the implant

becomes highly biocompatible. The degradable bone plate is also beneficial since no second operation is required for the sole purpose of the plate removal which may involve additional pain and risk [8].

CHAPTER 10. CONCLUSIONS

Based on the observed strain measurements taken on the proximal side of the fracture, the highest compressive strain was achieved when the proximal femur was attached to the bone plate using cables only. Thus, the stress shielding could be reduced by using cables rather than screws to attach the bone plate to the femur. While this configuration performed well under laboratory conditions, the femur has a higher probability of moving relative to the bone plate when cables are used as the exclusive attachment method. This can have the ill effect of causing deformities and can also lead to poor alignment of the fracture surfaces.

The finite element model developed in this study was able to match the stiffness results of the experiments within about 10% for the 1mm gap fracture case. The finite element model was less reliable when used to predict the stiffness values in the 5mm gap fracture case.

The finite element model had a tendency to underestimate the strain values from positions 1 through 5. The correlation between the finite element results and the observed measurements was, however, quite strong. Therefore, by identifying an appropriate scaling factor, the results of the finite element program could be used to accurately predict the strain experienced along the hip stem, greater trochanter, bone plate and the medial side of the femur below the lesser trochanter. The finite element model was not able to accurately predict the tensile strain experienced along the medial surface of the distal femur.

Based on the experimental results, attaching the proximal end of the femur to the bone plate using only cables resulted in the least amount of stress shielding while maintaining a similar level of stiffness compared to the other configurations. While this configuration appeared to be the best under laboratory conditions, further research would likely be required to determine this construct's ability to maintain proper alignment of the bone segments given the absence of locking screws.

APPENDIX A List of Components Used in Experimental Study

Table A.1 List of materials used in the experimental study

Materials		Description	Qty
Composite Femur		Large Left Fourth Generation Composite Femur (Model #: 3406), Sawbones Worldwide, a division of Pacific Research Laboratories, Vashon, WA, USA	5
Bone Plate		Cable-Ready Grip System (Ref #: 401-055): non-locking, 8-hole plate, Zimmer Inc., Warsaw, IN, USA	5
Screw	Unicortical	4.5mm Cortex Screw 14mm (Product #: 214.014): 4.5mm in diameter, 14mm in length, Synthes Inc., West Chester, PA, USA	12
	Bicortical	4.5mm Cortex Screw 50mm (Product #: 214.050): 4.5mm in diameter, 50mm in length, Synthes Inc., West Chester, PA, USA	20
Cable		Synthes Cable; 1.8mm diameter, Stryker Howmedica Osteonics, Mahwah, NJ, USA	14
Hip Stem		No.2 – 37.5mm Offset Stem (Product #: 0580-0-372): Exeter Femoral Stem with Orthinox Head, Stryker Howmedica Osteonics, Mahwah, NJ, USA	5
Bone Cement		Surgical Simplex P Radiopaque Bone Cement (Product #: CEI121), Stryker Howmedica Osteonics, Mahwah, NJ, USA	5
Strain Gauge		General Purpose Strain Gages – Linear Pattern (Model #: CEA-06-125UW-350), Vishay Intertechnology, Inc., Malvern, PA, USA	40

APPENDIX B Angle of Femoral Head Removal

The femoral heads were removed for the hip stem implantation to produce the periprosthetic femurs. The angle of removal was approximately 35° with respect to the femoral shaft. More accurate angles of resection was measured for each specimen as shown below.

	Construct Number				
	1	2	3	4	5
Θ	34.3°	36.0°	37.1°	36.0°	37.1°

Figure B.1 Measured angle of femoral head removal for hip stem implantation

APPENDIX C Correlation Coefficient between Experimental and Finite Element Study

The values of strain were measured while applying an axial compression of 1000N to the tip of femoral ball. The femurs were placed with 15° adduction to simulate the double leg stance. The normal strain criteria was used in the finite element model to measure the strain values.

C.1 Level II Constructs

C.1.1 Construct 1

Table C.1.1 Collected Strain Values for Construct 1 (Level II)

		Strain ($\mu\epsilon$)	
Strain Gauge Position		Experimental Study	FE Model
Top	1	452.4	416.6
	2	2.9	9.1
Middle	3	53.8	53.0
	5	-499.8	-395.0
	6	-479.1	-386.3
Bottom	4	-66.4	-68.1
	7	-5.6	231.1
	8	128.2	586.4

Figure C.1.1 Correlation coefficient graphed for Construct 1 (Level II)

C.1.2 Construct 2

Table C.1.2 Collected Strain Values for Construct 2 (Level II)

