HIP FRACTURES: UNDERSTANDING THE MECHANISM AND SEEKING PREVENTION THROUGH PROPHYLACTIC AUGMENTATION OF THE PROXIMAL FEMUR

by

Peter Michael de Bakker

B. Eng., University of Western Ontario, 2003

A THESIS SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF

MASTER OF APPLIED SCIENCE

in

THE FACULTY OF GRADUATE STUDIES

“Mechanical Engineering”

THE UNIVERSITY OF BRITISH COLUMBIA

JULY, 2006

© Peter de Bakker, 2006
ABSTRACT

Introduction: In addition to having increased mortality and decreased mobility, hip fracture patients are more likely to sustain a second hip fracture than people who have never fractured a hip. There is currently no surgical technique that can be used to instantly strengthen the contralateral femur.

Objectives: The primary objective was to evaluate the mechanical feasibility of augmenting the proximal femur with a novel implant to prevent hip fracture. This involved developing implants to prevent proximal femur fracture and quantifying the effect of the implants on the propensity of femurs to fracture. The secondary objective was to describe the initiation and progression of proximal femur failure during hip fracture to better understand the injury mechanism.

Methods: Four cadaveric femurs were fractured in a fall configuration while being filmed with a high-speed camera. Visual analysis of the video images was used to describe the initiation and progression of fracture. Eight implant designs were developed and assessed with a finite-element model of a proximal femur. Of these designs, the Carbon Sleeve and Gamma Nail implants underwent a preliminary experimental assessment using a single pair of femurs. The Neck-Contouring Composite was further investigated using four pairs of femurs to compare to the Femoroplasty concept, which was assessed with three pairs of femurs.

Results: In the hip fracture mechanism experiments, the four femurs were found to fail in a two stage process, with fracture initiating in the superior neck followed by a second failure in the inferior neck or intertrochanteric region. The preliminary experimental assessment of the Carbon Sleeve and Gamma Nail implants found that neither had a large effect on femur strength, with differences in failure load between control and augmented femurs of -8% and +1% respectively. The Femoroplasty implants had failure loads that were 24% higher that controls (p = 0.071). The Neck-contouring Composite implants had failure loads that were 18% higher than controls (p = 0.095).

Summary and Conclusion: Hip fractures were seen to occur in a two stage process with failure initiating in the superior neck. Although only four specimens were tested, these experiments point to the superior neck as a region of interest for the development of screening tools for hip fracture risk assessment, targeted therapy for bone strengthening and surgical prophylaxis. The augmentation experiments found that it was possible to increase in the strength of the proximal femur by up to 24%.
# TABLE OF CONTENTS

Abstract ................................................................................................................................. ii
Table of Contents .................................................................................................................. iii
List of Tables ........................................................................................................................ vi
List of Figures ......................................................................................................................... vii
Acknowledgements .............................................................................................................. x
Chapter 1: Introduction .......................................................................................................... 1
  1.1 Anatomy of the Hip Joint ............................................................................................... 1
  1.2 Bone .............................................................................................................................. 2
  1.3 Osteoporosis ................................................................................................................ 5
  1.4 Material Properties ...................................................................................................... 6
    1.4.1 Material Properties of C cancellous Bone ............................................................ 6
    1.4.2 Material Properties of Cortical Bone ...................................................................... 7
  1.5 Hip Fracture .................................................................................................................. 8
    1.5.1 Hip Fracture Location ......................................................................................... 9
    1.5.2 Risk Factors for Hip Fracture .............................................................................. 10
    1.5.3 Clinical Treatment of Hip Fracture .................................................................... 12
    1.5.4 Outcome of Hip Fracture ................................................................................... 12
  1.6 Second Hip Fracture ...................................................................................................... 13
    1.6.1 Second Hip Fracture Location ........................................................................... 15
    1.6.2 Risk Factors for Second Hip Fracture ................................................................. 15
    1.6.3 Outcome of Second Fracture .............................................................................. 17
  1.7 Hip Fracture Prevention ............................................................................................... 18
    1.7.1 Pharmacological Hip Fracture Prevention ............................................................ 18
    1.7.2 Biomechanical Hip Fracture Prevention Techniques ........................................... 21
  1.8 Biomechanics of Hip Fracture ....................................................................................... 21
    1.8.1 Fractures Due to Falls or Falls Due to Fracture? .................................................. 22
    1.8.2 Fall Orientation .................................................................................................... 22
    1.8.3 Hip Impact Resulting from a Fall ........................................................................ 23
    1.8.4 Load Distribution in the Femur During Fall ........................................................ 23
    1.8.5 Relative Contribution of Cortical and Cancellous Bone to the Strength of the Femoral Neck ........................................................................................................ 24
    1.8.6 Fracture Initiation ............................................................................................... 24
    1.8.7 In Vitro Hip Fracture Testing ............................................................................... 24
  1.9 Objectives ...................................................................................................................... 26
    1.9.1 Primary Objective ............................................................................................... 26
    1.9.2 Secondary Objective ........................................................................................... 26
Chapter 2: Methods ............................................................................................................. 27
  2.1 Hip Fracture Mechanism: Experimental Analysis ......................................................... 27
    2.1.1 Specimens ............................................................................................................ 27
    2.1.2 Experimental Apparatus ..................................................................................... 28
    2.1.3 Specimen Preparation ........................................................................................ 29
    2.1.4 Strain Gauges ...................................................................................................... 29
    2.1.5 Failure Test Protocol .......................................................................................... 30
    2.1.6 Videography ........................................................................................................ 30
  2.2 Hip Fracture Mechanism: Finite Element Analysis ....................................................... 32
Introduction

2.2.1 Specimen ................................................................. 32
2.2.2 QCT Imaging ............................................................ 32
2.2.3 Bone Geometry ........................................................ 33
2.2.4 Bone Density Distribution ......................................... 33
2.2.5 Mesh Generation ....................................................... 34
2.2.6 Material Properties .................................................. 35
2.2.7 Failure Criterion ...................................................... 36
2.2.8 Applied Loads ......................................................... 36
2.2.9 Model Validation ...................................................... 37
2.3 Design of Femur Augmentation Implant ......................... 38
  2.3.1 Design Criteria ...................................................... 38
  2.3.2 Implant Designs ..................................................... 39
2.4 Experimental Assessment of Implants ............................ 41
  2.4.1 Specimens ............................................................ 41
  2.4.2 Control Group Femurs ............................................. 42
  2.4.3 Composite Pin ........................................................ 42
  2.4.4 Gamma Nail .......................................................... 43
  2.4.5 Neck-contouring Composite ..................................... 44
  2.4.6 Femoroplasty ........................................................ 46
  2.4.7 Experimental Measures .......................................... 47
  2.4.8 Statistical Analysis ............................................... 48
Chapter 3: Results ............................................................ 49
  3.1 Fracture Mechanics: Experimental Results ..................... 49
    3.1.1 Mechanical Test Results ...................................... 49
    3.1.2 Strain analysis .................................................. 50
    3.1.3 Fracture Type .................................................... 52
    3.1.4 Failure Location and Fracture Progression ................ 52
  3.2 Finite Element Model Results .................................... 58
    3.2.1 Cadaver Model Strain Measurements ........................ 58
    3.2.2 Strain Predicted by Finite Element Model ................ 61
    3.2.3 Failure of Intact Finite Element Model of Femur ........ 63
  3.3 Finite Element Analysis of Augmented Femurs ................ 64
  3.4 Cadaveric Assessment of Augmentation Designs ............... 66
    3.4.1 Carbon Sleeve (Implant b) .................................... 67
    3.4.2 Gamma Nail (Implant h) ...................................... 68
    3.4.3 Femoroplasty ................................................... 69
    3.4.4 Neck-contouring Composite (Implant f) ..................... 70
Chapter 4: Discussion ...................................................... 73
  4.1 Synthesis of Results ............................................... 73
    4.1.1 Fracture Mechanism Experiments ............................ 73
    4.1.2 Augmentation Results .......................................... 76
    4.1.3 Augmentation Results: Finite Element Model .............. 77
    4.1.4 Augmentation Results: Experimental Model ................ 78
    4.1.5 Augmentation Results: Comparison of Experimental to FE Results 81
    4.1.6 Augmentation Results Summary ................................ 82
  4.2 Comparison to Similar Studies .................................. 83
    4.2.1 Finite Element Model .......................................... 83
LIST OF TABLES

Table 1-1 Ultimate strength for femoral cortical bone from Reilly (1975) [24] ........................................ 8
Table 1-2 Modulus and Poisson's ratio for femoral cortical bone from Reilly (1975) [24] ............ 8
Table 1-3 Second Hip Fracture ........................................................................................................ 14
Table 1-4 Relative risk of second hip fracture ............................................................................... 16
Table 2-1 Donor information for specimens used in fracture mechanism experiments ......................... 28
Table 2-2 Summary of apparent densities and modulus for the cancellous elements ....................... 36
Table 2-3 Donor information for specimens used in experimental assessment of implant designs ......... 42
Table 3-1 Summary of results from fracture mechanics experiments .............................................. 49
Table 3-2 Summary of results from carbon sleeve augmentation test ............................................ 67
Table 3-3 Summary of results from Gamma Nail augmentation test .............................................. 68
Table 3-4 Ultimate loads for augmented and control femurs in femoroplasty group ....................... 69
Table 3-5 Work of fracture for augmented and control femurs in femoroplasty group ................... 70
Table 3-6 Fracture types for augmented and control femurs in femoroplasty group ....................... 70
Table 3-7 Maximum temperature increase and volume of bone cement used for each specimen that was augmented with the neck-contouring composite .................................................. 70
Table 3-8 Ultimate loads for augmented and control femurs in neck-contouring composite group ... 71
Table 3-9 Work of fracture for augmented and control femurs in neck-contouring composite group .......................................................... 71
Table 3-10 Fracture types for augmented and control femurs in neck-contouring composite group ... 72
Table 3-11 Maximum temperature increase and volume of bone cement used for each specimen that was augmented with the neck-contouring composite .................................................. 72
Table 4-1 FEM validation results from Lotz et al. [100] ................................................................. 83
Table 4-2 Summary of failure loads and work of fracture from in vitro hip fracture studies ............ 87
Table 4-3 Comparison of augmentation by Heini et al. and the femoroplasty and neck-contouring composite procedures from this thesis ................................................................. 89
LIST OF FIGURES

Figure 1-1 Anatomy of hip joint. Modified from Netter, 2002 [2] .................................................. 2
Figure 1-2 Cortical and cancellous bone from Khan, 2001 with permission [4] ............................. 3
Figure 1-3 Strength and modulus of cancellous bone plotted against density. From Hayes, 1991
with permission [19] ....................................................................................................................... 6
Figure 1-4 Hip fracture location from Zuckerman, 1996, with permission [37] ............................. 10
Figure 1-5 Fracture load vs BMD from Lotz and Hayes, 1990 [46] ................................................. 11
Figure 1-6 Direction of load applied to proximal femur from acetabulum and general stress
distribution through the cross section of the neck. Blue (+) indicates compressive stress
and red (-) indicates tensile stress. From Turner, 2005 with permission [85] ......................... 22
Figure 1-7 Fall type loading configuration. The femur is held with the shaft at 10° from the
horizontal and is internally rotated 15°. The load is applied to the greater trochanter. The
head and distal shaft are free to translate in the horizontal plane From Eckstein et al., with
permission [93] ....................................................................................................................... 25
Figure 2-1 Photograph and schematic diagram of the experimental apparatus. The yellow arrows
on the photograph show the degrees of freedom at the proximal and distal ends of the
femur. ........................................................................................................................................ 29
Figure 2-2 Strain gauge location on superior neck (left) and inferior neck (right). White beads
were bonded to femur to investigate the possibility of using video analysis to track failure
in future experiments ................................................................................................................. 30
Figure 2-3 Test set-up for the fracture mechanism experiments. The load was applied to the
femur in the test apparatus by the Instron. Two cameras filmed the test, one from the
anterior side and one from the posterior side. Two 250W lights were used to illuminate the
specimen ...................................................................................................................................... 31
Figure 2-4 Camera still on the left shows the anterior surface of the femur and a mirror image of
the inferior surface of the femur. Camera still on the right shows the posterior surface of
the femur and a mirror image of the superior surface of the femur. ........................................ 31
Figure 2-5 Schematic of loads applied to the finite element model .............................................. 37
Figure 2-6 Strain gauge locations on femur specimen 1090R ...................................................... 38
Figure 2-7 Finite element models of implant designs .................................................................. 40
Figure 2-8 Injection of bone cement (left) and insertion of carbon sleeve (right) in the composite
pin procedure ............................................................................................................................. 43
Figure 2-9 Anteroposterior and lateral radiographs of specimen 1161 L after augmentation with
the composite pin ....................................................................................................................... 43
Figure 2-10 Anteroposterior and lateral radiographs of 1171 R after augmentation with Gamma
Nail ............................................................................................................................................... 44
Figure 2-11 Device used to aim guide wire .................................................................................. 45
Figure 2-12 Kyphon and custom built balloons (left) and balloon inflated inside the femur (right)
.................................................................................................................................................. 45
Figure 2-13 Anteroposterior and lateral radiographs of 1157 L .................................................... 46
Figure 2-14 Anteroposterior and lateral radiographs of 1153R after undergoing femoroplasty .. 47
Figure 2-15 Typical load-displacement for control femur showing failure load. The failure was
defined to occur at the ultimate load and the work of fracture was defined as the area under
the load displacement curve up to the failure load. ................................................................... 48
Introduction

Figure 3-1 Load-displacement curves for the specimens 1004 L, 1061 L, 1169 R and 1171 L loaded to failure at 100 mm/s

Figure 3-2 Strain measured in the inferior and superior femoral neck of 1004 L plotted against applied load

Figure 3-3 Strain measured in the inferior and superior femoral neck of 1061 L plotted against applied load

Figure 3-4 Fracture types in specimens used in fracture mechanics tests

Figure 3-5 Images corresponding to the first (left) and second (right) peaks of the load-displacement curve of 1004 L. The rotation shows the movement of the head of the femur seen at the first peak. The failure indicates a visible yielding at the second peak

Figure 3-6 Images corresponding to the final peak (left) and after the final peak in the load-displacement curve of specimen 1004 L

Figure 3-7 Images corresponding to the start of the loading sequence (left) and the loaded femur after passing two small peaks (right). The numbers 1 and 2 refer to the locations of failure at the first and second peaks respectively

Figure 3-8 Images corresponding to failure seen at the ultimate load (left) and at the final drop in load (right)

Figure 3-9 Images showing femur prior to fracture (left) and immediately following the initiation of fracture (right) in specimen 1169 R

Figure 3-10 Image showing final failure of specimen 1169 R

Figure 3-11 Images showing femur prior to fracture (left) and immediately following the initiation of fracture (right) in specimen 1171 L

Figure 3-12 Image showing final failure of specimen 1171 L

Figure 3-13 Strain measurements at three locations in a plane through the proximal neck when the femur was loaded to 435 N

Figure 3-14 Strain measurements at three locations in a plane through the distal neck when the femur is loaded to 435 N

Figure 3-15 Strain measurements at three locations in a plane through the distal neck when the femur is loaded to 435 N

Figure 3-16 Comparison of strains measured experimentally and strains predicted by finite element model

Figure 3-17 Plot of predicted strain vs. measured strain at 9 locations

Figure 3-18 Posterior view of von Mises strain distribution in proximal femur when loaded to 3618 N in a fall configuration

Figure 3-19 Anterior and slightly inferior view of von Mises strain distribution in proximal femur when loaded to 3618 N in a fall configuration

Figure 3-20 Predicted failure load for intact model and eight implant designs

Figure 3-21 Ultimate load of all augmented and control femurs plotted against total proximal femur aBMD. Linear trend lines were drawn through the data points representing the control femurs (R^2 = 0.74) and the augmented femurs (R^2 = 0.79)

Figure 3-22 Photographs and radiograph of femur augmented with carbon sleeve after it had been fractured

Figure 3-23 Post-fracture images of femur augmented with Gamma Nail

Figure 4-1 Locations of initial compressive failure from fracture mechanics experiments. Locations are shown on a single femur

Figure 4-2 Post-fracture images of 1004 L showing proximity of fracture to superior gauge (left) and inferior gauge (right)
Figure 4-3 Failure location in proximal femur from Keyak et al., with permission [103]........ 85
Figure 4-4 Predicted failure location (grey elements) in proximal femur from Oden et al. [104] 85
Figure 4-5 Femoral anteversion shown for person lying on their side [116]......................... 92
Figure 4-6 Load-displacement curve for the specimen 1153 R. This specimen was augmented
with the femoroplasty procedure. The ultimate load, which was 6470 N, and the load at
which there was an initial non-linearity in the curve, which was 4828 N, are shown........ 95
Figure A-1 Load-displacement curve for femur augmented with carbon sleeve implant and
matched-pair control from donor 1161 .................................................................................. 107
Figure A-2 Load-displacement curve for femur augmented with Gamma Nail implant and
matched-pair control from donor 1171 .................................................................................. 108
Figure A-3 Load-displacement curve for femur augmented with femoroplasty implant and
matched-pair control from donor 1153 .................................................................................. 109
Figure A-4 Load-displacement curve for femur augmented with femoroplasty implant and
matched-pair control from donor 1160 .................................................................................. 109
Figure A-5 Load-displacement curve for femur augmented with femoroplasty implant and
matched-pair control from donor 1169 .................................................................................. 110
Figure A-6 Load-displacement curve for femur augmented with neck-contouring composite
implant and matched-pair control from donor 1090 .............................................................. 111
Figure A-7 Load-displacement curve for femur augmented with neck-contouring composite
implant and matched-pair control from donor 1149 .............................................................. 111
Figure A-8 Load-displacement curve for femur augmented with neck-contouring composite
implant and matched-pair control from donor 1154 .............................................................. 112
Figure A-9 Load-displacement curve for femur augmented with neck-contouring composite
implant and matched-pair control from donor 1157 .............................................................. 112
ACKNOWLEDGEMENTS

Over the course of my thesis, I have collaborated with many professors, students and staff in Division of Orthopaedic Engineering and the Bone Health Group. They have shared with me their knowledge, intellect, insight and time.

In particular, I would like to give special thanks to my supervisors, Drs. Tom Oxland, Pierre Guy and Göran Fernlund. They have guided and advised me well throughout these last few years. Their passion for research has been a great inspiration to me. I would also like to thank Dr. Antony Hodgson for taking the time to serve on my committee.

Several professors have been generous with their time, ideas and support. Thank you to Dr. Peter Cripton for giving me great advice on this project and beyond and for getting me started on the fracture mechanism part of the thesis. Thank you to Dr. Heather McKay for constant encouragement and to Dr. Karim Khan for great career guidance. To both Drs. McKay and Khan, thank you for including me in the Bone Health Group. Thank you to Dr. Steve Robinovitch for taking the time to help shape this project. Thank you also to Dr. Rizhi Wang, who was so generous with his knowledge about bones and bone failure.

Many people in the lab collaborated with me on this project. Thank you to Cecelia Tang and Dr. Danmei Liu for helping me get started. Thank you to Dr. Teresa Liu-Ambrose and Sarah Manske. They have helped me with every aspect of this project and they were a joy to work with. Thank you to Vincent Ebacher for his help with strain gauges and to Amy Saari for her assistance with high speed video. Thank you to Simon Sjovold for being so open with his ideas and for always finding a way to fix what I thought was beyond repair.

As always, my family has been my greatest support throughout this process. Thank you to my parents for teaching me the importance of finding my passion and encouraging me to pursue it. A special thank you to my Mom for her editing expertise. Finally, thank you to Jennifer Dagsvik for everything.
Chapter 1: Introduction

The purpose of this study was to design and evaluate surgical augmentation procedures for the prevention of hip fracture. The clinical question addressed the scenario immediately after an individual sustains a hip fracture. It could be stated as “Can the contralateral femur be augmented so that it will not break the next time the patient falls?” This question was asked because patients who fracture a hip are at an increased risk of suffering another hip fracture. Given the increased mortality and decreased mobility that result from hip fracture, patients could benefit greatly from having their contralateral femur reinforced. There are currently a number of approaches to decreasing hip fracture risk, including pharmacological treatments aimed at increasing bone mass and external mechanical devices used to dissipate the energy from a fall. There is currently no clinical technique to surgically augment the femur. That is the gap that this study aimed to fill.

1.1 Anatomy of the Hip Joint
The hip joint is a ball-and-socket-type synovial joint located at the proximal end of the lower limb, connecting the lower limb and the pelvic girdle. The articulating surfaces of the hip joint are located on the acetabulum and the femoral head (Figure 1-1). These surfaces are covered with a thin layer of articular cartilage.

The acetabulum is the socket of the ball-and-socket joint. The acetabulum is hemispherical with a notch located at the inferior part of the acetabular rim. This rim is extended by a fibrocartilaginous ring called the acetabular labrum, which deepens the socket and also covers the acetabular notch. The femoral head is the ball of the ball and socket joint. It is approximately two thirds of a sphere. It sits on the neck of the femur, which is oriented at about 115 to 140° from the long axis of the femur in the coronal (frontal) plane and at an angle of 10 to 30° of anteversion from the same plane [1]. The neck is also offset to the shaft, being anteriorly
translated. Where the neck meets the body of the femur, there are two prominent projections, the lesser and greater trochanters.

