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Biomechanical Investigations of Medial Opening Wedge High Tibial Osteotomy: Gait Analysis, Materials Testing and Dynamic Radiography

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A thesis submitted in partial fulfillment of the requirements for the Doctor of Philosophy degree in Biomedical Engineering
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BIOMECHANICAL INVESTIGATIONS OF MEDIAL OPENING WEDGE HIGH TIBIAL OSTEOTOMY: GAIT ANALYSIS, MATERIALS TESTING AND DYNAMIC RADIOGRAPHY

(Thesis format: Integrated Article)

by

Kristyn M Leitch

Graduate Program in Biomedical Engineering

A thesis submitted in partial fulfillment
of the requirements for the degree of
Doctor of Philosophy

The School of Graduate and Postdoctoral Studies
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London, Ontario, Canada

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Abstract

This thesis aimed to develop and assess biomechanical methods to assist in the evaluation of medial opening wedge high tibial osteotomy (HTO). Five studies using diverse methods were performed, including three-dimensional (3D) gait analysis, materials testing of HTO fixation plates, and dynamic radiography in patients after surgery. *Study 1* compared external knee joint moments during walking before and after varus or valgus producing osteotomy in patients with lateral or medial compartment osteoarthritis, and in healthy participants. The results highlighted the importance of alignment on gait biomechanics with changes in frontal plane angular impulse highly correlated to changes in mechanical axis. *Study 2* compared the 3D external knee moments before and after medial opening wedge HTO during level walking and during stair ascent. Long-term changes in knee moments after HTO were observed during both activities, with decreases in the peak knee adduction and internal rotation moments. *Study 3* developed and tested a multi-axis fixation jig placed within a materials testing machine for assessing HTO fixation plates in a manner more representative of walking. The need to incorporate gait data into materials testing studies was highlighted, showing the importance of including a frontal plane moment during testing. *Study 4* used this multi-axis fixation jig to compare flat to toothed HTO fixation plates under cyclic loading conditions. Preliminary results suggested little difference in the load at failure between the plates; however, the potential for the tooth to increase micro-motion across the osteotomy site and strain on the lateral cortical hinge should be a focus of future testing. *Study 5* was a proof-of-concept study to test dynamic single-plane flat-panel (FP) radiography for use in detecting *in-vivo* micro-motion after medial opening wedge HTO. Preliminary results suggested dynamic FP radiography has the potential to assess fixation stability; however, results also suggested modifications in the registration algorithms may be required to increase confidence in distinguishing true motion from registration error. Overall, this thesis demonstrates that a mix of biomechanical methods can be used to advance medial opening wedge HTO, with particular focus on informing future methods of investigation to improve HTO fixation designs.

Keywords

Knee osteoarthritis, Medial opening wedge high tibial osteotomy, Fixation plates, Gait biomechanics, Materials testing, Dynamic single-plane flat-panel radiography

Co-Authorship Statement

The following thesis contains manuscripts that are published in peer-reviewed journals, under review, or in preparation for submission.

Chapter 2, "*Changes in valgus and varus alignment neutralize aberrant frontal plane knee moments in patients with unicompartmental knee osteoarthritis"* is published in the *Journal of Biomechanics.* The manuscript was co-authored by Kristyn M. Leitch, Trevor B. Birmingham, Cynthia E. Dunning, and J. Robert Giffin. Kristyn Leitch was primarily responsible for study design, data collection, analysis, and manuscript preparation. Trevor Birmingham supervised the study design, data collection, analysis, and manuscript preparation. Cynthia Dunning and Robert Giffin assisted with study design, analysis and manuscript preparation.

Chapter 3, "*Medial Opening Wedge High Tibial Osteotomy Decreases Peak Knee Internal Rotation and Adduction Moments During Level Walking and Stair Ascent"* is under review in *Clinical Biomechanics.* The manuscript was co-authored by Kristyn M. Leitch, Trevor B. Birmingham, Cynthia E. Dunning, and J. Robert Giffin. Kristyn Leitch was primarily responsible for study design, data collection, analysis, and manuscript preparation. Trevor Birmingham supervised the study design, data collection, analysis, and manuscript preparation. Cynthia Dunning and Robert Giffin assisted with study design, analysis and manuscript preparation.

Chapter 4, "*Development of a Multi-Axis Fixation Jig for Testing High Tibial Osteotomy Plates: An Application of In-vivo Gait Data"* under review in the *Journal of Biomechanics* The manuscript was co-authored by Kristyn M. Leitch, Trevor B. Birmingham, Jacob M. Reeves, J. Robert Giffin and Cynthia E. Dunning. Kristyn Leitch was primarily responsible for experimental design, data collection, analysis, and manuscript preparation. Cynthia Dunning supervised the experimental design, data collection, analysis, and manuscript preparation. Trevor Birmingham and Robert Giffin assisted with experimental design, analysis and manuscript preparation. Robert Giffin performed the surgery on the sawbone. Jacob Reeves assisted in data collection and provided editorial assistance.

Chapter 5, *"In-vitro Biomechanical Investigation of Plate Designs Used for Medial Opening Wedge High Tibial Osteotomy"* was co-authored by Kristyn M. Leitch, Trevor B. Birmingham, Timothy A. Burkhart, J. Robert Giffin, and Cynthia E. Dunning. Kristyn Leitch was primarily responsible for experimental design, data collection, analysis, and manuscript preparation. Cynthia Dunning supervised the experimental design, data collection, analysis, and manuscript preparation. Trevor Birmingham and Robert Giffin assisted with experimental design, analysis and manuscript preparation. Robert Giffin also performed the surgeries on the sawbones. Timothy Burkhart assisted in experimental design, data collection.

Chapter 6, titled "*Micro-motion in the Tibia After Medial Opening Wedge High Tibial Osteotomy Using Dynamic Single-Plane Flat-Panel Radiography: A Proof-of-Concept Study"* was co-authored by Kristyn M. Leitch, Matthew G. Teeter, Xunhua Yuan, Steven Pollman, Cynthia Dunning, Trevor B. Birmingham, and, J. Robert Giffin. Kristyn Leitch was primarily responsible for study design, ethics approval, data collection, analysis, and manuscript preparation. Matthew G. Teeter assisted with study design, ethics approval, data collection and analysis, and provided editorial assistance and mentorship. Xunhua Yuan assisted with data collection. Steven Pollman developed custom software used by Kristyn Leitch for data analysis. Robert Giffin, Trevor Birmingham and Cynthia Dunning assisted with study design, analysis and manuscript preparation. Robert Giffin also performed the surgeries and implanted the tantalum beads.

Acknowledgments

I would like to express my sincere appreciation to the individuals who made completing my thesis a possibility. I would like to begin by thanking my supervisors, Drs. Trevor Birmingham and Cynthia Dunning. I truly appreciate your mentorship and support throughout the course of my doctoral studies. You have instilled in me the qualities and attributes needed to move forward in my research career.

Dr. Robert Giffin, thank you for your many contributions, particularly the orthopaedic insight into my work and for always finding time for me. It was always a pleasure to watch true poetry in motion.

Mr. Ian Jones, thank you for making the past 10 years at WOBL such a great experience. I truly appreciate the time you have taken to share your knowledge with me. But most of all thank you for your friendship.

Dr. Matthew Teeter, thank you for sharing your imaging expertise with me. I have learned a great deal from you and will always be grateful for your continued support and guidance. I would also like to acknowledge other members in the Imaging Research Laboratories at Robarts, particularly; Steve Pollman for his amazing programming skills, and Xunhua Yuan for his assistance with data collection.

My fellow lab members at WOBL, I am so grateful for the friendships I have made over the years. I would also like to thank Dr. Tim Burkhart, Jake Reeves and Dr. Yara Hosein for all of their help at BTL and other lab members of BTL for making it such a great place to work.

I would like to thank the staff at University Hospital who helped make this research possible, specifically Erin Lawrence, Heather Boulianne, Jonathan Collier, and Doug Cesarin. I also had the pleasure of working with the amazing staff at the Fowler Kennedy Sport Medicine Clinic (University Campus). I would especially like thank Cheryl Pollard, Kathy Cuthbertson, and Marsha Yerema for all their assistance.

Furthermore, I would especially like to acknowledge the participants who took part in these studies, giving freely of their time, as this research would not have been possible without them.

I would also like to acknowledge University Machine Service for all of their assistance in the design and manufacturing of the multi-axis fixation jig.

I would like to acknowledge the financial support I have received, provided by The University of Western Ontario and the Joint Motion Program - A CIHR training program in Musculoskeletal Health Research and Leadership.

A final thank you goes to my family. I could never have accomplished this without your love and support over the years.

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List of Abbreviations

2D	Two-Dimensional
3D	Three-Dimensional
AP	Anteroposterior
ANOVA	Analysis of Variance
BMI	Body Mass Index
%BW·Ht	Percent Body Weight Times Height
%BW·Ht·s	Percent Body Weight Times Height Times Seconds
CI	Confidence Interval
COM	Centre of Mass
CoVs	Coefficients of Variation
CT	Computed Tomography
FP	Single-Plane Flat-Panel
FOV	Field of View
fps	Frames Per Second
GRF	Ground Reaction Force
HTO	High Tibial Osteotomy
Hz	Hertz
MAA	Mechanical Axis Angle
ML	Medial-Lateral

MRI	Magnetic Resonance Imaging
N	Newton
OA	Osteoarthritis
PD	Proximal-Distal
RSA	Radiostereometric Analysis
SD	Standard Deviation
WBL	Weight-Bearing Line

Chapter 1

Introduction

Overview: *Medial opening wedge high tibial osteotomy (HTO) is surgical treatment option for the management of medial compartment knee osteoarthritis. The surgery is described as a biomechanical intervention designed to alter dynamic knee joint loading, with the aim of improving patient function and decreasing pain. The early success of the surgery depends largely on the stability of the type of plate fixation used. As such, the overall goal of this thesis was to develop and test various biomechanical methods to assist in the assessment of medial opening wedge HTO. This chapter introduces osteoarthritis of the knee, some of the risk factors for the initiation and progression of the disease, medial opening wedge HTO surgery, the importance of plate fixation in HTO, and current biomechanical methods for assessing HTO, including their limitations. The chapter concludes with specific objectives and hypotheses for this thesis.*

1.1 Demographics and Burden of Osteoarthritis

Osteoarthritis (OA) is one of the most common joint diseases (Vos, 2012), affecting 17% of the population greater than 65 years of age and approximately 5% of the population greater than 26 years of age globally (Lawrence, 2008).With no cure, the world's growing population and increasing life expectancies, the prevalence of OA is only expected to increase. Osteoarthritis is a growing public health care concern with substantial direct and indirect costs (Gupta *et al.*, 2005; Bitton, 2009). In 2011, the annual economic burden of OA was estimated to reach $405 billion by the year 2020 in Canada alone (Bombardier *et al.*, 2011). This growing burden on societies and health care systems emphasizes the need to establish treatments to limit OA progression.

1.2 Osteoarthritis of the Knee

Although the progressive loss of hyaline articular cartilage is often considered the hallmark of the disease, OA involves the whole joint (Hunter and Felson, 2006). There are concomitant changes in the bone underneath the cartilage (Felson *et al.*, 2000); including sclerosis (remodeling and thickening) of the subchondral bone, and formation of osteophytes (Felson *et al.*, 2000; Dieppe and Lohmander, 2005). Osteoarthritis also affects the soft-tissue structures in and around the joint, including, inflammation of the synovium, ligament laxity and muscle weakness (Felson *et al.*, 2000). Osteoarthritis can affect any synovial joint in the body (Felson *et al.*, 2000; Hunter and Felson, 2006; Dieppe and Lohmander, 2005); however, it occurs most often in weight-bearing joints, with the knee being one of the most commonly affected (Guccione *et al.*, 1994; Lawrence *et al.*, 2008; Englund, 2010; Brouwer *et al.*, 2007).

