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Biomechanics Analysis of Anterior Cortical Perforation in Antegrade Femoral Nailing

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Abstract

Hip and femur fractures are a common problem in an aging population. Cephalomedullary fixation is a common method of treating hip and femur fractures, with a known complication of anterior cortical perforation of the distal femur. The literature describes risk factors, such as the influence of the start point at the greater trochanter, but there is no consensus on management. Some cases are treated with restricted weightbearing and other cases with revision surgery. Restricted weightbearing increases perioperative complications including mortality and decreases functional outcomes.

We analyze the effect of an anterior, neutral, and posterior start point on the axial, bending, and torsional stiffness of the femur. We also analyze the proximal and distal stresses of the femur when loaded in axial stiffness. We compare a femur with an anterior cortical perforation of the distal femur with a femur without perforation.

The posterior start point has increased sagittal stiffness compared to the neutral and anterior start points. There is no difference in axial, coronal bending, or torsional stiffness, or proximal or distal stresses. Between a femur with a posterior start point with perforation or without perforation, there is no difference in axial, bending, or torsional stiffness or proximal or distal stresses.

A case report is presented of an 89-year-old woman with a basicervical fracture who underwent cephalomedullary nail fixation and suffered an anterior cortical perforation of the distal femur. Her weightbearing was not restricted postoperatively and she was ambulating at 6 weeks. She did not fracture at the perforation.

Keywords

Anterior cortical perforation of distal femur, cephalomedullary nail, start point

Summary for Lay Audience

Femur and hip fractures are a common problem in an aging population such as Canada. Allowing patients to move soon after surgery is an important goal of the care of hip fracture patients. The choice of surgery for hip fractures depends on the pattern of the fracture. One of the options involves a rod going into the main portion of the femur and a screw going into the head of the femur. This is called a cephalomedullary nail.

The positioning of each of the components of the cephalomedullary nail is critical to the success of the surgery. One complication of the the surgery is having the tip of the nail break through the front wall of the femur. The average femur has a curve, which may be more curved than many nails. Depending on the position of the nail, the risk of perforation caused by the tip breaking through the front wall may increase.

The studies currently published describe many examples of perforation, but there is no agreement on how to treat this problem. Options include revision surgery or not allowing patients to place weight through their operative leg, but this is associated with poor outcomes.

Our thesis shows that the perforation does not significantly weaken the femur, with no difference between the strengths of the femurs. A femur that is 35% weaker has been shown to have an increased risk of fracture. This means that patients with a perforation of the front of their femur may be allowed to place weight through their operative leg.

We present a case report of an 89-year-old female suffering a hip fracture that was treated with a long cephalomedullary nail. An anterior cortical perforation of the distal femur was noted intraoperatively and managed successfully without weightbearing restrictions or revision surgery.

Co-Authorship Statement

Chapter 1	Michael Ching – Sole author
Chapter 2	Michael Ching – Study design, data collection, statistical analysis, manuscript preparation
	David Sanders – Study design
	Aaron Gee – Data collection
	Radovan Zdero – Study design, data collection, statistical analysis, manuscript preparation
Chapter 3	Michael Ching – Sole author
Chapter 4	Michael Ching – Sole author

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Chapter 1: Literature Review

1 Introduction

Hip fractures are a common problem in an aging population with projected numbers of hip fractures on the rise. A common method of treatment of certain hip fractures is cephalomedullary nail fixation. A rare but recognized complication of this procedure is anterior cortical perforation of the distal femur. There is no consensus in the literature on management of anterior cortical perforation. Current strategies include prolonged non weightbearing or revision surgery, both of which have negative consequences for the patient. This thesis aims to determine the effect of an anterior cortical perforation in the distal femur due to cephalomedullary nailing. This chapter will outline the relevant literature.

1.1 Anatomy and Physiology

1.1.1 Osteology

Bone is a natural composite material with complex organisation. The outer dense layer of bone is called cortical bone, and the inner spongy bone is called trabecular bone. A network of canals called Haversian canals penetrates the bone to accommodate blood vessels and provide nutrients. Osteocytes live within channels called canaliculi. Osteoblasts work to form new bone while osteoclasts work to turnover old bone.[1] Bone geometry adapts to physical loading, with decreased bone density shown in astronauts and patients subjected to bedrest following illness or injury.[2]

The femur is the largest bone in the human body, reaching adult dimensions around age 15.[2] The shape of the femur continues to change with age but not significantly after age 30.[2,3] Proximally, the femur is comprised of the femoral head and neck and the greater and lesser trochanters. The greater trochanter serves as the attachment site for the external rotators of the hip. There is a variable anatomy to the greater trochanter with respect to the piriformis fossa.[4] The greater trochanter is generally the point of impact in a sideways fall, which renders the femoral neck vulnerable to fractures.[2] The femoral head and neck are predominantly composed of trabecular bone.[2]

The shaft of the femur runs from the lesser trochanter to the metaphyseal flare of the distal femur. The femoral shaft is predominantly cortical bone.[2] The average femoral shaft is significantly wider in the sagittal plane compared to the coronal plane.[3] Thickness of the anterior cortex ranges from 2.2 to 7.0mm.[5] On the sagittal plane, there is an anterior bow to the femur. This anterior bow has recently been recognized as a factor in anterior cortical penetration of the distal femur.

Different measurements have been proposed for measurement of the anterior bow of the femur. The most commonly used is the radius of curvature of the femur. There has been a wide range of radius of curvatures reported in the literature. Published values include 72cm by Harma, 76cm by Karakas, 89cm by Schmutz, 96cm by Lakati, 102cm by Su, 104cm by Maehara, 109cm by Johnson and Tencer, 114cm by Harper, 120cm by Egol, 138cm by Gonzalez, and 144cm by Harper and Carson.[6-13] Some studies have differentiated between the radius of curvature for the medullary canal, and the radius of curvature for the anterior cortex. Buford found no difference between these two radii of curvature, but the largest published study of 3922 femurs measures a medullary radius of curvature of 112cm and an anterior cortical radius of curvature of 145cm.[5,14] Other measurements include a tangential angle between the proximal shaft and the distal shaft. With this measurement, mean anterior bowing is 15.43 ± 4.78 degrees.[3]

Although there is a wide range of means reported in the literature, the range for individual femurs may be even greater. Lakati reports a range of radius of curvature from 52cm to 165cm.[10] Harper reports a range from 69cm to 189cm, and Harma reports a range from 11cm to 167cm.[7,8] The range of radius of curvature in 426 Chinese femurs as measured by Su was 62cm to 203cm.[12] It is clinically relevant that such a wide range exists for anterior bowing of the femur. Implants have been designed for certain populations, such as the Asian version of the Proximal Femoral Nail Antirotation (PFNA-II).[15] While these implants may be better suited for a population group as a whole, there will always be a small subset of femurs that are more bowed than the mean. These patients may be at considerable risk of anterior cortical perforation regardless of the implant used.

Attempts have been made to identify factors affecting the anterior bow of the femur with no clear consensus. Anterior bowing has been shown in some studies to increase in women up until the age of 55 years.[7,9] Schmutz reports that height, age, ethnicity, and gender all significantly predicted the radius of curvature ($p = 0.000$).[13] Other studies have found no correlation between gender, age, or femoral curve.[16] The role of ethnicity is unclear. Egol found a lower radius of curvature for black femurs compared to white femurs ($p < 0.001$).[6] Schmutz reports a lower radius of curvature of 79cm for Asian femurs compared to 97cm in Caucasian femurs.[13] In the largest study of anterior bowing, Maratt analyzed 3922 femurs and found that only the length of the femur correlated with the radius of curvature ($p < 0.001$), which has also been independently reported by Su. They propose that any differences due to ethnicity may be accounted for due to the difference in average height, and therefore, average femoral length.[12,14]

The literature has also reported a difference in anterior bowing between different locations of the femur divided by the proximal third, middle third, and distal third of the femur. In a Chinese population, the distal third of the femur was significant more bowed with a radius of curvature of 72cm compared to 93cm for the middle third and 108cm for the proximal third ($p < 0.001$). This distal bow was more pronounced in shorter femurs.[17] This difference in the bowing when comparing the proximal, middle, and distal thirds of the femur was also highlighted in a CT study of Japanese femurs.[16] The significance of this difference is that the focally increased bowing of the distal femur may add to the risk of anterior cortical perforation.

1.1.2 Musculature

Several muscles attached to the femur are involved in movement of the hip, femur, and knee. Hip flexion is predominantly performed by the iliopsoas, which has a combined tendon that attaches to the lesser trochanter. Attachments to the greater trochanter allow for abduction and external rotation, and include the gluteus medius, gluteus minimus, piriformis, superior and inferior gemelli, obturators internus and externus, and the quadratus femoris. Originating from the anterior surface of the femur and involved in knee extension are the vastus lateralis, intermedius, and medialis. The articularis genu arises from the distal anterior surface of the femur and attaches to the bursa of the knee joint. Muscles that insert on the posterior aspect of the femur include the adductor magnus, longus, and brevis. The biceps femoris, gastrocnemius muscles, and the plantaris originate from the posterior aspect of the femur and are involved in knee flexion.

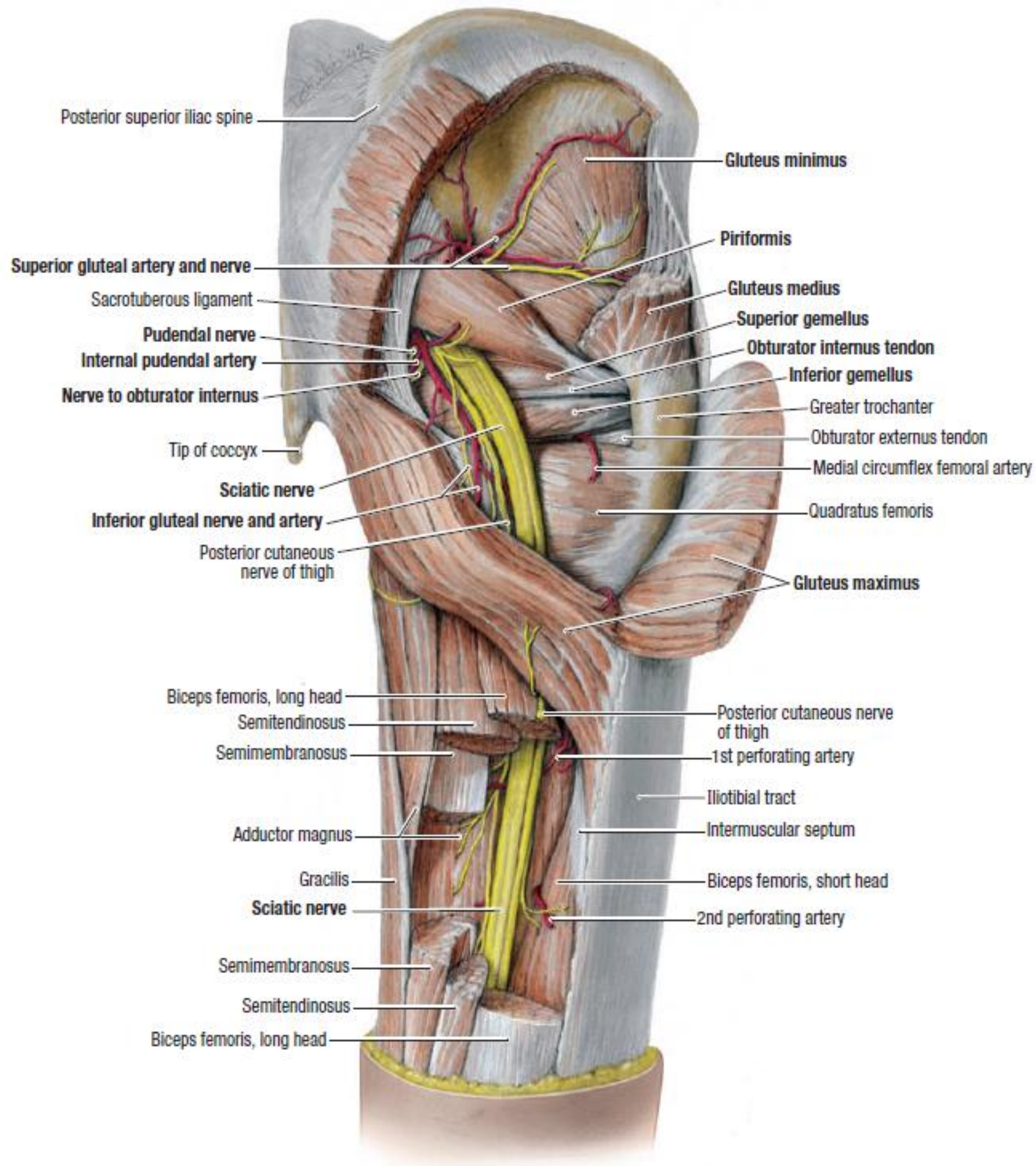

Figure 1.1. Anatomy of the gluteal muscles. (Grant's Atlas of Anatomy, 13th Ed.)

1.1.3 Forces and Mechanics

Many forces act on the femur. Weight bearing provides a primarily compressive force along the length of the femur.[18] Due to the anteromedial position of the head relative to the shaft, weight bearing also causes a bending and torsional moment. Soft tissues minimize this bending, yet there is still a constant tensile force on the lateral femur.[19]

Many studies have analyzed the different forces on the femur at different times of the gait cycle.

Gait can be broadly classified into the stance phase and the swing phase. Loads are always significantly higher during stance phase than during swing phase.[20] There are two peak forces during the stance phase, at early stance and at late stance.[21] The amplitude of these peaks correlates with walking speed and stride length.[22] The compressive force through the femur has been measured to be between 1.5-3.7 body weights during walking.[19,23] In running, this can increase up to 12 times body weight.[22,24] Conversely, a reduced walking speed decreases the forces through the femur.[25] Descending stairs produces forces of 2.8 body weights.[26] Torsional forces are increased with anterior loading such as stair climbing, reaching 2.2% of body weight.[19] During walking the torsional forces are small and constant along the femoral shaft.[27] Walking aids such as crutches and canes have been measured to decrease joint load during partial weightbearing, but rarely below 60-65% body weight.[19]

Muscle groups about the hip and femur have a significant role on distributing forces. In finite element models comparing strains with and without muscle, the exclusion of muscles from the analyses led to 50% higher strains in the proximal femur.[27,28]

Fractures occur when forces overcome the strength of bone.[29] The location of the fracture is determined by the position and direction of an applied force. For instance, peak stresses occur in the subcapital region during one-legged stance, but peak stresses are located in the intertrochanteric region during a simulated fall.[30] The initial yielding of a fracture involves micro-structural damage at the level of individual trabeculae.[31] Many models have shown that fractures start on the tensile surface of bone. [25,32-34] This may be partially explained by force analyses showing that the mean tensile strength of bone is roughly 70% of the mean compressive strength.[31] In the shaft of the femur, the tensile forces are located on the lateral cortex.[25,35] Peak compressive strengths are medial. The anterior femur is subjected to peak tensile loads during stair ascent, squatting, and when sitting and rising from a chair.[25]

Analyses of forces in a femur with an antegrade intramedullary nail show that the forces through the nail were relatively constant throughout the nail during all phases of gait, and that the axial compression force was one magnitude greater than shear forces through the nail.[20]

1.2 Hip Fractures

1.2.1 Osteoporosis

Osteoporosis is a bone disease defined by the World Health Organization as a bone mineral density at the hip or at the spine of at least 2.5 standard deviations below the mean peak bone mass of young healthy adults. Bone density is measured by dual-energy X-ray absorptiometry.[36] The decreased bone mass leads to alterations in the microarchitecture of bone resulting in fragility and an increased risk of fractures.[36] Prevalence worldwide is increasing. Many risk factors have been identified including age, metabolic or endocrine disorders, and lifestyle factors.[36] It is commonly a disease of postmenopausal women.[2]

The underlying cause of osteoporosis is an imbalance between bone resorption and formation, where bone resorption by osteoclasts outpaces formation.[36] Cortical thinning caused by bone resorption is compensated by periosteal apposition through many sites of the body resulting in expansion of the radius of long bones. This does not occur in the femoral neck as it is an intracapsular structure with no periosteum. Therefore, femoral neck fractures increase in incidence with osteoporosis and aging.[37]

1.2.2 Fragility Fractures

Fragility fractures are fractures at common sites frequently associated with osteoporosis. Classically fragility fractures were thought to be fractures of the thoracolumbar spine, proximal humerus, proximal femur, and distal radius. Recent evidence suggests that 14 different fractures should be considered potentially osteoporotic fractures. This includes the proximal femur, pelvis, femoral diaphysis, proximal humerus, distal femur, patella, distal humerus, distal radius, humeral diaphysis, scapula, proximal tibia, ankle, proximal forearm, and the spine.[38] 30% of fractures in men, 66% of fractures in women, and 70% of inpatient fractures are potentially osteoporotic.[38] Analyses of hip fractures forces show that the force from a fall from standing height exceeds the femoral strength of an older individual on average by 50%.[39]

Bone mineral density alone is not predictive of fracture risk, but is one of many factors, including risk of falls, force at impact, and location of impact.[2,39-41] Previous fracture is a risk factor for future fracture with a relative risk of 1.86.[42] The mortality rate of fractures associated with osteoporosis ranges from 15-30%, a rate similar to breast cancer and stroke.[36] Osteoporosis also carries a significant morbidity as 50% of women with osteoporotic hip fractures develop disability which may lead to institutionalization.[36]

1.2.3 Demographics

The prevalence of hip fractures increases with age. Ninety percent of hip fractures occur in patients over 70 years of age, and more than ninety percent of hip fractures in this population is due to a simple fall from standing height.[39]

In Canada, the mean age of patients sustaining a hip fracture has been increasing.[43] In the 1960s, the mean age of hip fracture was 73 years.[44] By the 1981, the mean age was 78 years, and in 1992, the mean age was 80 years ($p < 0.001$).[45] Over a five-year study period, there were 2,150 hip fractures in one Canadian city of 350,000 people, resulting in an annual incidence of 12 hip fractures per 10,000 people.[46] This number increases to 33 per 10,000 of patients over the age of 50.[45] The fracture risk is similar across provinces, and the hip fracture rates in Canada are lower than that of other countries, such as the United State of America, Germany, and the United Kingdom.[47,48] Age-specific analyses has shown that the age-specific hip fracture rate has decreased over a twenty-year period ($p < 0.001$). For women, there has been a 31.8% decrease in hip fracture rates. The hip fracture rate also decreased in men by 25%.[43] However, women are two and a half times as likely as men to experience a hip fracture.[49]

There will be a projected 88,124 hip fractures annually in Canada by 2041.[49] Cost analyses including hospitalization, rehabilitation, chronic care, home care, and information care estimates a mean 1 year cost of hip fracture of 26,527 Canadian dollars.[50] Costs are significantly lower for patients returning the community ($21,385) versus those who are transferred to long term care facilities ($44,156) or readmitted to long term care facilities following their hip fracture ($33,729) ($p < 0.001$).[50] Only 59% of community-dwelling patients return to the community following hip fracture.[50] The annual cost of hip fracture in Canada is expected to rise to $2.4 billion by 2041.[50]

1.2.4 Fracture Location

The location of fracture can be classified as intracapsular or extracapsular. Intracapsular hip fractures such as subcapital or femoral neck fractures are associated with injury to the retinacular arteries supplying the femoral head. With a displaced intracapsular fracture, the risk of non-union and avascular necrosis of the femoral head is high. Extracapsular fractures can be further divided into intertrochanteric and subtrochanteric. Depending on fracture comminution, the greater and lesser trochanters may be separate fragments. Basicervical hip fractures may classify as either intracapsular or extracapsular depending on individual fracture pattern.[51]

There is a demographic distribution of hip fractures. In women, the proportion of intertrochanteric fractures rises with age, from 35% in women aged 55-59 to 51% in women aged 84 and above.[46] In men, the proportion of intertrochanteric hip fractures decreases slightly with age, from 47% in men aged 55-59 to 44% in men aged 84 and above.[46]

1.2.5 Fracture Stability

The concept stability of an intertrochanteric fracture was first introduced by Dimon in 1967. Two-part intertrochanteric fractures are deemed stable. Unstable fractures do not have cortical contact between the proximal and distal fracture fragments. This may be due to comminution of the medial calcar, the posterior greater trochanter, or both. In the original paper, 140 (46%) of 302 consecutive fractures were classified as unstable.[52] More contemporary classifications are available, such as the AO/OTA classification, where 31-A1 fractures are stable, 31-A2 fractures are potentially unstable, and 31-A3 fractures are deemed unstable.[53,54] Factors that can affect stability of a two-part fracture include obliquity of the fracture pattern.[55]