The hip joint is enclosed by a strong and loose fibrous capsule that is cylindrical in shape [3]. The fibrous capsule attaches medially to the acetabular rim and laterally to the base of the neck of the femur. The fibrous capsule is reinforced by three ligaments of the hip joint: the iliofemoral ligament, the ischiofemoral ligament and the pubofemoral ligament. The synovial membrane lines the fibrous capsule. This membrane completely encloses the joint cavity and contains the synovial fluid. Blood is supplied to the femur through the reticular arteries, which run under the synovial membrane into the neck and head of the femur, and by the artery of the ligamentum teres.

1.2 Bone

Bone has several characteristics that are relevant to this study: its classification as cortical or cancellous, its microstructure and its ability to remodel. First, bone can be classified as cortical or cancellous. Both of these types are found in the proximal femur. Long bones such as the femur have three distinct regions: the diaphysis, the metaphysis and the epiphysis (Figure 1-1). In the proximal femur, the metaphysis and epiphysis consist primarily of cancellous bone with a
thin layer of cortical bone on the external surface of the femur. In contrast, the diaphysis includes a thick outer layer of cortical bone and very little cancellous bone.

![Figure 1-2 Cortical and cancellous bone from Khan, 2001 with permission](image)

Bone is classified as cortical or cancellous depending on the organization its structure (Figure 1-2). The most evident difference between these two types of bone is that cortical bone is much more dense than cancellous bone. The porosity of cortical bone is approximately 10%, while the porosity of cancellous bone is typically between 50% and 90% [5]. Cortical bone is made up primarily of osteons with interstitial bone between the osteons. Osteons (or Haversian systems), are cylindrical in shape and run parallel to the long axis of the bone. In the centre of the cylinder is a channel, the Haversian canal, which contains blood vessels, lymphatics, nerves and loose connective tissue. These Haversian canals are surrounded by approximately 20 to 30 cylindrical layers of lamellar bone. On the outside of each osteon is a layer of cement. The Haversian canals are interconnected by small perpendicular canals that are called Volkmann’s canals.

Cancellous bone, on the other hand, is characterized as a cellular solid consisting of a network of interconnected plate- and rod-like trabeculae [6]. The bone is arranged in a lattice structure that is aligned with the forces usually applied on the bone. The higher porosity of cancellous bone gives it more surface area for cellular activity. As a result, the bone turnover rate of cancellous bone is 8 times greater than that of cortical bone. The pores contain bone marrow which produces blood cells and bone cells.
In addition to classifying bone by type, it is important to look at its microstructural characteristics. At the microstructural level, bone is made of mineralized collagen. It has three major components: an organic component, an inorganic component and water. The organic matrix of bone is primarily made up of collagen. Type I collagen accounts for approximately 90% of the protein in bone and the other 10% consists of noncollagenous matrix proteins, other collagen types, lipids and other macromolecules. The inorganic component of bone is primarily made up of a calcium phosphate mineral, which is analogous to crystalline calcium hydroxyapatite \( (Ca_{10}(PO_4)_6(OH)_2) \).

Approximately 2% of the organic matrix consists of cells that are responsible for the formation and resorption of bone. The major types of bone cells are osteoclasts, osteocytes, osteoblasts and bone lining cells. Osteoclasts are large bone resorbing cells. They attach to the bone, solubilize the apatite crystals and then digest the organic matrix. Bone lining cells line all surfaces of bone and regulate the flux of ions into and out of the bone. The layer of bone lining cells on the outside surface of bone is called the periosteum, and the layer on the inside surface is called the endosteum. Osteoblasts are bone forming cells that are derived from bone lining cells [7]. They produce unmineralized bone matrix and are also involved in the mineralization of bone. At the end of their bone forming life, osteoblasts can be transformed to bone lining cells or osteocytes, or they can die. When osteoblasts are buried between lamellae of bone, they become osteocytes. Osteocytes are the most abundant cell type in bone. They communicate with each other and with cells that line the outside of the bone through small canals called canaliculi. It is believed that osteocytes transmit information about strain magnitudes and strain distribution to other cells through processes that are housed in these canals.

A third important characteristic of bone is that it remodels throughout life and adapts to the mechanical loading to which it is subjected. This behaviour was summarized by Julius Wolff in Wolff’s Law, which can be stated as: “Bone will optimize structure, so as to withstand functional loading, and to ensure the metabolic efficiency of locomotion” [8]. Bone remodelling involves the coupling of bone absorbing osteoclasts and bone forming osteoblasts. In cortical bone, this coupling takes the form of cutting cones which couple osteoclasts and osteoblasts. The cutting cone bores through cortical bone forming a new osteon. Cancellous bone remolds on the
surface of the bone. Osteoclasts absorb bone at specific sites and the hole in then filled with osteoid. Bone remodelling occurs on bone surfaces such as periosteal, endosteal, Haversian canal and cancellous surfaces.

1.3 Osteoporosis

Osteoporosis is a major risk factor for hip fracture [9-12]. The World Health Organization (WHO) defines osteoporosis as “a disease characterized by low bone mass and microarchitectural deterioration of bone tissue leading to enhanced bone fragility and a consequent increase in fracture risk” [13]. It is not well understood whether the effects of osteoporosis are the result of inadequate bone formation or too much bone resorption [14]. Most researchers in the field emphasize only the amount and distribution of bone. It is thought that in addition to decreased bone density, osteoporosis could also be associated with a reduction in the mineral content in the bone, a reduction in cancellous connectivity, the accumulation of cement lines, increased cortical porosity and the accumulation of fatigue damage [14]. All of these factors contribute to the increased fragility of osteoporotic bone.

Osteoporosis is usually diagnosed by measuring bone mineral density (BMD). The WHO definition of osteoporosis is quantified as being a BMD that is less than 2.5 standard deviations below the mean value for a young and healthy person. Tenenhouse et al. used this definition of osteoporosis to determine the incidence of osteoporosis in Canada [15]. Among women age 50 or older, 12.1% were diagnosed with osteoporosis based on lumbar spine BMD, 7.9% were diagnosed with osteoporosis based on femoral neck BMD, and the combined incidence was 15.8%. Among men age 50 or older, 2.9% were diagnosed with osteoporosis based on lumbar spine BMD, 4.8% were diagnosed with osteoporosis based on femoral neck BMD, and the combined incidence was 6.6%.

Decreased bone density has a dramatic effect on the mechanical properties of bone, and this is discussed in the following section. The relationship between bone density and the incidence of first and second hip fractures is discussed in the sections on risk factors for first and second fracture.
1.4 Material Properties

Bone is a very diverse tissue in terms of its material properties. In order to give some insight into the behaviour of bones, this section will discuss material properties of both cortical and cancellous bone.

1.4.1 Material Properties of Cancellous Bone

The apparent density of cancellous bone is the density of a volume of cancellous when the volume includes both trabeculae and the empty space between them. The apparent density has been found to be related to the material properties of cancellous bone (Figure 1-3). This relationship is very important because it makes it possible to estimate the material properties of bone using conventional medical imaging techniques.

The relationship between apparent density and ultimate strength has been reported as having both a linear [16] and a power law relationship [17]. Gibson reviewed a number of studies and plotted compressive strength against apparent density from the measurements made in the studies [18]. They found that the compressive strength of cancellous bone varies from less than 1 MPa to nearly 100 MPa. It was found that over a wide range of densities, compressive strength is related to bone density squared. This relationship was found by Carter and Hayes to be

\[ \sigma = 68\varepsilon^{0.06} \rho^2 \],

where \( \sigma \) is in MPa, \( \varepsilon \) is in \( s^{-1} \) and \( \rho \) is in \( g/cm^3 \) [17].

Figure 1-3 Strength and modulus of cancellous bone plotted against density. From Hayes, 1991 with permission [19]
Carter and Hayes found that the Young’s modulus was proportional to the density cubed [17]. They quantified the relationship by the equation \( E = 3790 \rho^{0.06} \rho^3 \), where \( E \) is in MPa. Like other relationships between material properties and density, this relationship is not universally accepted and more recent research by Keaveny and Hayes suggests that the modulus is proportional to density squared [6].

Aging has been associated with decreases in cancellous BMD [20]. Riggs et al. used quantitative computed tomography (QCT) to measure cancellous BMD at various skeletal sites. They found an age-related difference in femoral neck cancellous BMD of -56\% in women when comparing women over 80 years of age to women in the 20-29 years age group. This difference for the same age groups in men was -45\%.

The Poisson’s ratio of cancellous bone is not a well understood property, due partly to the fact that it is very difficult to measure. In a review by Keaveny and Hayes, it was found that Poisson’s ratios measured experimentally in cancellous bone varied from just below zero to just below one [6]. This large range indicates that Poisson’s ratio of cancellous bone could be as variable as its strength and Young’s modulus. It depends on location of the sample, direction of loading and other factors. In finite element models of bone, it is often assumed to be 0.3, which is an average value measured experimentally.

1.4.2 Material Properties of Cortical Bone

The material properties of cortical bone are similarly complex. Cortical bone is anisotropic and mildly viscoelastic, and therefore its material properties depend on direction and rate of loading. Table 1-1 and Table 1-2 give some average values for ultimate strength, Young’s modulus and Poisson’s ratio for femoral cortical bone when loaded in both the transverse and longitudinal directions. Clearly, cortical bone is stronger when it is loaded in the longitudinal direction than in the transverse direction [21]. It is stronger and less anisotropic when loaded in compression than when loaded in tension.

The strain rate dependence of the material properties of bone has been investigated by several authors [22, 23]. In the study by Wright and Hayes, human femoral bone was tested over a wide
range of strain rates and it was found that the ultimate strength of cortical bone is proportional to the strain rate raised to the 0.07 power [23]. Further, the modulus of elasticity was found to be proportional to the strain rate raised to the 0.05 power. Most often both strength and modulus are assumed to be proportional to strain rate raised to the 0.06 power.

<table>
<thead>
<tr>
<th>Table 1-1 Ultimate strength for femoral cortical bone from Reilly (1975) [24]</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Loading Mode</strong></td>
</tr>
<tr>
<td>----------</td>
</tr>
<tr>
<td>Longitudinal Tension</td>
</tr>
<tr>
<td>Longitudinal Compression</td>
</tr>
<tr>
<td>Longitudinal Shear</td>
</tr>
<tr>
<td>Transverse Tension</td>
</tr>
<tr>
<td>Transverse Compression</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Table 1-2 Modulus and Poisson's ratio for femoral cortical bone from Reilly (1975) [24]</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Loading Mode</strong></td>
</tr>
<tr>
<td>----------</td>
</tr>
<tr>
<td>Longitudinal</td>
</tr>
<tr>
<td>Transverse</td>
</tr>
<tr>
<td>Shear</td>
</tr>
</tbody>
</table>

The strength and modulus of elasticity of cortical bone decrease with age. The longitudinal modulus of elasticity and the tensile yield strength decrease by about 2% per decade, while the ultimate stress was also found to decrease at about 2% per decade and the ultimate strain decreased at about 5% per decade [25]. These decreases corresponded to a decrease in energy absorbed of approximately 7% per decade. Overall, these results imply that the cortical bone of the elderly is much more likely to fracture than the cortical bone of the young, because it has a lower ultimate strength and it can absorb less energy before breaking.

1.5 Hip Fracture

The number of Canadians aged 65 or older who fractured a hip in 1993 was 23,375 [26]. Of these patients, 76.2% were women and 23.8% were men. The risk of hip fracture among Canadians increases exponentially with age. Using this trend along with the increase in the population of Canadians of age 65 or older projected by Statistics Canada, Papadimitropolous et
al. predicted an exponential increase in the incidence of hip fractures in this age group. They estimated that in the year 2041, approximately 88,124 Canadians over 65 would fracture a hip. Overall increases in hip fracture rates have also been predicted for the United States [27-29] and worldwide [28, 30]. Most studies base their predictions on current incidence of hip fracture for different age groups. However, some authors suggest that there is also an age-independent increase in hip fracture [31, 32]. A review paper has estimated the age-adjusted rate of increase to be between 0.8% and 3.0% per year for men and between -1.6% and 2.7% per year for women [31].

The annual direct cost of hip fractures in Canada is estimated at $650 million annually and is projected to increase to $2.4 billion by 2041 [26]. The cost per fracture in Canada has been estimated to be $26,527 during the first year of care [33]. The annual cost directly associated with hip fracture in the United States has been estimated to be $8.7 billion annually. The estimated cost per fracture in the United States has been estimated to be between $32,428 and $81,300 [34, 35].

1.5.1 Hip Fracture Location

Hip fractures can be classified according to their general location. Because fractures can span several regions of the proximal femur, the classifications developed by researchers are, to some extent, subjective but were empirically developed following recurrent patterns and therefore represent clinical conditions. Several authors have classified fractures as being in the femoral neck, intertrochanteric region or subtrochanteric region [36, 37], see Figure 1-4.

Zuckerman indicated that approximately 5 to 10% of hip fractures occur in the subtrochanteric region, with the remaining 90 to 95% divided evenly between femoral neck and intertrochanteric fractures. Michelson et al. reported that 14% of hip fractures were subtrochanteric, 49% were intertrochanteric and 37% were femoral neck. Other authors classify hip fractures as intra-capsular or extracapsular depending on their relationship with the joint capsule of the hip. This study will use the classification shown in Figure 1-4, which represents the classification that is most commonly used in a clinical setting, as it describes the most common fracture patterns and relates them to identifiable anatomical structures.
1.5.2 Risk Factors for Hip Fracture

A number of risk factors for hip fracture have been identified. The two most significant are falls and osteoporosis. Most of the other risk factors are related in some way to falls or osteoporosis.

Over 90% of hip fractures are associated with falls [38, 39]. A fall generally refers to a fall from standing height or lower, which would not be expected to result in a fracture in young, healthy people. Between 35 and 40% of people over the age of 65 living at home fall at least once a year and between one third and one half of those fall twice or more a year [40]. Of these falls, only about 1% result in a hip fracture [41]. Although most falls do not result in a fracture, they can lead to fear of falling, loss of confidence and functional deterioration [41]. Cummings and Nevitt found that four important factors determine whether a fall will result in a hip fracture: fall orientation, protective responses, local shock absorbers and bone strength at the hip [42].

Studies have also shown that osteoporosis is a significant risk factor for hip fracture. Osteoporosis is commonly measured by dual x-ray absorptiometry (DXA), a clinical imaging tool that is the gold standard for osteoporosis diagnosis [43]. DXA uses two beams of different energy to produce a two-dimensional representation of the attenuation distribution of the bone. The output of DXA scans is aBMD (g/cm²), which is an estimation of the areal density of the
bone. Hip aBMD has been shown to correlate with both hip fracture risk in clinical studies [9-12] as well as femur strength in biomechanical tests [44-46].

A prospective-cohort study involving 9,704 women found that the relative risk for hip fracture was 2.4 per standard deviation decrease in femoral neck BMD [11]. The researchers also found that about 51% of hip fractures were attributable to osteoporosis when it is defined as a T-score of less than 1.5, and only about 28% of hip fractures were attributable to osteoporosis when it is defined as a T-score of less than 2. Pulkkinen et al. found that combining BMD with measurements of neck-shaft angle and cortical thickness improved the prediction of hip fracture [47]. This would highlight the fact that hip fracture risk is related to both bone density and falls; however, it could also point out the inability of DXA to characterize bone strength.

![Figure 1-5 Fracture load vs BMD from Lotz and Hayes, 1990 [46]](image)

To refute the last statement, biomechanical failure tests consistently show a correlation between failure load and aBMD [44-46]. Lotz and Hayes measured BMD and fracture load in vitro [46]. Figure 1-5 shows fracture load plotted versus average intertrochanteric equivalent bone mineral density determined by quantitative computed tomography. It can be seen from this plot that intertrochanteric BMD is a good predictor of femoral strength. Although femoral strength alone does not determine whether a hip will fracture, this in vitro study supports the results mentioned above of the ability of BMD to predict fracture risk with an important contribution of fall risk to fracture risk.
1.5.3 Clinical Treatment of Hip Fracture

Most hip fractures are treated with surgery, however some hip fractures can be treated non-surgically [48]. It is possible to treat non-displaced, intracapsular fracture in patients less than 70 years of age with bed rest followed by limited mobilization, although the risk of fracture displacement tends to favour some form of minimally invasive operative repair in such situations. A review of the hip fracture care in Canada by Statistics Canada further supports that only a minority of patients with hip fractures (less than 6%) are treated non-operatively [49].

A systematic review by Chilov et al. provided evidence-based guidelines for the treatment of fractured hips [50]. They suggest that trochanteric fractures should be treated surgically with a compression hip screw and plate. They found that this treatment has less chance of failure leading to reoperation making it more cost-effective in the long run. Undisplaced femoral neck fractures should have internal fixation with a method that is familiar to the surgeon such as cancellous bone screws or compression screw and plate. They did not find any treatment for displaced femoral neck fractures that is clearly superior and suggest that patient factors should guide the surgeon’s decision. The two options for displaced femoral neck fractures are internal fixation or hemiarthroplasty. Hemiarthroplasty is much less likely to fail than internal fixation. The patient’s age, presence of arthritis, availability and cost of the different types of treatment and surgeon experience and preference should aid in the selection of a surgical treatment. Lyons had similar recommendations and noted that hemiarthroplasty is favored in the United States and the United Kingdom while internal fixation with screws is favored in Scandinavian countries [48]. The previously mentioned report from Statistics Canada shows that 64% of those with femoral neck fracture were treated with some form of arthroplasty, while 33% underwent internal fixation [49].

1.5.4 Outcome of Hip Fracture

Hip fractures have serious consequences on mortality and mobility. The one-year mortality rate for hip fracture has been found to be between 12 and 36% [51]. A review of 32,590 hip fracture patients aged 65 or older admitted to hospital with a fracture of the femoral neck between 1968 and 1998 found that 32.7% of these patients died within a year of fracturing their hip [52]. First-year fatality rates were higher for men than for women. Fatality rates decreased over the first
year after fracture and levelled out by the 12th month, with no significant difference in the fatality rate of men or women compared to the general population. First-year fatality rates increased sharply with age. Fatality rates decreased between the late 1960s and early 1980s, but have not decreased significantly over the past 20 years. The change in the treatment of hip fractures over the years to a more operative approach favouring early mobilization of patients over the years suggests an overall benefit to operative care.

Those who survive a hip fracture face reductions in their mobility. At one year after a hip fracture, 40% of patients cannot walk and 60% have trouble with at least one essential activity of daily living (such as driving or shopping), and 80% are restricted in other activities [53]. Magaziner et al. assessed hip fracture patients using a number of measures of independence [54]. They found that patients became more dependent on all measures, ranging from 20% being unable to put on their pants unassisted to 90% being unable to walk up 5 stairs unassisted. Rosell and Parker found that the number of people who could walk without aids fell from 59% prior to fracture to 26% after fracture [55].

1.6 Second Hip Fracture
Though several studies have examined the epidemiology of second hip fractures, the incidence and relative risk of second hip fractures is still not well known. It is generally agreed that the risk of fracturing a hip is increased by the occurrence of a previous hip fracture. An early study on the occurrence of a second hip fracture found that the risk of suffering a hip fracture increased 20 times after an initial hip fracture [56]. More recently, Schroder et al. found that the risk increased 9 times in men and 6 times in women [57]. However, Melton et al. found that the risk increased only 1.6 times [58].