Within the tibiofemoral joint, articular cartilage degradation is most prevalent in the medial compartment (Cooke *et al.*, 1997; McAlindon, 1992). The normal ‘wear and tear’ due to cyclic joint loading during everyday activity was thought to initiate the disease because of its association with age; however, the initiation of OA usually stems from interplay between several systemic and biomechanical factors (Felson *et al.*, 2000; Englund, 2010; Andriacchi and Mündermann, 2006) (Figure 1.1). For example a person may be genetically predisposed to develop the disease but it will not develop until a biomechanical change occurs, such as injury.

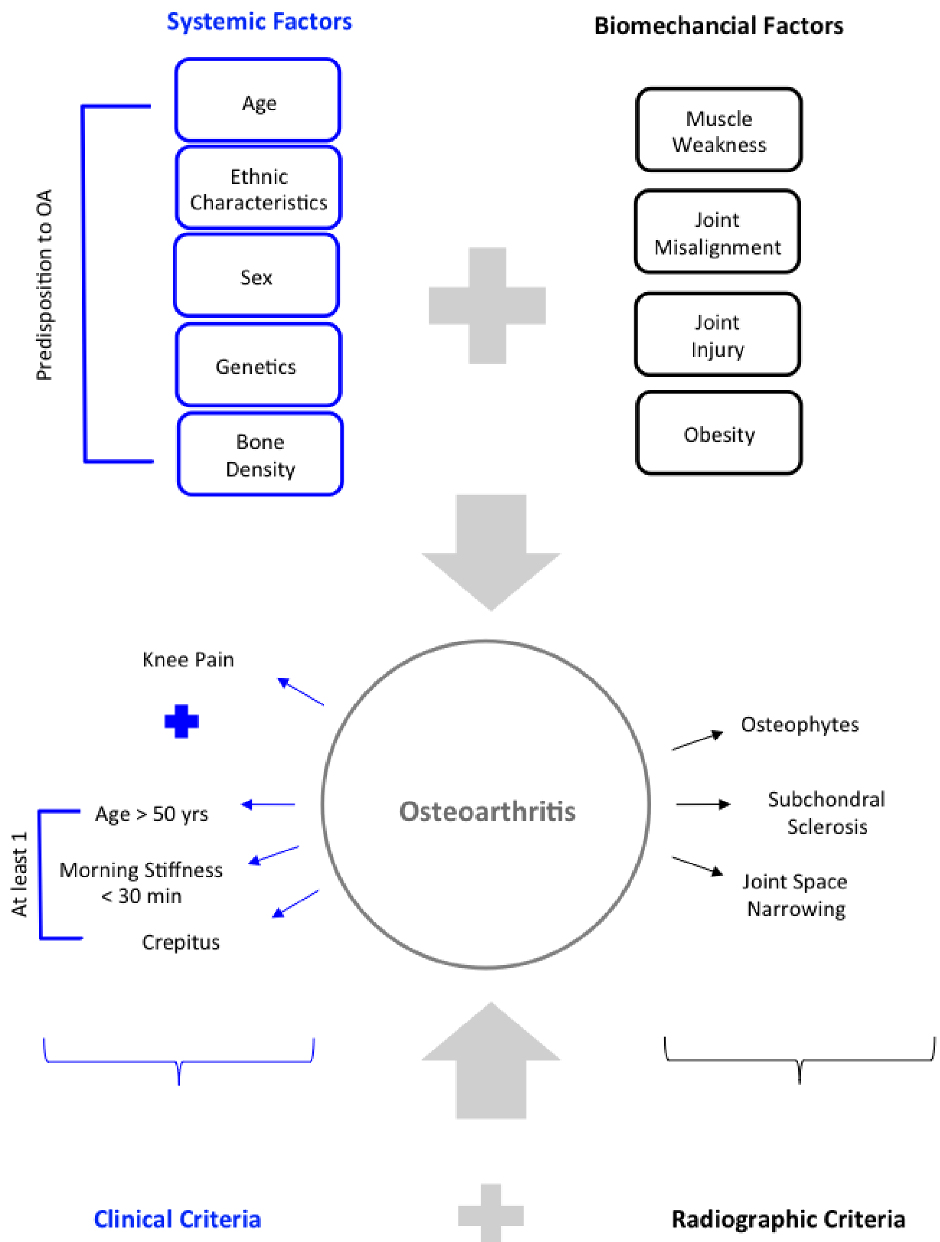

Figure 1.1: Schematic representation of the relationship between systemic and biomechanical factors leading to the initiation of OA. Also represented in the schematic are the clinical and radiographic criteria for the diagnosis of OA based on Altman *et al.*, 1986 and Kellgren and Lawrence, 1957.

Diagnosis of OA typically relies on the assessment of clinical and radiographic features. Various criteria exist, such as those proposed by Kellgren and Lawrence (1957) and Altman *et al.,* (1986) (Figure 1.1). Altman *et al.,* (1986) described criteria for diagnosis of knee OA which includes knee pain and at least one of the following; age greater than 50 years, morning stiffness lasting no longer than 30 minutes, or crepitus (cracking or popping sounds or sensations) with active motion. Kellgren and Lawrence, (1957) developed a commonly used five point rating scale (0 – No OA, 4 – Severe OA) using radiographs to determine the severity of knee OA based on: joint space width, presence/absence of osteophytes, and sclerosis of the subchondral bone.

1.3 The Role of Lower Limb Alignment on Knee Joint Load

1.3.1 Lower Limb Alignment

Lower limb alignment is typically determined through bilateral weight-bearing anteroposterior (AP) radiographic evaluation. The gold standard measurement for quantifying lower limb alignment is the mechanical axis angle (MAA), which is the angle formed at the knee joint centre, between a line drawn from the centre of the hip to the centre of the knee, and a line drawn from the centre of the ankle to the centre of the knee (Specogna *et al.*, 2007; Brown and Amendola, 2000) (Figure 1.2).

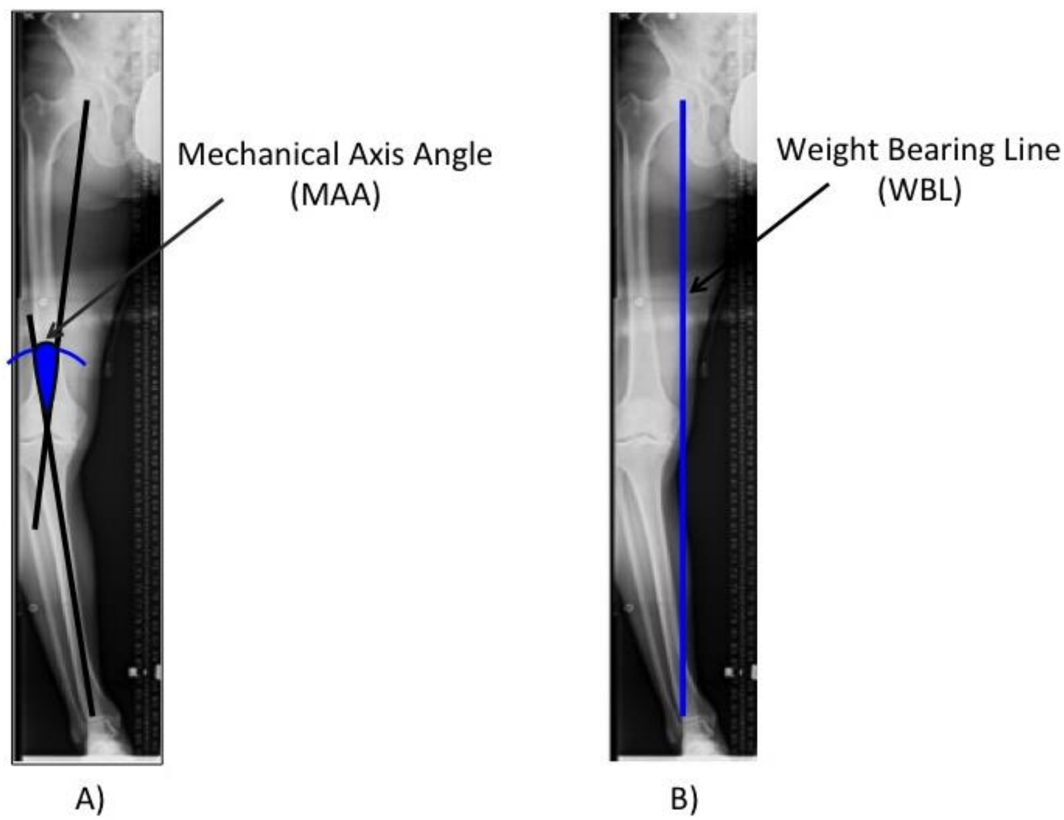

Figure 1.2: Lower limb alignment **A)** Mechanical axis angle (MAA) of a varus aligned lower limb. The MAA is the angle formed at the knee joint centre, between a line drawn from the centre of the hip to the centre of the knee, and a line drawn from the centre of the ankle to the centre of the knee. **B)** Weight-bearing line (WBL) of a varus aligned lower limb. The WBL is drawn from the centre of the hip to the centre of the ankle.

Based on this assessment, alignment is then typically classified as valgus ("knock kneed"), neutral, or varus ("bow legged"). Epidemiological studies suggest the frontal plane alignment of the lower limb plays an important role in the progression of knee OA (Sharma *et al.*, 2010, 2012), and the direction of alignment, varus or valgus, can influence which compartment of the tibiofemoral joint is affected, medial or lateral (Brouwer, 2007; Hunter *et al.*, 2007; Cicuttini *et al.*, 2004; Sharma *et al.*, 2001; Cerejo *et al.*, 2002). It is well documented that varus alignment is associated with the progression of medial compartment knee OA and may also play a role in the onset of the disease (Sharma *et al.*, 2012). Although it is not as well documented, evidence does suggest valgus alignment is associated with lateral compartment OA progression in persons with established knee OA (Wise *et al.*, 2012).

Varus malalignment has also been associated with medial tibia cartilage loss in individuals with OA (Cicuttini *et al.*, 2004; Eckstein *et al.*, 2008; Sharma, 2008; Sharma *et al.*, 2012). The mechanism by which lower limb alignment is thought to contribute to cartilage loss is by altering the loading pattern within the knee joint. Hsu *et al.*, (1988), demonstrated 75% of the knee joint load passed through the medial compartment of the knee in individuals with neutral alignment, when simulating one-legged weight-bearing stance. In studies investigating load on the medial compartment of the knee after total knee arthroplasty (TKA), with an instrumented tibial prosthesis, loads were suggested to range between 52% and 64% (D'Lima *et al.*, 2008; Zhao, 2007). For individuals with varus alignment this imbalance in load between the medial and lateral compartments is exacerbated (Johnson *et al.*, 1980*;* Harrington, 1983; Bruns *et al.*, 1993; Andriacchi, 1994). When lower limb alignment is quantified as the mechanical axis (hip-knee-ankle) angle using full-limb standing radiographs, instrumented knee implant data suggest the load on the medial compartment during walking increases 5% for every 1° increase towards varus (Halder *et al.*, 2012).

Overall varus alignment plays a crucial role in the progression of medial compartment knee OA by contributing to a perpetuating cycle of cartilage loss and subsequent joint space narrowing, and increased medial compartment loads, further increasing varus alignment (Figure 1.3).

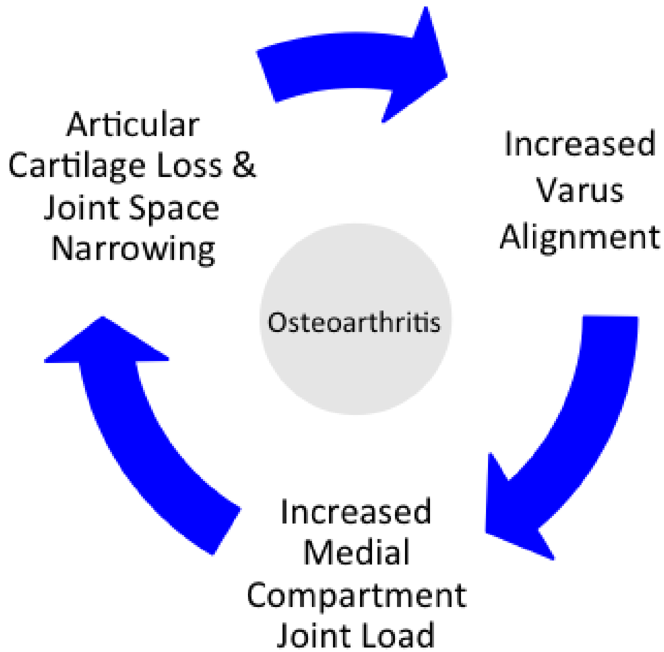

Figure 1.3: A schematic representing a "vicious" cycle that contributes to the progression of medial compartment knee OA. The cycle consists of articular cartilage loss and joint space narrowing, increase in varus alignment and increased medial compartment joint load.