1.3 Treatment Options

1.3.1 Non-Operative

The vast majority of hip fractures are treated operatively. A systematic review by Handoll in 2008 identified only five randomised trials of operative versus nonoperative management, involving 428 elderly patients. Many of the studies included were not applicable to current practice, and only one trial provided relevant evidence.[56] Hornby compared nonoperative treatment with traction versus surgery for extracapsular fractures. There was no significant difference in 6-month mortality or pain. Surgery decreased length of stain and improved anatomic outcomes. Patients treated conservatively lost more independence as a result of their hip fracture.[57] For intracapsular fractures, conservative management is limited to undisplaced or valgus impacted fractures.[58] The current standard of care is to proceed with surgical management where it is indicated and safe to do so, due to the benefits of early mobilisation and the risks of prolonged hospital stay.[56,59]

1.3.2 Operative

1.3.2.1 Arthroplasty

Intracapsular fractures can affect the blood supply of the femoral head. Attempting to treat displaced intracapsular fractures with internal fixation may lead to an increased risk of non-union, avascular necrosis, or implant failure. In cases where vascularity of the femoral head is at risk, arthroplasty provides successful treatment of hip fractures. There is a vast amount of literature on arthroplasty which is out of the scope of this paper. Options include total hip arthroplasty or hemiarthroplasty. Within hemiarthroplasty, both monopolar and bipolar hemiarthroplasty are commonly performed. Fixation into the proximal femur can be performed by press-fit femoral stems as well as cemented fixation. The surgery can be performed through a variety of approaches, including the direct anterior, direct lateral, and posterior approaches. The choice of approach and implant are typically due to surgeon experience and comfort. Complications of arthroplasty include leg length discrepancy, abductor muscle weakness, and risk of dislocation. Outcomes of arthroplasty are comparable to internal fixation.[58]

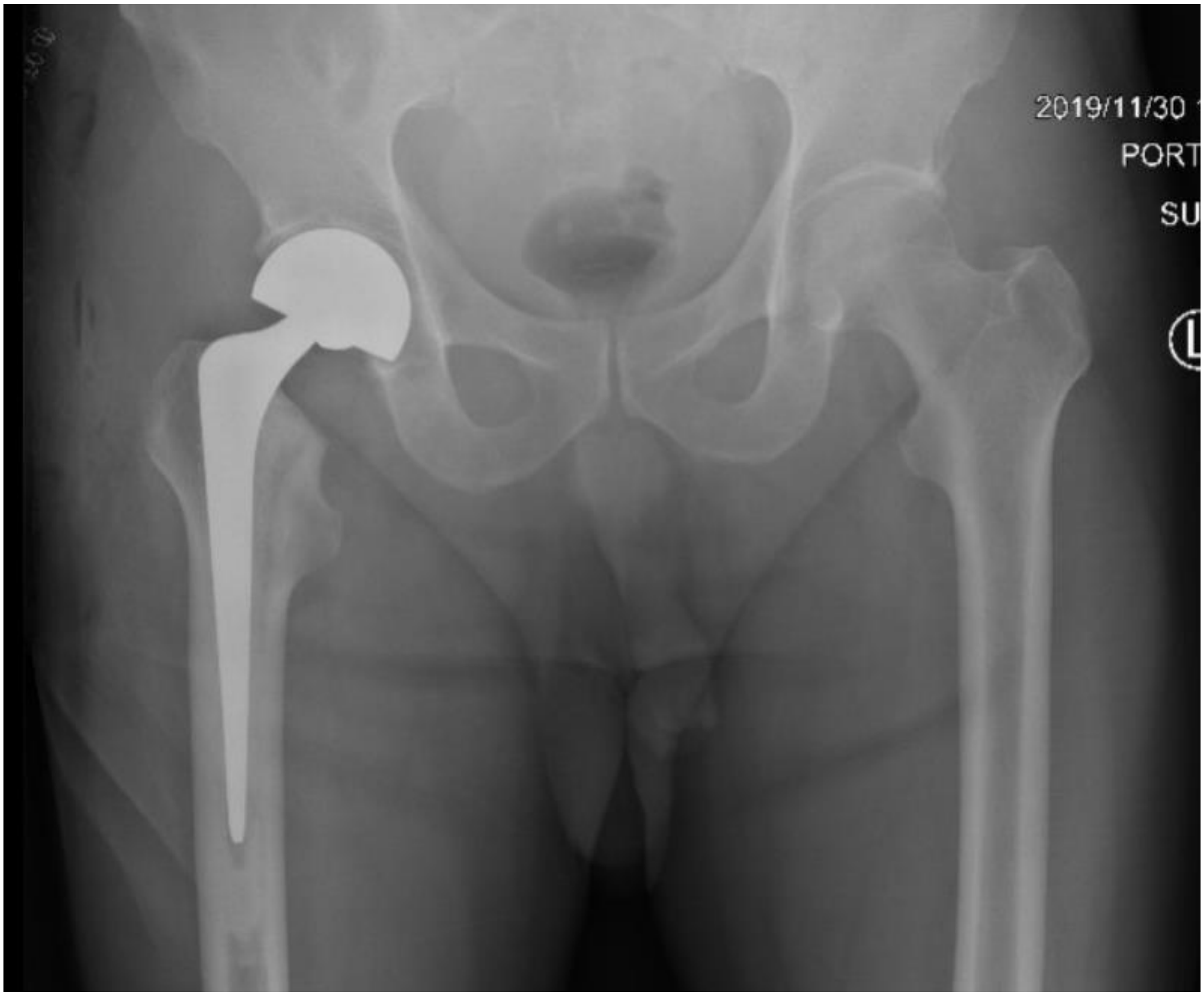

Figure 1.2. Post-operative image of a bipolar hemiarthroplasty for femoral neck fracture. (M Ching)

1.3.2.2 Cannulated Screws

Nondisplaced fractures of the femoral neck may be amenable to treatment with cannulated screws. The ideal patient population for cannulated screws is typically younger than that for arthroplasty. The ideal configuration is three cannulated screws placed in an inverted triangle, with screws placed into the subchondral bone of the femoral neck. This construct provides stabilization against shear forces and rotational forces while allowing for compression to achieve union.[60]

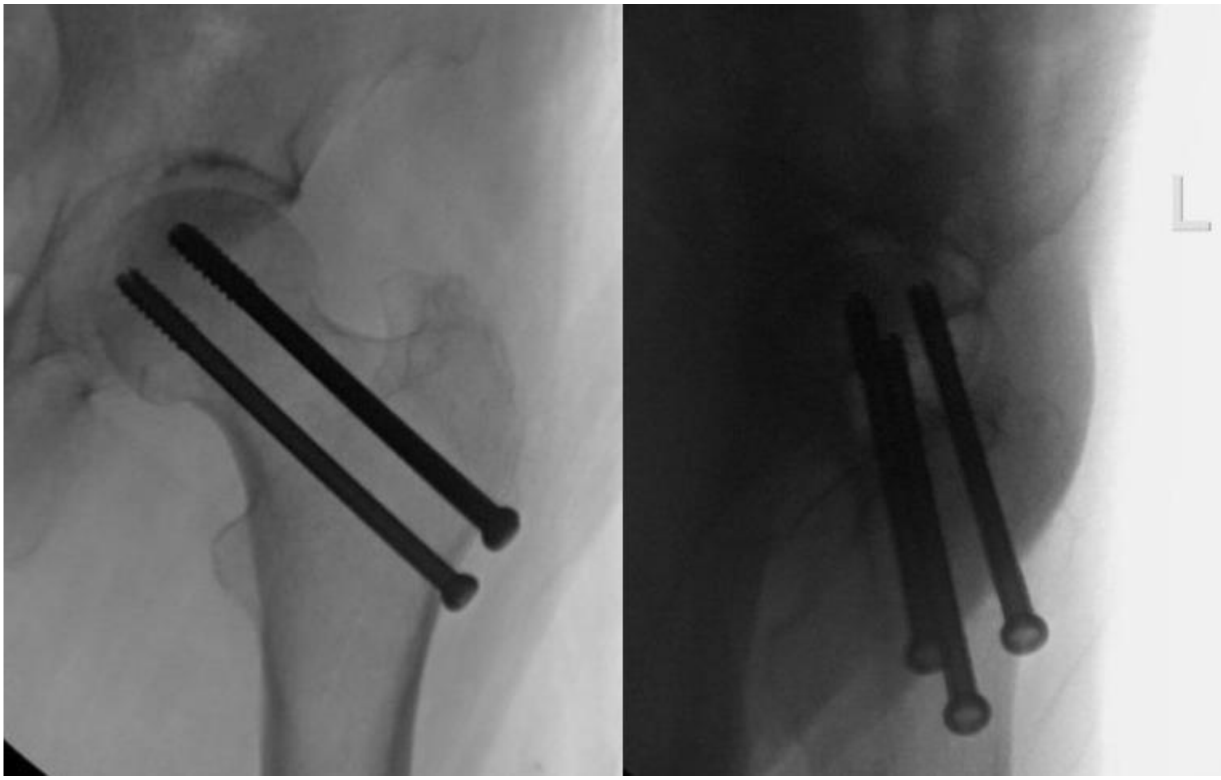

Figure 1.3. Intra-operative fluoroscopic imaging of cannulated screw fixation. (M Ching)

1.3.2.3 Sliding Hip Screw

The sliding hip screw, also known as a screw-plate construct, involves a single lag screw going into the femoral head. This lag screw is inserted into a barrel within the plate. The barrel allows for sliding of the screw, which provides an ability for the fracture site to compress to improve union rates. Indications for the sliding hip screw including an intact lateral cortex and sufficient posteromedial calcar.[61] The plate is designed to be fixated to the lateral cortex of the femur with a variable amount of screws, with typical constructs having two to four screws. In biomechanics testing, the two-hole sliding hip screw has shown to be as stable as the four-hole sliding hip screw in cyclic and failure loads.[62] Some designs allow for the insertion of locking screws into the femur through the side plate, and other designs allow trochanteric stabilization with proximal screws.[63]

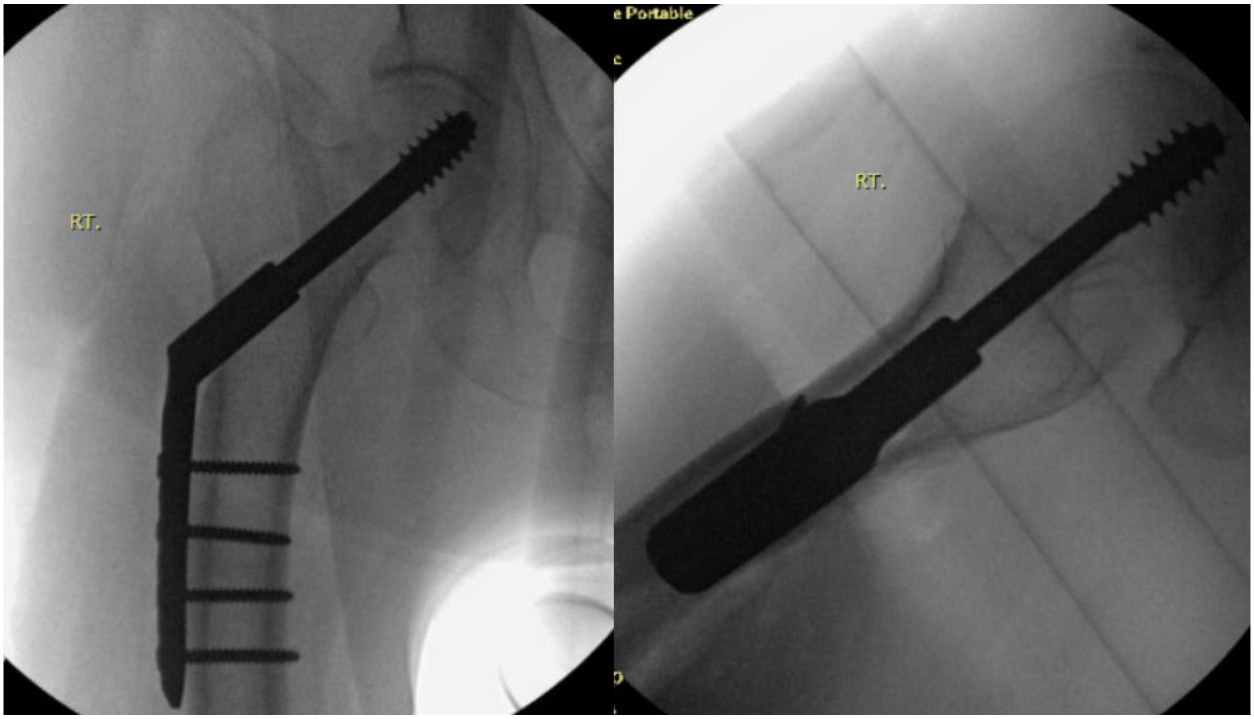

Figure 1.4. Intra-operative fluoroscopic imaging showing fixation with a sliding hip screw. The lag screw inserted into the femoral head is allowed to slide through the barrel of the plate, allowing compression through the fracture site for optimal healing. The barrel is attached with a fixed angle to the plate on the lateral cortex of the femur, which is affixed with screws. (M Ching)

1.3.2.4 Cephalomedullary Nailing

Cephalomedullary nailing is a construct involving fixation of the femoral head and internal stabilization in the intramedullary canal of the femur. Many implants are designed for the lag screw in the femoral head to allow compression across a fracture site, and the distal portion of the intramedullary nail is designed to allow for locking to the femur to control length and rotation. Many studies have compared the cephalomedullary nail with the sliding hip screw.

Barton studied 210 patients randomized to cephalomedullary nail or sliding hip screw and showed equivalent outcomes at 1 year.[64] Bhandari published a meta-analyses showing that early Gamma nails prior to 2000 increased the risk of femoral shaft fractures compared to a sliding hip screw, but that recent implant designs did not carry the same risk.[65] The large lag screw of a cephalomedullary nail has been shown to resist cut-out of the femoral head more than that of a sliding hip screw.[66] Cephalomedullary nail fixation is associated with less blood loss ($p < 0.001$) and lower rate of implant failure ($p = 0.004$)

but more fluoroscopy time ($p < 0.001$).[67] Cephalomedullary fixation has also been shown to decrease the hospital length of stay and re-operation rate, which may be able to offset the higher implant cost.[68,69]

Many studies agree that the cephalomedullary nail has equivalent outcomes to a sliding hip screw for stable intertrochanteric fractures. However, the cephalomedullary nail has shown clear benefits in unstable fractures. A randomized study of 426 intertrochanteric fractures showed that the cephalomedullary nail more frequently preserved the fracture position obtained perioperatively and was recommended for more comminuted hip fractures.[70] Kokoroghiannis recommends using cephalomedullary nails over sliding hip screws for multi-fragmentary fractures or fractures with transverse or reverse obliquity.[55] Biomechanics testing comparing cephalomedullary fixation with the sliding hip screw shows that cephalomedullary fixation has higher fixation strength in comminuted subtrochanteric fractures.[71]

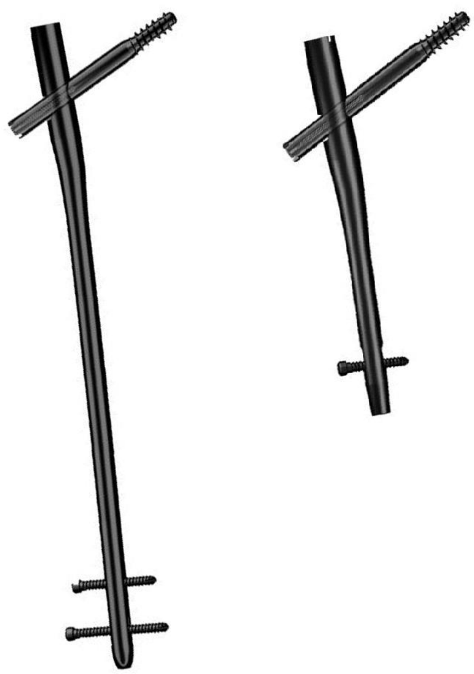

Figure 1.5. Examples of long and short cephalomedullary nails. There is a lag screw that is inserted into the femoral head along with distal locking screws that are inserted through the femoral shaft. (Stryker)

1.4 Femur Fractures

The most common mechanism for a fracture of the femoral shaft or the distal femur is an indirect trauma on a bent knee.[72] Rarely, the mechanism is a direct crush injury. There is a classic bimodal distribution for fractures of the femoral shaft and the distal femur. There is one peak for young men in their 30s and another for elderly women.[72] The average age of patients with a femoral shaft fracture tends to be younger than that of a proximal femur fracture. Court-Brown determined the average age of proximal femur fractures to be 80.5 years of age compared to the average age of femoral shaft fractures of 68 years. 22% of femoral shaft fractures occur in patients less than 50 years of age. 9% occur in patients aged 50 to 65, 11% occur in patients aged 65 to 75, and the remaining 58% occur in patients over the age of 75.[38] The average age of distal femur fractures is even less at 61 years. 37% of distal femur fractures occur in patients under the age of 50.

A subset of femur fractures include atypical femur fractures that are associated with bisphosphonate use, with an average incidence of 18.2 per 100,000 person-years.[73] Atypical femur fractures have been correlated with an increased femoral bow, although the mechanism is not clear.[74] The magnitude of bowing has been associated with the location of the atypical femur fracture, with an increased femoral bow resulting in a more distal diaphyseal fracture. The underlying cause is not elucidated.[75]

Operative treatment requiring technical expertise is the mainstay of femoral shaft and distal femur fractures.[72,76] The ideal construct of fixation is dependent on patient characteristics and individual fracture pattern. Conservative measures are a rare option reserved for poor surgical candidates or nondisplaced fractures in non-ambulatory patients.[72]

1.5 Cephalomedullary Nailing

1.5.1 History of Cephalomedullary Nailing

The first reports of intramedullary fixation arose from the 16th century by Bernardino de Sahagun, an anthropologist who travelled to Mexico with Hernando Cortes. Wooden sticks were placed into the medullary canals of patients with long bone nonunions.[77] Other materials have been used, such as an ivory intramedullary nail that allowed for the first interlocked device, described by Gluck in the 1890s.[77] The transition to metal rods occurred during World War I, but due to high infection rate, was not widely accepted until Smith-Peterson utilized stainless steel nails for femoral neck fractures in 1925.[77,78] Johannsen developed cannulation of the nails to allow use of a guide wire.[78]

Gerhardt Kuntscher was born in 1900 and pioneered contemporary femoral nailing. He developed interlocked nailing in Germany in the 1940s, inspired by the Smith-Peterson nail.[76,77] His original nail was V-shaped and made of stainless steel, but this was not well received, and he transitioned to a cloverleaf-shaped nail within the decade.[77] His initial nails were quite large, 16mm for a woman and up to 18mm for a man.[78] The first solid metallic nail was the Hansen-Street nail introduced in the United States in 1947.[77] The 1950s saw the advent of the flexible reamer and the use of interlocking screws, introduced by Modny and Bambara in 1953.[77]

The Zickel nail was the first cephalomedullary device, introduced in 1967. The proximal portion of the nail contained a hole through which a separate nail could be placed into the femoral head. A set screw could be inserted to prevent backout of the nail. This screw is still present in some current designs.[77]

In the 1970s, the dominant design was a slotted cloverleaf-shaped interlocked nail, such as the AO and the Grosse-Kempf nails.[77] These are considered second-generation due to their ability to lock the nail both proximal and distal to the fracture, first introduced in 1972.[78] Other advancements in the 1970s include the expansion of indications for reamed nails to include open fractures of the femur and tibia. Closed nails were introduced by Russell-Taylor in 1986.[78]

Titanium nails and smaller diameter nails were introduced in the 1990s.[77,78] Slotted nails were replaced by nonslotted designs that increased torsional rigidity.[77] Brumback advised immediate weight bearing in fractures treated with a nail as early as 1988.[77,78] Retrograde nails were introduced by Seligson, Green, and Henry.[78]

The recent third generation of cephalomedullary nailing addressed errors in nail design, entry portal, and malalignment.[78] The greater trochanter was initially used as a start point for straight nails, but documented complications included varus malunion and medial comminution. The start point for straight nails was then transitioned to the piriformis fossa.[76] Multiple interlocking screw options were added.[78] Aiming guides were developed but due to the slight alteration in geometry of the nail upon insertion, these aiming guides were not accurate enough to be relied on.[76]

1.5.2 Nail Designs

There are currently many different designs of cephalomedullary fixation. The choice of individual implant is often left to the surgeon. These different designs include the Stryker Gamma nail, the Zimmer Natural nail, the Synthes Proximal Femoral Nail Antirotation, the Smith and Nephew Trigen InterTan, and many others. Some studies have compared implants with each other. D'Arrigo compared the Trochanteric Gamma Nail with the Proximal Femoral Nail Antirotation device. The Trochanteric Gamma Nail had higher operative times ($p = 0.04$), blood loss ($p = 0.03$), and complications ($p = 0.01$) but clinical outcomes were equivalent.[79] Wu compared the InterTan and Gamma3 nail, showing that the InterTan required longer fluoroscopy and operative times but had lower cut-out ($p = 0.024$) and femoral shaft fractures ($p = 0.044$).[80] The TFN-Advanced nail has been shown to be easier to insert with smaller deformation than the Proximal Femoral Nail Antirotation.[81] Overall, there is no agreement on any one superior cephalomedullary device for all situations.