Selected studies that have looked at the occurrence of second hip fracture are summarized in Table 1-3. The studies by Shabat et al., Chiu et al., Boston, Dretakis et al., Dinah, Pearse et al. and Di Monaco et al. looked at all hip-fracture patients admitted to their respective hospitals over a period of time. When patients were admitted, they were checked for a previous contralateral fracture. Using these data, the authors found that between 2.3 and 10.6% of hip-fracture patients had previously fractured their other hip.
### Table 1-3 Second Hip Fracture

<table>
<thead>
<tr>
<th>Study</th>
<th>Number of subjects</th>
<th>Number of contralateral fractures</th>
<th>Occurrence of contralateral fracture</th>
<th>Mean time interval</th>
<th>Mean Age at 1st fracture</th>
<th>Length of study (years)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Admittance studies</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Boston, 1982 [59]</td>
<td>500</td>
<td>54</td>
<td>10.6%</td>
<td>75% within 3 years</td>
<td>79 (at second)</td>
<td>2</td>
</tr>
<tr>
<td>Chiu et al., 1992 [60]</td>
<td>1514</td>
<td>35</td>
<td>2.3%</td>
<td>23.9 mths</td>
<td>79</td>
<td>5</td>
</tr>
<tr>
<td>Di Monaco et al., 2002 [61]</td>
<td>372</td>
<td>39</td>
<td>10.5%</td>
<td>-</td>
<td>82</td>
<td>3</td>
</tr>
<tr>
<td>Dinah, 2002 [62]</td>
<td>186</td>
<td>22</td>
<td>11.8%</td>
<td>-</td>
<td>83</td>
<td>-</td>
</tr>
<tr>
<td>Dretakis et al., 1981 [63]</td>
<td>1333</td>
<td>99</td>
<td>7.4%</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Dretakis et al., 1998 [64]</td>
<td>1685</td>
<td>106</td>
<td>6.3%</td>
<td>3.4 years</td>
<td>79</td>
<td>4</td>
</tr>
<tr>
<td>Pease et al., 2003 [65]</td>
<td>-</td>
<td>49</td>
<td>12%</td>
<td>31 mths (median)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Shabat et al., 2003 [66]</td>
<td>886</td>
<td>84</td>
<td>9.5%</td>
<td>-</td>
<td>77</td>
<td>-</td>
</tr>
<tr>
<td><strong>Retrospective studies</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Melton et al., 1982 [58]</td>
<td>1145</td>
<td>81</td>
<td>7.1%</td>
<td>-</td>
<td>-</td>
<td>34</td>
</tr>
<tr>
<td>Schroeder et al., 1993 [57]</td>
<td>3898</td>
<td>235</td>
<td>6.0%</td>
<td>3.3 years</td>
<td>74 - men</td>
<td>16</td>
</tr>
<tr>
<td>Wolinsky and Fitzgerald, 1994 [67]</td>
<td>368</td>
<td>27</td>
<td>7.3% or 3.0% /year</td>
<td>1.7 years</td>
<td>79.7</td>
<td>8</td>
</tr>
<tr>
<td><strong>Prospective studies</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chapurlat et al., 2003 [68]</td>
<td>632</td>
<td>50</td>
<td>7.9% or 2.3% /year</td>
<td>2.3 years</td>
<td>75</td>
<td>3.8</td>
</tr>
<tr>
<td>Dolk, 1989 [69]</td>
<td>282</td>
<td>49</td>
<td>17.4%</td>
<td>-</td>
<td>-</td>
<td>10</td>
</tr>
<tr>
<td>Stewart et al., 1999 [70]</td>
<td>394</td>
<td>27</td>
<td>6.9%</td>
<td>-</td>
<td>-</td>
<td>5-10</td>
</tr>
</tbody>
</table>

The studies by Melton et al., Schroeder et al. and Wolinsky et al. were retrospective studies. These studies tracked hip fracture patients using hospital admittance records and Medicare billing information. They found that second hip fractures occurred in 6.0% to 7.3% of hip-fracture patients over the periods of time studied.

The studies by Chapurlat et al., Stewart et al. and Dolk et al. prospectively followed hip fracture patients. They found that over the period of their studies, between 6.9% and 17.4% of hip fracture patients fractured their contralateral femur.
Overall, the incidence of second hip fracture is estimated to be between 2.3% and 17.4%. Although the incidence of second hip fracture is not accurately known, the studies tend to agree that incidence of hip fracture is greater in patients who have suffered a hip fracture than in controls.

1.6.1 Second Hip Fracture Location
Two points are worth noting regarding the location of second hip fractures. First, approximately 92% of second hip fractures occur in the contralateral hip [57, 68]. After a hip fracture, the risk of fracturing the same hip again is less than what it would have been if it had not already been fractured [58, 71]. This could be due to strengthening from internal fixation or callus formation around the healing hip. Second, many authors have reported that contralateral hip fractures tend to occur in the same part of the proximal femur as the first fracture [57-59, 64-66, 68, 71]. For example, Schroder et al. found that 68% of contralateral fractures were preceded by a fracture of the same type [57]. Therefore, most second hip fractures occur in the contralateral femur and in the same region as the first hip fracture.

1.6.2 Risk Factors for Second Hip Fracture
A number of studies have analyzed risk factors for second hip fracture. This information is potentially useful in assessing candidates for a prophylactic intervention. The findings from some of these studies are summarized in Table 1-4.

Chapurlat et al. followed a group of 632 women who had suffered a hip fracture to determine if it was possible to predict who would fracture a second hip [68]. They found that 53 women fractured another hip after an average time interval of 2.3 years. This incidence of second hip fracture was 4 times the incidence of a first hip fracture in the same cohort of women. They assessed 39 potential risk factors. They found that women who walked for exercise, women who had normal depth perception and women who were taking estrogen at baseline were less likely to fracture a second hip. The relative risk was increased for women who had lost weight since the age of 25 and for those who had a low calcaneal bone mineral density.
Stewart *et al.* followed 394 women with a hip fracture [70]. Of these women, 27 suffered a second hip fracture over a 5-to-10-year period. The average time interval between the hip fractures was 2.9 years. They found several predictors of second hip fracture to be significant. These predictors were weight, broadband ultrasound attenuation as measured by the McCue CUBA Clinical (BUAMCC), neck BMD and total body BMD.

Wolinsky *et al.* examined 368 people who had hip fractures, and 27 of these people later fractured another hip after an average of 613 days [67]. They found that of the 29 potential risk factors that they assessed, the only ones that had significant predictive ability were perceived health status and reported problems with dizziness.

Propensity to fall could have predictive value in assessing who is at risk for a second fracture. Dretakis *et al.* asked patients how many times they fell per year when they were admitted for either a first or second hip fracture [64]. They found that those admitted for a second fracture were 4 times as likely to have fallen twice or more per year. Stewart *et al.* looked at the number of times the patient had fallen in the twelve months prior to attending the clinic as well as the number of times they fell after attending [70]. The number of times the patient had fallen prior to attending was not statistically significant (RR=1.38, 95% CI [0.94-2.03]). Those patients who fell after attending were more likely to suffer a second hip fracture. This could be explained by

### Table 1-4 Relative risk of second hip fracture

<table>
<thead>
<tr>
<th>Variable</th>
<th>Relative Risk</th>
<th>95% Confidence Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Chapurlat et al., 2003 [68]</em></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Walking for exercise</td>
<td>0.5</td>
<td>0.3-0.9</td>
</tr>
<tr>
<td>Normal depth perception</td>
<td>0.5</td>
<td>0.3-0.9</td>
</tr>
<tr>
<td>Weight loss since age 25</td>
<td>2.7</td>
<td>1.6-4.6</td>
</tr>
<tr>
<td>Calcaneal BMD *</td>
<td>1.5</td>
<td>1.1-2.0</td>
</tr>
<tr>
<td>Currently taking estrogen</td>
<td>0.5</td>
<td>0.3-0.9</td>
</tr>
<tr>
<td><em>Stewart et al., 1999 [70]</em></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>2.01</td>
<td>1.26-3.21</td>
</tr>
<tr>
<td>BUAMMcC*</td>
<td>1.64</td>
<td>1.06-1.55</td>
</tr>
<tr>
<td>Neck BMD*</td>
<td>2.02</td>
<td>1.27-3.22</td>
</tr>
<tr>
<td>Total body BMD*</td>
<td>1.69</td>
<td>1.07-2.68</td>
</tr>
<tr>
<td>Mobility*</td>
<td>1.45</td>
<td>1.07-1.98</td>
</tr>
<tr>
<td>New fall since attendance</td>
<td>1.63</td>
<td>1.08-2.48</td>
</tr>
<tr>
<td><em>Wolinsky et al., 1994 [67]</em></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Perceived health</td>
<td>2.21</td>
<td>1.03-4.72</td>
</tr>
<tr>
<td>Dizziness</td>
<td>2.58</td>
<td>1.20-5.51</td>
</tr>
</tbody>
</table>

* Relative risk is given per standard deviation from the mean
the fact that the vast majority of patients that re-fractured would have done so in a fall. Wolinsky *et al.* asked how many falls the patient had in the year prior to the start of the study [67]. They found no relation between this variable and a subsequent hip fracture. This could be because the surveys were filled out at the start of the study and not at the time of the first fracture.

Chiu *et al.* found that concomitant neurological diseases (stroke or Parkinson’s) were found more frequently in patients with two hip fractures [60]. They also found that sequential hip fractures occurred more commonly in institutionalized patients. They found that a biochemical change of osteomalacia at the time of the first hip fracture was also associated with the occurrence of a second hip fracture. These studies have identified BMD, weight and weight loss and perceived health, among other factors, as tools that could be used to identify people at risk for second hip fracture.

### 1.6.3 Outcomes of Second Fracture

It has been suggested by several authors that the outcome of a second hip fracture is worse than that of a first fracture [59, 64, 65]. The three outcomes that were found to be worse in second hip fractures were the type of fracture, patient’s mortality rate and the patient’s loss of mobility. With regard to the type of fracture, Dretakis *et al.* found that second hip fractures tended to be more unstable and displaced than the first [64]. They suggested that this could be due to a progressive reduction of bone mass as well as the impairment of the patient’s mobility. Boston *et al.* looked at the mortality rate of hip fracture patients. They found that patients who fractured their first hip had a mortality rate of 13% at 3 months while those who fractured a second hip had a mortality rate of 30% at 3 months [59]. This difference suggests that an increased mortality rate is associated with second hip fractures when compared to first hip fractures.

Pearse *et al.* looked at the mobility of patients with sequential contralateral hip fractures [65]. They found that after a first fracture, only one of 24 patients who could walk without supports before the fracture could do so after, though they could still walk without the assistance of an able-bodied person. After their first fracture, 91% of the patients who could walk without assistance of an able-bodied person prior to their fracture could do so after. After a second fracture, only 53% of patients who could walk independently (including those who used supports
such as a cane) prior to the second fracture could still walk without help. They also found that second hip fractures had a negative effect on social independence. Of the patients in their study who lived at home prior to their first fracture, 64% were able to return home. After these patients suffered another fracture, only 54% returned home. There was no statistically significant difference between the length of hospital stay after the first and second fractures. Overall, they found that patients who fractured a hip on average became less mobile and less socially independent. After a second fracture, patients became even less mobile and socially independent. These changes in level of function following a second hip fracture along with the noted increase in mortality motivate the need to develop second hip fracture prevention strategies.

1.7 Hip Fracture Prevention

There are a number of pharmacological and biomechanical interventions that are used clinically or have been proposed to be used clinically to reduce the risk of hip fracture. Pharmacological interventions aim to improve the strength of the bone by increasing the bone density. Biomechanical interventions aim to dissipate the energy from a fall or increase the strength of the femur. All of these types of interventions are discussed in the following sections.

1.7.1 Pharmacological Hip Fracture Prevention

A number of drugs have been studied as treatments for osteoporosis including calcium and vitamin D, bisphosphonates, hormone replacement therapy, calcitonin, parathyroid hormone and selective estrogen-reception modulators. These pharmacological interventions can reduce the risk of hip fracture by slowing the rate of bone turnover. The ability of these drugs to increase BMD and prevent hip fracture as well as side effects associated with them are discussed below. Some of these drugs have been shown to reduce the risk of hip fracture, while others appear to only reduce the risk of vertebral fractures. All of these drugs have been shown to increase BMD. Because hip fractures are less common than vertebral fractures, larger studies are required to show a significant effect.

Calcium and vitamin D3 supplements are known to be effective in the prevention of osteoporosis. The Canadian Medical Association guidelines for the treatment of osteoporosis state that "adequate calcium and vitamin D through diet or supplements are essential for the
prevention of osteoporosis and, taken together, are essential adjuncts to preventative therapy” [72]. They caution that calcium and vitamin D should not be used as the sole treatment for osteoporosis. A large placebo-control study found that women who were treated with calcium and vitamin D had 43% fewer hip fractures than controls [73]. They also had a 2.7% increase in BMD compared with a 4.6% decrease in BMD for controls. Another study by this group found that calcium and vitamin D were a cost effective method of hip fracture prevention [74]. An additional benefit of vitamin D therapy is that it increases muscle strength and thus could potentially reduce the risk of falling in the elderly [75].

Bisphosphonates are a class of compounds that act by selectively inhibiting osteoclast function. This slows the rate of bone resorption and thus increases bone density. The Canadian Medical Association recommends bisphosphonates as a first line preventative therapy in postmenopausal women and men with low bone mass or osteoporosis. Hodsman et al. reviewed a number of randomized control trials that looked at the effect of these drugs on the incidence of vertebral, non-vertebral and hip fracture [76]. They found that patients who were treated for 3-4 years had BMD increases of 1.6 to 3.8% in the femoral neck. These increases in BMD translated to significant reductions in vertebral fracture incidence, however only two of the studies reviewed found a statistically significant reduction in hip fracture incidence (RR = 0.5).

The use of estrogen replacement therapy for prevention of osteoporotic fractures is controversial, and the results of most studies that look at hip fracture are inconclusive [77]. The Women’s Health Initiative is a large randomized control trial that studied the effect of estrogen and progestin on 16,608 women aged 50 to 79 [78]. They found that daily use of estrogen plus progestin reduced the risk of hip fracture (RR=0.66, CI (0.45-0.98)) but increased the risk of breast cancer (RR=1.26), venous thromboembolic disease (RR=2.11), stroke (RR=1.41) and coronary heart disease (RR=1.29). The benefits of hormone replacement therapy may be short term. A study by Yates et al. used data from women who participated in the National Osteoporosis Risk Assessment [79]. They found that women who had ceased using hormone replacement therapy for 5 years had a risk of hip fracture similar to the general population. Women who had ceased using hormone replacement therapy within the previous 5 years had an increased risk of hip fracture (RR=1.65, CI (1.05-2.59)).
Calcitonin is a peptide hormone that occurs naturally in the body. It cannot be taken orally and is usually taken in a nasal spray. Recombinant salmon calcitonin is the standard form of the drug because it is more potent in humans than the human form of calcitonin. A review by Brown and Josse found that nasal calcitonin has been shown to be effective in the prevention of vertebral fractures in severely osteoporotic women but has not been proven to reduce non-vertebral fractures [72]. Another study found a reduced risk of hip fracture (RR = 0.1) in patients taking a low dose of calcitonin [80]. They did not find a reduced risk in patients taking higher dosages.

Parathyroid hormone can stimulate both bone formation and resorption resulting in an increase or decrease in BMD, depending on how it is taken. Continuous infusion leads to greater bone resorption than daily injections. Neer et al. studied the effect of parathyroid hormone on the incidence of fractures in 1,627 postmenopausal women with prior vertebral fractures [81]. The study was terminated early because of the development of osteosarcomas in a long-term toxicology study in rats.

Selective estrogen-receptor modulators block conformational changes of the estrogen receptor. Raloxifene hydrochloride is the only selective estrogen-receptor modulator that is approved for the prevention and treatment of osteoporosis [72]. In a study by Ettinger et al. the effect of raloxifene on fracture risk was examined in postmenopausal women [82]. They found a 30% reduction in the incidence of vertebral fractures but no significant difference in the number of hip fractures in particular. They did find that raloxifene increased femoral BMD.

Overall, pharmacological interventions have been shown to increase BMD and reduce the risk of fractures in general. However, few drugs have been shown to reduce hip fractures specifically, and all carry risks of side effects. In the case where a risk reduction was observed, the results occurred after 3-4 years of treatment with the least effect on elderly frail individuals. In the setting of prevention of a second hip fracture where most occur within 2 years, a strategy which increases bone strength earlier would be favourable.
1.7.2 Biomechanical Hip Fracture Prevention Techniques

Biomechanical interventions for hip fracture prevention include hip protectors, which are used clinically, and the "femoroplasty" procedure, which has been investigated in an in vitro biomechanical study. Hip protectors have been widely investigated as a method of reducing hip fracture incidence, but their efficacy is a subject of debate. Hip protectors are made of some form of external padding that helps to absorb the impact energy of a fall. A systematic review by Parker et al. looked at 13 randomized control studies [83]. They separated the studies into those in which the participants were cluster-randomized by care unit, nursing home and nursing home ward and those in which the participants were individually randomized. They pooled the studies with individual randomization and found that the incidence of hip fracture was not reduced by wearing hip protectors. The studies with cluster randomization found that, for those living in institutional care with a high background incidence of hip fracture, hip protectors appear to reduce the incidence of hip fracture. They found that compliance was a problem. This could be because the hip protectors are uncomfortable, unattractive or, in institutional populations, difficult to manage in the setting of concurrent incontinence management.

A new surgical procedure called a "femoroplasty" has been proposed to prevent hip fracture. In this procedure, polymethylmethacrylate (PMMA) bone cement is injected into the proximal femur. In a cadaver study, this procedure was found to increase the failure load of the proximal femur by 82% when it was loaded to failure in a fall loading condition [84]. In this study, they caution that this procedure generates a significant amount of heat with a resultant increase in temperature to an unacceptable level. This procedure has not been evaluated clinically.

1.8 Biomechanics of Hip Fracture

The study of hip fracture requires an understanding of the biomechanics of hip fracture, including the mechanism of fracture, the characteristics of falls, load distributions in the femur, the contribution of cortical and trabecular bone to the strength of the femoral neck, fracture initiation and previous biomechanical research. The loading on the femur during gait is much different than that seen in a fall (Figure 1-6). The diagram in Figure 1-6 is a simplification of the stress in the femoral neck as it only shows the force applied to the femur from the pelvis. This general stress distribution demonstrates that during gait the inferior neck experiences large...
compressive stresses, while the superior neck experiences relatively small tensile stresses. In a fall, this general stress distribution is reversed, with the superior neck experiencing large compressive stresses and the inferior neck experiencing smaller tensile stresses.

![Figure 1-6 Direction of load applied to proximal femur from acetabulum and general stress distribution through the cross section of the neck. Blue (+) indicates compressive stress and red (-) indicates tensile stress. From Turner, 2005 with permission [85]](image)

1.8.1 Fractures Due to Falls or Falls Due to Fracture?
There is some controversy over what proportion of hip fractures occur due to the fall mechanism described in the previous section and what proportion occur by other mechanisms. It is often quoted that over 90% of hip fractures are associated with falls [28], but it is unknown what proportion of these fractures associated with a fall were caused by the fall and what proportion occurred immediately prior to the fall [86]. Intrinsic factors that have been proposed to cause hip fractures without trauma include severe osteoporosis, muscle contraction, fatigue or stress fractures and localized disease such as metastatic cancer. A review by Youm et al. found that between 11% and 25% of hip fractures were caused by the “leg giving away” or “spontaneous fracture” [87]. Although it is often stated that 90% of fractures are caused by a fall, it is likely that a proportion of these fractures are caused by other mechanisms.

1.8.2 Fall Orientation
The direction of a fall has been associated with both the likelihood of sustaining a fracture and the type of fracture that occurs. Falls to the side are more likely to cause hip fracture than other types of falls [9, 88-90]. Nevitt and Cummings found that elderly community-dwelling women who fractured a hip were more likely to have fallen on their side or straight down (odds ratio
(OR) = 3.3) and they were more likely to have landed on or near their hip (OR = 32.5) than those whose fall did not result in a fracture [89]. Different types of hip fracture have been found to be associated with different types of falls. Hopkinson-Woolley and Parker found that falls that involved a twisting motion were associated with extracapsular fractures [91]. Overall, falls to the side and falls where the hip contacts the ground first are more likely to cause a fracture, and falls that involve a twist motion are more likely to result in extracapsular fractures.

1.8.3 Hip Impact Resulting from a Fall

Fall biomechanics experiments have been used to measure velocity at impact and peak ground force and to estimate the loading rate on the femur. When the hip hits the ground in a fall, the energy of the fall is absorbed by the body. Researchers have studied this impact using human subjects fall and crash dummies in pelvis release experiments. Using video analysis of subjects falling on mats, the velocity of impact at the greater trochanter during a sideways fall has been estimated to be between 1.99 and 4.79 m/s [41, 92, 93]. The velocities were found to be higher in subjects that contracted their muscles during the fall.

In order to estimate the forces in a fall, the impulse at impact has been investigated using pelvis release experiments, where live subjects are dropped from small heights onto a force plate [41, 94, 95]. The peak forces have been measured to be between 1145 and 6100 N. The peak force was found to be higher in people who landed with their trunk upright and in people who flexed their muscles when they fell. These impulse curves from these tests along with estimates of the stiffness of the soft tissue surrounding the femur have been used to estimate the displacement rate at the greater trochanter of the proximal femur. Dr. Steve Robinovitch estimated this loading rate to be approximately 330 mm/s [96].

1.8.4 Load Distribution in the Femur During Fall

Finite element modelling has been used to examine the relative load carried by the cortical and cancellous bone in the proximal femur. A finite element analysis of the proximal femur during a fall found that the relative load carried by cortical and cancellous bone during elastic loading varied with location in the proximal femur [97]. Lotz et al. found that cortical bone supports 30% of the load in the subcapital region, 50% of the load at the mid-neck, 96% of the load at the
base of the neck, and 70% of the load in the intertrochanteric region during a fall. This analysis found that the superior neck was loaded primarily in compression and the inferior neck was loaded primarily in tension. This indicates that in a fall, cortical bone carries most of the load in the lateral neck and intertrochanteric region, and cancellous bone carries most of the load in the medial neck.