1.3.2 Dynamic Knee Joint Load

Abnormal compartment loading has been shown to be a major contributing factor to the progression of medial compartment knee OA (Andriacchi and Mündermann, 2006; Dieppe *et al.*, 1993; Miyazaki *et al.*, 2002) and may also play an important role in the development of the disease (Andriacchi and Mündermann, 2006; Miyazaki *et al.*, 2002; Amin *et al.*, 2004; Seedhom, 2006). The exact mechanism by which loading may initiate OA is complex; however, studies suggest the knee is conditioned to a certain amount of stress throughout our lives during every day activities, such as walking. Sudden bursts of high load, prolong loading, or abnormal loading due to injury, contribute to cartilage degradation and subsequent OA (Andriacchi and Mündermann, 2006; Amin *et al.*, 2004;

Seehom, 2006; Bennell *et al.*, 2011). It is also through these same mechanisms that altered knee joint loads contribute to the progression of the disease.

Since walking is the most common activity of daily living, gait analysis has become an important part of evaluating joint loading. During the stance phase of walking a ground reaction force (GRF) vector originates at the centre of pressure of the foot and runs towards the body's centre of mass (COM), passing medially to the knee joint, creating a moment about the knee joint centre in the frontal plane (Andriacchi, 1994) (Figure 1.4). This is the case in neutral alignment and regardless of the presence or absence of OA.

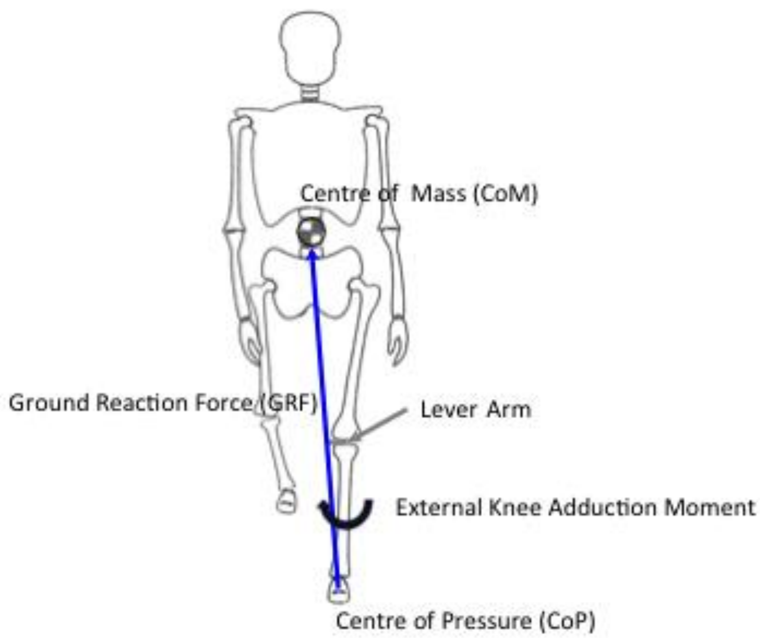

Figure 1.4: Schematic of the external knee adduction moment. Although the knee adduction moment is determined through inverse dynamics, for simplicity it can be summarized by two main components. The product of the magnitude of frontal plane ground reaction force (GRF) and the perpendicular distance between the projection vector and the knee joint centre of rotation (lever arm). *Adapted from Perry (1992).*

This moment tends to adduct the shank about the knee in the frontal plane creating what is commonly known as the external knee adduction moment. The adduction moment is dependent upon inertial forces, the magnitude of the frontal plane component of the GRF vector and the perpendicular distance from the knee joint centre to the frontal plane component of the GRF – known as the frontal plane lever arm (Figure 1.4). The knee adduction moment has shown to be associated with influencing the force distribution between the medial and lateral compartments of the knee (Kutzner *et al.*, 2013; Harrington, 1983; Andriacchi, 1994; Zhao *et al.*, 2007; Hurwitz *et al.*, 1998; Shelburne *et al.*, 2006) and therefore is commonly suggested as a reliable, indirect measure of knee joint load (Miyazaki *et al.,* 2002; Schipplein and Andriacchi, 1991; Andriacchi, 1994; Birmingham *et al.,* 2007). The knee adduction moment also has important clinical implications. It has been suggested that high knee adduction moments strongly predict OA progression in patients with varus gonarthrosis when evaluated by radiographic and quantitative magnetic resonance imaging (MRI) measures (Miyazaki *et al.,* 2002; Bennell *et al.*, 2011). For example, a higher knee adduction impulse at baseline was independently associated with greater loss of medial tibial cartilage volume over 12 months (Bennell *et al.*, 2011). Despite its strengths the external knee adduction moment has important limitations. For example, it does not account for muscular contributions to joint loading. It is therefore possible to have changes (increases or decreases) in co-contraction of muscles, and therefore changes in internal knee loading, that would not be detected by changes in the external knee adduction moment.

1.3.3 Relationship Between Dynamic Knee Joint Load and Alignment

Although there is a direct relationship between the magnitude of radiographic lower limb varus alignment *(i.e.,* a static measure) and the magnitude of the external knee adduction moment during walking, the reported size of this relationship varies widely (Specogna *et al.*, 2007; Hurwitz *et al.*, 2002; Moyer *et al.*, 2010; Andrews *et al.*, 1996; Wada *et al.*, 1998; Harrington, 1983; Prodromos *et al.*, 1985; Johnson *et al.*, 1980; Teixira and Olney; 1996; Hilding *et al.*, 1995). Several studies have reported moderate-to-high correlations (Specogna *et al.*, 2007; Hurwitz *et al.*, 2002; Moyer *et al.*, 2010; Andrews *et al.*, 1996;

Wada *et al.*, 1998; Hilding *et al.*, 1995), while others have reported low correlations (Harrington, 1983; Prodromos *et al.*, 1985; Johnson *et al.*, 1980; Teixira and Olney, 1996). Although these measures are related, it does not appear possible to accurately predict the knee adduction moment based on only the MAA. Common amongst studies is the suggestion that differences between static and dynamic measures are due to potential confounding influences from other gait characteristics. It is also generally suggested that both measures of static lower limb alignment (*i.e.*, MAA) and dynamic knee joint loading (*i.e.*, external knee moments) should be considered when designing and evaluating interventions aimed at altering the loading pattern within the knee.

1.4 Medial Opening Wedge High Tibial Osteotomy

Currently, no known cure exists for OA. Interventions aim to improve patient health–related quality of life, by reducing symptoms and slowing disease progression. A variety of surgical and non-surgical treatment options have been developed for knee OA, with the intention of reducing or altering the loading pattern within the joint. Medial opening wedge high tibial osteotomy (HTO) is an operative treatment for the management of medial compartment knee OA with varus deformity (Fowler *et al.*, 2000; Parker and Viskontas, 2007). The primary goal of HTO surgery is to shift the weight-bearing load in the knee joint laterally (*i.e*., to a more neutral position) away from the diseased compartment by realigning the mechanical axis of the tibia. The operation is typically performed on patients who are physiologically young and active (age < 60 years), and have isolated medial compartment degeneration of the joint with associated varus deformity (Dowd *et al.*, 2006).

Radiographic assessment is an important component in the preoperative planning for HTO (Fowler *et al.*, 2000; Amendola, 2003). A number of measures are taken from bilateral weight-bearing anteroposterior (AP) views in full extension. These include the weight-bearing line (WBL), which is a straight line drawn from the centre of the hip to the centre of the ankle (Figure 1.2), the MAA, and anatomical axes of the tibia and femur. Using the method described by Dugdale *et al.* (1992), and depending on the magnitude of the deformity and status of the articular cartilage in the lateral tibiofemoral compartment, these measures are used to estimate the required correction needed to move the WBL laterally up to a maximum position of 62.5% of the medial-to-lateral width of the tibia.

The surgery typically now takes place under fluoroscopic control. A guide pin is drilled medial-to-lateral through the proximal tibia at an optimal angle approximately 3cm below the medial joint line (Figure 1.5). Below the guide pin and using flexible and rigid osteotomes, the osteotomy is opened slowly to the predetermined width. The plate is fixed proximally and distally with 3 cancellous, and 3 cortical screws (for a Contour Lock plate), respectively. In osteotomies greater than 7mm cancellous allograft bone is used to fill the gap. Figure 1.5 illustrates a series of intraoperative fluoroscopic images depicting the medial opening wedge HTO technique described by Fowler *et al.,* (2000).

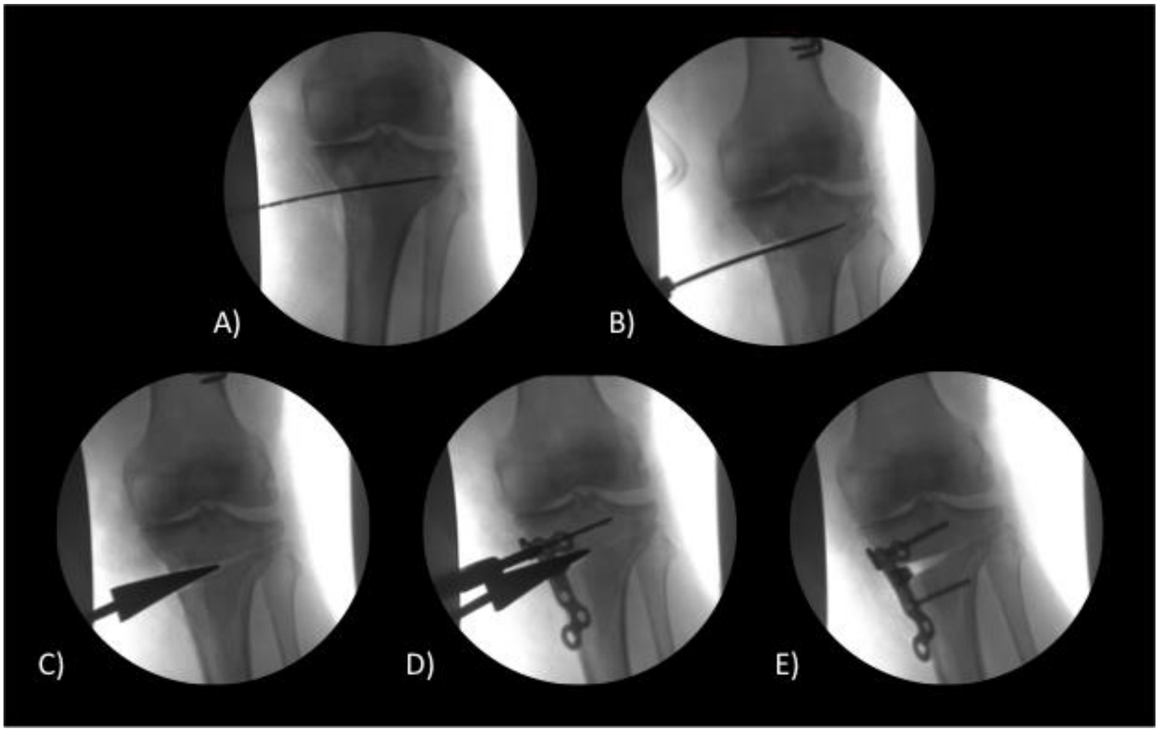

Figure 1.5: A series of intraoperative fluoroscopy images depicting the medial opening wedge HTO technique. **A)** An osteotomy guide pins drilled through the medial tibia. **B)** An oscillating saw is used to cut the tibia medially, anteriorly, and posteriorly **C)** Osteotome Jack is inserted into the bone cut. The Osteotome Jack is opened until the desired correction is achieved. **D& E)** Contour Lock HTO plate is inserted and fixed in place with three proximal cancellous screws and three distal cortical screws.