Many contemporary designs have both a short and long version. Long nails were developed to address the risk of diaphyseal fracture with the short nail, as well as to expand the indications for cephalomedullary nailing to include subtrochanteric and diaphyseal fractures.[82]

Boone studied 194 intertrochanteric fractures and found that long nails compared to short nails have a higher estimated blood loss (135 ± 92mL vs 93 ± 47mL) and transfusion rate (57% vs 40%) ($p = 0.002$). Operative time was also increased (57 ± 19min vs 44 ± 11min) ($p < 0.001$). Length of stay and rates of perioperative fractures were similar.[83] Merli compared 100 short nails with 60 long nails and found no significant difference between long and short nails for length of hospital stay, mean time to union, postoperative complications including fractures, and postoperative rehabilitation and return to function. The long nail was associated with longer surgeries, increased blood loss, and increased transfusion requirements. The short nail group had more postoperative pain and increased need for walking aids.[84] Sellan compared 71 short and 37 long nails. Blood loss was higher in the long nail group without a significant effect on number of patients requiring transfusion ($p = 0.582$) or average units transfused per patient ($p = 0.982$). Mean operative time was higher for long nails ($p = 0.021$).[85]

Concerns have arisen regarding the risk of diaphyseal fracture after short nailing due to the stresses at the tip of the short nail, with an overall incidence of 1.7%.[86,87] Sellan found no difference in postoperative fracture for the long and short nails ($p = 0.350$).[85] Norris performed a systematic review of 13,568 patients showing a trend towards a lower risk of secondary diaphyseal fracture in long nails, but it was not statistically significant ($p = 0.28$).[87]

A biomechanical analysis in cadaveric bone performed by Daner III showed there was no difference in stiffness of the short or long cephalomedullary nail. Both implants failed at the distal interlocking screw.[88] Another biomechanical comparison in synthetic bone showed no difference in failure load between the long nail (4027 ± 547N) and the short nail (4038 ± 246N), and that all implants failed once again at the distal interlocking screw.[89]

The choice between the long and short nails remains controversial with a trend towards higher postoperative fractures in the short nail that does not reach statistical significance, at the expense of increased operative time and blood loss in the long nail.

1.5.3 Stryker Gamma3 Nail

The Gamma nail was developed in the 1980s, aiming to overcome some of the clinical problems with the Zickel nail.[90] It was developed separately in Halifax, United Kingdom, and Strasbourg, France. The designs were merged and was designated “The Standard Gamma Nail” in 1988.[90] The Long Gamma Nail was introduced in 1992. The Standard Gamma Nail was modified to create the Trochanteric Gamma Nail in 1997, which replaced the Standard Gamma Nail.[90]

The Gamma nail has three main components. An intramedullary rod is passed from the proximal femur into the femoral shaft distal to the fracture. A lag screw is inserted from the lateral cortex, through the proximal nail, and into the femoral head. A set screw is placed into the proximal portion of the nail providing rotational control of the lag screw, and can either lock the lag screw or allow for compression.[91]

Modifications were made to address complications caused by nail design. Excessive medial curvature of the implant initially caused fractures of the greater trochanter. The short version of the nail was shortened to 200mm. Three distal diameters of the short nail are now available, 12mm, 14mm, and 16mm.[91]

The currently available long nail has a proximal diameter of 15.5mm. The proximal medial-lateral bend is 4 degrees. The lag screw can be inserted at a neck-shaft angle of 120, 125, or 130 degrees. The nail is available in two radii of curvature, 1.5m and 2.0m. For the 1.5m nail, available distal diameters are 10mm, 11mm, 13mm, and 15mm. For the 2.0m nail, available distal diameters are 11mm, 13mm, and 15mm. Nails of length 260mm to 480mm are available in 20mm increments.

Successful outcomes with the Gamma nail have been reported. Bojan studied 3,066 consecutive Gamma nails in a patient population with a median age of 81, where 88% of fractures were due to a simple fall. The Standard Gamma Nail was used in 1,623 patients, the Trochanteric Gamma Nail in 933 patients, and the Long Gamma Nail in 473 patients. The overall complication rate was 5.6%, including intraoperative anesthetic complications and postoperative complications such as lung embolism, deep vein thromboses, or cardiorespiratory problems. There were 137 (4.5%) fracture related complications, with 104 (3.4%) of these being difficulty with the distal interlocking screw resulting in multiple attempts or misplacement. Introduction of a radiolucent targeting guide significantly dropped this complication rate to 1.1% ($p < 0.001$). There were 13 intraoperative fractures at the lateral cortex of the femur and 4 perforations of the distal anterior cortex of the femur. Cut-out through the femoral head causing revision was present in 1.85%. The remainder of the cases healed uneventfully.[90] Docquier analysed 439 hip fractures treated with the short Gamma nail. The union rate at 10 months was 81%, with a 7.1% cut-out rate and 3.1% diaphyseal fracture rate necessitating revision surgery.[92] A smaller series by Hotz with 32 proximal femur fractures treated with the long gamma nail had a 100% union rate.[93]

1.5.4 Surgical Technique

Insertion of a cephalomedullary nail relies on a few crucial steps for success. First is patient positioning, which can be done on a fracture traction table or in lateral position, which requires skilled assistants. Reduction of the fracture is identified on fluoroscopy prior to instrumentation. An appropriate start point is identified and the starting guide pin and entry reamer or awl is introduced. A bulb-tipped guide wire is then advanced into the distal femur and the surgeon may now ream the canal. The nail is inserted and biplanar fluoroscopy is utilised to place a lag screw into the femoral head. In some designs, a set screw is inserted. Finally, distal locking screws can be inserted. The specific details of each of these surgical steps will be discussed below.

1.5.4.1 Start Point

Two separate start points at the proximal femur have been described for cephalomedullary nailing. The choice of the start point depends mainly on the implant design, and in specific cases, the fracture pattern may play a role. In general, a straight nail requires a start point in line with the medullary canal of the femur, which aligns with the piriformis fossa. A trochanteric start point has been described for trochanteric nails which require a lateral bend in the proximal portion of the nail. The importance of the start point cannot be understated, yet Kale performed a survey of 100 Orthopaedic surgeons in 2006 where only four surgeons were able to accurately label the start point on radiographs.[94] Accuracy of the start point is crucial as multiple attempts will weaken the proximal femur and the fixation.[95]

The piriformis start point involves the use of a straight nail. A radiographic analysis by Gausepohl showed that the ideal entry point was found in 88% of patients to be at the medial border of the greater trochanter overlying the tendinous insertion of the piriformis muscle. In the sagittal plane, the axis of the medullary cavity was on average 2.1cm anterior to the posterior surface of the greater trochanter.[96] Intraoperative fluoroscopy is recommended for the exact localization an adequate piriformis start point.[94,97] Concerns have arisen with the use of the piriformis start point due to the risk of neurovascular complications and damage to branches of the medial circumflex femoral artery which may cause avascular necrosis of the femoral head.[98,99] In addition, an anatomic study has shown that 25% of proximal femurs have a greater trochanter that overhangs the piriformis fossa and would obstruct the ideal nail position.[4]

The trochanteric start point requires the use of a specifically designed nail. The use of the trochanteric start point with a straight nail increases the risk of varus malalignment and iatrogenic fracture comminution.[100] Due to the variability in the anatomy of the greater trochanter, there is also variability in the ideal entry point.[4,100,101] Streubel showed that the ideal entry point was medial to the tip of the greater trochanter in 70% of patients and lateral to the tip in 23% of patients. Ricci describes the ideal entry point as just lateral to the long axis of the femur, regardless of the location at the tip of the greater trochanter.[100] Linke stresses that fluoroscopy should be used to identify the start point instead of relying on anatomic landmarks.[98] On the lateral view, the start point should be colinear with the long axis of the femur and the femoral neck, which is often at the anterior one third of the greater trocanter.[53,100,102] A start point anterior to the longitudinal axis of the femoral neck is at a biomechanical disadvantage.[103] The trochanteric start point has decreased the incidence of varus malalignment but it is not without risk to the gluteus medius tendon.[100] McConnell performed a cadaveric study using a 17mm reamer at the trochanteric start point and quantified the damage to the gluteus medius tendon with a range of 15% to 53% with a mean of 27%.[102]

1.5.4.2 Lag Screw

Proper placement of the lag screw is crucial to success of cephalomedullary nailing. The lag screw combined with the proximal tip of the intramedullary nail provides three points of proximal fixation. There are two important aspects of the lag screw that have been identified. The first is the contact of the lag screw with the lateral cortex of the femur. The second is the placement of the tip of the lag screw within the femoral head.

Abram studied 223 Gamma nails over a 5-year period and assessed factors affecting failure of the implant. The overall failure rate was 7.2%. Half of the failures were due to inadequate contact between the lag screw and the lateral cortex of the femur. Inadequate contact had a failure rate of 25.8% and an odds ratio of 7.5 ($p < 0.001$).[104]

Placement of the tip of the lag screw into the femoral head is crucial for adequate fixation into the cancellous bone of the femoral head. The tip-apex distance has been used as a measure of lag screw positioning. On anteroposterior and lateral radiographs, the distance from the tip of the lag screw is measured to the center of the femoral head. These two measurements are then added together. A tip-apex distance greater than 25mm has been shown to correlate with implant cut-out through the femoral head, and in some cases, this has shown to be the only significant factor.[64,66,105] A systematic review by Rubio-Avila in 2013 showed that a tip-apex distance greater than 25mm had a relative risk of cut-out of 12.71. In comparing the mean tip-apex distance of patients experiencing cut-out compared to those that did not, patients experiencing cut-out had a higher tip-apex distance by a mean of 6.54mm.[106]

Biomechanical analyses has shown that if a central position is not achieved, it would be preferable to be posterior and inferior to the center-center position. An inferior lag screw position reduces the fracture translation in a biomechanical study with 15 ± 3.4mm compared to 20 ± 2.8mm of a true center lag screw ($p = 0.004$) and decreased fracture gap distraction of 7 ± 4mm compared to 13 ± 2.8mm ($p < 0.001$).[107] Kuzyk demonstrates that an inferior lag screw produces the highest axial and torsional stiffness.[108]

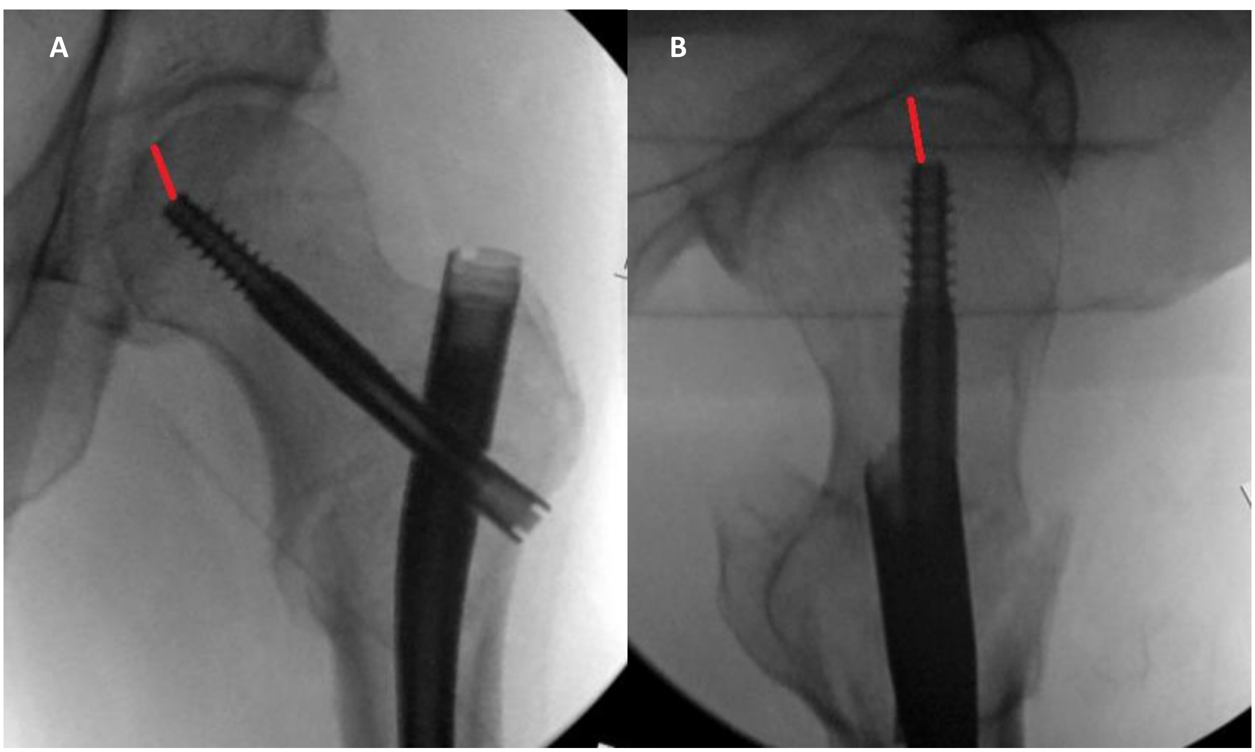

Figure 1.6. Tip-apex distance. The distance from the tip of the lag screw to the center of the femoral head on the anteroposterior view (A) is added to the distance from the tip of the lag screw to the center of the femoral head on the lateral view (B). (M Ching)

Recent evidence has emerged regarding a calcar-referenced tip-apex distance. This is a measurement made on the anteroposterior radiograph, where the apex of the femoral head is determined by drawing a line tangent to the medial calcar of the femoral neck. The intersection of this line with the femoral head is then used to measure the calcar-referenced tip-apex distance, favouring an inferior lag screw placement. Kashigar retrospectively reviewed 77 femurs with an overall lag screw cut-out rate of 13% (10/77). In multivariate analysis, the calcar referenced tip-apex distance was the only significant predictor.[109] Puthezhath reviewed 10 failures in 67 cephalomedullary constructs and determined that a higher tip-apex distance was not a predictor of cut-out when the calcar-referenced tip-apex distance itself was less than 25mm. In their series, a lower calcar-referenced tip-apex distance led to decreased cut-out ($p < 0.001$).[110]

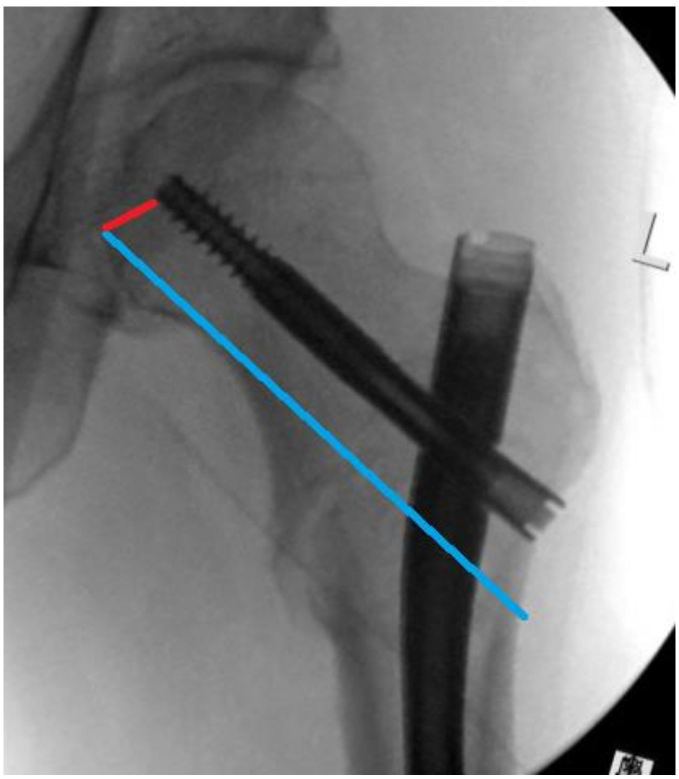

Figure 1.7. The calcar-referenced tip-apex distance uses a different position on the anteroposterior view compared to the traditional tip-apex distance. A line is drawn tangent to the medial calcar until it meets the curvature of the femoral head (blue line). The distance from this point is measured to the tip of the lag screw (red line). (M Ching)

1.5.4.3 Locking Screws

Distal locking screws are inserted from the lateral cortex of the distal femur through the nail, providing bicortical fixation of the distal nail. As the lag screw and the proximal portion of the intramedullary nail provide three point fixation against rotation, many studies have stated that interlocking screws may not be needed in a stable fracture pattern that is not at risk of rotational or axial instability.[53,61,86,111] However, some proponents have shown that unlocked nails may not be sufficient.

Ahrengart found no difference in healing rate between locked and unlocked Gamma nails in a study of 426 intertrochanteric fractures.[70] Kane analyzed 14 matched pairs of cadaveric femurs with a stable intertrochanteric fracture treated with and without distal locking. The femurs with distal locking screws had increased internal ($p = 0.026$) and external ($p = 0.009$) rotational stiffness and showed less displacement at yield and peak torques.[112] Skála-Rosenbaum prospectively analysed 849 stable intertrochanteric fractures treated with short nails. 70% did not have distal locking. The overall postoperative fracture rate was 2% with 17 fractures detected. Only one fracture occurred in a locked nail, whereas 16 cases occurred in unlocked nails ($p = 0.037$). They argue that unlocked nails do not guarantee sufficient stability and recommend the routine use of distal locking with short nails.[113]

A biomechanics study in unstable intertrochanteric fractures treated with a long nail showed that distal locking results in increased maximal torsional load ($p = 0.001$) and increased rotational stiffness ($p = 0.004$).[114] Other biomechanics studies investigated loading of the fractured femur treated with a cephalomedullary nail and found that distal locking did not inhibit loading at the fracture site and did not change the pattern of proximal femoral strain.[61,115]

Many constructs allow for multiple distal locking screws. Some studies have analysed the effect of two distal locking screws compared to one. Hajek performed a comparison of a slotted locking nail with either one or two distal screws in cadaveric femurs and found no difference in torsional rigidity or axial load to failure.[116] Brumback demonstrates that constructs with two distal locking screws have higher fatigue strength than only one distal locking screw ($p < 0.05$).[117] Wang argues that unstable fracture patterns and subtrochanteric fractures where the implant must bear higher loads may necessitate two distal locking screws.[118]

1.6 Outcomes

1.6.1 Post-Operative Weightbearing

Immediate weight bearing after hip fracture surgery is an important goal. Immediate weight bearing maximizes the chance of full or nearly full recovery.[59,119] Chudyk reports in a large systematic review that the most frequently reported positive outcomes are associated with measures of ambulatory ability.[120] Conversely, prolonged non weightbearing of surgically managed fractures is associated with delayed healing and worse outcomes.[121] Medical complications of immobilization and bed rest include muscle atrophy and weakness, disuse osteoporosis, decreased cardiac reserve, orthostatic hypotension, venous thromboembolism, pneumonia, pressure sores, loss of balance and coordination, and urinary tract infections.[122,123] Ottesen analysed 4,918 patients treated for hip fractures. 3,668 were allowed to weight bear as tolerated postoperatively, and experienced fewer major adverse events, fewer infections, less transfusion, shorter length of stay, and decreased 30-day mortality.[124] Adunsky followed 217 patients admitted for rehabilitation after hip fracture and concluded that encouraging outcome results are achieved with full weightbearing after hip fracture.[125] Additionally, limited weightbearing for even the first 2-4 weeks after surgery is associated with negative functional outcome at 1 year ($p < 0.001$).[126]

Immediate weight bearing after hip fracture surgery is also safe in the vast majority of fractures. Cephalomedullary fixation allows early weight bearing of hip and femur fractures without significant implant failure.[127] This has been considered safe even in highly comminuted femoral shaft fractures.[117] Retrospective series have reported that immediate weight bearing following hip and femur fractures have low complication rates following cephalomedullary nailing.[128] Koval analyzed 473 patients who had suffered hip fractures and were treated surgically with immediate weight bearing. They report 16 (3.4%) revisions and recommend unrestricted weight bearing in elderly patients after hip fracture surgery.[129] A survey of 20 Canadian Orthopaedic surgeons showed that the majority prescribed full weight bearing, but factors such as poor bone quality and certain types of fracture pattern may predispose a surgeon to prescribe partial weightbearing.[119]

One of the drawbacks of prescribing partial weightbearing is that compliance is often an issue. Braun reports less than 50% compliance with weightbearing recommendations following lower extremity surgery in 30 patients with a mean age of 61.2 years, with increased deviation as time passed during the four-week study period.[121] In a series of 23 patients trained to partially bear weight, 21 patients exceeded weightbearing by a mean of 35.3% body weight. There was reportedly little relationship between prescribed weightbearing and actual weightbearing, with no patients able to accurate reproduce the level of weightbearing to which they were trained.[130] Other analyses of different populations show that elderly patients may be much less able to comply compared to younger patients. Kammerlander compared 16 elderly patients and 18 younger patients given weightbearing restrictions. While the younger group had 14 (78%) patients comply with the restrictions, only 1 (6%) of the elderly patients was able to comply and only for a short term ($p < 0.001$). Of the remaining elderly patients, 11 (69%) exceeded the specific load by more than twofold.[131] In summary, elderly patients are unable to maintain weightbearing restrictions. It is therefore critical that elderly patients with a surgically managed hip fracture be able to ambulate with full weightbearing whenever possible.