1.8.5 Relative Contribution of Cortical and Cancellous Bone to the Strength of the Femoral Neck
Cortical and cancellous bone both contribute to the strength of the proximal femur. Destructive mechanical tests have been used to measure the effect of removing the cancellous bone on the strength of the femoral neck [98]. The researchers found that removing the cancellous bone from the femoral neck resulted in a 40% decrease in failure load compared with matched pair controls when the neck was loaded in isolation from the rest of the proximal femur.

1.8.6 Fracture Initiation
Although it has been shown that cancellous bone plays a significant role in carrying load during a fall, a number of studies suggest that it is cortical bone that is of primary importance in the structural failure of the femur. In an editorial by Ferretti et al., it is asserted that hip fractures initiate in the intertrochanteric and femoral neck cortices; however, no conclusive experimental evidence is provided to back up these assertions [99]. A group at Cambridge has also proposed that it is cortical bone that initiates hip fractures in the femoral neck. Their fracture model hypothesizes that the impact of a fall causes a compressive buckling in the superolateral cortex of the femoral neck followed by failure due to tensile or torsional stresses in the remainder of the neck [100]. This theory is based on structural differences between people who fracture their hip and those who do not, as well as structural changes in the cortex of the femur with aging. Their studies comparing femoral necks from people who have fractured their femurs to those of people who have not have found differences between the two groups in cortical thickness and porosity.

1.8.7 In Vitro Hip Fracture Testing
Hip fractures have been reproduced experimentally by loading cadaver femurs to failure in apparatuses that simulate falls as well as apparatus that simulate stance loading. Experiments that
load femurs in a stance configuration have fixed the shaft of the femur in a vertical position and applied a downward force to the head of the femur. A study by Beck et al. that loaded femurs to failure in a stance loading configuration found that the femurs broke in a vertical plane through the femoral neck from the base of the femoral head to the lesser trochanter [101]. They noted that the fracture plane differed from what was seen clinically. As discussed in Section 1.9.1, the injury mechanism for spontaneous fractures is likely to be more complicated than a straight vertical force.

Figure 1-7 Fall type loading configuration. The femur is held with the shaft at 10° from the horizontal and is internally rotated 15°. The load is applied to the greater trochanter. The head and distal shaft are free to translate in the horizontal plane From Eckstein et al., with permission [93]

A number of studies have reproduced hip fractures similar to the fractures seen clinically by simulating fall loading. Although these studies generally use similar test apparatuses, they vary slightly in terms of the constraints on the femur, the location where the load is applied and the loading rate. In the most commonly used configuration, the femur is held with the shaft 10° from the horizontal and is internally rotated 15°. Lochmuller et al. and Eckstein et al. used this configuration, with the load applied to the femur at the greater trochanter [102, 103] (Figure 1-7). In this configuration, the crosshead acts like the floor hitting the greater trochanter. Other researchers have used the same femur orientation and applied the load to the head and restricted the vertical translation of the greater trochanter [44, 104, 105]. Pinilla et al. examined the effect of internal rotation on the failure load of cadaver femurs and found that the failure load decreased with increasing angle of internal rotation [106]. The internal rotation of 15° is not, however, based on published fall biomechanics data and has been used because it is a reasonable approximation of a sideways and slightly backwards fall.
Loading rate has been shown to have an effect on the fracture load of femurs. Courtney *et al.* showed that increasing the loading rate from 2 mm/s to 100 mm/s increased the failure load of femurs by 20% [104]. The increase in loading rate did not, however, have an effect on the energy to failure. Most other researchers looking at hip fracture have used quasi-static loading rates of 0.5 mm/s to 6.6 mm/s.

1.9 Objectives
As stated earlier, there is a need to prevent second hip fracture. There is currently no surgical technique to instantly strengthen proximal femur for hip fracture prevention. To address this need, the following primary and secondary objectives were identified.

1.9.1 Primary Objective
The primary objective of this study was to evaluate the mechanical feasibility of augmenting the proximal femur with a novel implant in order to prevent hip fracture. Specifically, I aimed to develop implants to prevent proximal femur fracture and quantify the effect of implants on the propensity of femurs to fracture through finite element modelling and mechanical testing with a cadaver model.

1.9.2 Secondary Objective
The secondary objective of this project was to describe the initiation and progression of proximal femur failure using an experimental hip fracture model, and a finite element analysis of hip fracture.
Chapter 2: Methods

The Methods section of this thesis is divided into the following four sections, the first two relating to the secondary objective of the study, and the third and fourth sections relating to the primary objective:

1. experimental methods relating to the determination of the failure mechanism of hip fracture;
2. analytic methods relating to the determination of the failure mechanism of hip fracture;
3. methods used in the design of implants; and
4. methods relating the assessment of the implants.

To meet the objectives of this experiment, two models of hip fracture were developed: an experimental model and an analytic model. These models are fully described in the Hip Fracture Mechanism sections. The other two sections describe how the models were used to meet the objectives of the section. They refer back to the first two sections for full descriptions of the models.

2.1 Hip Fracture Mechanism: Experimental Analysis

2.1.1 Specimens

Four fresh-frozen, human proximal femur specimens were obtained from the Faculty of Medicine, University of British Columbia and LifeLegacy Foundation (Tuscon, AZ, USA). The femurs were stored in a freezer at -21°C. Anteroposterior radiographs were obtained and examined by an Orthopaedic Surgeon (Dr. Pierre Guy) for evidence of previous fracture, local area of lucency or pathology (e.g. metastases) which could alter mechanical testing results. DXA scans were performed with a Hologic QDR 4500W bone densitometer (Hologic Inc., Waltham, MA) using the standard protocol for the proximal femur. Donor information along with total proximal femur areal bone mineral density (aBMD) is presented in Table 2-1.
Table 2-1 Donor information for specimens used in fracture mechanism experiments

<table>
<thead>
<tr>
<th>Donor</th>
<th>Side</th>
<th>Sex</th>
<th>Age</th>
<th>Weight (kg)</th>
<th>Height (cm)</th>
<th>aBMD (g/cm²)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1004</td>
<td>L</td>
<td>M</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>0.867</td>
</tr>
<tr>
<td>1061</td>
<td>L</td>
<td>F</td>
<td>72</td>
<td>63</td>
<td>157</td>
<td>0.844</td>
</tr>
<tr>
<td>1169</td>
<td>R</td>
<td>M</td>
<td>72</td>
<td>90.7</td>
<td>170.18</td>
<td>0.764</td>
</tr>
<tr>
<td>1171</td>
<td>L</td>
<td>F</td>
<td>91</td>
<td>40.8</td>
<td>157.48</td>
<td>0.722</td>
</tr>
</tbody>
</table>

2.1.2 Experimental Apparatus
An apparatus was built to reproduce the loads on the femur during a fall (Figure 2-1). This device was modelled after the device used by Lochmuller et al. [103]. The apparatus allowed the application of a load to the greater trochanter by a materials testing system while supporting the head of the femur and the distal shaft. The support at the head allowed full translation and rotation of the head, restricting only its vertical movement. The potting that held the distal end of the femur allowed translation in the horizontal plane and rotation in the coronal plane. The bottom of the apparatus consisted of two 11.5-mm-thick hardened steel plates, ground flat to within 50 μm. The bottom plate was 43 cm x 38 cm and sat on the base of the materials testing system (Instron 8874, Instron Corporation, Canton, MA). The second plate was 51 cm x 31 cm and was separated from the bottom plate by a layer of 0.95 cm diameter ball bearing set in steel plates. Two angled pieces of aluminum were bolted to the top plate. These angled plates supported a 19.05 mm diameter steel pin on circular Rulon bearing surfaces. The height of the pin was adjustable to accommodate different sizes of femur. The pin supported an aluminum tube that was 7.3 cm in diameter and 20.2 cm in length. This aluminum tube held the distal end of the femur. The head of the femur was supported by a steel plate that sat on a layer of 0.95 cm diameter ball bearings.
2.1.3 Specimen Preparation

Prior to testing, each femur was thawed to room temperature overnight. The femur was cut at the midpoint between the top of the greater trochanter and the bottom of the lateral condyle and the soft tissue was dissected away. Care was taken to remove as much of the periosteum in the intertrochanteric and femoral neck region as possible without damaging the underlying cortical bone. To pot the femur, it was positioned in the aluminum tube so that the distance from the top of the greater trochanter to the support pin was 2/3 of the length of the femur. The shaft axis of the femur was oriented parallel to the tube. The neck axis of the femur was internally rotated 15° [103]. The pot was then filled with PMMA covering the femur between the mid-length cut and the proximal 1/3rd. The potted femur was then placed in the apparatus with the head supported by a tennis ball shell and a 0.7-mm-thick piece of foam to distribute the load on the femoral head and prevent local crushing. The height of the distal pin was adjusted so that the shaft of the femur was at an angle of 10° with respect to the horizontal [103]. A PMMA pad was moulded to the greater trochanter and the loading plate of the materials testing machine to prevent local crushing by distributing the applied load.

2.1.4 Strain Gauges

Femoral neck strain was measured on the surface of two of the femurs in this test (Specimen numbers 1004L and 1061L) using two uniaxial strain gauges (KFG-3-350-C1-11L1M2R, Omega Engineering Inc., Stamford, CT). The surface was prepared and the gauges were applied following the application protocol of Carter et al. [107]. One gauge was applied to the superior
Methods

surface of the femoral neck and one gauge was applied to the inferior neck (Figure 2-2). The gauges were connected to a signal conditioner (SCXI-1000, National Instruments, Austin, TX) and sampled along with the axial load from the load cell at a frequency of 500 Hz, which was the limit of the software.

![Figure 2-2 Strain gauge location on superior neck (left) and inferior neck (right). White beads were bonded to femur to investigate the possibility of using video analysis to track failure in future experiments.](image)

2.1.5 Failure Test Protocol

All femurs were loaded to failure with a set displacement rate of -100 mm/s applied at the greater trochanter using a materials testing system (Instron 8874, Instron Corporation, Canton, MA). The tests were controlled using a Fastrak Console (Instron Corporation, Canton, MA). Load and displacement data were acquired using a 12-bit data acquisition card, sampled at 1000 Hz. Axial force was measured using a biaxial load cell (Model 211-113, SensorData Technologies Inc., Sterling Heights, MI; serial number 97533). Displacement was measured using an Instron Linear Variable Differential Transformer (± 50 mm; serial number 0291).

2.1.6 Videography

Two high-speed video cameras were used to film the tests to track the failure of the femur (Phantom v9.0, Vision Research, Wayne, NJ, USA). Images were captured at a resolution of 384 x 384 pixels, a sample rate of 9,111 frames per second and an exposure time of 99 μs. The cameras were controlled using Phantom Camera Control V 8.4.630 (Vision Research, Wayne, NJ). The femurs were illuminated using two 250 W photographic analysis lights (North Star, Wayne, NJ).
Two femurs (1169R and 1171L) were initially tested with both cameras filming the anterior surface of the femur. After these initial tests, the protocol was refined and the last two femurs (1004L and 1061L) were filmed from both sides (Figure 2-3), using mirrors to see the top and the bottom of the femoral neck (Figure 2-4). These last two femurs had the strain gauges attached and had small white beads bonded to them. The beads were added to track the deformation of the femur. The conditioned load signal from the load cell was also acquired by the Phantom Camera Control software at a rate of 9,111 Hz so that the applied load at each frame was recorded.

Figure 2-3 Test set-up for the fracture mechanism experiments. The load was applied to the femur in the test apparatus by the Instron. Two cameras filmed the test, one from the anterior side and one from the posterior side. Two 250W lights were used to illuminate the specimen.

Figure 2-4 Camera still on the left shows the anterior surface of the femur and a mirror image of the inferior surface of the femur. Camera still on the right shows the posterior surface of the femur and a mirror image of the superior surface of the femur.
2.2  **Hip Fracture Mechanism: Finite Element Analysis**  

To aid in the design and analysis of the femoral augmentation device, a finite element model (FEM) of a proximal femur was developed. To develop this model, a Quantitative Computed Tomography (QCT) scan was taken of a femur and the geometry and density were analyzed and exported to the FEM software, where a mesh was generated. Finally, the model was validated using mechanical experiments.

2.2.1  **Specimen**  

The specimen used for this model was a previously frozen human proximal femur that was obtained from the Faculty of Medicine, University of British Columbia. The donor for this specimen was a 73-year-old woman. An anterioposterior radiograph was obtained using standard femur protocol. A radiologist (Dr. Bruce Forster) examined the film and found no indication of previous fracture or metastatic bone disease. A DXA was performed using a Hologic QDR 4500W bone densitometer (Hologic Inc., Waltham, MA) to measure the bone mineral density of the specimen. The T-Score of the proximal femur was found to be -2.2 in the total proximal femur region.

2.2.2  **QCT Imaging**  

To prepare the specimen, the femur was cut at mid-shaft and the muscles, tendons and ligaments were dissected away. The proximal end of the femur was submerged in ultrasound gel to provide a medium surrounding the bone. The bone was held rigid, with the shaft axis perpendicular to the scan plane and the femoral neck axis parallel to the horizontal. The bone was placed on top of Model 3 CT Calibration Phantom (Mindways Software Inc., San Francisco, CA, USA) so that each image of the bone would also contain the phantom. The bone was scanned using a GE LightSpeed Ultra 16 slice helical scanner (General Electric Healthcare Technologies, Waukesha, WI, USA). The scan was performed by a trained technologist at settings of 120.0 kV, 100 mA, table height of 129.5 cm, slice thickness of 1.25 mm, matrix size of 512 × 512 pixels and pixel size of 0.49 mm × 0.49 mm. A total of 168 consecutive images were obtained.
2.2.3 Bone Geometry
The CT images were segmented using Analyze 5.0 (AnalyzeDirect Inc, Lenexa, KS, USA) to determine the geometry of the femur. The segmenting procedure involved tracing two boundaries on each slice, the outer surface of the bone and the boundary that separates the cortical or subchondral from the cancellous bone or intermedullary canal. This segmentation was done using the thresholding function of the program, with manual override to ensure continuity of the bone. The cortical bone was separated from the cancellous bone, so that during meshing the cortical elements would contain only cortical bone. When the geometry had been defined for the entire proximal femur, it was exported into the finite element analysis software (ANSYS 8.0, ANSYS Inc., Canonsburg, PA, USA).

2.2.4 Bone Density Distribution
Analyze 5.0 was also used to determine the density distribution of the bone. A density map of the proximal femur was exported using the program. The density map contained the location of each voxel and the corresponding attenuation expressed in Hounsfield Units (HU). The phantom was used to relate the HU values to a $K_2HPO_4$ equivalent density for each voxel. The equivalent $K_2HPO_4$ density has been shown to relate to the material properties of bone [108]. This equivalent density was later used to determine the distribution of material properties and to apply these material properties to the cancellous elements in the completed mesh.

**Calibration Phantom**
The phantom consisted of five rods of reference materials that contained known amounts of low and high atomic number materials. The rods were previously calibrated against liquid $K_2HPO_4$/water solutions and replicate solutions of precisely known water and $K_2HPO_4$ densities. The equivalent water density of the rods varied from 923.2 mg/cm$^3$ to 1119.5 mg/cm$^3$. The $K_2HPO_4$ equivalent density varied from -53.4 mg/cm$^3$ to 375.8 mg/cm$^3$.

**Calibration**
The scan was calibrated following the calibration procedure outlined in the phantom manual. Briefly, this involved tracing a region of interest around each of the columns in the phantom in the Analyze 5.0 program. The average attenuation in HU was then found for each column. A
linear regression was then performed using these values and the known equivalent water and $K_2HPO_4$ equivalent densities of each column. This analysis yielded two imaging-technique specific parameters that were used to relate the attenuation of the bone to a $K_2HPO_4$ equivalent density with the following linear function:

$$\rho_{K_2HPO_4} = \frac{\mu_{ROI} - \beta_{CT}}{\sigma_{CT}}$$

Where,
- $\mu_{ROI}$ = CT number within a region of interest of the bone, in HU
- $\rho_{K_2HPO_4}$ = $K_2HPO_4$ equivalent density of the bone within the region of interest
- $\sigma_{CT}$ = parameter defining the response of the CT scanner to $K_2HPO_4$
- $\beta_{CT}$ = parameter characteristic of the CT number scale

The values for the parameters were determined to be:

$$\sigma_{CT} = 1.419$$
$$\beta_{CT} = -16.0$$

This linear transformation was used to convert the density distribution from HU to a $K_2HPO_4$ equivalent density for each voxel using Matlab 6.1 (Mathworks, Natick, MA).

### 2.2.5 Mesh Generation

The geometry exported from Analyze consisted of a list of points, with each point representing a voxel on the outer surface of the cortical bone or the surface representing the boundary between the cortical and cancellous bone. These points were formatted and scaled so they could be read as an input file in ANSYS. The bone surface points were cropped so that one third of the bone length remained. This was done to be consistent with the mechanical testing protocol outlined in Section 2.1.

The points that map the outer and inner surfaces of the cortical bone were used to define the volume occupied by the bone. In order to facilitate the automatic generation of the mesh, the
bone was partitioned into 164 volumes, 84 representing cortical bone and 80 representing cancellous bone. Each volume was created manually through a three-step procedure. First, splines were traced through the points at the surface of the volume. These splines were used to define the boundaries of the volume. Second, Coon’s patches were used to fit areas to the splines. These areas contoured the bone surface and enclosed the volume that was being created. Finally, the volume was created using the defined boundary areas.

The mesh was created using the automated meshing tool in ANSYS 8.0. Twenty-node brick elements with mid-nodes (Solid95) were used in the mesh. This element also had the option of creating four-sided tetrahedral elements and five-sided pyramid elements which were both used to model the cancellous bone. These element types were used to include implants because the geometry was too complex to model the cancellous bone as six-sided brick element. The initial mesh of the intact (pre-implant) bone was comprised of 1,734 cortical brick elements and 15,254 cancellous elements that were either pyramid or tetrahedral.

2.2.6 Material Properties
The material properties of the bone were assigned in a manner similar to Lotz et al. 1991 [109]. The elements that comprise the outer shell of the bone were assigned cortical material properties. The cortical bone was given an isotropic and homogeneous stiffness of $E=16.3$ GPa and a Poisson’s ratio of 0.3. The stiffness of cancellous bone was assigned in a density-dependent manner, according to the formula

$$ E = 0.7(QCT)^{4/3} $$

where $E$ is the elastic modulus of the bone in MPa and $QCT$ is the Quantitative CT density in mg/cm$^3$ $K_2HPO_4$ [108, 109]. In order to speed up the model’s computational time, the cancellous bone was divided into 20 different materials (Table 2-2). Each material was assigned a modulus corresponding to the mean modulus of the elements that make up the material. A Poisson’s ratio of 0.3 was used for all cancellous bone.
Table 2-2 Summary of apparent densities and modulus for the cancellous elements

<table>
<thead>
<tr>
<th>Material</th>
<th>Apparent Density (g/cm³)</th>
<th>Modulus (MPa)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0.04</td>
<td>13</td>
</tr>
<tr>
<td>2</td>
<td>0.07</td>
<td>32</td>
</tr>
<tr>
<td>3</td>
<td>0.12</td>
<td>65</td>
</tr>
<tr>
<td>4</td>
<td>0.15</td>
<td>92</td>
</tr>
<tr>
<td>5</td>
<td>0.18</td>
<td>117</td>
</tr>
<tr>
<td>6</td>
<td>0.20</td>
<td>141</td>
</tr>
<tr>
<td>7</td>
<td>0.23</td>
<td>165</td>
</tr>
<tr>
<td>8</td>
<td>0.25</td>
<td>191</td>
</tr>
<tr>
<td>9</td>
<td>0.28</td>
<td>217</td>
</tr>
<tr>
<td>10</td>
<td>0.30</td>
<td>247</td>
</tr>
<tr>
<td>11</td>
<td>0.34</td>
<td>285</td>
</tr>
<tr>
<td>12</td>
<td>0.37</td>
<td>327</td>
</tr>
<tr>
<td>13</td>
<td>0.41</td>
<td>381</td>
</tr>
<tr>
<td>14</td>
<td>0.47</td>
<td>452</td>
</tr>
<tr>
<td>15</td>
<td>0.53</td>
<td>543</td>
</tr>
<tr>
<td>16</td>
<td>0.60</td>
<td>646</td>
</tr>
<tr>
<td>17</td>
<td>0.67</td>
<td>746</td>
</tr>
<tr>
<td>18</td>
<td>0.73</td>
<td>845</td>
</tr>
<tr>
<td>19</td>
<td>0.79</td>
<td>942</td>
</tr>
<tr>
<td>20</td>
<td>0.95</td>
<td>1212</td>
</tr>
</tbody>
</table>

2.2.7 Failure Criterion

A maximum von Mises strain criterion was used to predict the failure [109, 110]. Failure was defined as when the von Mises strain of any cortical element reached 0.011 [6, 109]. This failure criterion has been found to accurately predict the failure load in previous studies [110]. Cancellous bone was considered separately in a manner similar to Lotz et al., 1991 [109]. Lotz et al. reported the load where cancellous failure begins as the “yield load.” In this study the pattern of cancellous yielding was examined, however, the cortical failure was used as the predicted failure load of the femur. A von Mises failure criterion was also used to determine cancellous failure with a maximum yield strain of 0.010 [111].