Postoperative guidelines for weight-bearing limit are individual to surgeon and other factors including the degree of correction and the type of hardware used for the osteotomy. Typical postoperative care includes; protected weight-bearing with crutches and a tracker/hinge brace for up to 6 weeks. If signs of healing are evident through clinical and radiographic evaluation at 6 weeks progression from 2 crutches-to-single crutch-to-full weight-bearing is permitted at 12 weeks. Gait re-training, range of motion exercises, pain management, and maintenance of surrounding joint strength and function are the focus for early postoperative rehabilitation.

Following HTO, significant improvements in pain and function have measured through self-report questionnaires in 1-4 year follow-up evaluations (El-Azab *et al.*, 2011; Ramsey *et al.*, 2007; Briem *et al.*, 2007; Birmingham *et al.*, 2009; Spahn *et al.*, 2006; W-Dahl *et al.*, 2005). High tibial osteotomy has also been shown to significantly reduce the external knee adduction moment during walking (Wada *et al.*, 1998; Prodromos *et al.*, 1985; Birmingham *et al.*, 2009; W-Dahl *et al.*, 2005; Weidenhielm, 1995). However, despite these positive results, 1-35% of cases result in adverse events, such as; delayed union (insufficient healing in a given time period), non-union, lateral cortical hinge disruption, and hardware failure leading to loss of correction (Miller *et al.*, 2009; Nelissen and van Langelaan, 2010; Asik *et al.*, 2006; Martin *et al.*, 2012; Esenkaya *et al.*, 2006; Niemeyer, 2010; Lee and Byun, 2012; Floerkemeier *et al.*, 2013; Yacobucci *et al.*, 2008; Spahn, 2004; Brouwer *et al.*, 2006; Kuremsky *et al.*, 2010; Meidinger *et al.*, 2011; Takeuchi *et al.*, 2012), that all may be partly related to the type of fixation used (Miller *et al.*, 2009; Nelissen and van Langelaan, 2010; Spahn, 2004).

1.4.1 Importance of Initial Fixation Stability

A variety of fixation plates have been specifically designed for medial opening wedge HTO and final plate selection is usually based on surgeon's preference. The function of the plate is to provide a stable fixation to maintain the achieved correction while promoting healing through micro-motion (Claes *et al.*, 1998; Brinkman *et al.*, 2008; 2010). Complications that have been shown to be associated with plate design and fixation technique are loss of correction, non-union, and disuse muscle atrophy due to a prolonged course of restricted weight-bearing (Miller *et al.*, 2009; Nelissen and van Langelaan, 2010; Spahn, 2004; Kawazoe and Takajashi, 2003). For example Spahn, (2004) report that 11-16.4% of complications following HTO were a result of implant failure. Miller *et al.*, (2009) suggest there is a relationship between the type of plate used and the incidence of loss of correction; and that a stable fixation minimizes the possibility of complications. Studies investigating the effects of mechanical factors on the fracture healing process in animal and computer models suggest there is an optimal balance between stability and micro-motion to encourage bone healing (Kenwright and Goodship, 1989). A stiff fixation minimizes micro-motion and suppresses healing

(Kenwright and Goodship, 1989), whereas an unstable fixation with too much movement can lead to non-union (Kenwright and Goodship; 1989; Goodship *et al.*, 1985). The amount of initial weight-bearing postoperatively also depends strongly on the type of fixation used, with duration of protected weight-bearing during rehabilitation after surgery ranging from 2-12 weeks (Asik *et al.*, 2006; Noyes *et al.*, 2006; Staubli *et al.*, 2006; Takeuchi *et al.*, 2009). Therefore, plate design can have a significant impact on stability of the medial opening wedge HTO and ultimately on complication rates and rehabilitation times.

1.5 Review of Current Methods for theEvaluation of HTO

The measurement of the HTO fixation stability, healing of the osteotomy and the effect of HTO on patient function *in-vivo* are all important goals for the clinical well-being of the patient and for research into fixation design. A number of techniques have been used to assess HTO and the stability of the fixation; however, each method has its own strengths and limitations

.

1.5.1 3D Gait Analysis

Quantitative 3D gait analysis is a common tool used in the study of knee OA and interventions aimed to treat this disease. With this technique, reflective or active markers are attached to specific landmarks on the surface of a subject, and high-speed cameras track joint segments. This method provides excellent kinematic measurements, and when combined with a force plate, kinetic measurements as well, particularly external moments about the knee. In gait analysis knee moments are typically reported as normalized knee moments in percent body weight times height (%Bw·Ht) to control for differences between patients due to these variables (Robbins *et al.*, 2011). Studies using gait analysis have shown medial opening wedge HTO to be effective in decreasing the magnitude of the external knee adduction moment (Wada *et al.*, 1998; Ramsey *et al.*, 2007; Birmingham *et al.*, 2009; Wang *et al.*, 1990; Noyes *et al.*, 2000). Although gait analysis may provide excellent information about an individual's functional knee biomechanics, alignment, and indicators of joint loads, it cannot provide quantitative information about underlying joint micro-motion and therefore how stable the HTO fixation is.

1.5.2 *In-vitro* Biomechanics

Biomechanical investigation is commonly used to evaluate the stability of fracture fixation plates. These studies typically involve the use of cadaveric or artificial bone models (*e.g.*, Sawbones®, Vashon, Washington, USA) along with a materials testing machine to apply load (Agneskirchner *et al.*, 2006; Miller *et al.*, 2005; Hernigou *et al.*, 1987; Stoffel *et al.*, 2004; Spahn and Wittig, 2002; Pape *et al.*, 2010; Maas *et al.*, 2013). These studies are extremely useful for comparing various fixation techniques and can provide valuable information about the movement at the osteotomy site (micro-motion) under various loading conditions (load-controlled cyclic tests to failure, single load to failure, *etc.*). Results based on biomechanical testing of fixation plates have suggested the design of the implant strongly influences the primary stability of the medial opening wedge HTO (Brinkman *et al.*, 2010); however, which fixation system is the most reliable is still controversial (Amendola and Bonasia, 2010).

Previous *in-vitro* testing has typically not taken into consideration gait biomechanical data to provide a reference for load application; rather, they have relied on the use of static, radiographic WBL measurements for their experimental setup (Agneskirchner *et al.*, 2006; Gaasbeek *et al.*, 2005; Miller *et al.*, 2005; Pape *et al.*, 2010; Zhim *et al.*, 2005; Stoffel *et al.*, 2004; Maas *et al.*, 2013). When planning an HTO surgery, surgeons typically use this static measure of alignment as a guide to achieve the desired amount of correction, by shifting the location of this line to fall within the tibial plateau. Although such static measures of lower limb alignment are correlated with the external knee adduction moment they may not adequately represent dynamics knee joint load (Leitch *et al.*, 2013; Specogna *et al.*, 2007; Hurwitz *et al.*, 2002; Wada *et al.*, 1998; Hilding *et al.*, 1995). Using *in-vivo* gait analysis data, specifically variables primarily responsible for external loading of the knee, to establish experimental parameters for testing medial opening wedge HTO fixation devices could provide further insight for optimal fixation design.

1.5.3 Imaging

1.5.3.1 Radiography

The simplest method to assess the anatomical changes achieved with HTO and healing afterwards *in-vivo* is the plain film x-ray. This film is typically acquired while the patient is standing and taken in the anteroposterior direction. These films are commonly used clinically, to assess the change in alignment after surgery, give an indication of the amount of bony union (healing) that has occurred (Amendola, 2003; Brinkman *et al.*, 2008), and give an indication of the condition of the lateral cortical hinge. The x-ray image quality, patient position and direction/orientation of the x-ray source and detector can all influence results. Although this radiographic method may provide an indication of the amount of healing that has occurred, it does not provide information on the stability of the fixation under dynamic loads.

1.5.3.2 Radiostereometric Analysis & Biplane Radiography

Radiostereometric analysis (RSA) is a biplane x-ray technique that can obtain 3D measurements of micro-motion in the lower limb with systems capable of real time image acquisition (Selvik, 1990). Due to its high accuracy when measuring skeletal movement and fracture micro-motion, RSA is an ideal method to study fixation of orthopaedic implants (Kärrholm *et al.*, 2006; Kärrholm, 1989; Madanat *et al.*, 2006). This method typically requires implantation of tantalum beads (at least 3 non-collinear markers) into the body segment to be studied or relies on shape-matching techniques (Valstar *et al.*, 2005; Hurschler *et al.*, 2009).

Despite its potential, a limited number of studies have been conducted using RSA methods and focus on the long-term stability of the fixations and are typically static in nature (Brinkman *et al.* 2010; Gaasbeek *et al.*, 2005; Luites *et al.*, 2009; Magyar *et al.*, 1999; Pape *et al.*, 2013). Studies that have used RSA to evaluate medial opening wedge HTO have shown adequate stability of the opening wedge technique (Gaasbeek *et al.*, 2005; Luites *et al.*, 2009; Magyar *et al.*, 1999) and have provided insight into rehabilitation protocols for various fixation plates (Brinkman *et al.*, 2010;Pape *et al.*, 2013). One of the reasons for this is the limited availability of centres equipped for such studies because of both cost and technical reasons. This method requires two complete x-ray systems, which nearly doubles the cost. Other limitations include the limited field of view, defined by the intersection of the two x-ray beams, and restrictive set-up (Yuan *et al.*, 2002; Ioppolo *et al.*, 2007). Both limit the type of activities that a subject can perform, and make it technically difficult to ensure the joint under examination remains with the operating volume during dynamic activities.

Biplane radiography uses digital radiography systems capable of real-time image acquisition. Marker-based techniques rely on the same principles as RSA, however model-based techniques have been developed to overcome the requirement of implanting markers into the skeletal segments (Bey *et al.*, 2008, Li *et al.*, 2004, You *et al.*, 2001). Model-based techniques require a model of the 3D geometry of the segment under examination (typically obtained from a CT scan). Similar to RSA the major limitations of this techniques are requiring two x-ray systems as well as the limited field-of-view defined by the intersection of the two x-ray beams and restrictive set-up (Li *et al.*, 2008).

1.5.3.3 Single-Plane Radiography

Roentgen single-plane analysis (RSPA) is a new approach to the study of musculoskeletal movement that overcomes some of the limitations of conventional RSA, but is based on similar principles (Yuan *et al.*, 2002). This approach uses single-plane dynamic imaging and the known 3D geometry of implanted markers in a skeletal segment to estimate the 3D position and orientation (pose) of that skeletal segment (Seslija, 2009; Yuan *et al.*, 2002). The 3D pose of the skeletal segment, implanted with markers, is determined by performing a 3D-to-2D registration between the 3D geometry of the markers (determined from a standard RSA examination or a computer tomography (CT) scan) and their corresponding projections in the 2D radiographs (Seslija, 2009). The accuracy of single-plane systems has been reported as 0.1mm to 1.0mm in-plane and 0.7mm to 2.1mm out-of-plane for translational measurements and 0.3° to 1.7° for rotational measurements about all axes (Yuan *et al.*, 2002; Ioppolo *et al.*, 2007; Tang *et al.*, 2004; Garling *et al.*, 2005).

Single-plane radiography systems are more widely available in most hospital environments and have a larger field of view in comparison to biplane configurations. This results in the ability to capture and measure numerous dynamic activities. The main limitation of single-plane radiography is the decreased accuracy in measuring out-of-plane translations (orthogonal to the image plane) (Banks *et al.*, 1996; Garling *et al.*, 2005; Ioppolo *et al.*, 2007).

A hospital single-plane radiography system has been adapted for use in measuring knee joint kinematics (Figure 1.6). The system, when combined with an *a priori* model of anatomy from a patient CT scan, should be capable of measuring *in-vivo* motion of osteotomies before union under different fixation modalities.