		Strain ($\mu\epsilon$)	
Strain Gauge Position		Experimental Study	FE Model
Top	1	482.3	448.4
	2	40.7	19.0
Middle	3	24.2	25.7
	5	-425.7	-396.1
	6	-476.8	-404.1
Bottom	4	-125.3	-110.0
	7	114.0	233.9
	8	360.3	620.5

Figure C.1.2 Correlation coefficient graphed for Construct 2 (Level II)

C.1.3 Construct 3

Table C.1.3 Collected Strain Values for Construct 3 (Level II)

		Strain ($\mu\epsilon$)	
Strain Gauge Position		Experimental Study	FE Model
Top	1	486.0	414.4
	2	43.4	11.1
Middle	3	32.6	36.7
	5	-639.0	-409.7
	6	-674.5	-424.1
Bottom	4	-38.6	-66.1
	7	-110.2	302.9
	8	53.9	659.0

Figure C.1.3 Correlation coefficient graphed for Construct 3 (Level II)

C.1.4 Construct 4

Table C.1.4 Collected Strain Values for Construct 4 (Level II)

		Strain ($\mu\epsilon$)	
Strain Gauge Position		Experimental Study	FE Model
Top	1	485.6	424.1
	2	35.7	19.6
Middle	3	43.4	49.6
	5	-507.3	-405.1
	6	-502.9	-413.0
Bottom	4	-125.5	-99.1
	7	234.2	253.2
	8	436.1	638.8

Figure C.1.4 Correlation coefficient graphed for Construct 4 (Level II)

C.1.5 Construct 5

Table C.1.5 Collected Strain Values for Construct 5 (Level II)

		Strain ($\mu\epsilon$)	
Strain Gauge Position		Experimental Study	FE Model
Top	1	464.5	460.5
	2	15.4	14.3
Middle	3	52.2	45.3
	5	-490.1	-414.4
	6	-421.9	-416.3
Bottom	4	-44.9	-10.2
	7	-37.4	29.8
	8	80.6	73.0

Figure C.1.5 Correlation coefficient graphed for Construct 5 (Level II)

C.2 Level III Constructs

C.2.1 Construct 1

Table C.2.1 Collected Strain Values for Construct 1 (Level III)

		Strain ($\mu\epsilon$)	
Strain Gauge Position		Experimental Study	FE Model
Top	1	422.9	411.8
	2	2.9	8.4
Middle	3	24.2	46.1
	5	-432.6	-373.8
	6	-442.8	-380.7
Bottom	4	1.2	-102.2
	7	227.8	231.5
	8	433.8	637.2

Figure C.2.1 Correlation coefficient graphed for Construct 1 (Level III)

C.2.2 Construct 2

Table C.2.2 Collected Strain Values for Construct 2 (Level III)

		Strain ($\mu\epsilon$)	
Strain Gauge Position		Experimental Study	FE Model
Top	1	487.0	453.3
	2	38.4	34.1
Middle	3	19.8	20.1
	5	-425.7	-363.7
	6	-482.2	-426.1
Bottom	4	-130.3	-139.9
	7	164.9	185.3
	8	416.9	465.8

Figure C.2.2 Correlation coefficient graphed for Construct 2 (Level III)

C.2.3 Construct 3

Table C.2.3 Collected Strain Values for Construct 3 (Level III)

		Strain ($\mu\epsilon$)	
Strain Gauge Position		Experimental Study	FE Model
Top	1	436.1	412.1
	2	38.2	11.4
Middle	3	11.9	69.3
	5	-505.2	-417.1
	6	-520.0	-489.7
Bottom	4	-126.3	-94.8
	7	124.2	290.4
	8	411.0	721.3

Figure C.2.3 Correlation coefficient graphed for Construct 3 (Level III)

C.2.4 Construct 4

Table C.2.4 Collected Strain Values for Construct 4 (Level III)

		Strain ($\mu\epsilon$)	
Strain Gauge Position		Experimental Study	FE Model
Top	1	464.5	413.0
	2	47.6	40.8
Middle	3	24.6	-31.1
	5	-487.0	-335.1
	6	-514.0	-395.6
Bottom	4	-130.9	-116.6
	7	256.2	281.1
	8	487.5	763.6

Figure C.2.4 Correlation coefficient graphed for Construct 4 (Level III)

C.2.5 Construct 5

Table C.2.5 Collected Strain Values for Construct 5 (Level III)

		Strain ($\mu\epsilon$)	
Strain Gauge Position		Experimental Study	FE Model
Top	1	429.6	414.4
	2	17.1	15.9
Middle	3	-4.6	17.2
	5	-477.2	-416.4
	6	-452.2	-429.2
Bottom	4	-139.7	-126.3
	7	349.9	329.7
	8	612.1	661.4

Figure C.2.5 Correlation coefficient graphed for Construct 5 (Level III)

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