2.2.8 Applied Loads

The model was loaded to reproduce the loading experienced by the proximal femur during the mechanical loading test set-up described in section 2.1. To reproduce this loading, the model was “potted” in a stiff cylinder at 15° internal rotation (Figure 2-5). The distal end of the pot was
fixed so that it could rotate about an axis representing the pin from the mechanical test set-up, but could not translate in any direction and could not rotate about any other axis. The node where the head would make contact with the head support plate was fixed so that it could not translate vertically. This allowed the head to translate in the horizontal plane and rotate about the contact point. The 16 cortical elements closest to this point were made rigid to prevent large local deformations at the point load. The greater trochanter was loaded vertically in a manner reproducing the load applied by the Instron. The load was distributed over the area that was covered by the PMMA in the mechanical test set-up.

![Figure 2-5 Schematic of loads applied to the finite element model](image)

2.2.9 Model Validation

The femur used in the model was instrumented with 9 uni-axial strain gauges in a manner similar to Lotz et al. [108]. The gauges were positioned so they were coplanar at three locations: subcapital, basicervical and subtrochanteric (Figure 2-6). The location and orientation of each gauge was mapped onto the mesh. The femur was then cyclically loaded to 432 N using the test set-up described in section 2.1. The strain data for one cycle of loading was then compared to the models predicted strain under the same loading conditions.
2.3 Design of Femur Augmentation Implant

To investigate the mechanical feasibility of augmenting the proximal femur for hip fracture prevention, this study identified criteria for this augmentation and generated design alternatives. A preliminary assessment of these designs was done using finite element modelling.

2.3.1 Design Criteria

The following criteria were identified for the design of an implant that would be both successful in achieving the primary objective of this project and feasible from a clinical point of view. The implant would have to:

- double the strength of the proximal femur,
- be biocompatible,
- be suitable for insertion in a minimally invasive procedure, and
- allow for revision surgery.

The overall goal of this study was to increase the strength of the proximal femur. The specific goal of doubling the strength of the proximal femur was based on the findings of Courtney et al. that there is an age-related difference in strength of -50% between the younger femurs and older femurs. Younger people, who have stronger femurs, seldom fracture their hips. Therefore, if the
age-related decrease in femur strength in older patients could be repaired, they would be much less likely to fracture their hips.

In order for the implant to be clinically relevant, it must be biocompatible as well as suitable for insertion in a minimally invasive procedure, and it must allow for revision. To ensure that the implant is biocompatible, it must be manufactured from materials that have been shown to be biocompatible in similar applications. Whether the implant can be inserted in a minimally invasive procedure must be assessed by a clinician. To meet this requirement, potential designs must be reviewed in terms of the surgical time required to perform the procedure and the amount of tissue that must be cut to perform the procedure, as well as the size and positioning of the implants. Because all orthopaedic implants can fail, the implant must allow for revision. For this criterion, the implant must be able to be removed and replaced in the event of implant failure or infection. This criterion is also best evaluated by a clinician.

2.3.2 Implant Designs
A number of designs were generated, based on the design criteria (Figure 2-7). The design of these implants was influenced by the results of the finite element modelling investigation of the hip fracture mechanism. When these implants were designed, the hip fracture mechanism experiments had not yet been performed. The design process also included attempting to perform surgical concepts on composite femurs (Model 3306 Third Generation Composite Femur, Pacific Research Laboratories Inc., Vashon, WA, USA).

A prior study on femur augmentation found that injecting bone cement into cadaver femurs resulted in strength increases of 82% [84]. However, this study found that the heat generated by the cement curing was too great for this procedure to be considered for clinical use. In the initial design process of the present study, a concept that was determined to be of interest was to create a composite of PMMA and a carbon sleeve. Setting a carbon fiber sleeve in a polymer increases the strength and stiffness of the polymer while maintaining the polymer's ability to be inserted through a small hole and spread out before setting. Several sizes of carbon sleeve were implanted into composite femurs, and it was determined that it would be feasible to insert carbon sleeves into the proximal femur. Preliminary finite element modelling revealed that when using pins
through the proximal femur, composite materials were predicted to be approximately as effective as much stiffer materials such as steel. Because it was expected that the cement could anchor better in the bone, the composite material was chosen for further investigation.

Figure 2-7 Finite element models of implant designs

Implants (a)-(e) were based on the concept of implanting a carbon sleeve and filling it with bone cement. The intact model was modified to include a hole in the lateral surface of the intertrochanteric region and composite pins through the femoral neck to the head. The pins varied both in location and size. The small pins used in implants (a)-(d) were 5.5 mm in diameter. The modulus of elasticity of the small implants was calculated to be 30 GPa. The larger composite pin in implant (e) was 12 mm in diameter and its modulus of elasticity was 19 GPa. The interface between the implants and the bone was assumed to be perfectly rigid.

Implant (f) models a carbon sleeve set in bone cement that contours the cortex of the femoral neck. This implant is 3 mm thick and hollow on the inside.

Implant (g) used the small composite pin from implants (a)-(d) in the superior neck. A wire was used in the inferior neck. The wire was anchored in the femoral head using an anchoring disk.
that is 15 mm in diameter. The other end of the wire was attached to a nut on the lateral surface of the femur. The anchoring disk was based on an anchor that can be inserted into the cancellous bone and expanded to improve its hold.

Implant (h) models the Trochanteric Gamma™ Nail (Stryker Inc., Kalamazoo, MI, USA). The geometry of the implant was determined from the company website (http://www.stryker.com) and by taking measurements from an implant. The implant is made from stainless steel and was assumed to have a stiffness of 200 GPa.

2.4 Experimental Assessment of Implants
Based on the results from the finite element analysis, three of the implants were selected for an initial experimental assessment using one pair of femurs for each design. These implants were based on implants (b), (f) and (h). Of these implants, implant (f) was selected for further investigation and comparison with the femoroplasty concept of Heini et al. [84].

2.4.1 Specimens
Nine pairs of fresh-frozen, human proximal femora were obtained from the Faculty of Medicine, University of British Columbia (n = 1 pair) and LifeLegacy Foundation (Tuscon, Arizona) (n = 8 pairs). The femurs were stored in a freezer at -21° C. Anteroposterior radiographs were obtained and examined by an Orthopaedic Surgeon (Dr. Pierre Guy) for evidence of previous fracture and metastases. DXA scans were performed with a Hologic QDR 4500W bone densitometer (Hologic Inc.,Waltham, MA) using the standard protocol for the proximal femur. Donor information and total proximal femur aBMD for both left and right femurs are presented in Table 2-3.
Table 2-3 Donor information for specimens used in experimental assessment of implant designs

<table>
<thead>
<tr>
<th>Donor</th>
<th>Gender</th>
<th>Age</th>
<th>Weight (kg)</th>
<th>Height (cm)</th>
<th>aBMD (g/cm$^2$)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Left</td>
</tr>
<tr>
<td>1090</td>
<td>F</td>
<td>73</td>
<td>-</td>
<td>-</td>
<td>0.734</td>
</tr>
<tr>
<td>1149</td>
<td>F</td>
<td>36</td>
<td>81.6</td>
<td>157.48</td>
<td>1.072</td>
</tr>
<tr>
<td>1153</td>
<td>M</td>
<td>63</td>
<td>74.8</td>
<td>180.34</td>
<td>0.760</td>
</tr>
<tr>
<td>1154</td>
<td>F</td>
<td>89</td>
<td>49.9</td>
<td>149.86</td>
<td>0.414</td>
</tr>
<tr>
<td>1157</td>
<td>F</td>
<td>72</td>
<td>56.7</td>
<td>142.24</td>
<td>0.791</td>
</tr>
<tr>
<td>1160</td>
<td>F</td>
<td>55</td>
<td>71.2</td>
<td>160.02</td>
<td>0.911</td>
</tr>
<tr>
<td>1161</td>
<td>F</td>
<td>78</td>
<td>63.5</td>
<td>137.16</td>
<td>0.612</td>
</tr>
<tr>
<td>1169</td>
<td>M</td>
<td>72</td>
<td>90.7</td>
<td>170.18</td>
<td>0.735</td>
</tr>
<tr>
<td>1171</td>
<td>F</td>
<td>91</td>
<td>40.8</td>
<td>157.48</td>
<td>0.722</td>
</tr>
</tbody>
</table>

2.4.2 Control Group Femurs

One femur from each pair was randomly selected and loaded to failure without an implant. These femurs represent the control group that was used to assess the effect of the implants on the failure of the femurs.

2.4.3 Composite Pin

This procedure was based on the implant design (b) from the finite element modelling. The orientation of the pin deviated slightly from the model. This discrepancy will be addressed in the Discussion section. In this surgery, an Orthopaedic Surgeon (Dr. Pierre Guy) implanted a carbon sleeve in the proximal femur and set it in bone cement. A single femur (1161L) was augmented in this manner. Initially a pilot hole was drilled through the lateral surface of the greater trochanter. Progressively larger holes were drilled until a 0.25-inch (6.35-mm) hole was drilled to a depth of 75 mm. The hole in the cortex was then expanded slightly to accommodate the insertion of device slightly larger than 6.35 mm. A batch of bone cement was then mixed (Surgical Simplex P, Stryker Inc., Kalamazoo, MI). The hole was retrograde-filled with cement using a cement plunger that was made of a 6.35-mm-diameter hollow steel tube with a small steel shaft to push the cement through (Figure 2-8). The filling device was then removed and a 0.5-inch (12.7-mm) diameter carbon sleeve was fit over the plunger (Soller Composites, New Hampton, NH). The sleeve was inserted into the hole and the inside of the sleeve was retrograde-filled with 6 mL of cement. The cement cured and the femur then had a carbon fiber bone.
cement composite through the neck. The cement distribution is shown in the radiograph in Figure 2-9.

![Figure 2-8 Injection of bone cement (left) and insertion of carbon sleeve (right) in the composite pin procedure](image)

![Figure 2-9 Anteroposterior and lateral radiographs of specimen 1161 L after augmentation with the composite pin](image)

### 2.4.4 Gamma Nail

In this procedure a Trochanteric Gamma™ Nail was implanted in the proximal femur. A single femur (1171 R) was augmented in this manner by an Orthopaedic Surgeon (Dr. Pierre Guy). The implant used was a Ø10 x 180 mm x 130° Gamma3 Trochanteric Nail Kit with a Ø10.5 x 100 mm Lag Screw and a Ø 5 x 40 mm Locking Screw (Stryker Trauma, Schonkichen, Germany). The surgery was performed according to the manufacturer’s protocol and radiographs were obtained (Figure 2-10).
Methods

Figure 2-10 Anteroposterior and lateral radiographs of 1171 R after augmentation with Gamma Nail

2.4.5 Neck-contouring Composite

In this procedure, the proximal femur was hollowed out and a carbon sleeve was set in bone cement, contouring the femoral neck. This procedure was performed on four femurs (1090 R, 1149 L, 1154 R and 1157 R) by an Orthopaedic Surgeon (Dr. Pierre Guy). To begin this procedure, a 0.9-mm guide wire was drilled through the lateral surface of the intertrochanteric region to the epiphyseal plate using a custom built aiming device (Figure 2-11). A 0.25-inch (6.35 mm) drill bit was then used to expand the hole. A 20-mm KyphX Xpander® Inflatable Bone Tamp (Kyphon Inc., Sunnyvale, CA) was used to hollow out the inside of the femoral neck. The balloon was inserted to the epiphyseal plate and inflated to a pressure of 9 atm, corresponding to a volume of approximately 5 mL. The balloon was deflated, retracted 5 mm and re-inflated. This step was repeated until the balloon reached the cortex. A curette was then used to ensure that the cancellous bone had been cleared in the femoral neck and in the trochanteric region.
One half of a package of Antibiotic Simplex (Howmedica International, Limerick, Ireland) was mixed according to the provided instructions. Prior to mixing, the liquid monomer was stored in a freezer at -20 °C. After 6 minutes, a 15 mL syringe with a large diameter steel tube attached to the end was filled with cement. The tube was inserted to the epiphyseal plate and the cement was injected as the syringe was pulled out. A 0.75-inch (19.05-mm) diameter braided carbon sleeve (Soller Composites, New Hampton, NH) was fit over a custom built balloon (Figure 2-12). This balloon was 40 mm in length and could expand to a much greater volume than the Kyphon balloon. The sleeve and balloon were inserted in the cement-filled cavity. The balloon was then inflated for 30 seconds to push the sleeve out to the cortex. The balloon was then deflated and removed. As much of the remaining cement as possible was then injected into the carbon sleeve. The balloon was then inserted into the sleeve again and inflated for 1 minute. This pushed the cement and the sleeve out to the cortex. The balloon was then deflated and removed. Cement was then used to fill the hole in the cortex.
Methods

As the cement cured, the temperature was measured using an infrared temperature probe (Omega OS523-3, Omega Engineering, Stamford, CT). The temperature was measured at the femoral head and on the anterior and posterior surfaces of the proximal femur. Measurements were taken every minute at all three surfaces over a period of 25 minutes. After the cement had cured, anteroposterior and lateral radiographs were taken (Figure 2-13).

2.4.6 Femoroplasty

In this procedure bone cement was injected into the proximal femur through a hole in the lateral surface of the proximal femur. This procedure was performed on three femurs (1153 R, 1160 R and 1169 L) by an Orthopaedic Surgeon (Dr. Pierre Guy). As in the femoroplasty procedure, a 0.9-mm guide wire was drilled through the lateral surface of the intertrochanteric region to the epiphyseal plate using a custom built aiming device. A 0.25-inch (6.35-mm) drill bit was then used to expand the hole. A full package of Antibiotic Simplex (Howmedica International, Limerick, Ireland) was mixed according to the provided instructions. A Miller™ Bone Cement Injector (Zimmer Inc., Warsaw, IA) was used to inject the cement into the proximal femur. A full package was injected into each femur.
As the cement cured, the temperature was measured using an infrared temperature probe (Omega OS523-3, Omega Engineering, Stamford, CT). The temperature was measured at the femoral head and on the anterior and posterior surfaces of the proximal femur. Measurements were taken every minute at all three surfaces over a period of 25 minutes. After the cement had cured, anteroposterior and lateral radiographs were taken (Figure 2-14).

2.4.7 Experimental Measures
In all failure experiments, the failure load, work of fracture and fracture type were determined. The failure load was defined as the ultimate load reached in the failure test [46]. The work of fracture was defined as the energy absorbed by the femur to reach the ultimate load. The fracture types were determined by an Orthopaedic Surgeon (Dr. Pierre Guy).
2.4.8 Statistical Analysis

Statistical analyses were performed to examine the effect of the femoroplasty implant and the neck-contouring composite implant vs. controls on failure load and work of fracture. Matched-pairs t-tests were used to assess the effect of the femoroplasty (n = 3) vs. controls (n = 3) and neck-contouring composite implants (n = 4) vs. controls (n = 4) separately. Although the sample sizes were small, parametric statistics were deemed to be appropriate because the t-test is fairly robust, even with a small sample. Two-tailed tests at $\alpha = 0.10$ were performed to look at the effect of augmentation on the two dependant variables. In the context of this feasibility study, an error of 10% was acceptable. In this study, a significant result would be used to justify a larger study with a more stringent statistical analysis.

The femur that was augmented with the gamma nail and the femur that was augmented with the composite sleeve were compared to their matched-pair controls using descriptive statistics because only a single femur was tested for each of these designs.

Figure 2-15 Typical load-displacement for control femur showing failure load. The failure was defined to occur at the ultimate load and the work of fracture was defined as the area under the load displacement curve up to the failure load.
Chapter 3: Results

The results from the cadaveric fracture mechanics experiments are presented first. This is followed by the results of the finite element model fracture mechanics experiments, including the validation and the failure analysis of the intact model. The results from the augmented femur finite element models are then presented. Finally, the results of the cadaveric augmented femur tests are presented.

3.1 Fracture Mechanics: Experimental Results

The results of the fracture mechanics tests are summarized in Table 3-1.

Table 3-1 Summary of results from fracture mechanics experiments

<table>
<thead>
<tr>
<th>Donor</th>
<th>aBMD (g/cm²)</th>
<th>Ultimate Load (N)</th>
<th>Work of Fracture (J)</th>
<th>Compression/Tension strain Ratio at Failure</th>
<th>Fracture Type</th>
<th>Initial Failure Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>1004 L</td>
<td>0.867</td>
<td>4607</td>
<td>20.4</td>
<td>-1.99</td>
<td>Basicervical</td>
<td>Superior Neck</td>
</tr>
<tr>
<td>1061 L</td>
<td>0.844</td>
<td>3361</td>
<td>15.5</td>
<td>-1.91</td>
<td>Intertrochanteric</td>
<td>Superior Neck</td>
</tr>
<tr>
<td>1169 R</td>
<td>0.764</td>
<td>3038</td>
<td>8.3</td>
<td>n/a</td>
<td>Femoral Neck</td>
<td>Superior Neck</td>
</tr>
<tr>
<td>1171 L</td>
<td>0.722</td>
<td>5113</td>
<td>16.8</td>
<td>n/a</td>
<td>Femoral Neck</td>
<td>Superior Neck</td>
</tr>
</tbody>
</table>

3.1.1 Mechanical Test Results

The load displacement curves for the four specimens used in the fracture mechanics tests are shown in Figure 3-1. These curves are used later in the chapter to explain events seen in the strain measurements and the video analysis.
Results

Figure 3-1 Load-displacement curves for the specimens 1004 L, 1061 L, 1169 R and 1171 L loaded to failure at 100 mm/s

3.1.2 Strain analysis

The strains measured in the specimens 1004 L and 1061 L are plotted against applied load in Figure 3-2 and Figure 3-3. In the specimen 1004 L, the strain in the inferior neck increased linearly to 3388 με at a load of 4326 N. At this point the applied load dropped and then increased to 4575 N, where the strain reached 4173 με. The bone fractured at this point. The strain in the superior neck decreased linearly with applied load to -7660 με where the first drop in load occurred. The strain then further decreased to -8299 με at fracture.

In the specimen 1061 L, the strain in the inferior neck increased linearly to 1116 με at a load of 1714 N. At this point in the test, the load dropped slightly (Figure 3-3). The strain then climbed to 2144 με at a load of 3047 N. After another small drop in load, the strain increased to 3095 με at a load of 3442 N. At this point the bone was fractured and load dropped. The strain in the inferior neck decreased linearly to -2921 με at the first drop in load. The strain then decreased to -4883 με at the second drop in load. It then reached -5924 με at fracture.
Results

Figure 3-2 Strain measured in the inferior and superior femoral neck of 1004 L plotted against applied load

Figure 3-3 Strain measured in the inferior and superior femoral neck of 1061 L plotted against applied load
3.1.3 Fracture Type

The fractured specimens are shown below in Figure 3-4. The fracture in specimen 1004 L went through the distal femoral neck and is classified as basicervical. The fracture in this femur was jagged and passed close to the strain gauges mounted to the femur. The fracture ran beneath the distal end of the superior strain gauge and passed approximately 1 cm distal to the inferior gauge. The fracture in specimen 1061 L passed superiorly through the distal femoral neck and inferiorly through the lesser trochanter. This type of fracture is classified as intertrochanteric. The fracture was located approximately 1 cm distal to the superior gauge and was not close to the inferior gauge. The fracture in specimen 1169 R ran obliquely though the femoral neck. This fracture was classified as a femoral neck fracture. The fracture in 1171 L also ran obliquely through the femoral neck and was also classified as a femoral neck fracture. There were no strain gauges on the specimens 1169 R and 1171 L.

![Figure 3-4 Fracture types in specimens used in fracture mechanics tests](image)

3.1.4 Failure Location and Fracture Progression

In this section, the progression of the fractures through the femurs will be qualitatively discussed for each femur.

Specimen 1004 L

The load displacement for this femur had three distinct peaks (Figure 3-1). At the first peak of 4390 N, the head and neck was seen to rotate slightly towards the shaft of the femur (Figure 3-5). At this point in the test, the inferior surface of the femur was loaded in tension, and the superior
surface was loaded in compression, as shown in the strain gauge readings (Figure 3-2). This suggests that this first peak was most likely the result of a failure in the head of the femur or in the support structure. Inspection of the fractured specimen did not reveal any obvious crushing in the femoral head, so this failure was likely the result of failure in the support foam or a shifting in the apparatus beneath the femoral head. At the second peak of 4607 N, a visible fracture appeared in the superior cortex of the proximal neck (Figure 3-5).

Figure 3-5 Images corresponding to the first (left) and second (right) peaks of the load-displacement curve of 1004 L. The rotation shows the movement of the head of the femur seen at the first peak. The failure indicates a visible yielding at the second peak.

The third peak in the test corresponded to the tensile failure seen in the inferior femoral neck (Figure 3-6). This peak occurred at a load of 3582 N. There was a time delay of 9.0 ms between the initiation of the compressive crack seen at the second peak and the initiation of the tensile crack seen at the third peak. This crack in the inferior neck took 1.5 ms to propagate through the neck and reach the crack in the superior neck.
Results

Specimen 1061 L
The load-displacement curve for this specimen had two small drops in load as the load increased to the ultimate load. It also had a large drop that occurred shortly after the ultimate load had been reached (Figure 3-1).