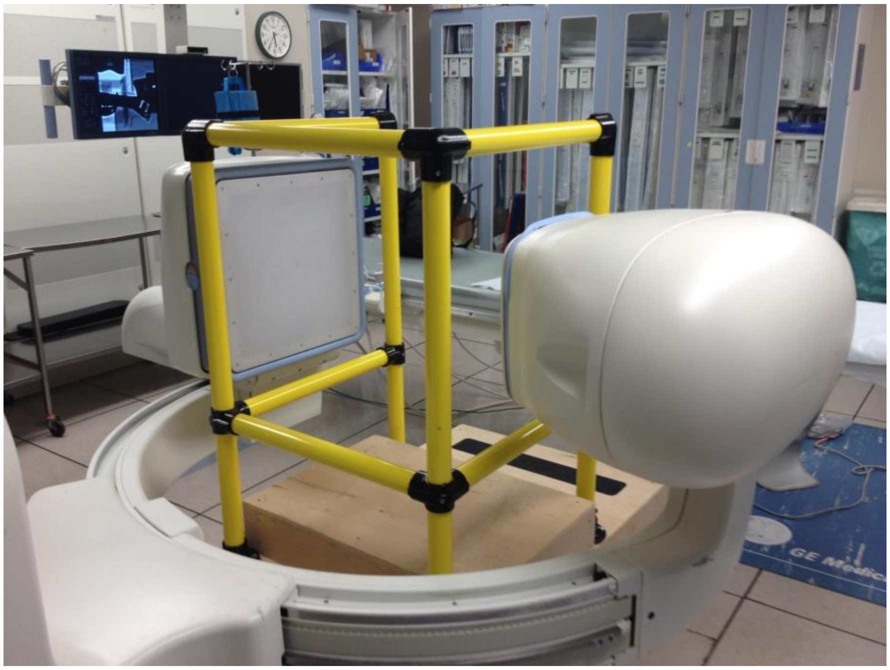

Figure 1.6: The GE Innova 4100 digital flat panel radiography system located at University Hospital, London Health Sciences Centre adapted for measuring *in-vivo* knee joint motion.

1.6 Study Rationale

As the number of people suffering from knee OA increases, the medical community must devise new methods to treat their pain and reduce quality of life. Medial opening wedge HTO is one such development, but further biomechanical investigation using newly developed tools and equipment is required to examine its efficacy and suggest possible areas of improvement. As such, the ***overall aim*** of this thesis was to develop and test biomechanical methods to assist in the evaluation of medial opening wedge HTO. The specific objectives and hypotheses for each study are listed below.

1.7 Specific Objectives and Hypotheses

The specific study objectives and hypotheses were:

1. To compare external knee moments during walking before and after varus or valgus producing osteotomies in patients with lateral or medial compartment knee OA, and in healthy participants with neutral alignment.

   Hypothesis: The knee adduction impulse and peak knee adduction moment would *increase* in patients after varus osteotomy, and *decrease* in patients after valgus osteotomy. Further, differences between patients and controls would be observed preoperatively, but not postoperatively. Finally, changes in frontal plane gait mechanics would be explained primarily by changes in MAA.

2. To compare 3D external knee moments before and after medial opening wedge HTO during level walking and during stair ascent.

   Hypothesis: There would be significant decreases in peak moments about the knee in all three orthogonal planes after HTO. Knee moments during stair ascent would be higher than those during level walking.

3. a. To develop and test a multi-axis fixation jig placed within a materials testing machine for assessing medial opening wedge HTO plate fixations in a manner more representative of walking.

b. To compare strain on the lateral aspect of the tibial osteotomy (cortical hinge) and strain on the medial opening wedge HTO plate under different lever arm conditions.

Hypothesis: The lateral cortical hinge (created by the HTO) and the HTO fixation plate would experience more strain when load was applied at a lever arm.

c. To evaluate the reliability of the strain measures obtained within and between test sessions.

Hypothesis: The strain measures obtained within and between test sessions would be reliable with coefficients of variation (CoVs) < 10%.

4. To compare medial opening wedge HTO fixations performed with either a flat or toothed Contour Lock plate, during cyclic loading conditions by quantifying resulting load at failure, micro-motion across the osteotomy site and strain on both the plate and the lateral cortex of the tibia.

   Hypothesis: There would be no difference between the two plates with respect to any of these measures (*i.e.*, load at failure, micro-motion, and plate/bone strains).

5. a. To provide the proof-of-concept as to whether or not dynamic single-plane flat-panel radiography could detect micro-motion in a fully healed tibia, as well as changes in micro-motion during bone healing, after medial opening wedge HTO.

   Hypothesis: Dynamic single-plane flat panel radiography has the potential to assess healing of the osteotomy by showing reduced micro-motion across the osteotomy site over time.

1.8 Thesis Overview

The thesis is written in an integrated article (manuscript) format that includes five studies, Chapter 2-to-6, with each of the above objectives corresponding to a chapter in the thesis. The studies were completed in three different laboratories from the Faculties of Health Sciences (Wolf Orthopaedic Biomechanics Laboratory), Engineering (Jack McBain Biomechanical Testing Laboratory) and Medicine and Dentistry (Robarts Research Institute). Experiments span methods in three-dimensional (3D) gait analysis, including level walking and stair ascent before and after HTO, materials testing of fixation plate designs using sawbones, and dynamic radiography of patients after surgery.

The first two studies used 3D motion capture and principles of inverse dynamics to evaluate changes in alignment and knee moments after HTO. The first examined changes in frontal plane alignment on gait biomechanics, while the second investigated the 3D external knee moments before and after medial opening wedge HTO during level walking and during stair ascent. Additionally, gait biomechanics contributed to the data used in the next two studies.

Studies three and four, introduced, validated and used a multi-axis fixation jig for the *in-vitro* biomechanical evaluation of medial opening wedge HTO. Study three focused on a multi-axis fixation jig to be used with a materials testing machine for assessing the stability of HTO plate fixations in a manner more representative of walking. This jig was then used in study four to compare two different surgical plate designs used in medial opening wedge HTO.

Although materials testing proved to be valuable for comparing different fixation plate designs, there are well-known limitations with *in-vitro* testing. As such, study five is a proof-of-concept study to test dynamic single-plane flat-panel radiography for use in detecting micro-motion *in-vivo* after medial opening wedge HTO during dynamic weight-shifting tests, by evaluating micro-motion between the proximal and distal segments of the tibia during recovery after surgery

The final chapter consists of a summary and general discussion of the findings of this thesis and provides recommendations for future work.

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Chapter 2

Changes in valgus and varus alignment neutralize aberrant frontal plane knee moments in patients with unicompartmental knee osteoarthritis

Overview: *To elucidate the effects of frontal plane lower limb alignment on gait biomechanics, we compared knee joint moments and frontal plane angular impulse before and after varus or valgus producing osteotomy in patients with lateral or medial compartment osteoarthritis, and in healthy participants with neutral alignment. Thirty-nine subjects participated (13 valgus gonarthrosis, 13 varus gonarthrosis, and 13 controls). Patients underwent 3D gait analysis and radiographic assessment of alignment (mechanical axis angle; MAA) before and 6 months after surgery, and were compared to controls. Mean changes (95% CI) in frontal plane angular impulse indicated a 0.82 %Bw·Ht·s (0.49,1.14) increase in adduction impulse in patients after varus osteotomy, and a 0.61 %Bw·Ht·s (0.37,0.86) decrease in adduction impulse in patients after valgus osteotomy, equating to a 53% and 45% change from preoperative values, respectively. Preoperative frontal plane angular impulse was significantly different between both patient groups and controls before surgery, but not after. The cross-sectional data suggest that frontal plane angular impulse is very highly correlated to MAA before surgery (R=0.87), but not after (R=0.39), and that an adduction impulse predominates until 7º of valgus, at which point an abduction impulse predominates. The prospective surgical realignment data indicate that for every 1º change in MAA toward varus, there is a 0.1 %BW·Ht·s (or 1.6 N·m·s) change in frontal plane knee angular impulse toward adduction, and vice versa. These overall findings illustrate the potent effects that lower limb alignment can have on frontal plane gait biomechanics.*[1]

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[1] A version of this work has been published: Leitch, K.M, Birmingham, T.B., Dunning, C.E., Giffin, J.R., 2013. Changes in valgus and varus alignment neutralize aberrant frontal plane knee moments in patients with uncompartmental knee osteoarthritis. J Biomech 46(7), 1408-1412.

2.1 Introduction

Epidemiological studies suggest frontal plane alignment of the lower limb, quantified as the mechanical axis angle (MAA), plays an important role in the development and progression of knee osteoarthritis (OA), presumably due to its effect on biomechanics (Sharma *et al.*, 2012; Sharma *et al.*, 2010). Gait analysis provides insight into how frontal plane alignment contributes to knee joint biomechanics, and how modifications in alignment can affect dynamic joint loads. In neutral alignment, the line of action of the ground reaction force (GRF) during single limb support passes medial to the knee joint center, creating a lever arm in the frontal plane, an external adduction moment about the tibiofemoral joint, and greater loads on the medial compared to lateral compartment (Andriacchi, 1994). In varus gonarthrosis, the knee adduction moment, angular impulse and distribution of load on the medial compartment is higher and more sustained (Landry *et al.*, 2007; Thorp et al, 2006a), with prospective risk factor studies suggesting potent effects on disease progression (Bennell *et al.*, 2011; Miyazaki *et al.*, 2002).

The effect of valgus alignment on knee biomechanics is less clear. Previous studies suggest load distribution shifts from greater medial compartment, to equal, to greater lateral compartment with increasing valgus (Bruns *et al.*, 1998; Harrington, 1983; Johnson *et al.*, 1980). Due to the typical predominance of a knee adduction moment during walking, it is unclear what degree of valgus is required to create an external abduction moment. Indeed, we are aware of limited published 3D gait analyses in patients with lateral compartment OA (Butler *et al.*, 2011; Weidow *et al.*, 2006).

Consistent with being a risk factor for OA, several treatments, both conservative and surgical, aim to change the moments about the knee in attempt to lessen aberrant loads on the more diseased compartment (Lutzner *et al.*, 2009; Reeves and Bowling, 2011). Surgical osteotomy provides a model in which to study the effects of changing alignment in patients with knee OA. Various osteotomy procedures can be performed at the proximal tibia and distal femur to correct limb malalignment in both varus and valgus directions (Dowd *et al.*, 2006). To elucidate the effects of frontal plane alignment on gait biomechanics, we evaluated knee joint moments before and after varus or valgus producing osteotomy in patients with lateral or medial compartment OA, and in healthy participants with neutral alignment. Our primary hypothesis was that the knee adduction impulse and peak knee adduction moment would increase in patients after varus osteotomy, and decrease in patients after valgus osteotomy. Further, differences between patients and controls would be observed preoperatively, but not postoperatively. Finally, changes in frontal plane gait mechanics would be explained primarily by changes in MAA.

2.2 Methods

2.2.1 Study Design

This study was approved by the institutional research ethics board. Thirty-nine subjects participated: 13 patients with valgus alignment (>2º) and lateral compartment OA (valgus gonarthrosis), 13 patients with varus alignment (<-2º) and medial compartment OA (varus gonarthrosis), and 13 asymptomatic controls with neutral alignment (0±2º) (Table 2.1). Patients with varus and valgus gonarthrosis were matched for frontal plane malalignment ±2º (yet in opposite direction). Patients underwent radiographic and gait analyses within 4 weeks prior to, and 6 months following, surgery. All patients with varus gonarthrosis received a medial opening wedge high tibial osteotomy (HTO). Seven patients in the valgus gonarthrosis group received lateral opening wedge HTO, while 6 received a lateral distal femoral opening wedge osteotomy. The general goal of osteotomy was to correct the preoperative deformity to achieve a postoperative limb alignment that was just beyond neutral. The specific angle was determined at the surgeon's discretion based on the magnitude of malalignment and the presence and severity of cartilage degeneration (visualized arthroscopically) in the opposite compartment of the original deformity (Birmingham *et al.*, 2009; Fowler *et al.*, 2000).

Table 2.1: Demographic and clinical characteristics.