1.6.2 Patient-Related Outcomes

Hip and femur fractures are associated with significant morbidity and mortality. Postoperative complications include delirium, cardiorespiratory complications, venous thromboembolism, anemia, urinary tract infections, fat embolism, electrolytic and metabolic disorders, and hardware failure or migration.[132-135] The mean prevalence of delirium has been reported to be as high as 35% in a series of 1,823 patients.[132]

Mortality rates remain high, with an in-hospital mortality rate of 4-7%, a six-month mortality rate of 11-23% and a 1-year mortality rate of 14-36%.[44,45,58,136-138] Estimates of excess mortality above and beyond an age-matched population with hip fracture during the first year after fracture range from 8.4-36%.[137] Risk factors for mortality include age above 85 years, decreased baseline function, increased comorbidities, and the development of in-hospital postoperative complications.[138,139] The increased risk of mortality from hip fracture persists up to 2 years after injury.[139] Mortality following distal femur fractures in the elderly population is similar to mortality following hip fracture.[140]

It is also difficult for patients who survive to return to their baseline function. 29-40% of patients suffering a hip fracture do not reach their pre-fracture levels of function at 1 year post-fracture. [119,141,142] Those who are able to return to the pre-fracture function require an average of 6 months to do so.[141] Survivors overall experience worse mobility, decreased quality of life, and higher rates of institutionalisation than age matched controls.[142] 10-20% of hip fracture patients are institutionalised following hip fracture.[142] Hip fracture survivors are four times more likely (Odds Ratio 4.2, $p < 0.001$) to be unable to mobilise in the community 2 years following hip fracture.[142]

1.6.3 Success Rates

Cephalomedullary nail fixation has shown successful clinical outcomes with infrequent failures. Sehat analysed 100 long Gamma nails with a mean patient age of 74 and mean follow-up of 10.8 months. Success was defined as stability of the fracture until union or death, and was achieved in 85% of cases.[143] The most common method of failure is cut-out through the femoral head, which is minimized with proper lag screw placement.[64,90,109,143] Other methods of failure have also been described.

Failure of the hardware itself is rare. Liu analysed 223 cases with 7 (3.1%) cases of implant failure. In three patients, the locking screws bent or fractured. In two cases, the locking screws loosened from the femoral shaft. The remaining two patients suffered breakage of the nail.[144] Rüden reports 13 (2.9%) hardware failures in 453 patients at a mean of 6 months (range 1-19 months) postoperatively. Ten of these failures were attributed to delayed union or non-union due to insufficient reduction of the fracture. Two of the failures was due to loss of the lag screw because of a missing set screw.[145]

Limited reports exist for fractures distal to the implant. Jegathesan describes a case series of 3 fractures distal to a long antegrade cephallomedullary nail. In two cases, the fractures were due to high energy trauma directed at the femoral condyles. The third case was a low energy fracture where the tip of the nail did not span the femur, and there was approximately 3cm of the femur left unprotected.[146]

1.7 Anterior Cortical Perforation

A known complication of long cephalomedullary nail constructs is perforation of the distal anterior cortex of the femur.[147] There are many risk factors that can lead to anterior perforation related to the implant, surgeon, and the patient. Factors related to the implant include a longer nail, a straighter nail with a higher radius of curvature, and a larger diameter nail.[148] A posterior start point is a risk factor dependent on the surgeon.[148,149] Patient related factors include a shorter femur and a femur with increased anterior bow and a decreased radius of curvature.[148]

The overall rate of anterior cortical perforation is low. Bazylewicz describes 1 (0.47%) perforation in 214 nails. Of note, 16% of nails were within 3mm of the anterior cortex in their study.[150] Bojan experienced 3 (0.63%) cases of perforation in 473 nails.[90] Roberts analysed 150 cases and found placement of the nail in the anterior one third of the distal femur in 71 (47%) of patients, where 38 (25%) of which had cortical impingement but without perforation.[148]

Many authors have described methods of preventing anterior cortical perforation of the distal femur. Amin and Ramiah have separately described bending the guide wire to allow the surgeon to direct it more posteriorly, away from the anterior cortex.[147,151] While this technique has been successful for some, Collinge published their experience that the guide wire tends to migrate towards the path of the nail in osteoporotic bone, and not vice versa.[2] Some authors advocate using the starting guide pin or the 4.2mm distal locking drill bit as a blocking screw to direct the guide wire posterior in the femoral shaft[147,152] Scolaro describes using as many as five bicortical 2mm Steinmann pins to guide the nail posteriorly.[153]

1.7.1 Effect of Femur Anatomy

As described previously, there is an anterior bow to the femur with a wide range of radius of curvature. Means have been reported from 72cm to 144cm.[6-13] The range of individual femurs is even greater. Lakati reports a range of radius of curvature from 52cm to 165cm.[10] Harper reports a range from 69cm to 189cm, and Harma reports a range from 11cm to 167cm.[7,8] The range of radius of curvature in 426 Chinese femurs as measured by Su was 62cm to 203cm.[12] Therefore, even with contemporary cephalomedullary nails with a low radius of curvature, a small portion of patients will be at risk of anterior cortical perforation due to the increased physiologic femoral bowing. In addition, anatomic studies have shown that the distal third of the femur has a smaller radius of curvature than the middle and proximal thirds of the femur, while the curvature of a cephalomedullary nail is uniform throughout. This results in a persistent risk of anterior cortical perforation.[16,17]

1.7.2 Effect of Nail Design

The design of cephalomedullary nails has evolved in response to the recognition of anterior cortical perforation of the distal femur as a complication, resulting in a decreased radius of curvature of contemporary nails. Egol analysed the nails available in 2004 and reported that they measured a radius of curvature from 186cm to 300cm, straighter than the average femur.[6] More recently in 2016, Lakati published that the radius of curvature of available nails ranged from 127cm to 200cm.[10]

In direct comparison of InterTan devices with a radius of curvature of 150cm versus 200cm, the 150cm radius nails were positioned more posteriorly compared to the 200cm radius nails ($p = 0.006$). In addition, only 1 of 32 (3%) 150cm nails abutted the anterior cortex of the distal femur while 3 of 26 (12%) 200cm nails abutted the anterior cortex, including one that caused a fracture of the distal anterior cortex.[53] Shetty studied long Gamma nails with a 200cm and 150cm radius of curvatures and had similar results. With the 150cm nails, only 5 of 27 (19%) of nails had the tip in the anterior third of the distal femur. However, with the 200cm nails, 20 of 25 (80%) had the tip of the nail in the anterior third of the distal femur with 2 fractures of the distal anterior cortex.[154]

Schmutz compared the TFN-Advanced nail, which has a radius of curvature of 100cm, to the Gamma3 R1.5 long nail, which has a radius of curvature of 150cm. 63 three-dimensional models were generated of Caucasian and Asian femurs and customized software was utilized to determine distal nail position. The Gamma nail with an increased radius of curvature had a more anterior position of the distal tip of the nail.[155] Yuan analysed the ease of insertion between the TFN-Advanced nail with a radius of curvature of 100cm and the Proximal Femoral Nail Antirotation with a radius of curvature of 150cm. Seven paired cadaveric femurs were used. The TFN-Advanced nail required less force at the end of insertion ($p = 0.002$) and showed decreased deformation ($p = 0.005$) compared to the straighter Proximal Femoral Nail Antirotation. Regardless of recent design changes in cephalomedullary nails, anterior cortical perforation of the distal femur remains a risk if the femur is sufficiently bowed.

1.7.3 Case Reports of Cortical Perforation

Case reports of anterior cortical perforation of the distal femur are abundant. Many cortical perforations are created from long antegrade nailing, but other systems such as the Reamer-Irrigator-Aspirator have been documented to cause anterior perforation.

Bojan reports 4 anterior cortical perforations in a series of 3,066 Gamma nails. Three were caused by long Gamma nails and one by the short Gamma nail.[90] Fantry reports one case of delayed anterior cortical perforation of the distal femur in a long unlocked nail. The three-week postoperative radiograph demonstrated perforation which was not present intraoperatively. The patient was treated non-operatively with protected weight bearing. Follow-up radiographs demonstrated healing and callous formation.[156] Ostrum reports three cases of anterior cortical perforation in cephalomedullary nailing for subtrochanteric fractures, one of which caused a displaced supracondylar fracture. This required revision. The other two perforations were treated non-operatively and the subtrochanteric fractures united.[157] Peña reports five cortical penetrations, three treated non-operatively with restricted weightbearing, and two treated with lateral locking plates.[158]

Anterior cortical perforations of the distal femur have also occurred during use of the Reamer-Irrigator-Aspirator system. Belthur reports such a perforation from eccentric reaming during harvesting. The patient was treated with partial weightbearing and did not fracture through the perforation. Pain resolved at 4 months.[159] Finnan applied the Reamer-Irrigator-Aspirator system to cadaveric bone and found one anterior cortical perforation with the piriformis start point, causing a fracture through the perforation.[160] Two anterior cortical perforations (10%) were caused in a series of twenty patients.[161] Both were treated with touch weightbearing for 4-6 weeks and progressed to radiographic and clinical union without further intervention.[162] Qvick documents two cases (1%) of supracondylar femur fracture necessitating retrograde femoral nails due to antegrade use of the Reamer-Irrigator-Aspirator. The first fracture occurred 6 days postoperatively due to a twist while standing. The second fracture occurred 41 days postoperatively due to a fall from standing height. No mention is made of weightbearing restrictions or other management prior to fracture and revision surgery.[163] The Reamer-Irrigator-Aspirator system has also been documented to cause medial tibial perforation when used to harvest bone graft from the tibia.[164] In all of these instances, perforation was caused by the eccentric reaming, as no nail was inserted.[165]

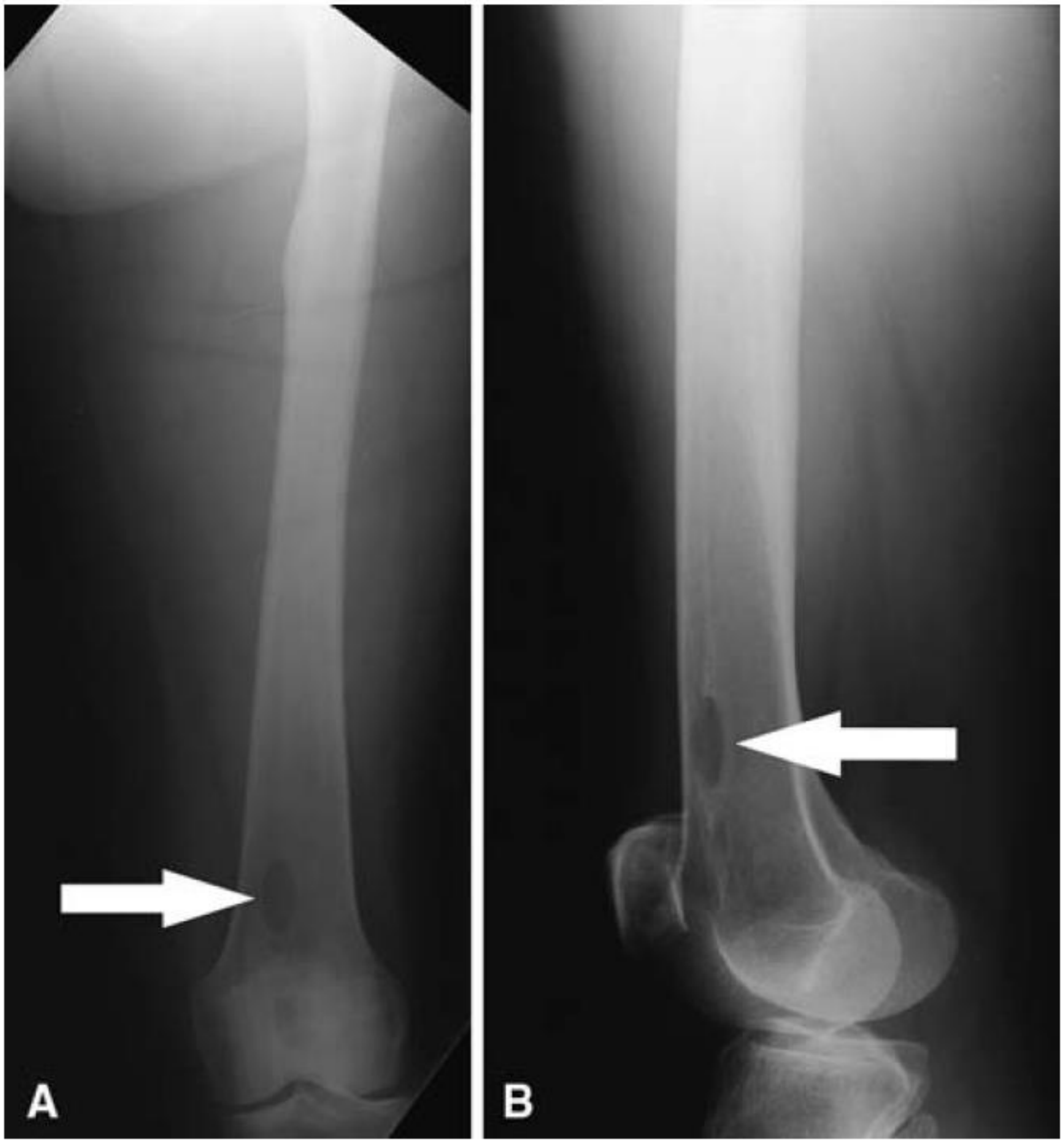

Figure 1.8. Anterior cortical perforation as a result of eccentric reaming during use of the Reamer-Irrigator-Aspirator system as published by Belthur, 2008.

There have been other instances of cortical windows being created in the shaft of the femur as part of an intended surgical procedure. Melmer describes an anterior window created in 38 procedures to aide cement removal in revision hip arthroplasty. This window was created at a site most optimal for cement removal without regard for the location of the revision stem, and in no cases did the revision stem bypass the window by two cortical diameters. Nevertheless, no fracture or implant loosening occurred.[166]

Sydney describes the use of multiple 9mm perforations on the anterior cortex for cement removal. They bypassed the most distal perforation by 5cm. 9 (4%) fractures were reported out of 219 cases. In 8 of these, the fractures were distal to the tip of the implant and were associated with trauma. Only one fracture occurred through a perforation site, and there was an associated fracture through the implant.[167] A third report of anterior perforation for cement removal has been made by Zweymüller. The implant bypassed the perforation by two cortical diameters in only one case (2.5%) of 41. There were no fractures with a mean follow-up of 7.4 years.[168] Metikala describes the use of a 5mm cannulated drill bit in the distal femoral articular surface to retrieve broken nails. No fractures occur through this 5mm window.[169] Wysocki describes two cases of periprosthetic femoral shaft fractures following a computer navigated total knee arthroplasty. The first case was of a 46 year old woman with two bicortical 3.2mm self drilling threaded pins inserted anterior to posterior in the distal third of the femoral shaft. She suffered a transverse shaft fracture through the distal hole at 10 weeks postoperatively during normal ambulation. The second case involved a 77 year old woman who suffered a similar fracture after falling at 9 weeks postoperatively. Both cases were treated with antegrade femoral nails.[170]

Defects created in the distal femur from hardware removal have also caused fractures. Davison followed 41 patients treated with lateral condylar femur plates for which 15 patients requested plate removal due to lateral knee pain. In 4 (27%) patients, a refracture of the distal femur occurred between 4 and 10 weeks of hardware removal during normal functional activities. The hardware had been removed between 5 and 18 months after the index procedure, with a mean of 13 months. The remaining 11 patients who requested hardware removal did not experience refracture.[171]

In perhaps the most relevant case reports in the literature, two authors independently report the creation of distal anterior or anterolateral windows to aid the insertion of locking screws. Ogbemudia performed distal locking of six antegrade cephalomedullary nails without use of the image intensifier. A 1cm by 0.5cm longitudinal anterolateral cortical window was created on the lateral condyle, through which the distal locking holes in the nail were identified. Locking screws were inserted without further incident. The patients performed isometric quadriceps exercises on postoperative day 3 and ambulated with non weightbearing on postoperative day 5. Partially weightbearing commenced 6 weeks postoperative and continued until 24 weeks.[172] An earlier publication by the same author describes insertion of distal locking screws in a pregnant woman for which fluoroscopy was deemed to be too high of a risk for the fetus. In this case, the longitudinal anterolateral cortical window in the lateral condyle was used for distal locking as well as to confirm passage of the guide wire into the distal femur. The patient was initially prescribed non weightbearing. She was lost to follow-up at 14 weeks but did not fracture before this time.[173] Kanellopoulos reports a series of six salvage cases where the image intensifier failed intraoperatively. In each case, the distal anterior femur was exposed and a central longitudinal window at the tip of the nail is created measuring approximately 3-4cm in length and 1.5-2.0cm in width. Partial weightbearing was initiated 6 weeks postoperatively, and all cortical windows healed within 3 months. No fractures through the window occurred.[174]

1.8 Biomechanics

1.8.1 Intact Femurs

Biomechanical analyses have been performed to assess femoral strength and load to failure of the femur. The main measures of biomechanics are stress, strain, stiffness, and load to failure. Stress is the force per unit area that can be applied before a material yields or breaks. Strain is the change in dimension of a material as a ratio of that dimension itself. Stiffness is a ratio of force over displacement. Load to failure is measured as the maximal load that can be applied before a material fails, where the definition of failure can be variable depending on the test and application.

Mean fracture loads vary across cadaveric femurs, especially with different ages of cadaveric bone. In axial testing, Anez-Bustillos measured a mean failure load of 6771 ± 2583 N in 10 cadaveric femurs with a mean age of 81.7 ± 10.7 years.[175] Holzer reports a mean failure load of 3504 ± 1570 N in cadaveric femurs with a mean age of 75.2 ± 7.0 years.[37] Fracture loads are higher for the distal femur than the femoral neck. Powell measured a mean fracture force of 10,040 N required for a direct impact to the distal femur.[176]

1.8.2 Cortical Defects

The effect of defects in the cortex depend greatly on the size of the defect, the thickness of the cortex, the shape or location of the defect, and many other factors. Many investigators have attempted to characterize the effect of cortical defects on the strength of bone. The location of cortical defects appears to play a large role in the different results that have been achieved.