Figure 3-6 Images corresponding to the final peak (left) and after the final peak in the load-displacement curve of specimen 1004 L

Figure 3-7 Images corresponding to the start of the loading sequence (left) and the loaded femur after passing two small peaks (right). The numbers 1 and 2 refer to the locations of failure at the first and second peaks respectively.
Results

The first peak load of 1714 N corresponded with a release of fluid from the posterior surface of the femur at the junction of the femoral neck and head (Figure 3-7). The second peak load of 3040 N corresponded with a release of fluid at the junction of the neck and head of the femur on both the superior and inferior surfaces (Figure 3-7).

![Figure 3-8 Images corresponding to failure seen at the ultimate load (left) and at the final drop in load (right)](image1)

The third peak load of 3361 N corresponded to a compressive failure seen in the distal superior femoral neck (Figure 3-8). This was followed by a tensile failure in the medial intertrochanteric region (Figure 3-8). The tensile failure occurred 28.9 ms after the compressive failure occurs. It was not possible to see how long the fracture took to progress across the intertrochanteric region.

**Specimen 1169 R**

The load-displacement curve for this specimen was linear until it had almost reached the ultimate load. There was a short horizontal region on the curve before the specimen reached the ultimate load of 3038 N (Figure 3-1). The load data was not synchronized with the video, so it was not possible to see exact loads at specific images. However, it was possible to estimate the loads for various images using the time stamp on the video. The fracture progressed through two distinct phases that were clearly evident from the video: an initial compressive failure followed by a tensile failure.
A crack first appeared on the anterior-superior surface of the cortex at the junction of the femoral neck and the head of the femur (Figure 3-9). This appeared to be a compressive failure and occurred at the time that the load displacement curve leveled off.

After the femur fractured in the anterior surface, it fractured in the inferior neck. As the inferior neck fractured, the head pulled away (Figure 3-10). The time elapsed between the first fracture
and the second fracture was 4.6 ms. The time elapsed between the plateau in the load displacement curve and the ultimate load was approximately 5 ms.

**Specimen 1171 L**

The load-displacement curve for this specimen was linear until it reached the ultimate load of 3841 N (Figure 3-1). The load dropped to 3095 N and then increased to 3841 N and subsequently dropped off. The load data for this test was also not synchronized with the video. This specimen also failed initially in compression, followed by a tensile failure.

![Figure 3-11 Images showing femur prior to fracture (left) and immediately following the initiation of fracture (right) in specimen 1171 L](image)

A crack first appeared in the superior cortex of the proximal femoral neck (Figure 3-11). This crack appeared to be a compressive failure. The time that the crack appeared on the video corresponded with the first peak in the load displacement curve.
The view of the initiation of the crack in the inferior neck was partially obscured by padding under the head of the femur (Figure 3-12). Based on what was visible and the motion of the femur, the fracture corresponded to the final drop in load seen in the load-displacement curve. The inferior neck fracture began 19.3 ms after the fracture in the superior neck began.

3.2 Finite Element Model Results

In this section, the results of the validation test will be presented. These will be followed by an analysis of the failure of the femur predicted by the model. Finally, the predicted strengthening effects of some implant designs will be shown.

3.2.1 Cadaver Model Strain Measurements

In this section the strain measured in the femur 1090R during non-destructive testing, which was used to develop the finite element, will be presented. This test was performed to validate the finite element model, but these results are also interesting because they reveal further information about the strain distribution in the femur during a fall.
The strains measured during one load cycle of the cadaver specimen in the simulated fall apparatus are plotted against the applied load in Figure 3-13, Figure 3-14 and Figure 3-15. The max applied load in this cycle was 435 N, which is well within the elastic region of the bone. The strains in the proximal femoral neck plane varied linearly with applied load (all $R^2 > 0.99$). The largest strain was in the superior neck (P1) and reached -607 με. The posterior neck gauge (P3) was also in compression and reached a strain of -217 με. The anterior gauge was in tension and measured a strain of 182 με.
In the distal neck (Figure 3-14) the strain also varied linearly with applied load (all $R^2 > 0.99$). The highest strain was seen in the anterior neck (D2), with the gauge reading 568 $\mu$e at the peak applied load. The superior (D1) and posterior (D3) gauges both measured compressive strain with maximum load readings of -536 $\mu$e and -547 $\mu$e respectively.

Figure 3-14 Strain measurements at three locations in a plane through the distal neck when the femur is loaded to 435 N
In the shaft (Figure 3-15), the measured strain also varied linearly with applied load ($R^2 > 0.99$ for S2 and S3, $R^2 = 0.97$ for S1). The anterior gauge (S2) measured the highest strain, with a reading of 434 με at maximum load. The lateral and posterior gauges measured compressive strain and had maximum load readings of -334 με and -107 με respectively.

3.2.2 Strain Predicted by Finite Element Model

The strains predicted by the finite element model at the nine gauge locations when loaded to 435 N are presented along with the measured strain in Figure 3-16. The mean absolute difference between measured and predicted strain was 138 με. The strains predicted in the proximal neck were the least accurate. The predicted strain underestimated the measured strain at P1 by 61% and at P3 by 60%. The predicted strain at P2 overestimated the measured strain by 90%. The predicted strains at the distal neck were more accurate. The finite element model underestimated the strain at D1 by 13%. The model overestimated the strain at D2 and D3 by 16% and 37% respectively. With the exception of location S3, where the model predicted a negligible amount of strain, the predicted strain was similar to the measured strain in the shaft. The gauges at S1 and S2 underestimated the measured strain by 4% and 23% respectively. The model predicted -1 με at location S3 and the gauge measured 107 με at this location.
Predicted strain was plotted against experimentally measured strain in a manner similar to Anderson et al. [112]. The predicted strain was found to correlate strongly with the measured strain ($r^2 = 0.87$), indicating that the model behaviour is a reasonable approximation of the actual behaviour of the femur.

Figure 3-16 Comparison of strains measured experimentally and strains predicted by finite element model

Figure 3-17 Plot of predicted strain vs. measured strain at 9 locations
3.2.3 Failure of Intact Finite Element Model of Femur

The intact model of the proximal femur was predicted to have a failure load of 3618 N. At this load the von Mises maximum strain of 0.011 was exceeded in the superior cortex of the distal femoral neck. The von Mises strain distribution of the posterior surface of the proximal femur when loaded to 3618 N is shown in Figure 3-18. At this load several elements in the superior cortex experienced high compressive strains that exceeded or were close to exceeding the von Mises failure criterion. A view of the anterior-inferior surface of the proximal femur is shown in Figure 3-19. In this figure it can be seen that the femur was quite far from failing in the inferior surface of the femur which was primarily loaded in tension. The predicted failure load was 11% higher than the 3285 N failure load of the contralateral femur.

Figure 3-18 Posterior view of von Mises strain distribution in proximal femur when loaded to 3618 N in a fall configuration
3.3 Finite Element Analysis of Augmented Femurs

The predicted failure loads of the eight augmented femur designs are shown below in Figure 3-20. Implant (a), which was a composite rod through the inferior neck, was predicted to have the least effect on the strength of the femur. The femur was predicted to fail at 4071 N, representing an increase of 13% over the intact femur model. The failure was predicted to occur in the superior distal neck in a manner similar to the intact femur.

Implant (b), which was a composite rod through the superior distal neck, had a greater strengthening effect. This model was predicted to fail in the superior distal neck at a load of 5584 N, representing an increase of 54% over the intact femur model.
Implant (c), which combined the rods of implants (a) and (b), had an effect similar to implant (b). It predicted failure at a load of 5765 N in the superior distal neck, representing an increase of 59% over the intact femur model.

Implant (d), which was a rod through the centre of the femoral neck, was not predicted to strengthen the femur by very much. The model predicted failure at a load of 4317 N, representing an increase of 19% over the intact femur model. The predicted location of failure was the superior distal neck with high strains also seen on the posterior surface of the base of the femoral neck.

Implant (e), which was a larger rod through the centre of the femoral neck, had a greater strengthening effect than implant (d). The model predicted failure at 5164 N, representing an increase of 43% over the intact femur model. The fracture was predicted to begin in the superior distal neck.

Implant (f), which was the neck-contouring composite, was predicted to fail at a load of 5952 N, representing an increase of 65% over the intact femur model. The predicted location of failure was the superior distal neck.

Implant (g), which is the same as implant (b) with a wire in the inferior neck to hold tension, had a lower failure load than implant (b). It was predicted to fail at 4693 N, representing an increase of 30% over the intact femur model. The fracture was predicted to initiate in the superior distal neck.

Implant (h), which was the Gamma Nail, was predicted to have the highest failure load. It was predicted to fail at a load of 6659 N, representing an increase of 84% over the intact femur model. The femur was predicted to fail in the superior distal neck but high strains were also seen in the inferior neck. The elements adjacent to the implant were ignored in the failure analysis. This is because they were assumed to be rigidly attached to the implant. This assumption caused very high strains in the elements in the greater trochanter and femoral neck that contacted the...
implant. If these elements are not ignored, the predicted failure load of the proximal femur is much less.

![Figure 3-20 Predicted failure load for intact model and eight implant designs](image)

**Figure 3-20** Predicted failure load for intact model and eight implant designs

### 3.4 Cadaveric Assessment of Augmentation Designs

Implant designs (e), (h) and (f) from the finite element experiments (Figure 3-20) and a femoroplasty implant were assessed with cadaver experiments. The ultimate loads of all control group femurs and augmented femurs are plotted against total proximal femur aBMD in Figure 3-21.
Results

Figure 3-21 Ultimate load of all augmented and control femurs plotted against total proximal femur aBMD. Linear trend lines were drawn through the data points representing the control femurs ($R^2 = 0.74$) and the augmented femurs ($R^2 = 0.79$).

3.4.1 Carbon Sleeve (Implant b)

The failure loads, energy to failure and fracture types are summarized in Table 3-2 for the specimen augmented with the carbon fiber sleeve implant as well as for the un-augmented contralateral femur.

Table 3-2 Summary of results from carbon sleeve augmentation test

<table>
<thead>
<tr>
<th>Specimen ID</th>
<th>Condition</th>
<th>aBMD (g/cm$^2$)</th>
<th>Ultimate Load (N)</th>
<th>$\Delta$ Load (N)</th>
<th>Energy to Ultimate Load (J)</th>
<th>$\Delta$ Energy (J)</th>
<th>Fracture Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>1161</td>
<td>Control</td>
<td>0.594</td>
<td>2308</td>
<td>-175</td>
<td>5.17</td>
<td>0.71</td>
<td>Intertrochanteric</td>
</tr>
<tr>
<td></td>
<td>Augmented</td>
<td>0.612</td>
<td>2133</td>
<td></td>
<td>5.88</td>
<td></td>
<td>Femoral Neck</td>
</tr>
</tbody>
</table>

The load-displacement curves for these femurs are given in Appendix A. The fractured specimens are shown below in Figure 3-22. The load-displacement curve for the intact femur was linear until it reached the ultimate load of 2308 N. The augmented femur increased linearly to a load of 970 N, at which point the load displacement curved oscillated before continuing in a linear manner to the ultimate load of 2133 N. The energy to failure for the control femur was 5.88 J. The energy to failure for the augmented femur was 5.17 J and the energy to the first peak of 970 N was 1.91 J.
3.4.2 Gamma Nail (Implant h)

The failure load, energy to failure and fracture type are summarized in Table 3-3 for both the femur with the Gamma Nail and the control femur.

Table 3-3 Summary of results from Gamma Nail augmentation test

<table>
<thead>
<tr>
<th>Donor ID</th>
<th>Condition</th>
<th>aBMD (g/cm²)</th>
<th>Ultimate Load (N)</th>
<th>Δ Load (N)</th>
<th>Energy to Ultimate Load (J)</th>
<th>Δ Energy (J)</th>
<th>Fracture Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>1171</td>
<td>Control</td>
<td>0.722</td>
<td>5113</td>
<td>62</td>
<td>16.85</td>
<td>27.48</td>
<td>Femoral Neck</td>
</tr>
<tr>
<td></td>
<td>Augmented</td>
<td>0.695</td>
<td>5175</td>
<td></td>
<td>44.33</td>
<td></td>
<td>Head and Neck</td>
</tr>
</tbody>
</table>

The load-displacement curves for these femurs are given in Appendix A. The fractured specimens are shown below in Figure 3-23. The load-displacement curve of the control femur increased linearly to the ultimate load of 5113 N. The load-displacement curve for the femur augmented with the Gamma Nail was linear until it reached a load of 3795 N. At this point the load dipped to 3372 N and proceeded to increase in a non-linear fashion to the ultimate load of 5175 N. The energy to ultimate load of the control femur was 16.85 J. The energy to the first dip in the femur augmented with the Gamma Nail was 9.65 J and the energy to the ultimate load was 44.33 J.
3.4.3 Femoroplasty

The load-displacement curves for the three pairs of femurs used to assess this design are shown in Appendix A. The ultimate loads of the augmented femurs are compared to the control femurs in Table 3-4. The mean ultimate load of the augmented femur was higher than the mean ultimate load of the control femurs (6530 N ± 1568 (S.D.) vs. 5257 N ± 2176 (S.D.)). The difference between the two treatments was significant (p = 0.071).

<table>
<thead>
<tr>
<th>Specimen ID</th>
<th>Ultimate Load (N)</th>
<th>Δ Load (N)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Control</td>
<td>Augmented</td>
</tr>
<tr>
<td>1153</td>
<td>5346</td>
<td>6470</td>
</tr>
<tr>
<td>1160</td>
<td>7388</td>
<td>8127</td>
</tr>
<tr>
<td>1169</td>
<td>3038</td>
<td>4993</td>
</tr>
<tr>
<td>Mean</td>
<td>5257</td>
<td>6530</td>
</tr>
<tr>
<td>S.D.</td>
<td>2176</td>
<td>1568</td>
</tr>
</tbody>
</table>

The work of fracture of the augmented femurs is compared to that of the control femurs in Table 3-5. The mean work of fracture of the augmented femurs was higher than the mean energy to ultimate load of the control femurs (31.98 J ± 12.36 (S.D.) vs. 17.41 J ± 11.17 (S.D.)). The difference between the two treatments was not significant (p = 0.125).
Table 3-5 Work of fracture for augmented and control femurs in femoroplasty group

<table>
<thead>
<tr>
<th>Specimen ID</th>
<th>Work of fracture (J)</th>
<th>Control</th>
<th>Augmented</th>
<th>△ Work (J)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1153</td>
<td>14.00</td>
<td>39.95</td>
<td>25.95</td>
<td></td>
</tr>
<tr>
<td>1160</td>
<td>29.89</td>
<td>38.25</td>
<td>8.36</td>
<td></td>
</tr>
<tr>
<td>1169</td>
<td>8.34</td>
<td>17.74</td>
<td>9.40</td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>17.41</td>
<td>31.98</td>
<td>14.57</td>
<td></td>
</tr>
<tr>
<td>S.D.</td>
<td>11.17</td>
<td>12.36</td>
<td>9.87</td>
<td></td>
</tr>
</tbody>
</table>

The fracture types for the augmented and control femurs are described below in Table 3-6. The fracture types were the same for two of the pairs of femurs. The augmented specimen 1160 fractured through the head and neck, while its control failed in the basicervical region.

Table 3-6 Fracture types for augmented and control femurs in femoroplasty group

<table>
<thead>
<tr>
<th>Specimen ID</th>
<th>Fracture Type</th>
<th>Control</th>
<th>Augmented</th>
</tr>
</thead>
<tbody>
<tr>
<td>1153</td>
<td>Intertrochanteric</td>
<td>Intertrochanteric</td>
<td></td>
</tr>
<tr>
<td>1160</td>
<td>Basicervical</td>
<td>Head/Neck</td>
<td></td>
</tr>
<tr>
<td>1169</td>
<td>Femoral Neck</td>
<td>Femoral Neck</td>
<td></td>
</tr>
</tbody>
</table>

The maximum temperature increase measured on the femurs and the volume of bone cement used is summarized below in Table 3-7. The mean temperature increase was 20° C. The full package of bone cement was injected into each femur.

Table 3-7 Maximum temperature increase and volume of bone cement used for each specimen that was augmented with the neck-contouring composite.

<table>
<thead>
<tr>
<th>Specimen ID</th>
<th>Max Temperature Increase (°C)</th>
<th>Volume of Bone Cement Used (mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1153</td>
<td>21</td>
<td>50</td>
</tr>
<tr>
<td>1160</td>
<td>23</td>
<td>50</td>
</tr>
<tr>
<td>1169</td>
<td>15</td>
<td>50</td>
</tr>
</tbody>
</table>

3.4.4 Neck-contouring Composite (Implant f)

The load-displacement curves for the four pairs of femurs used to assess this design are shown in Appendix A. The ultimate loads of the augmented femurs are compared to the control femurs in Table 3-8. The mean ultimate load of the augmented femurs was higher than the mean ultimate
load of the control femurs (4860 N ± 2611 (S.D.) vs. 4120 N ± 2611 (S.D.)). The difference between the two treatments was significant (p = 0.059).

<table>
<thead>
<tr>
<th>Specimen ID</th>
<th>Ultimate Load (N)</th>
<th>Control</th>
<th>Augmented</th>
<th>Δ Load (N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1090</td>
<td></td>
<td>3285</td>
<td>3746</td>
<td>461</td>
</tr>
<tr>
<td>1149</td>
<td></td>
<td>6996</td>
<td>8451</td>
<td>1455</td>
</tr>
<tr>
<td>1154</td>
<td></td>
<td>1654</td>
<td>2347</td>
<td>693</td>
</tr>
<tr>
<td>1157</td>
<td></td>
<td>4544</td>
<td>4896</td>
<td>352</td>
</tr>
<tr>
<td>Mean</td>
<td></td>
<td>4120</td>
<td>4860</td>
<td>740</td>
</tr>
<tr>
<td>S.D.</td>
<td></td>
<td>2253</td>
<td>2611</td>
<td>497</td>
</tr>
</tbody>
</table>

The work of fracture of the augmented femurs is compared to the control femurs in Table 3-9. The mean work of fracture of the augmented femurs was higher than the mean work of fracture of the control femurs (21.84 J ± 16.02 (S.D.) vs. 12.75 J ± 7.60 (S.D.)). The difference between the two treatments was not significant (p = 0.136).

<table>
<thead>
<tr>
<th>Specimen ID</th>
<th>Energy to Ultimate Load (J)</th>
<th>Control</th>
<th>Augmented</th>
<th>Δ Energy (J)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1090</td>
<td></td>
<td>11.55</td>
<td>17.83</td>
<td>6.28</td>
</tr>
<tr>
<td>1149</td>
<td></td>
<td>23.26</td>
<td>45.48</td>
<td>22.22</td>
</tr>
<tr>
<td>1154</td>
<td></td>
<td>5.09</td>
<td>11.02</td>
<td>5.93</td>
</tr>
<tr>
<td>1157</td>
<td></td>
<td>11.09</td>
<td>13.02</td>
<td>1.93</td>
</tr>
<tr>
<td>Mean</td>
<td></td>
<td>12.75</td>
<td>21.84</td>
<td>9.09</td>
</tr>
<tr>
<td>S.D.</td>
<td></td>
<td>7.60</td>
<td>16.02</td>
<td>8.97</td>
</tr>
</tbody>
</table>

The fracture types for the augmented and control femurs are described below in Table 3-10. Both femurs from Donor 1090 broke in the femoral neck. Two of pairs that fractured in the intertrochanteric region in the control femur broke in the subtrochanteric region in the augmented femurs. The other pair that fractured in the intertrochanteric region in the control femur fractured at the junction of the head and neck in the augmented femur.
Table 3-10 Fracture types for augmented and control femurs in neck-contouring composite group

<table>
<thead>
<tr>
<th>Specimen ID</th>
<th>Fracture Type</th>
<th>Control</th>
<th>Augmented</th>
</tr>
</thead>
<tbody>
<tr>
<td>1090</td>
<td>Femoral Neck</td>
<td>Femoral Neck</td>
<td></td>
</tr>
<tr>
<td>1149</td>
<td>Intertrochanteric</td>
<td>Subtrochanteric</td>
<td></td>
</tr>
<tr>
<td>1154</td>
<td>Intertrochanteric</td>
<td>Head/Neck</td>
<td></td>
</tr>
<tr>
<td>1157</td>
<td>Intertrochanteric</td>
<td>Subtrochanteric</td>
<td></td>
</tr>
</tbody>
</table>

The maximum temperature increase and volume of bone cement used in the neck-contouring composite augmentation procedure are listed below in Table 3-11. The maximum temperature increase was measured in the posterior surface of the proximal femur near the lesser trochanter in all specimens. The mean temperature increase was 11° C. One half of a package of bone cement was mixed for each specimen; however the full half package was not injected.