Characteristics	Valgus Gonarthrosis Group	Varus Gonarthrosis Group	Healthy Control Group
	Mean (SD)	Mean (SD)	Mean (SD)
Age (years)	49 (10)	50 (7)	44 (15)
No. of males	6/13 (46%)	7/13 (53%)	9/13 (69%)
Mass (kg)	91.81 (19.06)	92.21 (16.39)	85.64 (11.68)
Height (m)	1.76 (0.09)	1.73 (0.13)	1.74 (0.07)
BMI (kg/m^2)	29.48 (4.79)	30.85 (4.78)	28.18 (3.19)
Mechanical axis angle(°)[£]	6.64 (3.85)	-6.72 (3.92)	-0.19 (0.85)
Kellgren & Lawrence Grade[Ŧ]			
1	0	0	-
2	5	3	-
3	5	7	-
4	3	3	-

[£] Mechanical Axis Angle > 0° indicates valgus alignment, Mechanical Axis Angle < 0° indicates varus alignment

[Ŧ] Kellgren and Lawrence (KL) grades of OA Severity: 0=no OA present, 1= doubtful narrowing of joint space and possible osteophytic lipping, 2=definite osteopytes, definite narrowing of joint space, 3=moderate multiple osteophytes, definite narrowing of joint space, some sclerosis and possible deformity of bone contour, 4=large osteophytes, marked narrowing of joint space, severe sclerosis and definite deformity of bone contour (Kellgren and Lawrence, 1957).

2.2.2 Limb Alignment

Frontal plane alignment was measured from standing anteroposterior hip-to-ankle radiographs for patients (Specogna *et al.*, 2004), and from joint centers calculated from the gait analysis static trial for controls (Mündermann *et al.*, 2008). The MAA was defined as the angle formed between a line drawn from center of hip to centre of knee and a line drawn from center of ankle to center of knee.

2.2.3 Gait

Gait was evaluated using an eight-camera motion capture system (Eagle, EvaRT 4.2, Motion Analysis Corporation, Santa Rosa, CA, USA), floor-mounted force plate (OR6, AMTI, Watertown, MA, USA) and modified Helen Hayes marker set (detailed methods previously described in Birmingham *et al.*, 2007; Hunt *et al.*, 2006; Jenkyn *et al.*, 2008). Subjects walked barefoot at self-selected pace while 3D kinematic (60Hz) and kinetic (1200Hz) data were collected for a minimum of five trials.

Moments about the knee were calculated from the kinematic and kinetic data using inverse dynamics and were expressed as external moments relative to the tibial anatomical frame of reference (Orthotrak 6.0; Motion Analysis Corporation). Moments in each of the three orthogonal planes of movement were determined throughout stance phase and averaged over five trials of the same limb (operative limb, or limb closest to neutral for controls) while normalizing to body weight and height (%Bw·Ht). The frontal plane knee moment waveform was then integrated with respect to time to calculate the frontal plane knee angular impulse (%Bw·Ht·s) (Thorp *et al.*, 2006b), summing the positive portions (adduction impulse) and negative portions (abduction impulse). Knee moments in all three planes were then normalized to 100% of stance and peak values in the first and second halves of stance were identified.

2.2.4 Statistics

The frontal plane knee angular impulse was used as the primary outcome in statistical analyses, and compared between valgus and varus patients before and after surgery using a two-factor, group by time analysis of variance (ANOVA) with Scheffe post-hoc tests.

Postoperative values were compared between patient groups and controls using a one-way ANOVA. Knee moment peaks in all three planes were evaluated similarly. After peer review, additional tests were completed using analysis of covariance to control for walking speed when comparing the groups postoperatively in frontal plane angular impulse, peak knee adduction moment, and peak knee extension moment.

Associations among preoperative alignment and frontal plane angular impulse, and the change in these variables after surgery (postoperative value minus preoperative value), were evaluated using scatterplots and simple linear regression. An alpha value of 0.05 was used to denote significance for all analyses, performed using SPSS 20.0 (SPSS Inc., Chicago, USA) and Statistica 7.0 (StatSoft, Tulsa, OK, USA).

2.3 Results

Descriptive statistics for gait and alignment variables are summarized in Table 2.2 Ensemble averages before and after surgery are illustrated in Figure 2.1. For the frontal plane knee angular impulse, there was a significant group by time interaction ($p<0.001$), with a significant difference between groups preoperatively ($p<0.001$), but not postoperatively ($p=0.99$), and a significant change (in opposite directions) after surgery in both groups ($p<0.001$) (Figure 2.2). There were no differences in frontal plane angular impulse between controls and patients after surgery ($p=0.08$). There were less substantial findings in sagittal and transverse plane moment peaks. When compared to controls, the peak knee extension moment was significantly lower for both patient groups after surgery ($p=0.008$) (Figure 2.1). When controlling for speed there was a difference between groups after surgery in frontal plane angular impulse ($p=0.033$), no difference in peak knee adduction moment ($p=0.49$), and no difference in peak extension moment ($p=0.14$) (Figure 2.1).

Significant associations between lower limb alignment and frontal plane knee angular impulse are plotted in Figure 2.3: preoperatively ($R=0.88$, $n=39$), postoperatively ($R=0.39$, $n=39$), and for their changes ($R=0.88$, $n=26$).

Table 2.2: Descriptive statistics (mean and standard deviation) for gait, and alignment variables.

Variables	Valgus Gonarthrosis (n=13)		Varus Gonarthrosis (n=13)		Controls (n=13)
	Before Surgery	After Surgery	Before Surgery	After Surgery	
Frontal Plane Knee Angular Impulse (%Bw·Ht·s) [Ŧ]	-0.10 (0.49)	0.72 (0.39)	1.38 (0.40)	0.76 (0.38)	1.00 (0.19)
Knee Adduction Angular Impulse (%Bw·Ht·s)	0.24 (0.26)	0.75 (0.38)	1.42 (0.39)	0.81 (0.37)	1.04 (0.20)
Knee Abduction Angular Impulse (%Bw·Ht·s)	-0.34 (0.27)	-0.03 (0.02)	-0.04 (0.02)	-0.04 (0.03)	-0.04 (0.01)
Peak Knee Adduction Moment (%Bw·Ht)	0.88 (0.95)	1.60 (0.70)	3.09 (0.66)	1.65 (0.57)	2.24 (0.74)
Peak Knee Abduction Moment(%Bw·Ht)	-0.80 (0.63)	-0.05 (0.21)	-0.11 (0.15)	-0.22 (0.21)	0.04 (0.17)
Peak Knee Flexor Moment (%Bw·Ht)	0.36 (1.29)	0.25 (0.82)	0.42 (1.68)	0.37 (1.09)	0.97 (0.78)
Peak Knee Extensor Moment (%Bw·Ht)	-2.89 (1.45)	-2.41 (1.15)	-2.62 (1.28)	-2.24 (1.03)	-3.61 (1.25)
Peak Knee External Rotation Moment (%Bw·Ht)	0.54 (0.33)	0.35 (0.40)	0.33 (0.26)	0.41 (0.22)	0.46 (0.45)
Peak Knee Internal Rotation Moment (%Bw·Ht)	-1.03 (0.52)	-1.21 (0.41)	-1.41 (-2.03)	-1.11 (0.25)	-1.53 (0.45)
Gait Speed (m/s)	1.07 (0.13)	1.08 (0.19)	1.04 (0.21)	1.04 (0.18)	1.31 (0.15)
Mechanical Axis Angle(°)[£,*]	6.64 (3.85)	0.47 (3.73)	-6.72 (3.91)	0.54 (1.66)	-0.19 (0.85)

*Mechanical Axis Angle for Control Group were obtained from standing static gait trial

[Ŧ]The frontal plane knee angular impulse (%Bw·Ht·s) was defined as the sum of the integrals of the positive portion (adduction impulse) and negative portion (abduction impulse) of the frontal plane knee moment curve.

[£] Mechanical Axis Angle >0° indicates valgus alignment, Mechanical Axis Angle <0° indicates varus alignment

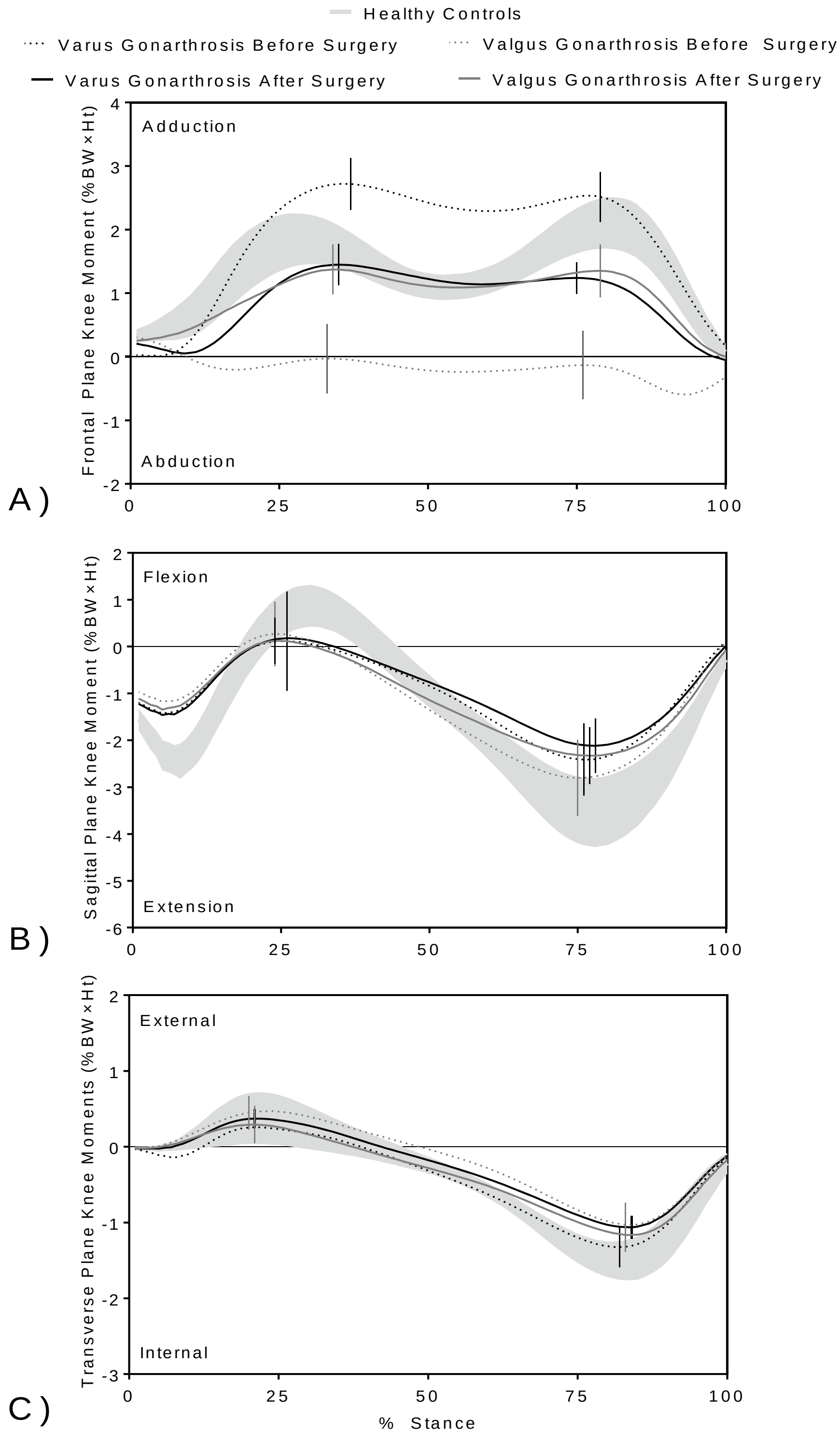

Figure 2.1: Ensemble averages (n=13) of **A)** Frontal Plane **B)** Sagittal Plane and **C)** Transverse Plane knee moments plotted over 100% of stance.. The shaded area represents the 95% confidence band for the healthy control population. Vertical bars represent 95% confidence intervals for peak values for both groups of patients before and after surgery.