Hipp showed that the length of an elongated defect in the shaft of a long bone strongly influences the torsional strength, as a transcortical defect with a diameter of 50% of the outer bone diameter will reduce torsional strength by 60%.[177] A defect as small as 10% of the bone diameter has been shown to reduce peak torque and energy absorption under torsional loading.[178] Chiba studied spherical cortical defects of varying diameters from 5mm to 30mm. The location of the center of the defect was varied from within the canal to outside. There was no difference in load to failure for inner or outer erosions as long as the defect did not perforate the entire thickness of the cortex. Once the full thickness of the cortex was disrupted, load to failure decreased significantly. This shows that cortical defects without full perforation of the cortex do not weaken the femur significantly.[179] Robertson performed testing of 12 paired cadaveric femurs and created lesions in one femur of each pair. Lesions ranged from 3cm to 6.5cm in length, 1cm to 3cm in width, and 10% to 100% of cortical thickness. Measured torsional strength was not significantly correlated with lesion area ($p > 0.05$) or percentage of cortical thickness removed ($p > 0.05$). There was a significant correlation between torsional strength and estimations of bone density via Dual-Energy X-Ray Absorptiometry. Bone strength of cadaveric bone may therefore be more related to the cadavers themselves rather than defects created.[180] Yeni arrived at a similar conclusion in cadaveric analyses of the mineral composition of femurs and tibias. The result of their calculations show that differences in bone composition can explain 35%-59% in variation of fracture toughness.[181]

The proximal femur has also been extensively studied. Alexander tested eight matched pairs of proximal femurs and created an osteolytic femoral neck defect in one femur of each pair. The size of the lesion varied from 22mm to 40mm. Mean failure load of intact femurs was 10,690 ± 3,090 N compared to 5,560 ± 2,030 N ($p < 0.001$) in femurs with a lesion. The average reduction in failure load was 48%.[182] Benca reports similar results in a study of sixteen matched pairs of femurs. A lesion measuring one-third of the femoral neck in was created in one femur of each pair. Failure load of intact femurs was 7,660 ± 3,340 N. When the lesion was superolateral along the neck, stiffness was decreased by 19% and the failure load decreased to 4,530 ± 1,560 N. With an inferomedial lesion, stiffness was decreased even further by 66% and failure load decreased to 1,890 ± 1,730 N.[183] Large lesions were investigated by Çaypınar in simulated single-stance loading. A 35% defect was created in the femoral neck of 21 cadaveric femurs. They were then loaded to 600 N. No fracture was detected. The lesion was then increased to 45% and the femurs were loaded, again without fracture. Upon increasing the lesion size to 55%, three femurs fractured before reaching 600 N at a mean of 455 N. The remaining 18 femurs were loaded until failure at a mean of 1,270 N. They conclude that the majority of osteoporotic bones with large metastates can withstand high forces of compressive loading.[184]

Yang studied the effect of cortical defects in the proximal femur resulting from hardware removal. 56 paired cadaveric femurs were used. The Proximal Femoral Nail Antirotation and Dynamic Hip Screw were inserted and removed. Compression loads were then applied until failure. The intact femurs measured a fracture load of 6,228 ± 1694 N and a stiffness of 991 ± 100 N/mm. Femurs with an implanted and removed Proximal Femoral Nail Antirotation had a decreased fracture load of 4,086 ± 1,628 N and stiffness of 656 ± 155 N/mm ($p = 0.014$). The femurs instrumented with a Dynamic Hip Screw also had decreased fracture load of 4,000 ± 1,588 N and stiffness of 656 ± 155 N/mm ($p < 0.001$). There was no statistical difference between the two experimental groups. However, fracture patterns were different, with intertrochanteric fractures in the cephalomedullary nail group and subtrochanteric fractures in the sliding hip screw group.[185] Miller performed a similar comparison of cortical defects following surgical instrumentation of cadaveric femurs. Three experimental groups were compared for simulated cephalomedullary nail entry with an intended piriformis portal. The contralateral femur served as the control. In group 1, a 10mm defect was created at the piriformis fossa. This defect was large in group 2 at 14mm. In group 3, the 14mm defect was located not at the piriformis fossa but on the superior aspect of the femoral neck. Stiffness and load to failure were decreased in group 3, suggested that the location of the defect is more important than the size.[186]

In the subtrochanteric region, Sivasundaram created 40mm diameter defects in the anterior, posterior, medial, and lateral subtrochanteric regions of the femur. There were five synthetic femurs in each group, with four intact femurs as controls. There was no difference in lateral bending stiffness between each group ($p = 0.069$). Torsional stiffness was decreased in the medial group compared to the intact, anterior, and lateral groups ($p < 0.013$). Medial defects showed less axial stiffness compared to the intact group ($p = 0.006$). Axial strengths to failure were also lower for the medial group compared to the anterior ($p = 0.001$) and posterior ($p = 0.001$) groups.[187]

Along the femoral shaft, the location of lesions appears to play a large role. Lateral femoral lesions are clinically important as they are the preferred location for venting of prophylactic fixation and for failed attempts of distal locking screws.[188] Fox performed a recent finite element analysis on the effect of defect location on synthetic femurs. Intact femurs served as controls. Experimental femurs were fractured and nailed, with venting holes of either 5mm or 10mm in either the anterior, lateral, or posterior surfaces. 18 synthetic femurs were used in total. Anterior and posterior venting holes had similar stresses to the intact femurs regardless of the defect size. Maximum tensile stresses were significantly higher in the femur with lateral holes, with a 7% increase from 5mm to 10mm holes. However, in all simulations, the femoral neck was the predicted site of failure.[189]

At the distal femur, less data is available regarding the effect of anterior or lateral cortical defects. Murray analysed the effects of defects in the lateral condyle in cadaveric femurs. A contained defect was created to simulate a giant cell tumour. Intact specimens had significantly higher load to failure than specimens with a defect.[190] Some of the arthroplasty literature has analyzed the effect of anterior defects such as notching. While presented here, this may be less applicable due to the creation of an anterior notch with an extension of the anterior femoral cut rather than perforation from a reamer. Lesh analyzes the effect of anterior notching on bending and torsional loads. Notches were created as full thickness defects just proximal to the anterior flange of a femoral component. Control femurs did not have a notch. In bending, femurs with an anterior notch fractured through the notch at a mean of 9,690 N while intact femurs fractured through the shaft at a mean of 11,813 N ($p = 0.0034$). In torsion, femurs with an anterior notch did not have a different fracture pattern but failed at a lower strength of 81.8 Nm compared to 134.7 Nm in intact femurs ($p = 0.01$).[191] Shawen reports similar results with a 3mm anterior notch. The notched femurs failed at an average torsional load of 98.9 Nm while the controls failed at 143.9 Nm ($p < 0.01$).[192] Finite element analyses performed by Zalzal show that anterior femoral notches greater than 3mm with sharp corners may be at highest risk for fracture.[193]

1.8.2.1 Estimation of Fracture Risk

The prediction of fracture risk is an evolving science. It has long been recognized that Orthopaedic surgeons cannot accurately estimate the reduction in strength or load bearing capacity of proximal femoral defects.[194] Initial attempts based on radiographs proved rather rudimentary. Dijkstra published in 1997 on the risk of pathologic subtrochanteric fracture with a longitudinal lesion with cortical disruption measuring 38mm or greater or an intramedullary lesion measuring 30mm.[195]

Mirels published a landmark paper in 1989 with a scoring system comprised of four components. Lesions were given a location score of 1 for the upper extremity, 2 for the lower extremity, and 3 for the trochanteric region. On radiographic appearance, a score of 1 was given for blastic lesions, 2 for mixed lesions, and 3 for lytic lesions. Based on size, a score of 1 was given for lesions less than a third of the width of the bone, a score 2 for lesions between a third and two-thirds, and a score of 3 for lesions greater than two-thirds of the width of the bone. Finally, a score from 1 to 3 was also given depending on the pain caused by the lesion. 78 lesions were followed for 6 months. 51 lesions with a mean score of 7 did not fracture, whereas 27 lesions with a mean score of 10 suffered a fracture. Mirels found that as the score increased above 7, so did the percentage risk of fracture, and recommended prophylactic fixation for scores of 8 or higher.[196] Mirels' score is easily applicable with high inter-rater reliability. Damron recruited 53 participants from five experience levels, including musculoskeletal radiologists, radiation or medical oncologists, Orthopaedic residents, Orthopaedic surgeons, and fellowship-trained Orthopaedic oncologists. There was a highly significant agreement across all levels of experience for overall Kappa and for the concordance between individual and overall scores.[197]

Benca analyzed the use of Mirels' criteria in 22 studies and found that the overall negative predictive value of Mirels' was between 86% and 100%, but positive predictive value was poor, between 23% and 70%.[198] Additionally, it has been shown that radiographs are inferior compared to computed tomography in estimating cortical thickness.[199]

Recent developments in fracture risk prediction include Computed Tomography Rigidity Analysis (CTRA), first published by Snyder in 2006.[175,200] Computer tomography of the bone in question is performed and simulated analyses of axial, bending, and torsional rigidities are performed. Reduction of greater than 35% any of these three loading parameters are considered a risk for fracture.[201] Additionally, strain analyses have been shown to correctly predict the location of fractures.[202,203]

In a comparison between CTRA and Mirels' score, CTRA was shown by Damron to have higher sensitivity (100% vs 66.7%), higher specificity (60.6% vs 47.9%), higher positive predictive value (17.6% vs 9.8%), and higher negative predictive value (100% vs 94.4%) when compared with a Mirels' cut-off of greater than or equal to 9. Multivariate logistic regression controlling for confounding variables indicated that CTRA was a better predictor of fracture ($p < 0.001$).[201]

1.8.3 Synthetic Femurs

Synthetic femurs have been created for biomechanics testing in response to the variability in human cadavers.[204] Synthetic femurs have been shown to react within the range of cadaveric specimens, with no significant differences detected. However, the inter-specimen variability of synthetic femurs was 20-200 times lower than cadaveric specimens.[205] Another analysis shows that the current fourth-generation composite femurs exhibit an inter- and intra-specimen variation under 10% for all cases and perform within the biological range of healthy adult bone less than 80 years of age.[206,207] Modes of testing between synthetic femurs and cadaveric femurs include bending, torsion, axial loading, cortical screw purchase, screw pull-out, and shear forces.[206-209]

Concerns have arisen regarding the external validity of the current fourth-generation composite femurs in osteoporotic fracture models. Basso compared the fourth-generation synthetic femurs with osteoporotic cadaveric femurs and found different fracture patterns. They conclude that the synthetic femurs should only be used to represent young healthy femurs.[210] Attempts were made to use the foam anatomic femurs as a representation of osteoporotic bone but this proved unsuccessful.[211] In response, a novel osteoporotic composite femur model was produced with lower inner foam density and a thinner cortical shell.[212] The first biomechanics study to use this novel synthetic femur was published as recently as October 2018.[206]

1.9 Rationale for Thesis

Anterior cortical perforation of the distal femur is a well recognized complication of cephalomedullary nailing. Recent advances in nail design in response to this complication have resulted in a decreased radius of curvature of newer cephalomedullary nails. However, due to the wide range of physiologic variation in the anterior bow of the femur, some femurs will remain at risk for anterior cortical perforation. The literature has documented many cases of this but there is no consensus on appropriate treatment. Current strategies include non-weightbearing or revision surgery, both of which pose significant consequences. Non-weightbearing has been shown to be a risk factor for medical and cardiorespiratory complications and decreases function at 1 year postoperatively. An unnecessary revision surgery subjects patients to increased risk of complications and infections. The rationale for this thesis was to explore the biomechanical effects of an anterior cortical perforation of the distal femur and apply this to clinical practice. As a posterior start point is a recognized risk factor for anterior cortical perforation and an anterior start point is biomechanically less favourable, this thesis will also explore the ideal start point from a biomechanical perspective.

1.10 Thesis Objectives

The objectives of this thesis are:

1. Perform a biomechanical analysis of osteoporotic validated synthetic femurs to assess the effect of different start points on axial, bending, and torsional stiffnesses and cortical strains.
2. Assess the effect of an anterior cortical perforation of the distal femur on the axial, bending, and torsional stiffnesses and cortical strains.
3. Provide evidence for postoperative weightbearing following a recognized anterior cortical perforation of the distal femur.

1.11 Thesis Hypotheses

The hypotheses of this thesis are:

1. There will be no difference in axial, bending, and torsional stiffness or cortical strains between the anterior, neutral, and posterior start points.
2. An anterior cortical perforation of the distal femur will not reduce axial or bending stiffness but will reduce torsional stiffness.

1.12 References

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Chapter 2: Biomechanics Analysis of Anterior Cortical Perforation in Antegrade Femoral Nailing

2.1 Introduction

Hip and femur fractures are common in Canada and are on the rise. The annual incidence of hip fractures is 33 per 10,000 patients over the age of 50.[1] There will be a projected 88,124 hip fractures annually in Canada by 2041 with an estimated annual cost of $2.4 billion.[2,3] One method of surgical fixation of hip and femur fractures is the cephalomedullary nail. One known complication of cephalomedullary nails is anterior cortical perforation of the distal femur, occurring in 0.47-0.63% of cases.[4-7] The clinical significance is unclear.

The risks factors for an anterior cortical perforation of the distal femur are well described, including a femur with increased anterior bow, a straighter nail, and a posterior start point.[8] Given that the start point is the factor that is most dependent on the surgeon, many studies have investigated the ideal point of entry for a trochanteric cephalomedullary nail.[9-11] There is variable anatomy in the greater trochanter with respect to the canal of the proximal femur, making identification of a uniform start point difficult.[11]

The ideal start point has been described as just lateral to the long axis of the femur on the anteroposterior radiograph, regardless of the location of the tip of the greater trochanter.[9] On the lateral view, the start point should be colinear with the long axis of the femur and the femoral neck, which is often at the anterior one third of the greater trocanter.[9,12,13] An anterior start point is at a biomechanical disadvantage.[14] However, a posterior start point increases the risk of anterior cortical perforation at the distal femur.[8] Multiple attempts in achieving an ideal start point may result in increasing the risk of iatrogenic or postoperative fracture of the greater trochanter.[15,16]

Perforations of the distal femur have also been reported with use of the Reamer-Irrigator-Aspirator, and as iatrogenic cortical windows to allow for distal locking of a cephalomedullary nail without use of intraoperative fluoroscopy.[17,18]

Currently published management of an anterior cortical perforation includes prolonged weightbearing restrictions or revision surgery. Restricted weightbearing has been shown to increase postoperative medical complications, reduce the ability to return to pre-injury function, and decrease outcomes at 1 year postoperatively.[19-22]

The purpose of this chapter is to examine the biomechanical effect of different start points in the sagittal plane on the greater trochanter and to identify acceptable start points between an anterior start, neutral start, and posterior start point. The effect of an anterior cortical perforation will also be investigated.

2.2 Materials and Methods

2.2.1 Synthetic Femurs

32 novel fourth-generation composite model of osteoporotic femora (medium-sized left femur Model 3503– 118; Pacific Research Laboratories, Inc, Vashon Island, WA) with 18mm inner diameter canal were used in this study. These have been validated to simulate osteoporotic bone and have been used in prior analyses of osteoporotic bone models.[23],[24] Synthetic femurs carry an advantage over cadaveric bone in that the inter-specimen variability is much lower than that available with cadaveric bone.[23]

8 intact femurs were first tested for mechanical stiffness to provide baseline values, distributed into 4 groups of 2 femurs each based on axial stiffness in rank order fashion (i.e. the femur with the highest stiffness was paired with the femur with the lowest stiffness; the femur with the 2nd highest stiffness was paired with the femur with the 2nd lowest stiffness, etc), and then randomly assigned by a blinded coauthor to one of the 4 implant groups; thus, there was a total of 1 intact femur group (i.e. Intact) and 4 implanted femur groups (i.e. Group 1 to 4) of 8 specimens each.

2.2.2 Instrumentation

Gamma3 R1.5 (Stryker) titanium nails were used with distal diameter of 10mm and length of 400mm. The neck-shaft angle was 125 degrees. A titanium lag screw measuring a diameter of 10.5mm and length 100mm was used. A set screw was tightened to the lag screw to lock the proximal construct. The proximal distal locking screw was fully threaded with a diameter of 5mm and length 55mm. The distal locking screw was fully threaded with a diameter of 5mm and length 75mm.

Five groups were created. Group 1 was designated the intact femur group without instrumentation. Groups 2-5 differed proximally by the start point. On the anteroposterior view, the start point was at the greater trochanter in all groups. Group 2 utilized a start point anterior to the midline of the proximal canal on the lateral view. Group 3 utilized a neutral start point in line with midline of the proximal canal. Groups 4 and 5 had an identical start point that was posterior to the midline of the proximal canal on the lateral view. Group 4 had an additional anterior cortical perforation of the distal femur.

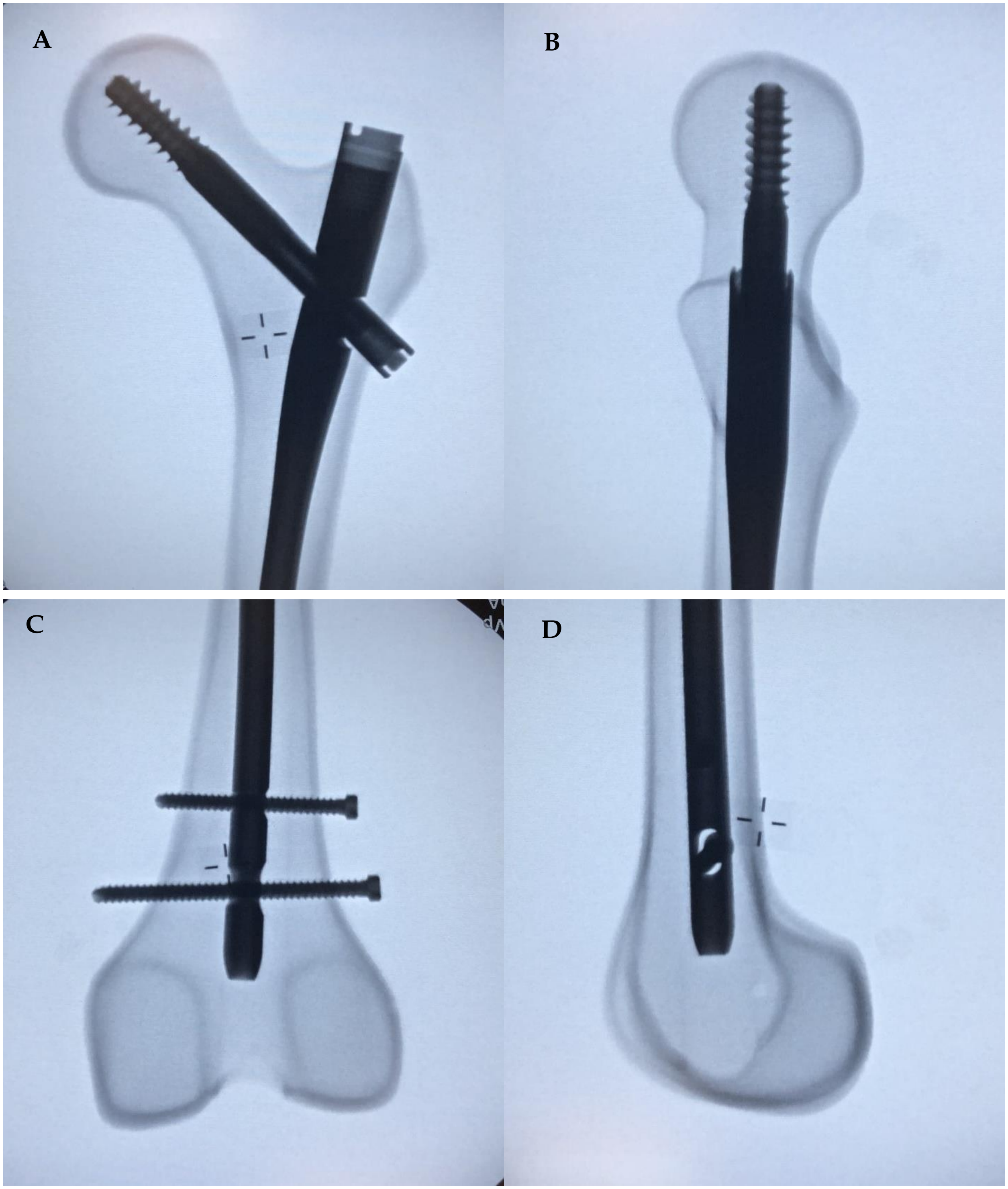

Figure 2.1. Radiographic images of hardware placement showing the proximal anteroposterior (A) and lateral (B) and distal anteroposterior (C) and lateral (D) radiographs. The start point for this cephalomedullary nail was neutral, resulting in a central position in the sagittal plane at the distal femur.