Table 3-11 Maximum temperature increase and volume of bone cement used for each specimen that was augmented with the neck-contouring composite

<table>
<thead>
<tr>
<th>Specimen ID</th>
<th>Max Temperature Increase (°C)</th>
<th>Volume of Bone Cement Used (mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1090</td>
<td>13</td>
<td>12</td>
</tr>
<tr>
<td>1149</td>
<td>9</td>
<td>9</td>
</tr>
<tr>
<td>1154</td>
<td>9</td>
<td>15</td>
</tr>
<tr>
<td>1157</td>
<td>11</td>
<td>13</td>
</tr>
</tbody>
</table>
Chapter 4: Discussion

In this thesis, I have described the failure of the proximal femur during hip fracture and addressed the design of a surgical implant that could be potentially be used for fracture prevention.

The fracture mechanism experiments in this study suggested that hip fractures occur in two stages. The initial failure was shown to occur in the superior neck which is loaded under compression in a fall. This initial event is quickly followed by tensile failure in the inferior neck or trochanteric region. These experiments provide experimental evidence that the superior femoral neck is the site of hip fracture initiation.

The femur augmentation portion of this thesis describes several new implant designs that could be used to improve the mechanical properties of the proximal femur. One of these implants was assessed using a cadaver model of hip fracture along with a previously designed concept. Although both showed promising improvements in both failure load and energy to failure, none of these improvements was statistically significant. The clinical significance of these strategies remains to be proven.

In this discussion, the results related to the objectives of this project will be synthesized. The results will then be compared to similar experiments in the literature. Finally, the strengths and weaknesses of this study will be discussed.

4.1 Synthesis of Results

4.1.1 Fracture Mechanism Experiments

This study met the objective of describing the fracture mechanism of the proximal femur during hip fracture. It was found that during four in vitro reproductions of hip fracture, the femur first failed in the superior cortex of the femoral neck, and then failed in the inferior cortex of the
femoral neck. This model of hip fracture was supported by video analysis, strain gauge measurements and finite element modelling.

The locations of the first compressive failure seen in the video analysis are plotted below in Figure 4-1. Two specimens failed in the superior lateral cortex of the femoral neck, and two failed in the superior medial cortex.

![Figure 4-1 Locations of initial compressive failure from fracture mechanics experiments. Locations are shown on a single femur](image)

This two stage model of hip fracture is supported by the strain measurements that were obtained from two specimens. The ratio of superior neck compressive strain to inferior neck tensile strain was almost 2 in both specimens. In one specimen (Donor ID 1004 L) the compressive strain reached -8299 με at fracture, which is within the range of experimentally determined yield strains for cortical bone [113]. The corresponding tensile strain in the superior neck was 4173 με. A visual analysis of the specimen after the test revealed that the fracture passed close to both gauges (Figure 4-2). Based on this information, it is possible that fracture initiated close to the superior gauge in this specimen. The fracture also passed close to the inferior gauge; however, given the low strain measured at this location, it is not likely that the fracture initiated near this
gauge. The sampling rate of the strain data was only 500 Hz so it was not possible to see which of the gauges experienced a drop in strain first. The other specimen that had strains measured had a similar result except that the maximum compressive strain in the superior only reached -5924 με.

The strain measurements taken on the specimen used to make the finite element model also indicated that the compressive strains in the neck were larger than the tensile strains. These gauges did not measure as pronounced a difference in the compressive and tensile strains. However, unlike the procedure in the fracture mechanism experiments, these gauges were not deliberately placed in locations that were expected to see the highest strains. The validation study found that the strain measured in the cadaver femur was similar to the strain predicted by the model, but there was a mean absolute difference of 138 με. Although this was a large difference, it was slightly better than that seen by Lotz et al. [109]. Other researchers who have used finite element models to predict hip fracture load have not performed this type of validation. They have used in vitro failure load measurements of the specimen [114, 115] or strain measurements in the contralateral femur [116].

The finite element model predicted that fracture would initiate in the lateral superior cortex of the femoral neck at a load of 3618 N. The finite element model assumed linear material...
properties, so it was not able to predict how the fracture would propagate after it had begun. After the superior lateral femoral neck, the region with the second highest strains was the posterior lateral neck (Figure 3-18). This suggests that the failure would progress though the posterior basicervical region. A non-linear model is required to assess what would happen after this initial failure.

A number of researchers have predicted that hip fractures initiate in the superior femoral neck. These predictions are based on comparisons of the cortex in the femoral neck of hip fracture patients with controls. Studies have found that when compared with control, the superior cortex of hip fracture patients was thinner [117], had higher porosity [117, 118], lower mineralization [119] and lower bone mass [117, 120]. Recently, a study by Mayhew et al. predicted that hip fractures initiate in the superior femoral neck due to compressive buckling [100]. They found that the superolateral cortex thinned a great deal with age. They also found that the curvature of the cortex in this region decreased with age. They hypothesized that these two factors combine to decrease the elastic stability of the structure, leaving it susceptible to buckling when the femur is loaded in a fall. Using beam theory, they hypothesized that after an initial compressive failure spanning half of the femoral neck, the cross-section of the femoral neck would be effectively cut in half, decreasing its bending resistance. They predicted that this would lead to a tensile or torsional failure in the remaining half femoral neck.

4.1.2 Augmentation Results
In the augmentation portion of this thesis, none of the implants investigated was found to meet the design criteria, in that none of them met the requirement of doubling the strength of the proximal femur. The finite element modelling did not find any implant that would double the strength of the proximal femur. However, the modelling did suggest that some of the implants would have large increases in failure load, so these designs were selected for further investigation with in vitro experiments. The in vitro experiments showed that the femoroplasty and neck-contouring composite had a significant strengthening effect. They also showed an increase in work of fracture, however, these differences were not statistically significant.
4.1.3 Augmentation Results: Finite Element Model

The finite element model predicted that the superolateral cortex would fail long before other regions of the femur would reach failure strains. As expected, the model also predicted that interventions that reinforced the superior neck region would be most successful at strengthening the proximal femur. Of the carbon fiber bone cement composite pins, the most effective implant was the implant featuring two pins through the femoral neck. When the bottom pin was removed, the predicted strengthening effect remained almost the same. The pins through the middle of the femoral neck and the pin through the lower femoral neck did not have such significant effects on strength. The pin in the bottom of the neck did not have much of an effect because the bone is already thick in that region. An analysis looking at the pin on its own found that even though it was placed low in the neck, the pin was loaded primarily in compression. This would indicate that the lower pin is close to the neutral axis of femoral neck. At this proximity it would not be able to affect the bending behaviour of the bone very much.

The pins through the center of the bone had a slightly larger effect on the strength of the bone. These pins were still close to the neutral axis of the bone and did not greatly affect the bending strength of the femoral neck.

The model of the Gamma Nail Implant predicted a large increase in strength. This was only true, however, if the bone elements at the bone implant interface were not considered. The model used a simplified rigid interface, which resulted in extremely high strains in the bone. The model was further complicated by the fact that the implant passed through the region of bone that was predicted to fail in the intact bone. It was not possible to tell whether these elements were experiencing high strains due to the simplified interface with the implant or whether these strains would be high even if the interface was modelled correctly.

The neck-contouring composite model also predicted a large increase in strength. This implant contoured the femoral neck closely and was securely anchored to the cortical bone. This implant model effectively increased the thickness of the cortex in the femoral neck. It was predicted to perform slightly better than the single pin through the superior cortex.
4.1.4 Augmentation Results: Experimental Model
The design criteria identified in the methods sections were that the implant must double the strength of the proximal femur, be biocompatible, be suitable for insertion in a minimally invasive procedure and allow for revision surgery. None of the implant designs that were assessed was found to meet these criteria. Initially, the carbon sleeve and the Gamma Nail were each implanted into a cadaver femur to assess their potential as augmentation devices. Neither of the femurs augmented with these devices was found to have a failure load or work of fracture larger than its matched-pair control. The femoroplasty and the neck-contouring composite were assessed using three and four pairs of femurs respectively. The augmented femurs for both implants were found to have significantly higher failure loads, but the differences in work of fracture were not significant.

Carbon Sleeve
This implant did not meet the design criterion of doubling the strength of the proximal femur. The femur augmented with the carbon sleeve had a failure load that was 175 N less than its matched pair control and a work of fracture that was 0.71 J greater than the control. The load-displacement curve of the augmented femur had a non-linear region before the load reached 1000 N (Figure A-1). This could have been due to a failure in the bone or a slipping at the bone-implant interface. The fracture in this specimen passed directly below the medial end of the implant. The fracture could have initiated near this location due to the local weakening cause by the removal of bone to make room for the implant. The fracture also passed through the hole created in the lateral surface of the greater trochanter to insert the implant. It is possible that the fracture initiated at the defect created by the hole used to insert the implant. This could also explain the weakening effect of the implant.

This implant met the other design criteria outlined in the methods section. Both of the materials used to make the implants are biocompatible. The amount of bone cement used in this procedure is small, so it is unlikely to cause significant damage to surrounding tissues. The implant was designed to be inserted through a small hole, so the procedure was minimally invasive. It was also designed to take up as much space as a cannulated screw to ensure that revision surgery
would be possible. Overall, this implant met three of the four criteria, but it is not practical for this application because it did not double the strength of the proximal femur.

**Gamma Nail**

The one femur augmented with the Gamma Nail was not strengthened. The femur augmented with the Gamma Nail had a failure load that was 62 N higher than its matched pair control and a work of fracture that was 27.48 J higher. The load-displacement curve of the augmented femur had a non-linear region before the load reached 3800 N (Figure A-2). This initial failure could have been clinically significant failure. The augmented femur failed in the head of the femur and also had some cracks running parallel to the femoral neck. There was no visible damage to the lateral surface of the greater trochanter. This test was videotaped and it appeared that the specimen failed initially in the head of the femur. That failure was followed by a fracture in the femoral neck. After the specimen had been fractured, the bone beneath the lag screw was crushed and the lag screw was separated from the superior neck. It seemed that because the implant was much stiffer than the bone, it did not deform with the bone, resulting in crushing below the implant.

The Gamma Nail implant is currently used for fracture fixation, so it is biocompatible and it does allow for revision surgery. Although the Gamma Nail is slightly more invasive than other strategies, these implants can be placed fluoroscopically using three small incisions. The additional support for a strategy which utilizes a known implant is the familiarity surgeons would have in implanting these. Because this implant did not result in a strengthening effect in the femur pair in which it was evaluated, it is not recommended for prophylactic reinforcement.

**Femoroplasty**

The femoroplasty procedure showed a small average increase in strength and increased the temperature of the proximal femur by a large amount. The femoroplasty experiments found an average difference in failure load of 1273 N and an average difference in work of fracture of 14.5 J. The difference in failure load was statistically significant. One of the augmented had a larger non-linear region prior to failure and the other two augmented femurs had smaller non-linear regions. The augmented femurs had fractures in similar locations to the controls, but the
fractures were different in appearance. The load-displacement curves for the augmented femurs all had non-linear regions prior to failure. This indicated that prior to fracture, there were some local failures. These failures could have occurred in the cancellous bone as it was pushed against the stiffer cement.

The large amount of PMMA used in this procedure resulted in an average, a peak temperature increase of 20°C. This large increase in temperature could result in damage to surrounding tissues in a clinical situation. For this reason, this procedure is not clinically relevant. Because the procedure did not double the strength of the proximal femur and because the large amount of heat generated during the curing of the cement, this procedure is not likely to be an acceptable method of hip fracture prevention.

**Neck-Contouring Composite**

The femurs augmented with the neck-contouring composite had a failure load that was on average 740 N higher than the controls and a work of fracture that was on average 9.09 J higher. These differences were not significant. The femurs augmented with the neck-contouring composite also tended to have non-linear regions in the load-displacement curve prior to fracture. This suggested that there were some failures in the specimen prior to fracture.

This procedure used much less cement than the femoroplasty procedure and this resulted in, on average, a peak temperature increase of 11°C. This increase in temperature is less than that seen in the femoroplasty; however, it could still potentially cause damage to surrounding tissue. Although this procedure generated much less heat than the femoroplasty, it did not double the strength of the proximal femur. For this reason, the neck-contouring composite was not shown to be a practical option for hip fracture prevention.

**Summary of Augmentation Results**

Of the four implants that were assessed experimentally, none of them met the design criteria outlined in the methods section. Although they all met two or three of the design criteria, none of the implants doubled the strength of the proximal femur.
4.1.5 Augmentation Results: Comparison of Experimental to FE Results

The finite element model tended to overestimate the strengthening effect of the implants assessed in this thesis. Some of the possible explanations for this discrepancy are addressed for each of the implants in this section. The general limitations of the finite element model discussed in Section 4.4.2 could also explain the differences between the finite element model and the experimental model.

**Carbon Sleeve**

The finite element model that this procedure most closely resembled was the model of the large composite pin through the centre of the neck. During this surgical procedure, it was found that the implant could not be implanted to the depth assumed in the finite element model. The implant could only be implanted to the epiphyseal plate. As a result, the medial end of the implant was not anchored to the load bearing surface of the femoral head. Also, the implant positioning was not exactly the same as was modelled. In the model, the implant was parallel to the femoral neck, but in the cadaver experiment, the implant was offset from the femoral neck axis and was more perpendicular to the shaft axis. Another difference was that the model assumed that the interface between the implant and the bone was perfectly rigid. Therefore, the model assumed that the implant was perfectly anchored to the bone, which was not the case experimentally. These differences between the model and the experiment could help explain the lower strengthening effect seen in the experiment.

**Gamma Nail**

The finite element model of the Gamma Nail predicted a large strengthening effect from the implant, which was not observed experimentally. The failure criterion of the finite element model did not model cancellous failure. In this implant, it seemed very likely that a large amount of the cancellous bone in the head and neck of the femur failed prior to the failure of cortical bone. The model also assumed that the implant was rigidly anchored to the surrounding bone. In the *in vitro* experiment it is likely that the lag screw was transmitting compressive force to the bone beneath it but was not loading the bone above and beside it.
Neck-contouring Composite

The finite element model also predicted that neck-contouring composite would have a large strengthening effect on the femur; however, the experimental results did not show such a large increase in strength. There are two possible explanations for this discrepancy. First, the finite element model of this design assumed that the implant would closely contour the neck of the femur. This implant orientation was found to be difficult to achieve in vitro. Figure 2-13 shows that the cement does not penetrate to the cortex. The inability to push the implant to the cortex could explain the discrepancy between the finite element and experimental results. Second, it was assumed that the carbon sleeve would be completely embedded in a thin layer of bone cement. Post fracture analysis of the specimens revealed this assumption to be incorrect. The carbon sleeves were not completely embedded in cement. The portions of the sleeve that were not embedded would have had inferior material properties to those assumed in the model. These two reasons could explain the discrepancy between the two models.

Summary of Augmentation Comparisons

Overall, the finite element model overestimated the strengthening effect of the implants when compared to the experimental results. This was likely due to the simplification of the interactions between the implants and the bone as well as the differences in implant orientation between the finite element models and experimental models.

4.1.6 Augmentation Results Summary

In both the finite element and experimental assessment of implants, it was found that none of the implants met all of the design criteria. The most promising implants were the femoroplasty and neck-contouring composite implants. The femoroplasty implant strengthened the femur by an average of 24%, however the procedure used 50 mL of bone cement and it resulted in an average surface temperature increase of 20° C. This volume of cement is much greater than the 7 mL volume that has been used in vertebroplasty on the lumbar spine [121]. Because there are no previous studies that have injected such a large volume of cement into a human body, it is not possible to say that 50 mL is acceptable.
The neck-contouring composite implant strengthened the femur by an average of 18% and the procedure used an average of 12 mL of bone cement. This smaller volume of bone cement is much lower than the volume used in the femoroplasty procedure and it is similar to the volume used in a vertebroplasty. Although one of the design criteria was to increase the strength of the proximal femur by 100%, it is possible that a strength increase of 18% could have clinical significance. Studies of the effect of pharmacological interventions on hip fracture risk have found that small increases in BMD can result in large decreases in hip fracture risk. Because BMD has been found to correlate to hip strength [19], it could be argued that increases in BMD result in proportional increases in femur strength. A placebo-control study on the effect of calcium and vitamin D on hip fracture risk found that calcium and vitamin D were associated with a 2.7% increase in BMD and a 43% decrease in hip fracture risk [73]. For this reason it is possible that the neck-contouring composite implant would be able to result in large decreases in hip fracture risk.

4.2 Comparison to Similar Studies

4.2.1 Finite Element Model

Most researchers who have used finite element models to look at hip fracture were concerned primarily with the ability of the model to predict failure load. Most studies do not use strain gauge data to validate their models. Lotz et al. used a procedure similar to the present study to validate their finite element model of two femur specimens [109]. They measured principal strains at roughly the same nine locations. However, their study used rosettes to measure principal strains in contrast to the present study which measured strain in a specific direction. Lotz et al. loaded Bone A in a stance loading configuration to loads of 445 N, and they loaded Bone B in a fall-type configuration to loads of 222 N. The mean absolute differences between measured and predicted principal strains are summarized in Table 4-1.

<table>
<thead>
<tr>
<th></th>
<th>Mean absolute difference in P1 (με)</th>
<th>Mean absolute difference in P3 (με)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bone A</td>
<td>309</td>
<td>167</td>
</tr>
<tr>
<td>Bone B</td>
<td>303</td>
<td>313</td>
</tr>
</tbody>
</table>

Table 4-1 FEM validation results from Lotz et al. [100]
Discussion

The present study had a mean absolute difference in measured strain of 138 με. Although this represents a single measurement of strain at nine locations, it indicates that the validation results are within the range found by Lotz et al.

The present study predicted a failure load of 3618 N, with failure initiating in the superior lateral femoral neck. This was compared to the experimental failure of the contralateral femur, which failed in the femoral neck at a load of 3285 N. A number of other studies have used finite element modelling to predict fracture location and load. The study by Lotz et al. found the highest von Mises strains in the anterior and posterior surfaces of the femoral neck. Although they do not specify a specific location of fracture initiation, this result is different than the result in present study, where the superior distal neck was the location of failure. They compared the failure load of their model with the failure load of the specimen that they determined experimentally. They found that the model loaded in a fall configuration predicted a failure load of 1360 N using a von Mises failure criterion. When the specimen was tested experimentally, they found that the specimen failed at 1710 N.

Another important study by Keyak et al. used automatically generated finite element models to predict failure in the proximal femur [114]. In this study, 18 femurs were used to create finite element models and were also loaded to failure experimentally. Using a linear material model and a von Mises stress failure criterion, they were able to accurately predict the failure load of the femurs. They found that:

\[
\text{Measured Fracture Load} = 1.24 \times (\text{Predicted Fracture Load})^{1.22} \quad (r = 0.949, p < 0.0001)
\]
Keyak et al. showed that failure initiated in the cancellous bone in the trochanteric region (Figure 4-3). In contrast to the study by Lotz et al., the study by Keyak et al. considered cancellous failure to be structural failure. This could explain why the actual failure load was underestimated by the predicted failure load in their study. The region of predicted failure in their study is close to the location of failure found in the present thesis work.

One study, by Oden et al., looked at the effect of increasing local bone density with drug therapy on the failure load of the proximal femur [115]. Although the proposed method of augmentation was different from the method proposed in the present study, the effect on the model was very similar. Oden et al. built a finite element model of the proximal femur and looked at the effect on the failure load of increasing the density of the bone in different regions of the femoral neck. Using non-linear material properties and a maximum principal strain failure criterion, they found that the femur failed at a load of 2218 N in the superolateral cortex (Figure 4-4).

Oden et al. found that, as in the present study, the greatest strength increases were seen when the bone adjacent to the superior neck was augmented. They predicted that when a bone volume of 4.92 cm$^3$ in the superior femoral neck had its density increased by 25%, the strength of the proximal femur was increased by 14.8%. The strength increases predicted by their model are
much less than the strength increases predicted in the current study. This is because bone density increases that are due to drug therapies can only moderately increase the local material properties of the bone.

4.2.2 Experimental Model
To begin, the experimental hip fracture model used in this study will be compared to models used in other studies. In Table 4-2, mechanical test parameters, work of fracture, failure load and fracture type proportions from this study are compared to previous studies. The results of the fracture mechanism experiments are presented separately from the results of the augmentation experiments. The results presented from the augmentation experiments do not include the augmented femurs. Only the control femurs are presented for comparison to other studies on cadaver femurs. When comparing the results in this thesis to other studies, it should be noted that there was some overlap in the experimental results. Of the 9 control femurs used in the augmentation experiments, the mechanical test results for 7 were also used in the study by Manske et al.