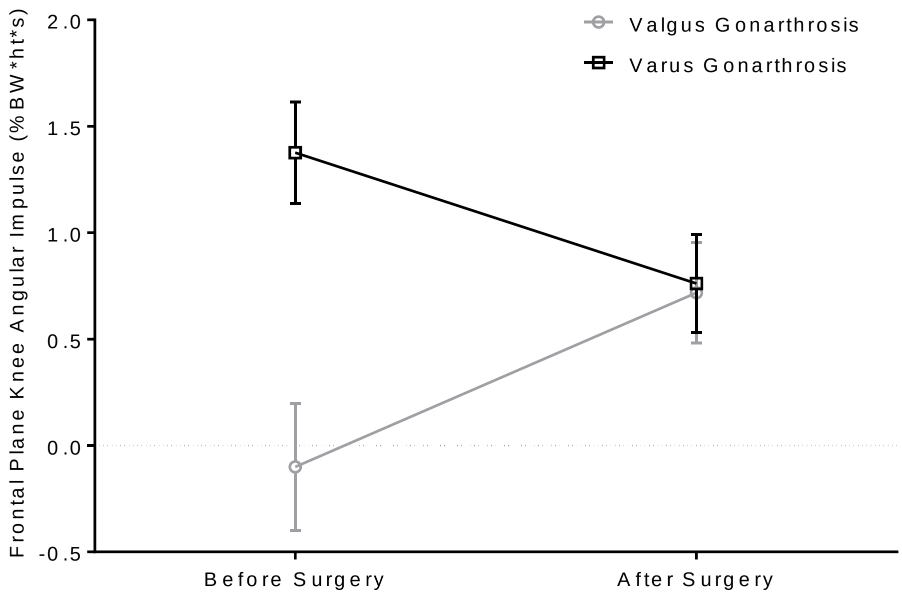

Figure 2.2: Means and 95% confidence intervals for the change in frontal plane knee angular impulse assessed before and after surgery for varus and valgus gonarthrosis.

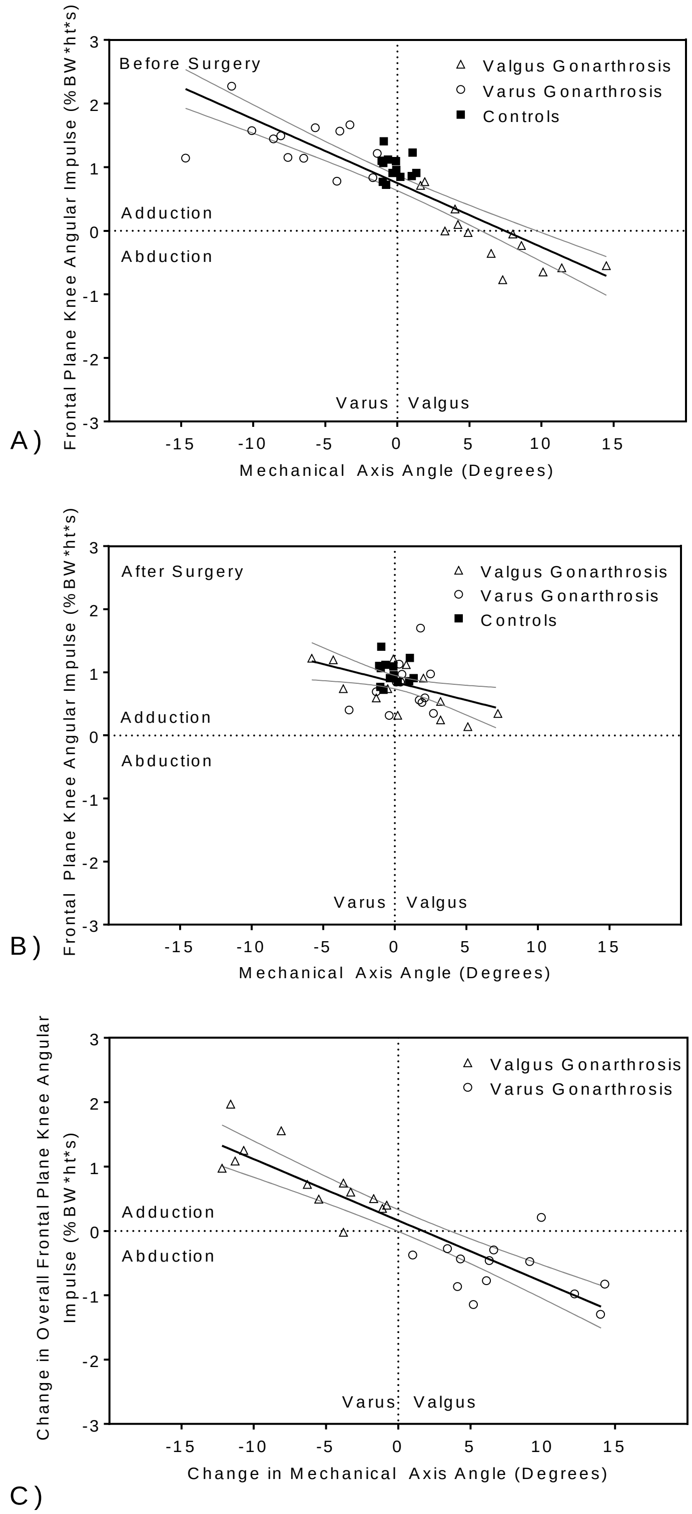

Figure 2.3: Scatterplots with mean regression line and 95% confidence interval showing the associations between mechanical axis angle and frontal plane knee angular impulse**A)** before surgery (R=0.88, n=39) **B)** after surgery (R=0.39, n=39) and **C)** for their change (R=0.88, n=26).

2.4 Discussion

The present findings emphasize the importance of lower limb alignment to frontal plane knee moments and therefore the distribution of loads between medial and lateral tibiofemoral compartments. Biomechanical modeling studies (Andriacchi, 1994; Bhatnagar and Jenkyn, 2010; Hsu *et al.*, 1990; Morrison *et al.*, 1970) and instrumented knee joint implant data (Halder *et al.*, 2012; Zhao *et al.*, 2007) suggest that approximately 55-to-70 percent of the load on tibiofemoral joint is borne by the medial compartment. Although many factors can contribute to the distribution of loads between compartments, the mechanical axis angle plays a major role. Even within samples of knees with relatively neutral alignment (*i.e.*, MAA+/-5º), recent data suggest that for every 1º increase in varus, there is a 5% increase in the load shared by the medial compartment (Halder *et al.*, 2012). The present cross-sectional, preoperative gait data show a very strong relationship (R=0.87) between alignment and frontal plane moment (more specifically, angular impulse) when a large range in values is present. Note that the frontal plane knee angular impulse consists predominantly of an adduction impulse, until 7º of valgus alignment, at which point the frontal plane knee angular impulse is predominantly an abduction impulse (Figure 2.3A). These results are in general agreement with cadaveric and radiographic studies that suggest a shift from greater medial to greater lateral compartment load at approximately 5-10º of valgus (Bruns *et al.*, 1993; Harrington, 1983; Johnson *et al.*, 1980).

The knee adduction impulse and peak knee adduction moment reflect somewhat different gait parameters and can behave differently (Thorp *et al.*, 2006b). The present results illustrate this with respect to the effect of speed. Controlling for differences in speed accentuated the statistical significance of differences between groups after surgery in frontal plane angular impulse, yet diminished differences in peak knee adduction moment. Not surprisingly, the difference between groups after surgery in the peak knee extension moment was also no longer significant after controlling for speed. Overall, the present findings suggest that when compared to healthy controls with neutral alignment, the present malaligned patients had more extreme external knee adduction and abduction moments before surgery *despite* their slower walking speed, yet less extreme adduction, abduction and extension moments after surgery partly *because* of their slower walking speed. It should be noted that gait speed is suggested to be inherently linked to the progression of OA (Astephen *et al.,* 2008) and some authors warn that controlling for speed (either during data collection or with the statistical analysis) may remove a significant portion of the main effect and decrease generalizability of findings (Astephen-Wilson, 2012).

The primary limitation in this study is that the loads on the tibiofemoral compartments were not directly measured, as they would be in patients with instrumented implants after arthroplasty (Halder *et al.*, 2012; Kutzner *et al.*, 2010; Zhao *et al.,* 2007). However, the present methods enable the investigation of a relatively large sample of younger patients with their native diseased tibiofemoral joint with substantial malalignment, and the results are consistent with studies directly evaluating compartment load. The present study builds upon previous cadaveric and radiographic studies, in that the external moments about the knee during gait encompass other characteristics (Hunt *et al.*, 2007; Hurwitz *et al.*, 2002; Linley *et al.*, 2010) that influence the distribution of loads on the tibiofemoral joint. The study also includes a large range of patients with varus and valgus alignment and controls, and uses osteotomy as a model to evaluate prospective changes in gait due to changes in alignment – this is rare, especially in the case of valgus alignment and lateral compartment disease.

The present findings also illustrate the potent effect of changing alignment. The large decrease in adduction moment after valgus producing osteotomy is consistent with previous studies (Birmingham *et al.*, 2009; DeMeo *et al.*, 2010; Lind *et al.*, 2013; Prodromos *et al.*, 1985; Wada *et al.*, 1998; Weidenhielm *et al.*, 1995; Wang, 1990). Importantly, we also observed a substantial increase in knee adduction moment after varus osteotomy. In the present sample, where a large range of values was made possible by matching patients with varus and valgus, the relationship between change in MAA and change in frontal plane angular impulse was very high (R=0.88), with 78% of the variation in the change in impulse explained by the change in alignment. The prospective surgical realignment data indicate that for every 1º change in MAA toward varus, there is a 0.1 %Bw·Ht·s (or 1.6 N·m·s) change in frontal plane knee angular impulse toward adduction, and vice versa (Figure 2.3C). Overall, these findings suggest that aberrantly high and low knee adduction moments can be neutralized with changes in frontal plane alignment.

2.5 References

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Chapter 3

Medial Opening Wedge High Tibial Osteotomy Decreases Peak Knee Internal Rotation and Adduction Moments During Level Walking and Stair Ascent

Overview: *Although previous research suggests medial opening wedge high tibial osteotomy (HTO) decreases the external knee adduction moment during walking, its potential effects in the sagittal and transverse planes are less clear, and its effects during stair climbing are unknown. The objective of this study was to investigate three-dimensional external knee moments before and after medial opening wedge HTO during level walking and during stair ascent. Fourteen patients with varus alignment and osteoarthritis primarily affecting the medial compartment of the tibiofemoral joint were assessed. Gait analysis and data reduction methods were similar to those used in Chapter 2 of this thesis. Three-dimensional motion analyses during level walking and stair ascent were evaluated using inverse dynamics before, 6 and 12 months after surgery. There were significant decreases (p<0.05) in the peak knee adduction, flexion and internal rotation moments, with only the adduction and internal rotation moments remaining decreased at 12 months for both walking and stair ascent. Standardized response means (SRM) ranging from 1.3 to 2.5 indicated large effect sizes. Both pre- and postoperatively, the peak knee adduction moment was significantly lower (p=0.001) during stair ascent than during level walking, while the internal rotation moment was significantly higher (p=0.003). Medial opening wedge HTO results in long-term changes in knee moments in the transverse plane in addition to the frontal plane, during both level walking and stair ascent. Overall, these results support medial opening wedge HTO as a mechanism for substantially altering the distribution of knee loads during ambulation.*[2].

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[2] A version of this chapter is currently under review: Leitch, K.M., Birmingham, T.B., Dunning, C.E., Giffin, J.R., 2014. Medial opening wedge high tibial osteotomy decreases peak knee internal rotation and adduction moments during level walking and stair ascent. Clin Biomech.

3.1 Introduction

Osteoarthritis (OA) is a prevalent condition with substantial and growing impact on individuals and societies globally (Vos *et al.*, 2012; Lawrence *et al.*, 2008; Bitton, 2009; Gupta *et al.*, 2005). The knee is the most common weight-bearing joint affected by OA (Guccione *et al.*, 1994; Lawrence, 2008; Englund, 2010) and most frequently involves the medial compartment of the tibiofemoral joint (Cooke *et al.*, 1997; McAlindon *et al.*, 1992). Biomechanical and epidemiological evidence emphasizes the importance of lower limb alignment, including its influence on the compressive load on the knee (D'Lima *et al.*, 2008; Zhao *et al.*, 2007; Hsu *et al.*, 1990; Harrington, 1983*)* and its effect on disease progression (Kutzner *et al.*, 2010; Brouwer *et al.*, 2007; Sharma *et al.*, 2001; 2010; 2012).