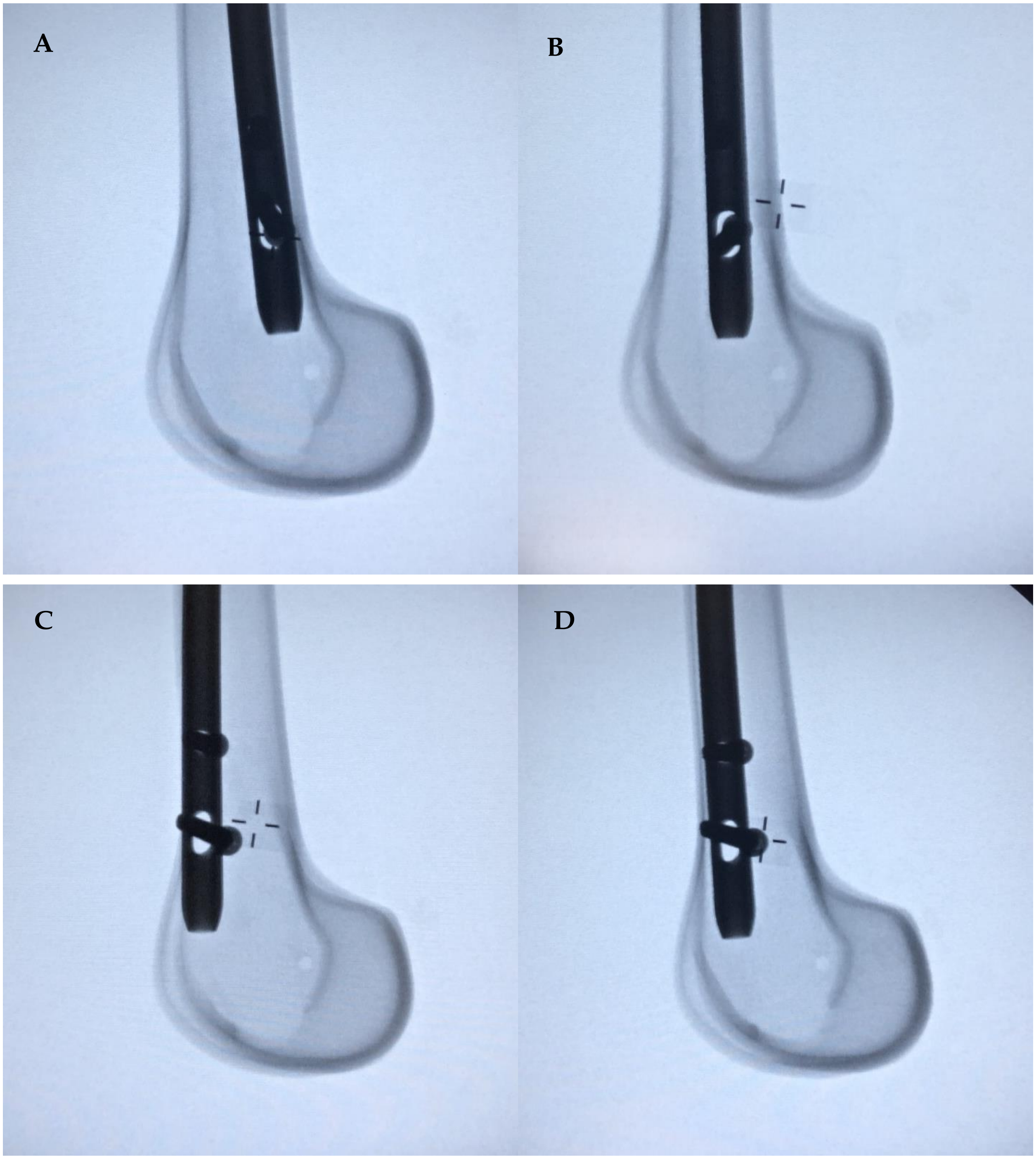

Figure 2.2. Radiographic images showing the difference in distal nail position depending on start point. (A) Group 1 had an anterior start point with a distal nail tip. (B) Group 2 had a neutral start point with a central tip. (C) Group 3 had a posterior start point with an anterior cortical perforation of the distal femur. (D) Group 4 had a posterior start point with an anterior nail position without perforation.

Cortical perforations were created via eccentric reaming of the anterior cortex of the distal femur, similar to a case of anterior cortical perforation of the distal femur caused by the Reamer-Irrigator-System as reported by Belthur.[17] A guide wire was advanced retrograde through the anterior cortex of the distal femur into the femoral shaft. The 10mm reamer was then passed over the guide wire (Figure 2.3) and advanced until the cortex was fully perforated. This perforation measured 10mm in width and approximately 6cm in length.

Figure 2.3. Eccentric reaming of the anterior cortex using the 10mm reamer created the anterior cortical perforation of the distal femur. The reamer was advanced further until the full thickness perforation had been created.

Instrumentation followed the manufacturer's recommendations following identification of a start point. The entry reamer was advanced, followed by the nail. A lag screw was inserted aiming for the center, center of the femoral head and advanced appropriately. A set screw was then placed in locking configuration. Two distal screws were then inserted freehand under fluoroscopic guidance using the perfect circle freehand technique.

2.2.3 Biomechanics Testing

Several aspects of the current biomechanical testing protocol should be highlighted. First, biomechanical tests were carried out in axial, coronal, sagittal, and torsional loading modes to thoroughly assess the mechanical stability of the specimens. Second, all mechanical tests were done at ambient room temperature using a mechanical tester (Instron 5967, Norwood, MA, USA) equipped with its own load cell (+/- 30 kN range, +/- 0.5% accuracy) and displacement transducer (1140 mm range, +/- 0.05% accuracy). Third, rosette strain gauge readings were also collected, since this is a long-established technique of non-destructively assessing local bone stresses leading to potential bone failure; however, rosette readings were only recorded for axial tests, since this is the loading mode most often assessed for potential bone failure by biomechanical studies on femur fixation. Fourth, applied force levels were lower than what might occur physiologically for many daily activities or injuries in order to avoid permanent gross damage to the implants allowing their reuse in multiple femurs and to avoid overshooting the operating limits of the rosettes. Finally, all test setups, loading regimes, measurement techniques, data analyses, and statistical analyses were based on previously established protocols.[25–31]

2.2.3.1 Axial Testing

Each intact and implanted femur was aligned in 7° of adduction in the coronal plane and aligned vertically in the sagittal plane to replicate the one-legged stance phase of walking (Figure 2.4). Distally, the condyles rested on top of a rigidly clamped and tailor-made cement block (Flowstone, King Packaged Materials Company, Burlington, ON, Canada) that matched the condylar geometry perfectly, thereby simulating the tibial plateau.

Proximally, the femoral head was inserted into a smooth metal cup mimicking the acetabulum. A vertical force was then applied to the superior surface of the femoral head through the metal cup using force control (preload, 25 N; max load, 250 N; load sustain, 120 s; load rate, 10 N/s) (Figure 2.5). The slope of the initial rise of the force-displacement graph (i.e. 25 to 250 N) was defined as axial stiffness, while the coefficient of determination was $R^2 > 0.96$ indicating the high linearity of the graph and that no gross damage was done to the femur or implant.

Rosette strain gauge readings were also collected during axial loading. Each intact and implanted femur was equipped with 2 rosettes (Model CEA-06-062UR-350, Vishay Micro-Measurements, Raleigh, NC, USA), which were each composed of 3 linear strain gauges arranged in a "rectangular" 0°-45°-90° pattern. Proximal rosettes were used due to the possibility of a difference in stresses caused by the different start points in the proximal femur. The proximal rosette was located on the anterior surface midway between the greater and lesser trochanters (i.e. the distance from the rosette's top edge to the greater trochanter was 1.25 inches) (Figure 2.6A), whereas the distal rosette was located 10 mm above the anterior perforation for perforated femurs or at the exact corresponding location for non-perforated femurs (i.e. the distance from the rosette's bottom edge to the intercondylar notch was 3.5 inches) (Figure 2.6B). Wire leads were soldered to the rosettes, secured to the femur using tape, and connected to an 8-channel data acquisition system via a quarter bridge Wheatstone configuration (Cronos-PL, IMC Mess-Systeme GmbH, Berlin, Germany), which was linked to a computer for data storage and analysis with dedicated software (Famos v5.0, IMC Mess-Systeme GmbH, Berlin, Germany). The manufacturer-provided gauge factor of 2.1 was used, which is an index for strain sensitivity at a particular temperature, i.e. ratio of resistance change to strain change. Each rosette reading was actually composed of 3 linear strain readings (Figure 2.6C) that were averaged for the middle 90 s of the 120 s load sustain period and then converted to a final Von Mises stress for each rosette; this represents the stress magnitude but not its type (i.e. tensile or compressive) or 3D direction (i.e. x, y, z directional components of the magnitude). To do so, the experimental values of $\varepsilon_{1,2,3}$ = measured linear strain readings, E = artificial cortical bone elastic modulus = 6 GPa, and v = artificial cortical bone Poisson's ratio = 0.26, were used to compute the final Von Mises stress for each "rectangular" rosette with these formulas:

S_{VM} = Von Mises stress = $\sqrt{S_{MAX}^2 + S_{MIN}^2 - S_{MAX}S_{MIN}}$

S_{MAX} = maximum principal stress = $\frac{E}{2}\left[\frac{(\varepsilon_1 + \varepsilon_3)}{(1-\nu)} + \frac{\sqrt{2}}{(1+\nu)}\sqrt{(\varepsilon_1 - \varepsilon_2)^2 + (\varepsilon_2 - \varepsilon_3)^2}\right]$

S_{MIN} = minimum principal stress = $\frac{E}{2}\left[\frac{(\varepsilon_1 + \varepsilon_3)}{(1-\nu)} - \frac{\sqrt{2}}{(1+\nu)}\sqrt{(\varepsilon_1 - \varepsilon_2)^2 + (\varepsilon_2 - \varepsilon_3)^2}\right]$

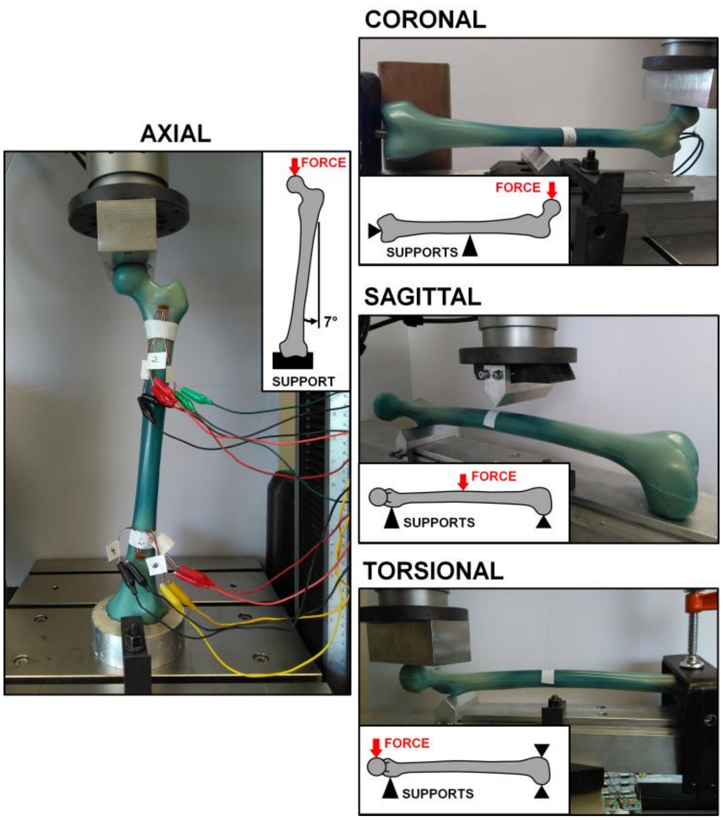

Figure 2.4. Biomechanical loading modes for axial, coronal, sagittal, and torsional tests. Only an Intact specimen is shown, but the setups were the same for all test groups. Rosettes and associated wiring were only used during axial tests.

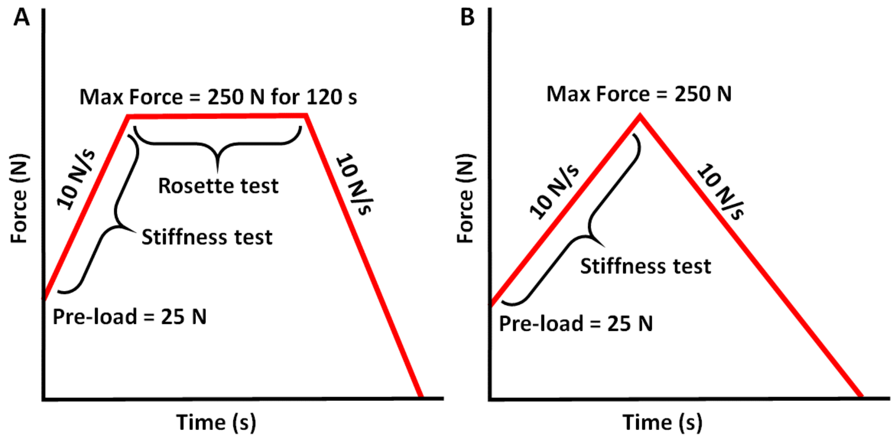

Figure 2.5. Biomechanical loading waveforms. (A) axial waveform, (B) coronal, sagittal, and torsional waveform.

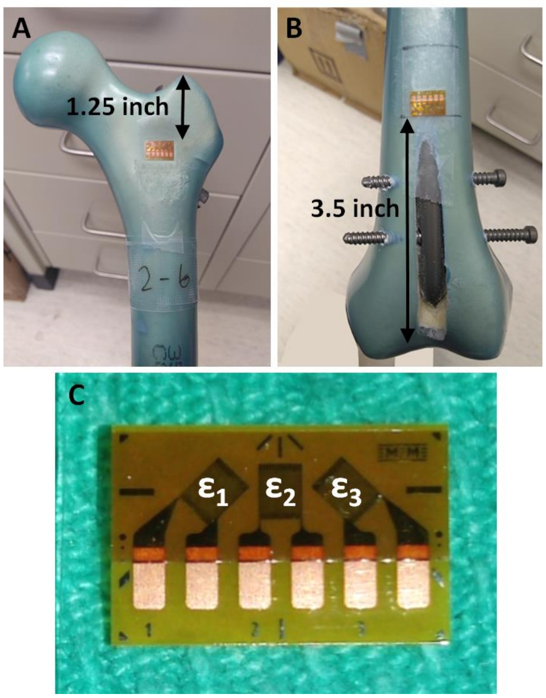

Figure 2.6. Rosette locations. (A) proximal rosette, (B) distal rosette, (C) close-up of rosette with linear strain gauges ε_1, ε_2, and ε_3. Wire leads are not shown so rosettes are clearly visible. Only a perforated femur is shown, but for all test groups the rosettes were at the same corresponding locations.

2.2.3.2 Coronal Testing

Each intact and implanted femur was placed horizontally into a 3-point bending test jig with the femoral head facing upwards to mimic side loading at about midshaft that might occur during an injury event (Fig.1). Specifically, a metal support triangle was placed under the shaft at a distance of 190 mm from the intercondylar notch, a support bolt was inserted superficially into the distal end of the intramedullary canal, and a support block was lightly pressed up against the posterior condylar surface to prevent femur rotation. A vertical force was then applied to the medial surface of the femoral head through a smooth metal cup using force control (preload, 25 N; max load, 250 N; load rate, 10 N/s) (Fig.2B). The slope of the initial rise of the force-displacement graph (i.e. 25 to 250 N) was defined as coronal stiffness, while the coefficient of determination was $R^2 > 0.99$ indicating the high linearity of the graph and that no gross damage was done to the femur or implant. No rosette readings were collected for this loading mode.

2.2.3.3 Sagittal Testing

Each intact and implanted femur was positioned horizontally into a 3-point bending test jig with the femoral head facing sideways to simulate front loading at midshaft that might happen during an injury event (Fig.1). Specifically, a metal support triangle was placed just proximal to the lesser trochanter, while the posterior surface of the condyles rested freely on top of a metal plate, so that the distance between the proximal and distal supports was 400 mm. A vertical force was then applied to the anterior surface of the femoral shaft through a metal triangle located at about midshaft (i.e. 203 mm from the proximal support triangle) using force control (preload, 25 N; max load, 250 N; load rate 10 N/s) (Fig.2B). The slope of the initial rise of the force-displacement graph (i.e. 25 to 250 N) was defined as sagittal stiffness, while the coefficient of determination was $R^2 > 0.99$ indicating the high linearity of the graph and that no gross damage was done to the femur or implant. No rosette readings were collected for this loading mode.

2.2.3.4 Torsional Testing

Each intact and implanted femur was placed horizontally into a test jig with the femoral head facing sideways to mimic femoral shaft rotation during physiological activities (Fig.1). Specifically, a metal support triangle was placed just proximal to the lesser trochanter, the posterior surface of the condyles rested on top of a metal plate, and the anterior surface of the condyles was clamped using a metal plate to prevent condylar rotation, so that the distance between the proximal and distal supports was 400 mm. A vertical force was then applied to the anterior surface of the femoral head through a smooth flat metal block using force control (preload, 25 N; max load, 250 N; load rate, 10 N/s) (Fig.2B). Note that, in addition to pure rotation around the shaft, this loading setup did produce some minor bending around the metal triangle support. The slope of the initial rise of the force-displacement graph (i.e. 25 to 250 N) was defined as torsional stiffness, while the coefficient of determination was $R^2 > 0.99$ indicating the high linearity of the graph and that no gross damage was done to the femur or implant. No rosette readings were collected for this loading mode.

2.2.4 Sample Size Calculation

Sample size calculation was performed via the University of British Columbia Statistics Power/Sample Size calculator.[32] Synthetic femurs have been shown to have inter-specimen variability less than 10% which was entered as the sigma value.[33,34] For an alpha value of 0.05 and a beta of 0.8, a sample size of 7 was calculated to detect a 15% difference between the mean of the groups. A 15% difference between groups was deemed adequate, as previous data has shown that the risk of pathologic fracture increases above a 35% reduction in axial, bending, or torsional stiffness.[35] 8 femurs were then utilized per group to allow for the distribution of 8 intact femurs into 4 groups of instrumented femurs as previously described.

2.2.5 Statistical Analysis

Statistical analysis to compare the stiffness and stress measurements of the 5 test groups was done using one-way ANOVA (analysis of variance) with SPSS 25 software (SPSS Inc., Chicago, IL, USA) to determine if there was any statistical difference using $p = 0.05$ as the criterion. If ANOVA showed $p > 0.05$, this meant there was no statistical difference between any test groups for that particular mechanical measurement, and the ANOVA p value was reported. But, if ANOVA showed $p < 0.05$, this meant there was a statistical difference somewhere, then the Tukey's Honestly Significant Difference method was used to identify exactly which pairwise comparisons were statistically different or non-different, and the Tukey p values were reported.

2.3 Results

2.3.1 Axial

Axial Stiffness		
	Mean (N/mm)	95% CI (N/mm)
Intact	300	256.7 - 343.2
Anterior	394.8	359.4 - 430.2
Neutral	434.1	380.2 - 487.9
Perforated	410.3	355.2 - 465.5
Posterior	425.1	345.8 - 504.4

Table 2.1 Showing the mean and 95% confidence interval for the stiffness of each group in axial stiffness testing.

There was a difference between groups with p = 0.002 on ANOVA.

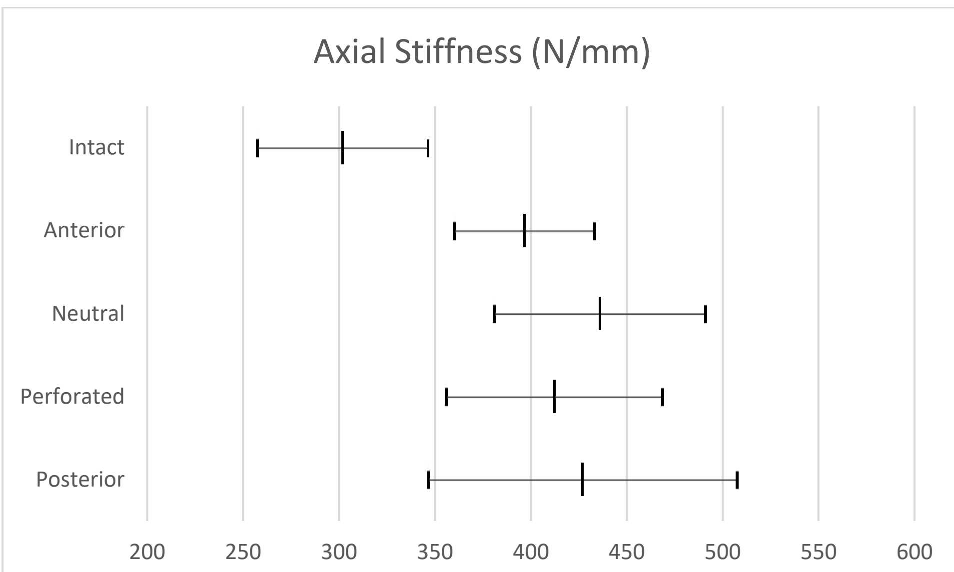

Figure 2.7 Showing the axial stiffness between groups.

Tukey's Honestly Significant Difference Axial	
Comparison	p value
Intact vs Anterior	0.052
Intact vs Neutral	**0.002**
Intact vs Perforated	**0.016**
Intact vs Posterior	**0.005**
Anterior vs Neutral	0.759
Anterior vs Perforated	0.990
Anterior vs Posterior	0.889
Neutral vs Perforated	0.951
Neutral vs Posterior	0.999
Perforated vs Posterior	0.991

Table 2.2 Showing the Tukey's Honestly Significant Difference for the axial stiffness testing.

There was a significant difference in axial stiffness between the intact femur and placement of the cephalomedullary nail in the neutral start point, posterior start point, and posterior start point with perforation. There was no significant difference between an intact femur without cephalomedullary fixation and one with intact cephalomedullary fixation from an anterior start point. There were no differences between any of the instrumented groups. There was no difference in axial stiffness between the posterior start point without perforation and with a perforation.