Although the experimental apparatus and protocol vary from study to study, the results from the mechanical tests in this thesis are similar to what has been seen previously. The mean energy to failure in the fracture mechanics and femur augmentation experiments were 16.7 J and 13.9 J respectively; the other studies found between 5.5 J and 67 J. The mean failure loads from the fracture mechanics and femur augmentation experiments were 3712 N and 4408 N respectively; the other studies found mean failure loads which ranged across studies between 2110 N and 4353 N.
Table 4-2: Summary of failure loads and work of fracture from in vitro hip fracture studies

<table>
<thead>
<tr>
<th>Author</th>
<th>Femur orientation</th>
<th>Loading rate (mm/s)</th>
<th>Loading location</th>
<th>Work of fracture (J) (Mean ± SD)</th>
<th>Failure load (N) (Mean ± SD)</th>
<th>Correlation of load and neck BMD (R²)</th>
<th>Fracture type*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beck et al., 1998 [122] (n=22)</td>
<td>load bisecting neck-shaft angle</td>
<td>0.5</td>
<td>Greater Trochanter</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>36% FN</td>
</tr>
<tr>
<td>Bouxsein et al., 1995 [44] (n=16)</td>
<td>10° from horizontal, 15° internal rotation</td>
<td>2</td>
<td>Head</td>
<td>-</td>
<td>3680 ± 1540</td>
<td>0.79</td>
<td>25% BC</td>
</tr>
<tr>
<td>Cheng et al., 1997 [123] (n=64)</td>
<td>10° from horizontal, 15° internal rotation</td>
<td>14</td>
<td>Head</td>
<td>-</td>
<td>3978 ± 1414</td>
<td>0.71</td>
<td>41% FN</td>
</tr>
<tr>
<td>Courtney et al., 1994 [104] (n=10)*</td>
<td>10° from horizontal, 15° internal rotation</td>
<td>100</td>
<td>Head</td>
<td>67 ± 59</td>
<td>4250 ± 1500</td>
<td>0.72</td>
<td>40% FN</td>
</tr>
<tr>
<td>Courtney et al., 1995 [105] (n=8)</td>
<td>10° from horizontal, 15° internal rotation</td>
<td>2</td>
<td>Head</td>
<td>5.5 ± 3</td>
<td>3440 ± 1330</td>
<td>0.92</td>
<td>63% BC</td>
</tr>
<tr>
<td>Eckstein et al., 2004 [102] (n=108)</td>
<td>10° from horizontal, 15° internal rotation</td>
<td>6.6</td>
<td>Greater Trochanter</td>
<td>-</td>
<td>3926 ± 1656</td>
<td>-</td>
<td>67% FN</td>
</tr>
<tr>
<td>Lochmüller et al., 2003 [45] (n=126)</td>
<td>10° from horizontal, 15° internal rotation</td>
<td>6.6</td>
<td>Greater Trochanter</td>
<td>-</td>
<td>-</td>
<td>0.53</td>
<td>50% FN</td>
</tr>
<tr>
<td>Lotz and Hayes 1990 [46] (n=12)</td>
<td>10° from horizontal, 30° internal rotation</td>
<td>0.7</td>
<td>Head</td>
<td>26.5 ± 11</td>
<td>2110 ± 1060</td>
<td>-</td>
<td>25% BC</td>
</tr>
<tr>
<td>Manske et al. (n=36)</td>
<td>10° from horizontal, 15° internal rotation</td>
<td>100</td>
<td>Greater Trochanter</td>
<td>-</td>
<td>4353 ± 1886</td>
<td>0.39</td>
<td>9% FN</td>
</tr>
<tr>
<td>de Bakker et al. (n=13)*</td>
<td>10° from horizontal, 15° internal rotation</td>
<td>100</td>
<td>Greater Trochanter</td>
<td>14.3 ± 7.3</td>
<td>4292 ± 1719</td>
<td>0.62§</td>
<td>15% BC</td>
</tr>
</tbody>
</table>

* BC = Basicervical, FN = Femoral Neck, IT = Intertrochanteric, SC = Subcapital
† Only specimens from “older” group are reported here
‡ Femurs from fracture mechanism experiments and control femurs from augmentation experiments are reported.
§ Correlation for total proximal femur BMD is reported
Given that the apparatus used in this study and in the study by Manske et al. was modelled after the apparatus used by Eckstein et al. and Lochmuller et al., it is surprising that these three studies found such different fracture type proportions. One possible explanation for this difference is that the present study used a much faster loading rate. To date no studies have looked at the effect of loading rate on fracture types in the proximal femur. Another possible explanation is that the studies by Lochmuller et al. and Eckstein et al. used specimens that had been embalmed, a process that has been shown to affect the mechanical behaviour of bone [124]. A third possible explanation is that although both papers state that the researchers internally rotated their femurs by 15°, the photographs of their apparatuses show femurs that are externally rotated. It has been shown that the angle of rotation can affect the mechanical properties of the proximal femur [106].

The only one of these studies to describe the location of fracture initiation was the study by Courtney et al., (1995). Those researchers state that of nine femurs from the older group, five fractures began in the inferior basicervical cortex; two began in the middle of the neck; and one began in the subcapital region. These findings are at odds with this study’s findings that hip fractures initiate in the superior neck. However, their finding is based on radiographic evidence, which assessed the process of crack propagation by visual inspection of a static, post-fracture image. In contrast, the present work attempted to dynamically document the events through high-speed video and simultaneous strain measurements method.

Overall, the experimental results in this thesis were similar to previous studies in terms of the failure load, work of fracture and fracture types. The location of fracture initiation found in the present study could not be compared to previous experimental work because this has not been previously examined experimentally.

4.2.3 Effect of Femur Augmentation

Only one previous study, by Heini et al., has looked at the effect of an augmentation procedure on the strength of the proximal femur [84]. In their study, femurs were injected with bone cement in a femoroplasty procedure. The failure load and energy of the augmented femurs were compared to their contralateral control group femur. Heini et al. tested ten pairs in a stance test
configuration and ten pairs in a fall test configuration. The results from the fall configuration test are compared with the femoroplasty and neck-contouring composite from the present study in Table 4-3.

Table 4-3 Comparison of augmentation by Heini et al. and the femoroplasty and neck-contouring composite procedures from this thesis

<table>
<thead>
<tr>
<th>Study</th>
<th>Control Failure load (N) (Mean ± SD)</th>
<th>Augmented Failure load (N) (Mean ± SD)</th>
<th>Control work of fracture (J) (Mean ± SD)</th>
<th>Augmented work of fracture (J) (Mean ± SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heini et al. [84]</td>
<td>2499 ± 695</td>
<td>4548 ± 1369</td>
<td>17</td>
<td>49</td>
</tr>
<tr>
<td>de Bakker et al.</td>
<td>5257 ± 2176</td>
<td>6530 ± 1568</td>
<td>17.4 ± 11.2</td>
<td>32.0 ± 12.4</td>
</tr>
<tr>
<td>Femoroplasty</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>de Bakker et al.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Neck-contouring</td>
<td>4120 ± 2253</td>
<td>4860 ± 2611</td>
<td>12.8 ± 7.6</td>
<td>21.8 ± 16.0</td>
</tr>
<tr>
<td>Composite</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

In the study by Heini et al., the femoroplasty femurs had an average failure load 82% higher than the control femurs and an average work of fracture that was 188% higher. In the present study, the difference in failure load and work of fracture for the femoroplasty pairs was 24% and 84% respectively. The difference in failure load and work of fracture for the neck-contouring composite pairs was 18% and 70% respectively. The femoroplasty procedure performed by Heini et al. was very similar to the femoroplasty procedure performed in the present study; however, the results were different. One possible explanation is that the present study used a much higher loading rate (100 mm/s vs 2 mm/s). Given the viscoelastic nature of bone, it is possible that the mechanical behaviour of augmented femur changes with loading rate. Another more likely explanation is that the control femurs in the previous study had a much lower failure load, leaving much more opportunity for improvement. In the present study, the control specimen with the lowest failure load saw the greatest percentage increase. This specimen broke at 3038 N, while its augmented partner failed at 4993 representing a 64% increase. Although this is only a single pair, when considered in combination with the results from Heini et al., it suggests that the femoroplasty procedure is more effective at strengthening weak femurs than strong ones.
4.3 Strengths

4.3.1 Fracture Mechanism

To the best of my knowledge, the hip fracture mechanism portion of this thesis is the first study to use experimental evidence to determine where hip fractures initiate and how they progress through the femur. The combination of high-speed video images with load, displacement and strain data provides more information about hip fracture than was previously available. When this experimental evidence is considered in conjunction with strain distributions predicted by finite element modelling, a complete picture of hip fracture is formed.

The experimental apparatus is a well-established model of hip fracture that has been used extensively by other groups to produce clinically relevant hip fractures. A fast loading rate was used because it is more reflective of the actual loading rate that occurs in a fall than the quasi-static loading that is used in most hip fracture studies. The experimental apparatus produced hip fractures that similar to fractures that are seen clinically based on the diagnosis of an orthopaedic surgeon.

The finite element model was a simple model, but it proved to be reasonably accurate when validated using experimental strain data. There was particularly good agreement in the distal neck, the region where we predicted fracture would initiate. This type of validation is not usually done on finite element models of hip fracture.

4.3.2 Femur Augmentation

Surgically augmenting the femur to prevent hip fracture is a new idea that has never been studied clinically. In addition to identifying regions to target for prophylaxis, the present study used both finite element modelling and experiments to assess the ability of several implants to strengthen the proximal femur. The result was a more thorough examination of the problem than in any previous study. The mechanical testing in the present study was done at a fast loading rate, which is an improvement on previous research.
4.4 Limitations

Invariably, research of this type involves some limitations. This section first describes the limitations of the mechanical test apparatus and the finite element model. It then moves on to the specific limitations of the fracture mechanics experiments and the femur augmentation experiments.

4.4.1 Mechanical Test Apparatus

The test apparatus used in this study reproduced a typical fall. There is still some question about what proportion of hip fractures result from a fall. Indeed, a number of biomechanical studies have used a stance type configuration to reproduce hip fracture [45, 125, 126]. Although it is possible that some hip fractures occur in that manner, it is improbable that this is the predominant mechanism for hip fracture.

The apparatus used in this study constrains the femur at an internal rotation of 15° with the shaft at 10° from the horizontal. There is a lack of published fall biomechanics data to justify this commonly used femur orientation. The first study to use this configuration by Courtney et al. [104] referenced a study by van den Kronenberg, that did not publish femur orientation in a fall [93]. Given that the orientation of the femur in mechanical testing has been shown to have a significant effect on the outcome of cadaveric fracture testing [106], it is important to orient the femur in a manner similar to a fall. A typical fall that causes fracture would likely be a fall to the side. In studies comparing patients with hip fractures to people who fell but did not break a hip, it has been established that patients who fall to the side are more likely to fracture a hip than people who fall in other directions [88-90].

The angle of anteversion of the femur is defined as the angle between the femoral neck and the vertical plane passing by the posterior aspect of the femoral condyles [127]. The angle of anteversion in adult populations is estimated to be 15° with a range of 2° to 49° [128]. This suggests that a fall directly to the side would result in an effective external rotation of 15° (Figure 4-5). This theoretical analysis of the loading during a fall is an over-simplification. In biomechanical studies of falls, participants have been shown to extend their arms, bend their legs and keep their torsos erect. These deviations from a straight-legged fall directly to the side would
result in a different loading configuration than that shown in Figure 4-5. This simple analysis of a fall calls the 15° of internal rotation used in this study into question.

The apparatus that was designed and built as part of this thesis was also used in a study by Manske et al., where it was found to produce a large percentage of intertrochanteric fractures. This high percentage of intertrochanteric fractures differs from the clinical situation, where the number of intertrochanteric fractures is approximately equal to the number of femoral neck fractures. One possible reason for the difference is that the femoral neck may not be loaded in compression as much as in a fall. In the apparatus used in this study, the head is free to translate in the horizontal plane. In a real fall, the head is constrained from moving in the horizontal plane by the pelvis. This could result in a load on the head that is directed not directly down, but at some angle closer to the femoral neck axis.
4.4.2 Finite Element Model Limitations

The finite element model reproduces the loading used in the experiments, so the limitations addressed above also apply to the model. The model used in this thesis was a simplistic model that did not fully capture the material properties of bone. It is known that the material properties of bone are anisotropic and non-linear, but the model used assumed that bone was isotropic and linear. The model also used cortical failure as its criterion for failure even though there was likely some cancellous failure prior to fracture [109]. This problem could be addressed by using non-linear material properties for both cancellous and cortical bone.

The models modified to include implants did not accurately model the interface between the implants and the cancellous bone. The rigid interface that was used would overestimate the ability of the implants to transmit load to the surrounding tissue.

4.4.3 Fracture Mechanism Experiments

The greatest limitation of the fracture mechanism experiments is that the determination of failure location and fracture progression was primarily done through qualitative analysis of video. Strain measurements were made on two of the specimens. However for these pilot experiments, strain was only measured in one direction at two locations, which provided a limited measurement of strain in the proximal femur that was dependent on our ability to identify both the locations and orientations of maximum strain. The sampling rate of the strain data was much lower than the frame rate of the video. As a result, it was not possible to track strain changes on the same time scale as the visual evidence of fracture was documented. Another limitation common to both the strain gauges and the video analysis is that it is only possible to track failure that occurs on the surface of the bone. These techniques do not provide insight into how the bone below the surface is deforming and failing.

There are some limitations in the study design. The sample size was only 4, and there were not enough of each fracture type to make generalizations about how different fractures begin. The test protocol for the first two femur tests used two cameras to film a single side of the femur. The other two femurs were filmed from both sides using mirrors to see the top and bottom of the
These two femurs also had strain gauges attached to the inferior and superior neck. This change in test protocol resulted in incomplete measurements in the first two specimens.

4.4.4 Femur Augmentation Experiments

The femur augmentation experiments found that of the two implants assessed with multiple femurs, neither showed a statistically significant increase in failure load or work of fracture. If more specimens had been used in each group, it might have been possible to find a difference between the augmented and control femurs. When this study’s results are compared with the results from Heini et al., it appears that the augmentation procedures were most effective on femurs that were weak. Because it is likely that this procedure would be used to reinforce the femurs of patients who are deemed to have very weak femurs, the femurs used to assess the device should be weak. Because BMD has been shown to be a predictor of femur strength, femurs should have been selected for this study based on their BMD.

A problem with the determination of the strength of implant designs is that it was difficult to assess when failure occurred in the proximal femur. In this study, the failure load was defined as the ultimate load reached in a mechanical test regardless or non-linearities seen in the load-displacement curve prior to failure. As exemplified in Figure 4-6, the load-displacement curves for some of the augmented femurs were not linear leading up to the ultimate load. In this curve for the augmented specimen 1153 R, the ultimate load was 6470 N. There was, however, an earlier non-linearity when the applied load reached 4828 N. It is very likely that there were some localized failures occurring in the femur, however, it is unclear if these represent a clinically significant structural failure. Non-linear load-displacement curves did not occur in all augmented femurs; however, they were more common in the augmented femurs than in the control femurs. If another failure criterion were used in this study, such as defining failure as any non-linearity in the load-displacement curve, it is likely that the augmented femurs would have shown even less of a difference in strength or they would have had a weakening effect.
Figure 4-6 Load-displacement curve for the specimen 1153 R. This specimen was augmented with the femoroplasty procedure. The ultimate load, which was 6470 N, and the load at which there was an initial non-linearity in the curve, which was 4828 N, are shown.

4.5 Future Work
As a result of this study, several research opportunities have been identified, which relate to the hip fracture model, the hip fracture mechanism, the identification of new risk factors for hip fracture, and femur augmentation.

Hip Fracture Model
As discussed in the Limitations section, there are some concerns about whether the testing apparatus used in this study reproduces the loading during a “typical” fall. This concern leads to an interesting question: how is the femur loaded during a fall? Although this question may sound trivial, it is a concern that has not been definitively answered. To create a better experimental model, one must understand how people fall when they fracture their hips. To address this issue, one would need to determine how people typically fall. To do this, patients who have fractured a hip should be interviewed to determine how they fell. This would include the direction of their fall, how their body was oriented at impact and where they hit the ground. This information could be gathered from patients as soon as possible to minimize recall bias. With this information, experiments could be designed to recreate these falls and measure kinematics in order to determine femur orientation at impact. Electromyography measurements could be taken.
to estimate muscle contraction during a fall as well. These fall experiments could then be used to estimate the load transmitted to the femur for each fall. Using this data, a clearer picture could be formed about how the average fall loads the femur and how much variability there is in fall loading.

**Hip Fracture Mechanism**

To improve our understanding of hip fracture mechanisms, further testing could be done. To provide more quantitative measurements of hip fracture mechanism, high frequency strain measurements could be used. If strain measurements are made at a frequency equal to the frame rate of the video collection, it would be possible to use strain measurements to explain fracture initiation and progression. If rosettes were applied at several locations in both the inferior and superior femoral neck, it would be possible to track fracture using strain data. For example, when a fracture occurs in the superior cortex, the adjacent gauges would likely measure a decrease in strain, followed by an increase or levelling off of strain. If a fracture occurred in the inferior cortex, gauges adjacent to the fracture would likely measure a sharp decrease in strain. If the timing of changes in local strain measurements coincides with the visual appearance of failure, it would provide support for the hip fracture mechanism model presented in this thesis. These measurements could also be used to explain how the bone is failing. For example, if large shear strains are measured, it could point to a shear failure. If strain measurements taken at failure locations measure peak strains below the yield strain of cortical bone, it would provide support for the cortical bone buckling hypothesis from Mayhew et al.

In addition to high speed video, high speed x-ray could also be used to track failure in the proximal femur. This technique would provide additional information about how the cancellous bone fails during hip fracture. This could indicate whether cancellous failure precedes or follows the surface failure seen in video analysis.

Post-fracture analysis of specimens could be undertaken to examine the micro cracking patterns adjacent to the fracture sites. The micro cracking patterns provide insight into how the bone was behaving immediately prior to fracture, and can help to identify where the fracture initiated. The
fracture patterns can also reveal whether the bone failed in tension or compression. This analysis could include both cortical and cancellous bone.

*Identifying New Risk Factors for Hip Fracture*

Imaging could be used to apply hip fracture mechanism information to predictive models of hip fracture risk. The mechanical tests described in the previous paragraph would allow us to determine where fractures begin. If cadaver bones were imaged with CT and micro CT prior to breaking them, we could measure cortex geometry, cortical density, cortical mineralization, cortical porosity, cancellous BMD, cancellous density and trabecular orientation at the general locations of failure identified in this thesis. These parameters could all be assessed as to their ability to predict failure. These experiments could potentially lead to improved clinical screening techniques for hip fracture and improved interventions for hip fracture prevention. These interventions could include targeted drug therapy or exercises designed to stimulate bone growth in areas of interest, and perhaps guide further surgical augmentation strategies.

*Femur Augmentation*

Based on the results of these experiments, a larger number of femurs are required to determine the effect of femur augmentation. The two implants that were tested in multiple cadaveric specimens showed promise as potential methods of femur augmentation.

If new implant designs are assessed in future studies, preliminary testing could be done using embalmed cadaver specimens, which are more easily obtained. Based on the results of this study, future designs should attempt to reinforce the superior femoral neck, which has been shown to be where hip fractures initiate. Future designs should call for materials that are not much stiffer than bone. Future designs should also limit the number and size of holes that are put in the proximal femur. Holes are known to be stress risers and can potentially be locations of fracture initiation as was hypothesized in the case of the carbon sleeve implant.
Chapter 5: Conclusions

5.1 Femur Augmentation
Implants for prophylactic augmentation of the femur were designed and structural testing found that the femoroplasty and neck-contouring composite implants significantly strengthened the femur. The augmented femurs also tended require more work to failure than the controls, however these differences were not significant.

5.2 Hip Fracture Mechanism
Hip fractures were found to occur in a two-stage event: an initial failure in the superior femoral neck followed by a failure in the inferior neck or intertrochanteric region. This pattern was seen in femurs with a variety of clinical fracture types. The initial fracture occurred due to large compressive loading in the superior neck. After this initial failure, the structure continued to carry a load until the inferior neck gave way in a tensile or shear failure.
REFERENCES


96. Manske, S., *Magnetic resonance imaging as an instrument to assess the association between femoral neck bone geometry and strength of the proximal femur.* 2005, University of British Columbia.


APPENDIX A Load-Displacement Curves for Augmented and Control Femurs
Carbon Sleeve

Figure A-1 Load-displacement curve for femur augmented with carbon sleeve implant and matched-pair control from donor 1161
Gamma Nail

Figure A-2 Load-displacement curve for femur augmented with Gamma Nail implant and matched-pair control from donor 1171
Appendix A

Femoroplasty

Figure A-3 Load-displacement curve for femur augmented with femoroplasty implant and matched-pair control from donor 1153

Figure A-4 Load-displacement curve for femur augmented with femoroplasty implant and matched-pair control from donor 1160
Figure A-5 Load-displacement curve for femur augmented with femoroplasty implant and matched-pair control from donor 1169
Neck-Contouring Composite

Figure A-6 Load-displacement curve for femur augmented with neck-contouring composite implant and matched-pair control from donor 1090

Figure A-7 Load-displacement curve for femur augmented with neck-contouring composite implant and matched-pair control from donor 1149
Figure A-8 Load-displacement curve for femur augmented with neck-contouring composite implant and matched-pair control from donor 1154

Figure A-9 Load-displacement curve for femur augmented with neck-contouring composite implant and matched-pair control from donor 1157