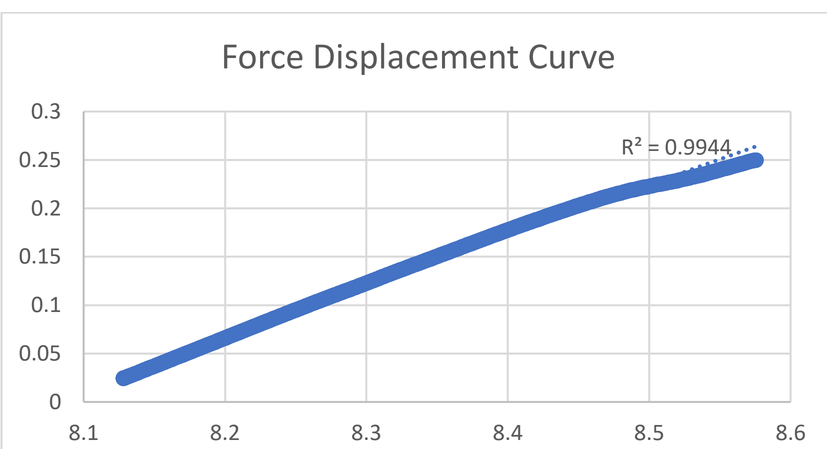

Figure 2.8 An example force displacement curve showing an R^2 value of 0.9944 (M Ching)

2.3.2 Coronal

Coronal bending stiffness		
	Mean (N/mm)	95% CI (N/mm)
Intact	10.25	9.88 - 10.63
Anterior	13.5	12.34 - 14.65
Neutral	13.97	12.80 - 15.14
Perforated	13.24	12.15 - 14.33
Posterior	13.76	12.53 - 15.00

Table 2.3 Showing the mean and 95% confidence interval for the stiffness of each group in coronal bending stiffness testing.

There was a difference between groups with $p < 0.001$ on ANOVA.

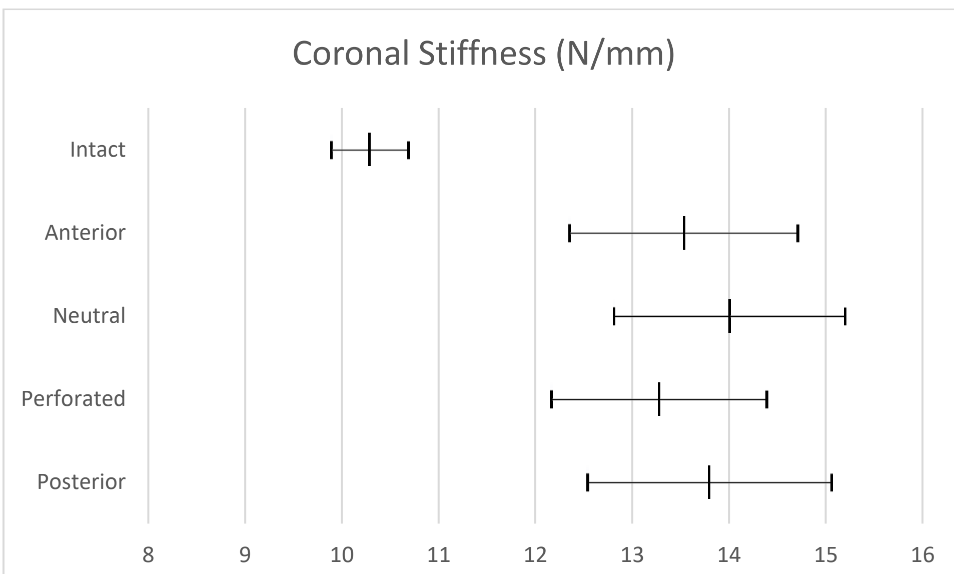

Figure 2.9 Showing the coronal bending stiffness between groups.

Tukey's Honestly Significant Difference Coronal	
Comparison	p value
Intact vs Anterior	**< 0.001**
Intact vs Neutral	**< 0.001**
Intact vs Perforated	**< 0.001**
Intact vs Posterior	**< 0.001**
Anterior vs Neutral	0.944
Anterior vs Perforated	0.994
Anterior vs Posterior	0.993
Neutral vs Perforated	0.777
Neutral vs Posterior	0.998
Perforated vs Posterior	0.919

Table 2.4 Showing the Tukey's Honestly Significant Difference for the coronal bending stiffness testing.

There was a significant difference in coronal bending stiffness between the intact femur and all groups of femurs instrumented with a cephalomedullary nail. There was no significant difference between any of the groups with a cephalomedullary nail. There was no difference in coronal bending stiffness between the posterior start point without perforation and with a perforation.

2.3.3 Sagittal

Sagittal Stiffness		
	Mean (N/mm)	95% CI (N/mm)
Intact	83.2	82.0 - 84.4
Anterior	110.3	104.7 - 115.9
Neutral	104.9	98.6 - 111.1
Perforated	119.3	114.4 - 124.1
Posterior	120.1	113.9 - 126.3

Table 2.5 Showing the mean and 95% confidence interval for the stiffness of each group in sagittal stiffness testing.

There was a difference between groups with p < 0.001 on ANOVA.

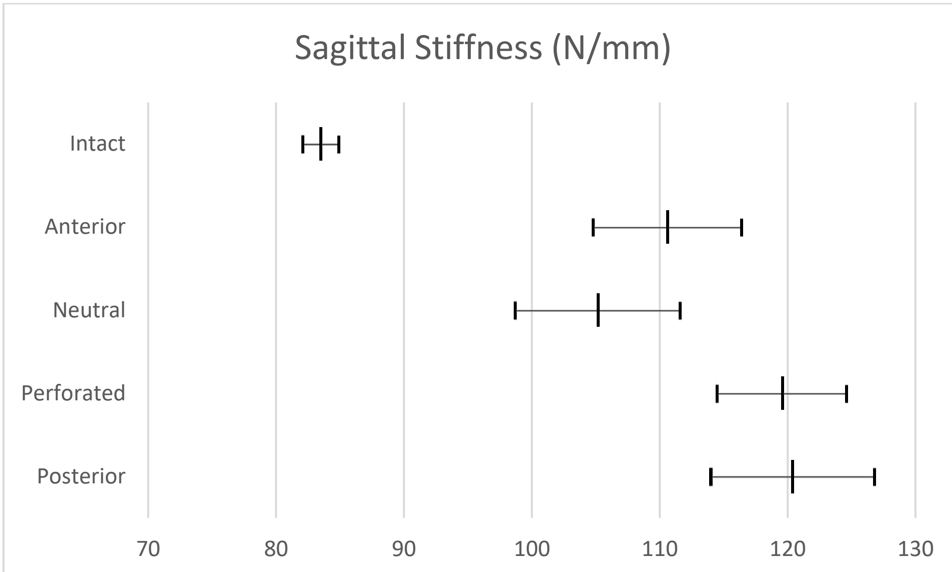

Figure 2.10 Showing sagittal stiffness between groups.

Tukey's Honestly Significant Difference Sagittal	
Comparison	p value
Intact vs Anterior	**< 0.001**
Intact vs Neutral	**< 0.001**
Intact vs Perforated	**< 0.001**
Intact vs Posterior	**< 0.001**
Anterior vs Neutral	0.416
Anterior vs Perforated	**0.047**
Anterior vs Posterior	**0.025**
Neutral vs Perforated	**< 0.001**
Neutral vs Posterior	**< 0.001**
Perforated vs Posterior	0.999

Table 2.6 Showing the Tukey's Honestly Significant Difference for the sagittal stiffness testing.

There was a significant difference in sagittal stiffness between the intact femurs and all groups of femurs with a cephalomedullary nail. Between the groups with a cephalomedullary nail, there was no difference between the anterior start point and the neutral start point. There was also no difference between the posterior start point with perforation and without perforation. The anterior and neutral groups showed significantly decreased stiffness compared to the posterior groups with and without perforation.

2.3.4 Torsional

	Torsional Stiffness	
	Mean (Nm/rad)	95% CI (Nm/rad)
Intact	91.9	88.4 - 95.4
Anterior	111.9	99.0 - 124.9
Neutral	121.5	114.0 - 129.1
Perforated	108.6	101.0 - 116.2
Posterior	112.7	104.6 - 120.8

Table 2.7 Showing the mean and 95% confidence interval for the stiffness of each group in torsional stiffness testing.

There was a difference between groups with $p < 0.001$ on ANOVA.

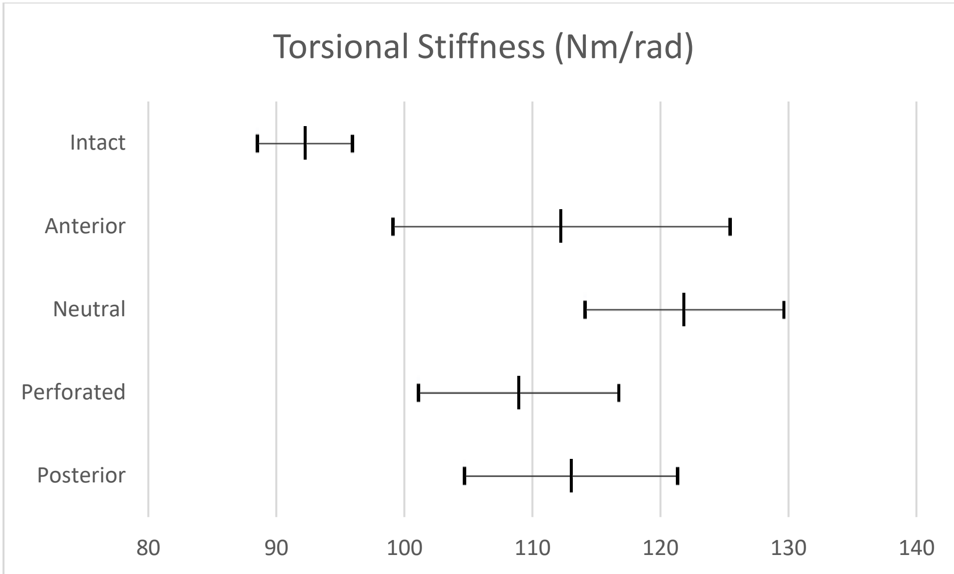

Figure 2.11 Showing torsional stiffness between groups.

Tukey's Honestly Significant Difference Torsional	
Comparison	p value
Intact vs Anterior	**0.003**
Intact vs Neutral	**< 0.001**
Intact vs Perforated	**0.018**
Intact vs Posterior	**0.002**
Anterior vs Neutral	0.338
Anterior vs Perforated	0.965
Anterior vs Posterior	1.000
Neutral vs Perforated	0.103
Neutral vs Posterior	0.426
Perforated vs Posterior	0.925

Table 2.8 Showing the Tukey's Honestly Significant Difference for the torsional stiffness testing.

There was a significant difference in torsional stiffness between the intact femur and all groups of femurs instrumented with a cephalomedullary nail. There was no significant difference between any of the groups with a cephalomedullary nail. There was no difference in torsional stiffness between the posterior start point without perforation and with a perforation.

2.3.5 Proximal Stress

Proximal Stress		
	Mean (MPa)	95% CI (MPa)
Intact	3.802	3.273 - 4.332
Anterior	1.896	1.328 - 2.465
Neutral	2.351	1.701 - 3.001
Perforated	2.756	2.166 - 3.346
Posterior	2.518	2.081 - 2.955

Table 2.9 Showing the mean and 95% confidence interval for the stress at the proximal femur as measured by the proximal strain gauge.

There was a difference between groups with $p < 0.001$ on ANOVA.

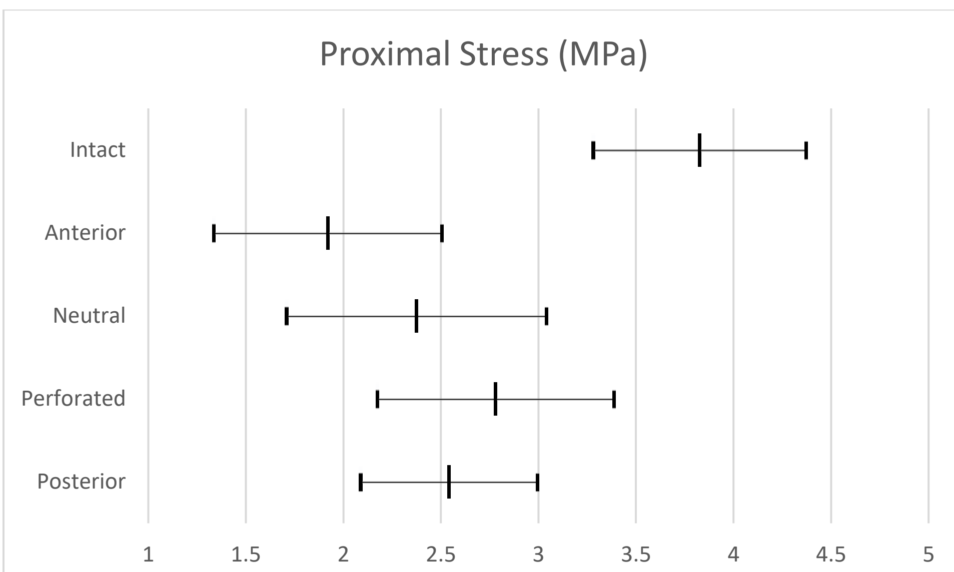

Figure 2.12 Showing proximal stresses between groups as measured by the proximal strain gauge.

Tukey's Honestly Significant Difference Proximal Stress	
Comparison	p value
Intact vs Anterior	**< 0.001**
Intact vs Neutral	**0.001**
Intact vs Perforated	**0.027**
Intact vs Posterior	**0.004**
Anterior vs Neutral	0.658
Anterior vs Perforated	0.098
Anterior vs Posterior	0.358
Neutral vs Perforated	0.745
Neutral vs Posterior	0.987
Perforated vs Posterior	0.953

Table 2.10 Showing the Tukey's Honestly Significant Difference for the stress at the proximal femur as measured by the proximal strain gauge.

There was a significant decrease in proximal stress between the intact femur and all groups of femurs instrumented with a cephalomedullary nail. There was no significant difference between any of the groups with a cephalomedullary nail. There was no difference in proximal stress between the posterior start point without perforation and with a perforation.

2.3.6 Distal Stress

Distal Stress		
	Mean (MPa)	95% CI (MPa)
Intact	2.058	1.528 - 2.589
Anterior	1.738	1.451 - 2.025
Neutral	2.234	1.797 - 2.672
Perforated	2.532	1.927 - 3.137
Posterior	2.272	1.819 - 2.725

Table 2.11 Showing the mean and 95% confidence interval for the stress at the distal femur as measured by the distal strain gauge.

There was no difference between any of the groups with a p = 0.096 on ANOVA.

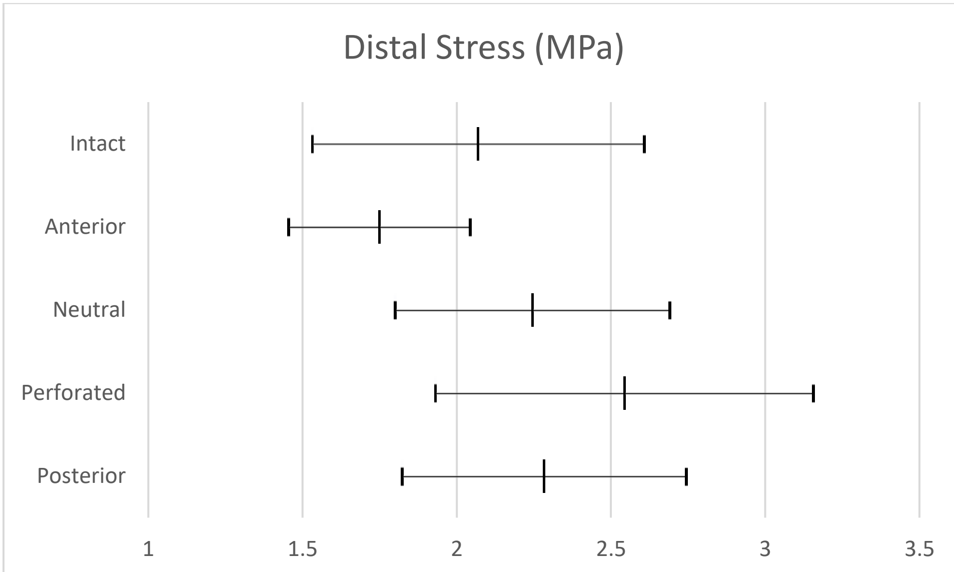

Figure 2.13 Showing distal stress between groups as measured by the distal strain gauge.

2.4 Discussion

In axial stiffness testing, the intact femurs were not statistically significant from the femurs with an anterior start point ($p = 0.052$). The neutral and posterior start points had increased stiffness compared to the intact femurs ($p < 0.017$). In coronal and sagittal bending and torsional testing, the intact femurs had decreased stiffness compared to all start points ($p < 0.019$).

2.4.1 Effect of Start Point

We found that in axial stiffness testing, a cephalomedullary nail with a neutral (434.1 N/mm) or posterior start point with (410.3 N/mm) or without perforation (425.1 N/mm) had 7% increased stiffness compared to a cephalomedullary nail with an anterior (394.8 N/mm) start point, although this did not reach statistical significance ($p > 0.759$).

In sagittal testing, the femurs with a posterior start point with and without perforation (119.3 N/mm and 120.1 N/mm) had increased stiffness compared to the anterior and neutral start points (110.3 N/mm and 104.9 N/mm) regardless of whether there was a perforation ($p < 0.048$). There was no statistically significant difference between the femur with a posterior start point with (119.3 N/mm) or without perforation (120.1 N/mm) ($p = 0.999$). There was no statistically significant difference between a femur with an anterior (110.3 N/mm) or neutral (104.9 N/mm) start point ($p = 0.416$).

In coronal testing, torsional testing, and proximal stress, there was a significant difference between the intact femurs and all groups of the instrumented femurs ($p < 0.028$), but no difference between any of the instrumented groups ($p > 0.098$). There was no difference between the femurs with a posterior start point with or without perforation.

The distal strain gauge did not show any difference between any of the groups, including intact femurs and instrumented femurs. ($p = 0.096$) There did not seem to be any effect from either the distal locking screws or a perforation of the anterior cortex of the femur. In Chapter 1, it was demonstrated that the distal anterior cortex of the femur experiences the lowest stresses through a gait cycle. The relatively low stresses experienced by the distal anterior cortex of the femur may explain the finding that a perforation did not significantly alter the stresses.

There was a statistically significant difference in sagittal stiffness between the femurs with an anterior or neutral start point compared the femurs with a posterior start point. The femurs with an anterior (110.3 N/mm) or neutral (104.9 N/mm) start point had decreased sagittal stiffness compared to the posterior start point (120.1 N/mm). This is in keeping with a prior publication showing that an anterior start point is at a biomechanical disadvantage.[14] There was no statistically significant difference in axial stiffness ($p > 0.759$), coronal bending stiffness ($p > 0.944$), torsional stiffness ($p > 0.338$), proximal stress ($p > 0.358$), or distal stress ($p > 0.345$).

2.4.2 Effect of Anterior Cortical Perforation

There was no difference between the femurs with a posterior start point with an anterior cortical perforation of the distal femur versus the posterior start point without a cortical perforation in any testing configuration ($p > 0.888$).

Testing Mode	Perforation		No Perforation		p value
	Mean	95% CI	Mean	95% CI	
Axial (N/mm)	410.3	355.2 - 465.5	425.1	345.8 - 504.4	0.991
Coronal (N/mm)	13.24	12.15 - 14.33	13.76	12.53 - 15.00	0.919
Sagittal (N/mm)	119.3	114.4 - 124.1	120.1	113.9 - 126.3	0.999
Torsional (N/mm)	108.6	101.0 - 116.2	112.7	104.6 - 120.8	0.925
Proximal (MPa)	2.756	2.166 - 3.346	2.518	2.081 - 2.955	0.953
Distal (MPa)	2.532	1.927 - 3.137	2.272	1.819 - 2.725	0.889

Table 2.12 Showing the comparison of the posterior start point groups with perforation and without perforation, with no significant differences for any testing mode.

The fracture risk of cortical defects in bone has been a subject of continuous investigation through the years. Cortical defects that have been studied including pathologic lesions, benign growths, and defects from instrumentation or hardware removal.[36-38] More recently, Computed Tomography Rigidity Analysis (CTRA) has been used to estimate fracture risk.[39,40] CTRA has been shown to have increased sensitivity (100% vs 66.7%), specificity (60.6% vs 47.9%), positive predictive value (17.6% vs 9.8%), and negative predictive value (100% vs 94.4%) compared to the well-known Mirel's score, and has been shown in multivariate logistic regression to be a better predictor of fracture ($p < 0.001$).[35]

The CTRA threshold for which risk of fracture increases is a reduction of 35% or greater in axial, bending, or torsional rigidities.[35] In our study, the axial stiffness was decreased by a magnitude of 3.5%, bending stiffness by 2.2%, and torsional stiffness by 3.6%, none of which were statistically significant ($p > 0.919$). As defined by the CTRA threshold of 35%, this would not increase fracture risk through the defect. CTRA has been shown to have a 100% negative predictive value.[35] Additionally, there was no difference in strains in the distal femur ($p = 0.889$) which has been shown to predict the location of a fracture.[41,42]

Previous biomechanical studies have also shown that fracture risk is increased in areas of tension, such as the lateral cortex of the femur.[38,43,44] The anterior femur is subjected to peak tensile loads during stair ascent, squatting, and when sitting and rising from a chair, but not during stance weightbearing and normal gait patterns.[43] It has also been shown that the increased fracture in osteoporotic bone may be due more to weakness in the bone itself rather than any defects that are created.[45] Therefore there is no increased risk of fracture due to an anterior cortical perforation during stance weightbearing and normal gait.

In the most relevant case series in the literature, Kanellopoulos published a case series of six anterior cortical windows at the distal femur, created intentionally for the purpose of distal locking screw insertion upon failure of the intraoperative image intensifier. These windows measured 1.5-2cm in width and 3-4cm in length, which are wider and shorter than the defects created by the reamer in our study. These patients were treated with restricted weightbearing and did not fracture through the defect.[46] This supports the results of the current study.

2.5 Conclusion

We show that the posterior start point has increased sagittal stiffness compared to the neutral and anterior start points. There is no difference in axial, coronal bending, torsional stiffness, or stresses at the proximal and distal femur. The ideal start point would therefore be slightly posterior to the long axis of the femoral canal when possible.

One known complication of a posterior start point is anterior cortical perforation of the distal femur. We show no statistically significant difference in axial, bending, or torsional stiffness, or proximal and distal stress, between a femur with perforation versus a femur without perforation. A decrease of 35% in axial, bending, or torsional stiffness is defined as the threshold for increased fracture risk via CTRA.[35] An anterior cortical perforation of the distal femur is well within these limits and therefore does not pose an increased risk for fracture.

Future directions would be documentation of successful treatment of an anterior cortical perforation of the distal femur without the need for revision surgery of restricted weightbearing. Additional biomechanics testing could be performed to load a perforated femur to failure and identify the mode of construct failure and the load required to do so.

Limitations of the study include the use of a synthetic bone model that does not account for in vivo muscle forces.

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Chapter 3: Anterior Cortical Perforation in Long Cephalomedullary Nailing Treated Nonoperatively Without Restricted Weightbearing: A Case Report

3.1 Introduction

Hip fractures are common in the elderly population, often caused by low energy mechanisms such as a fall from standing height.[1-3] The methods for surgical fixation often depend on fracture location and pattern. Extracapsular fractures have been successfully treated with cephalomedullary fixation.[4,5] This allows immediate weightbearing which has been show to improve patient outcomes following hip fracture.[6,7]

A rare but recognized complication of cephalomedullary nailing is anterior cortical perforation of the distal femur.[8] This occurs in less than one percent of cases.[9,10] However, there is no consensus in the literature on management. Published strategies range from non-weightbearing to revision surgery.[11,12] Treating these complications with non-weightbearing comes with significant negative consequences for the patient. Complications of immobilization include muscle atrophy and deconditioning, disuse osteoporosis, diminished cardiac reserve, pneumonia, venous thromboembolism, and pressure sores.[13,14] Even limiting weightbearing for the first 2-4 weeks after surgery is associated with negative outcomes at 1 year.[15]

The purpose of this chapter is to present a case presentation where anterior cortical perforation of the distal femur occurred in cephalomedullary nail fixation of a hip fracture and was treated successfully without restriction of weightbearing.

3.2 Case Presentation

The patient is an 89 year old woman who suffered a basicervical hip fracture from a fall from standing height. She resides in a nursing home and was dependent on ambulatory aids secondary to a stroke suffered in previous years.

Figure 3.1. Preoperative radiograph showing a left-sided basicervical hip fracture in the present case. Comminution of the greater trochanter is under-appreciated on this anteroposterior view.

She was brought to the operative theater and placed supine in the traction table. Standard procedure was following for a Stryker Gamma3 cephalomedullary nail. An appropriate start point was identified and the entry reamer was inserted. The bulb-tipped guide wire was advanced and a lateral radiograph was taken at the distal femur. The bulb-tipped guide wire was noted to be slightly anterior within the canal but not otherwise concerning. Sequential reaming was performed to 12mm. A 10mm diameter, 340mm length Stryker Gamma3 1.5R cephalomedullary nail with 125 degree neck shaft angle was inserted. A 10.5mm diameter, 90mm length lag screw was placed into the center, center position of the femoral head. Tip-apex distance measures 9mm.

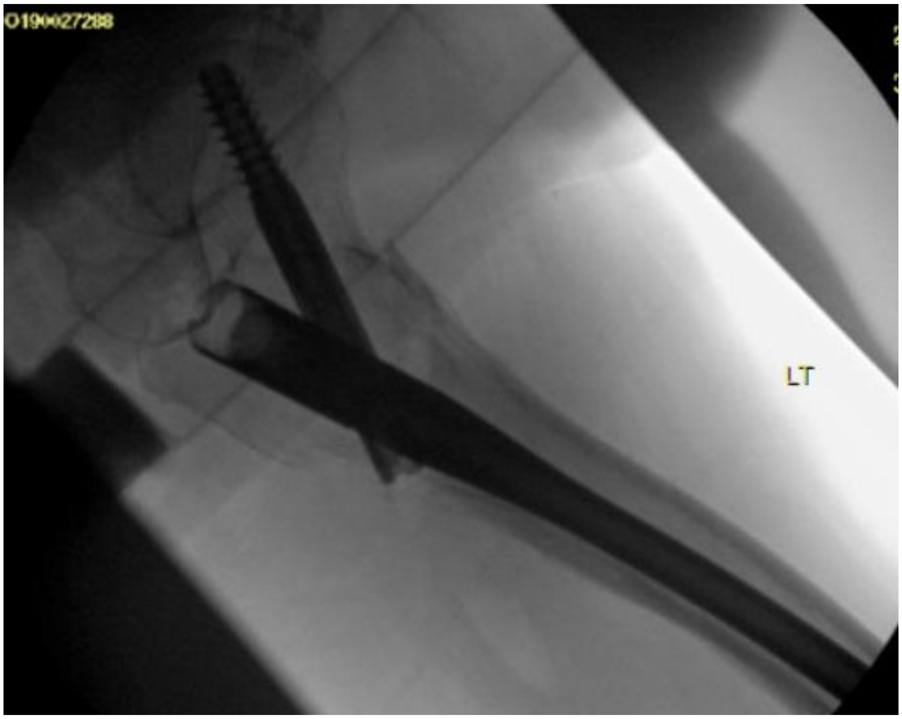

Figure 3.2. Intraoperative lateral radiograph at the hip showing appropriate position of the lag screw. The proximal portion of the cephalomedullary nail is noted to be posterior in the proximal canal.

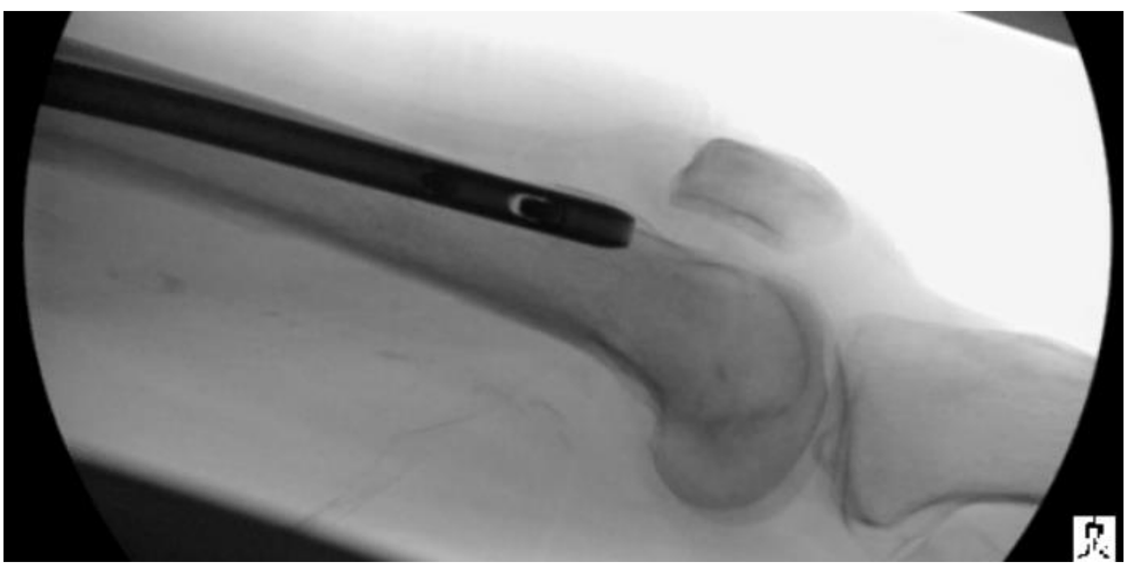

Figure 3.3. Intraoperative lateral radiograph identifying the anterior cortical perforation. The nail does not impact the patella and both distal locking screws were placed with satisfactory bicortical purchase in the distal femur.

Repeat lateral fluoroscopy of the distal femur for the purpose of distal locking screw insertion identified that the nail had perforated the anterior cortex of the distal femur. Both distal locking screws appeared to be located well within the cortex allowing for sufficient fixation. Two 35mm length 5mm distal locking screws were placed. The patient was allowed to ambulate without weightbearing restrictions. She was discharged on postoperative day 5.

At the 6-week follow-up, the patient was ambulating with a walker for short distances without issue. Slight pain was noted at the hip fracture but none at the distal femur. She suffered no postoperative complications. Repeat radiographs showed no change in position of the nail at the distal femur. The patient was then lost to follow-up.

Figure 3.4. Anteroposterior view of the hip at the 6-week postoperative visit. Callus formation is evident at the medial calcar. The lag screw remains in appropriate position in the femoral head. Tip to apex distance measures 9mm.

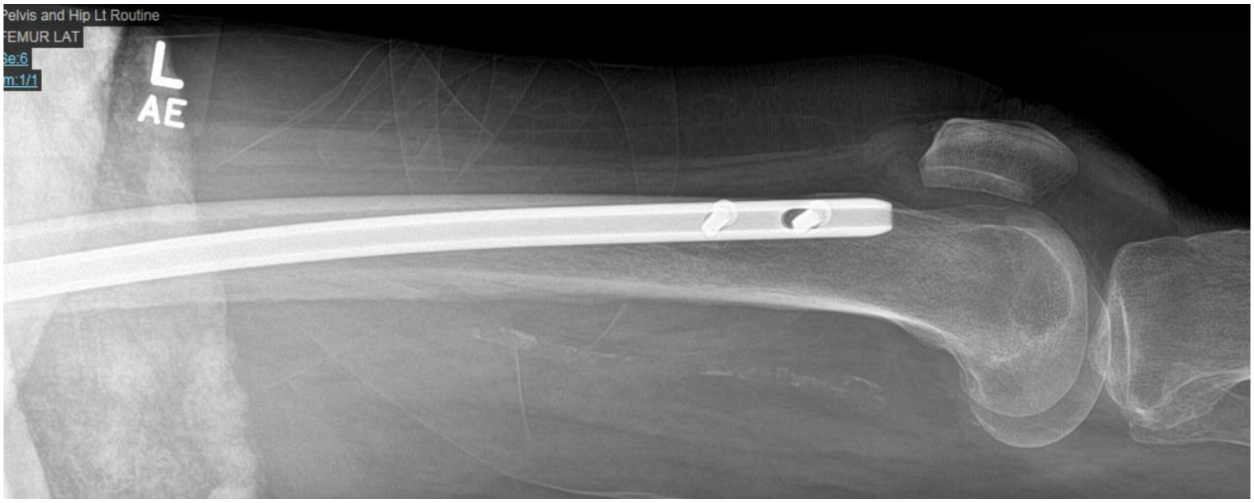

Figure 3.5. Lateral view of the distal femur at the first postoperative visit. The cephalomedullary nail remains in position with no evidence of hardware migration of stress reaction. There remains no impingement on the patella.

3.3 Discussion

Anterior cortical perforation of the distal femur is a rare complication, estimated at 0.47-0.63%.[9,10] Risk factors are well described, including the use of a straighter nail with an increased radius of curvature, a longer nail, a larger diameter nail, a posterior start point, and a femur with decreased radius of curvature and a greater degree of anterior bowing.[16]

In the presented case, a Stryker Gamma3 nail with a radius of curvature of 1.5m was utilized. A Gamma3 nail that is straighter with a radius of curvature of 2.0m is also available, which may have worsened the perforation. The start point on the greater trochanter was difficult to assess on intraoperative and postoperative films. The comminution of the greater trochanter may have played a contributing role. Critical examination of the lateral view would show that the proximal nail is posterior to the proximal canal, which would direct the nail anteriorly. The femur was appropriately reamed to 2mm greater than the nail diameter. The length of the nail was also appropriate.

Ostrum reports three cases of anterior cortical perforation of the distal femur. One case required revision and the other two were treated with extended non-weightbearing.[17]

Peña reports five cortical penetrations, three treated non-operatively with restricted weightbearing, and two treated with lateral locking plates.[12] Anterior cortical perforations of the distal femur have also occurred during use of the Reamer-Irrigator-Aspirator system. Belthur reports such a perforation from eccentric reaming during harvesting. The patient was treated with partial weightbearing and pain resolved at 4 months.[18] Two anterior cortical perforations (10%) were caused in a series of twenty patients. Both were treated with touch weightbearing for 4-6 weeks and progressed to radiographic and clinical union without further intervention.[19]

The majority of reported cases in the literature of anterior cortical perforation of the distal femur were treated with non-weightbearing. However, this has negative consequences for patients. Chudyk reports in a large systematic review that the most frequently reported positive outcomes are associated with measures of ambulatory ability.[20] Conversely, prolonged non weight bearing of surgically managed fractures is associated with delayed healing and worse outcomes.[21] Medical complications of immobilization and bed rest include muscle atrophy and weakness, disuse osteoporosis, decreased cardiac reserve, orthostatic hypotension, venous thromboembolism, pneumonia, pressure sores, loss of balance and coordination, and urinary tract infections.[13,14] Ottesen analysed 4,918 patients treated for hip fractures. 3,668 were allowed to weight bear as tolerated postoperatively, and experienced fewer major adverse events, fewer infections, less transfusion, shorter length of stay, and decreased 30-day mortality.[22] Limited weightbearing for even the first 2-4 weeks after surgery is associated with negative 1-year functional outcome ($p < 0.001$).[15] Therefore, postoperative hip fracture patients should not have their weightbearing restricted if possible.

Chapter 2 of this thesis presented the biomechanical properties of a femur with an anterior cortical perforation. With a cephalomedullary nail with a posterior start point, there was no difference in axial stiffness, lateral and coronal bending stiffness, or torsional stiffness in a femur with and without an anterior cortical perforation of the distal femur ($p > 0.918$). Proximal and distal strain gauges also produced no statistical differences ($p > 0.888$). The biomechanical data would therefore suggest that a femur with an anterior cortical perforation of the distal femur could be treated similarly to one without a perforation.

This case provides clinical evidence in agreement with the biomechanical data. An anterior cortical perforation of the distal femur was recognized intraoperatively. The patient continued to ambulate postoperatively under the guidance of physiotherapy without weightbearing restrictions. She presented at the 6-week postoperative visit with radiographic and clinical evidence of healing. There was no hardware migration or other complication at the distal femur.

3.4 Conclusion

We present a case of anterior cortical perforation of the distal femur where the cortical perforation did not impact management. The patient showed radiographic and clinical signs of healing at the 6 week follow-up.

This case represents clinical evidence in agreement with our biomechanical data that an anterior cortical perforation of the distal femur can be treated successfully without restricting weightbearing.

Our study is limited by the limited follow-up in the present case. Future directions would include the documentation of further cases of anterior cortical perforation of the distal femur treated successfully without restricted postoperative weightbearing.

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Chapter 4: General Discussion and Conclusion

4.1 The Effect of Start Point

Chapter 2 performed a biomechanical analysis of the start point in cephalomedullary nailing. With a trochanteric nail, the ideal start point from a biomechanical standpoint is posterior to the long axis of the femoral canal. This results in increased sagittal bending stiffness compared to the neutral and anterior start points ($p < 0.048$) without a statistically significant difference in axial ($p > 0.888$), coronal bending ($p > 0.776$), or torsional stiffness ($p > 0.102$). There is no statistically significant difference in proximal stress ($p > 0.097$) or distal stress ($p > 0.059$) with any start point. The surgeon must weight the benefit of this biomechanically advantageous start point against the risk of anterior cortical perforation of the distal femur.

4.2 Cortical Perforation of the Distal Femur

The biomechanical comparison made in Chapter 2 showed no difference in a cephalomedullary nail with a posterior start point with or without perforation in axial, coronal and sagittal bending, and torsional stiffness ($p > 0.918$) or with proximal or distal strains ($p > 0.888$).

Computed Tomography Risk Assessment (CTRA) used for assessing the fracture risk of cortical perforations and pathologic lesions relies on a threshold of a 35% decrease in axial, lateral bending, or torsional stiffness, with a reported negative predictive value of 100%.[1] The decrease in stiffness measured in our study did not meet these thresholds. Additionally, strain analyses have been shown to correctly predict the location of fractures, and there was no statistically significant change in proximal or distal strains associated with anterior cortical perforation of the distal femur.[2,3]

It may be reasonable to obtain a metal-reduction computed tomography scan to assess the shape of the cortical perforation in the immediate postoperative period and to rule out an occult fracture. The arthroplasty literature has shown that an anterior notch with sharp corners are at highest risk for fracture.[4] A computed tomography scan may be useful to rule out these possibilities.

Robertson has shown that in a study of cortical defects on bone strength, the strength of the bone is more dependent on the bone quality itself rather than defects created.[5] Yeni has shown that differences in bone composition can explain 35%-59% in variation of fracture toughness.[6] Therefore the risk of a periprosthetic fracture of the distal femur around an anterior cortical perforation may be due more to the quality of the bone rather than the perforation itself.

This evidence would support weightbearing without restriction in event of an anterior cortical perforation of the distal femur in an appropriate patient population. Chapter 3 demonstrated successful treatment of an anterior cortical perforation of the distal femur without restricted weightbearing.

4.2.1 Nail Design

There has been a recent evolution in nail design in response to recognition of anterior cortical perforation of the distal femur. The radius of curvature of available nails in 2004 are reported by Egol to range from 186cm to 300cm.[7] By 2016, the nail had become more curved with a radius of curvature from 127cm to 200cm as reported by Lakati.[8] This may still be too straight for the majority of human femurs, as the reported mean radius of curvature ranges from 72cm to 144cm.[7-14] Studies have also highlighted that there is a different radius of curvature for the proximal third, middle third, and distal thirds of the femur.[15,16] The distal third has the lowest radius of curvature. Therefore, the next step in evolution of the bow of a cephalomedullary nail may be an increased bow overall, and a more pronounced bow in the distal portion of the nail.

Regardless of accommodations made to the cephalomedullary nail, the range of radii of curvature of the human femur is vast, ranging from 11cm to 189cm, and some patients may remain at risk of anterior cortical perforation of the distal femur.[8-10]

4.3 Conclusion

This thesis shows that for the trochanteric cephalomedullary nail, a start point posterior to the long axis of the femoral canal is the most biomechanically advantageous. An anterior cortical perforation of the distal femur does not have a statistically significant biomechanical effect.

In Chapter 1 we hypothesized that there would be no difference between the axial, bending, and torsional stiffness or stresses between the different start points. This hypothesis has been proven false, as there is a difference in the sagittal stiffness between the anterior and neutral start points, and the posterior start point. We also hypothesized that an anterior cortical perforation would not reduce axial or bending stiffness, but would reduce torsional stiffness. This hypothesis has also been proven false as the anterior cortical perforation of the femur did not have any effect on axial, bending, or torsional stiffness, or proximal and distal stresses, with a similar start point at the proximal femur.

This paper supports further investigation into the safety of mobilization patients with an anterior cortical perforation of their distal femur without the need of either weight bearing restrictions or revision surgery.

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- PGY-1 Resident Boot Camp, Seminar Instructor, Schulich School of Medicine and Dentistry, Western University, London, Ontario, 2017-2019.
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- Resident Teacher for Medical Students, rated 6.9/7 for the 2017-2018 academic year, Schulich School of Medicine and Dentistry, Western University, London, Ontario, June 2018.
- Teaching Residents to Teach Bootcamp, Course Attendee, Schulich School of Medicine and Dentistry, Western University, London, Ontario, Nov 2017.
- Resident Teacher for Medical Students, rated 6.3/7 for the 2016-2017 academic year, Schulich School of Medicine and Dentistry, Western University, London, Ontario, June 2017.
- MCAT Course Instructor in Physics, Chemistry, and Biology, The Princeton Review, Toronto, Ontario, 2010-2012.
- Anatomy & Physiology Teaching Assistant, Faculty of Health Sciences, McMaster University, Hamilton, Ontario, 2010-2011.