Lower limb alignment has a strong influence on the distribution of load across the knee during ambulation. In neutral alignment, the moment about the knee in the frontal plane during the stance phase of gait causes force within the knee to be transmitted unevenly between the two tibiofemoral compartments, with approximately 55-70% of the load on the medial compartment (Hsu *et al.*, 1990; Schipplien and Andriacchi, 1991; Andriacchi, 1994; Bhatnagar and Jenkyn, 2010; Morrison *et al.*, 1970; Halder *et al.*, 2012; Zhao *et al.*, 2007). With varus alignment, this imbalance is exacerbated (Johnson and Wang, 1980; Harrington, 1983; Bruns *et al.*, 1993; Andriacchi, 1994*)*. When lower limb alignment is quantified as the mechanical axis (hip-knee-ankle) angle using full-limb standing radiographs, instrumented knee implant data suggest the load on the medial compartment during walking increases 5% for every 1° increase towards varus (Halder *et al.*, 2012). Although the size of the association depends on the characteristics of the sample, motion capture data suggest a 0.1 %Bw·Ht·s change in knee frontal plane angular impulse during walking for every 1° change towards varus (Leitch *et al.*, 2013).

The importance of the knee adduction moment to joint loading and medial knee OA progression in patients with varus alignment is well established (Schipplien and Andriacchi, 1991; Bennell *et al.*, 2011; Miyazaki *et al.*, 2002). However, moments about the knee in other planes may also be important and may aid in the understanding of treatments for knee OA. For example, changes in sagittal plane moments about the knee during gait can also alter medial contact force on the knee, (Walter *et al.*, 2010; Schipplien and Andriacchi, 1991) while transverse plane moments are associated with cartilage loss in knees with OA (Henriksen *et al.*, 2012). Additionally, transverse plane moments are significantly different in knees with moderate OA compared to asymptomatic knees (Astephen *et al.*, 2008).

Gait analysis appears to be particularly useful in the study of knee OA, partly because it represents relatively high, cyclic loading during functional conditions (Andriacchi and Mündermann, 2006). Stair climbing is another common functional activity encountered in daily living that places high cyclic loads on the knee (Kutzner *et al.*, 2010; Taylor *et al.*, 2004). Stair climbing requires greater lower limb range of motion (Reiner *et al.*, 2002; Rowe *et al.*, 2000) and strength (Nadeau *et al.*, 2003) compared to level walking. Stair climbing ability is also suggested to be an important aspect to the clinical evaluation of patients with knee OA (Yu *et al.*, 1997; Dobson *et al.*, 2013).

Medial opening wedge high tibial osteotomy (HTO) is a surgical lower limb realignment procedure for patients with varus alignment and OA confined primarily to the medial tibiofemoral compartment (Fowler *et al.*, 2000; Amendola and Bonasia, 2010). The goal of this surgery is to change the mechanical axis of the lower limb, thereby altering the loading pattern between the medial and lateral compartments. This, in turn, is suggested to relieve medial knee pain and possibly slow the structural progression of the disease. Clinical biomechanics studies suggest various changes after HTO procedures, including a decrease in the knee adduction moment by approximately 30-50% during level walking. (Wada *et al.*, 1998; Birmingham *et al.*, 2009; Prodromos *et al.*, 1985; Hunt *et al.*, 2009; Ramsey *et al.*, 2007). However, the effects of HTO on external knee moments in the sagittal and transverse planes are unclear, and its effect during stair climbing is unknown. Thus, the objective of this study was to investigate three-dimensional external knee moments before and after medial opening wedge HTO during level walking and during stair ascent.

3.2 Methods

3.2.1 Participants & Testing Procedures

Fourteen patients with varus alignment and OA primarily affecting the medial compartment of the tibiofemoral joint participated in this study (Table 3.1).

Table 3.1: Demographic and clinical characteristics (n=14).

Characteristic	Mean (SD)
Age (years)	48 (7)
No. of males	12(86%)
Mass (kg)	86.44 (14.02)
Height (m)	1.74 (0.08)
BMI (kg/m^2)	28.66 (3.89)
Mechanical Axis Angle(°)[£]	-7.6 (3.8)
Kellgren & Lawrence Grade[Ŧ]	
1	0
2	6
3	5
4	3

[£]Mechanical Axis Angle < 0° indicates varus alignment

[Ŧ] Kellgren and Lawrence (KL) grades of OA Severity: 1= doubtful narrowing of joint space and possible osteophytic lipping, 2=definite osteopytes, definite narrowing of joint space, 3=moderate multiple osteophytes, definite narrowing of joint space, some sclerosis and possible deformity of bone contour, 4=large osteophytes, marked narrowing of joint space, severe sclerosis and definite deformity of bone contour (Kellgren and Lawrence 1957).

The gait analysis method and data reduction of knee moments describe below are similar to those presented in Chapter 2 of this thesis. Three dimensional motion analysis during level walking and stair ascent was evaluated within one month before surgery, and 6 and 12 months after medial opening wedge HTO. Reflective markers were placed on each participant in a modified Helen Hayes configuration. Patients walked barefoot at a self-selected pace across an 8m walkway until five successful force plates strikes were collected (*i.e.,* the entire foot made contact with the plate, and there were no alterations in gait so as to hit the plate). Marker trajectories were captured at a rate of 60Hz using a 10-camera motion capture system (Motion Analysis Corporation, Santa Rosa, CA, USA). Ground reaction force data during level walking were recorded simultaneously with a ground-embedded force plate at 600Hz.

Subjects were also asked to perform three trials of stair-ascent at their self-selected pace. Subjects were barefoot, did not use a handrail for support and hit each step with one foot only. The staircase consisted of a series of five steps leading to a platform at the top (Figure 3.1). The steps (excluding the first step) were attached to two portable force plates (collecting a 600Hz) mounted on a custom made platform. The first step (8H x 11.5D x 36W inches) was a wood box (Step 1) that allowed subjects to step up to a portable platform with two mounted force plates and stairway system (7H x 11.5D x 23.75W inches) consisting of steps 2 to 5 (Advanced Mechanical Technology Inc., Watertown, MA, USA) (Croce and Bonato, 2007) (Figure 3.1).

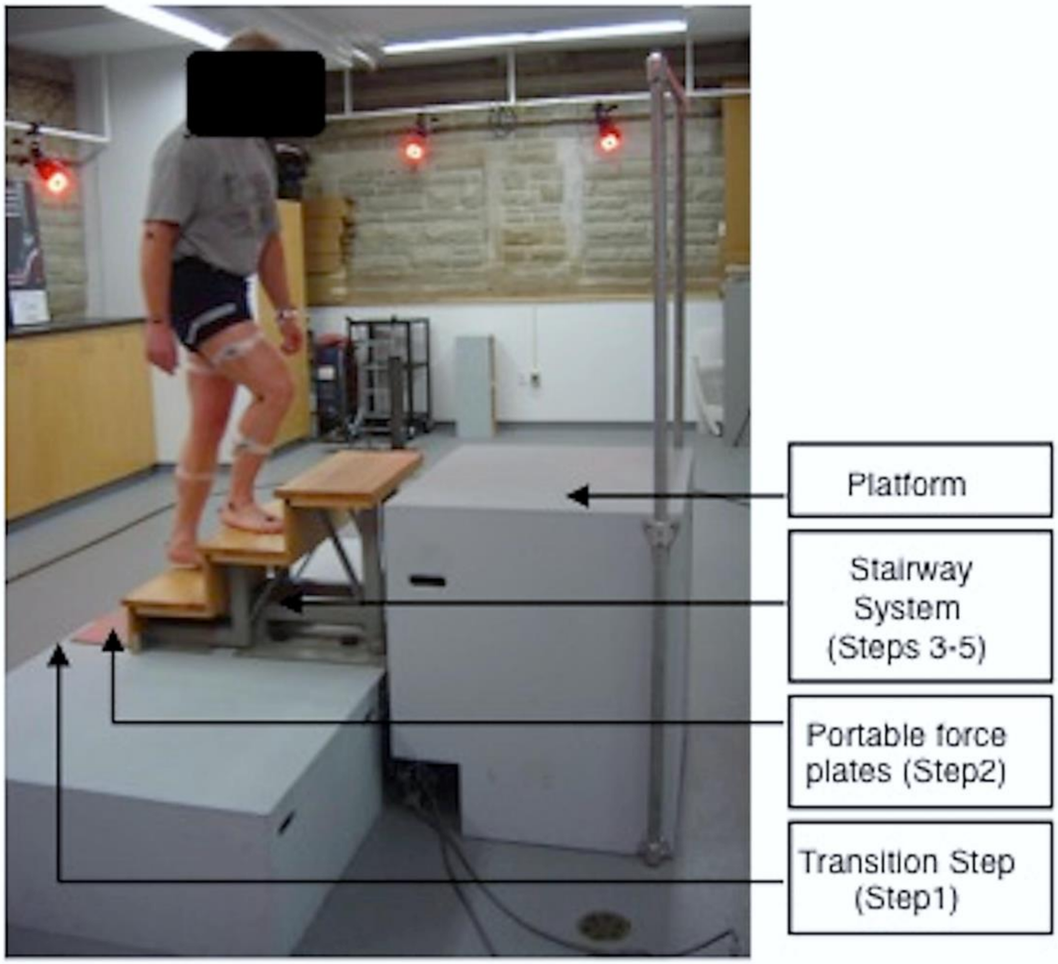

Figure 3.1: Staircase setup**.** The stairway system is bolted to the portable force plates. The surrounding boxes are independent of each other and do not touch the portable force plates.

3.2.2 Data Reduction & Analysis

Data were filtered using a two pass, fourth-order Butterworth filter at a cutoff frequency of 6Hz (Cortex-64 4.0, Motion Analysis Corporation, Santa Rosa, CA, USA, & Custom Programs, Visual Basics, Microsoft, Mississauga, ON, Canada). Moments about the knee were calculated from the camera and force plate data using inverse dynamics and expressed as external moments relative to the tibial anatomical frame of reference (Cortex-64 4.0, Motion Analysis Corporation, Santa Rosa, CA, USA). Using custom written programs (Visual Basics, Microsoft, Mississauga, ON, Canada) the stance phase was determined for knee moments in each of the three orthogonal planes of movement, then normalized to body weight and height (%Bw·Ht) and time normalized to 100% of stance. Peak values were identified and averaged over five trials for level walking and three trials for stair ascent, for the operative limb. From the stairs data, only the moments in the stance phase of the second ascending step were analyzed.

Lateral trunk lean (Hunt *et al.*, 2008) and walking speed (Robbins and Maly, 2009) were also evaluated because of their potential effect on knee moments. Trunk lean was evaluated by calculating the angle from a vertical line connecting the midpoints of the acromion processes and the midpoints of the anterior superior iliac spines (Hunt *et al.*, 2008). Walking speed was evaluated by calculating the distance the centre of mass travelled (change in distance) and dividing this value by the duration of the trial.

3.2.3 Statistical Analysis

Each peak moment was compared before and after surgery using a two-factor, ambulation condition (walking vs. stair ascent) by time (before HTO, 6 and 12 months after HTO) analysis of variance (ANOVA), with Scheffe post-hoc tests planned following significant main effects or interactions (STATISTICA, Release 7, Statsoft, Tulsa, OK, USA). Effect sizes describing the overall changes were calculated using standardized response means (*i.e.*, the mean change from preoperative to 12 months postoperative divided by the standard deviation of the change).

3.3 Results

Ensemble averages for the moments about the knee during 100% of stance for walking and stair ascent before and after HTO are illustrated in Figure 3.2. The 95% confidence intervals (CIs) are also shown for the peak mean values (Figure 3.2). Summary statistics for all variables are reported in Table 3.2. There were significant main effects for both the type of ambulation ($p<0.01$) and for time ($p<0.05$) for the peak knee adduction, flexion and internal rotation moments.

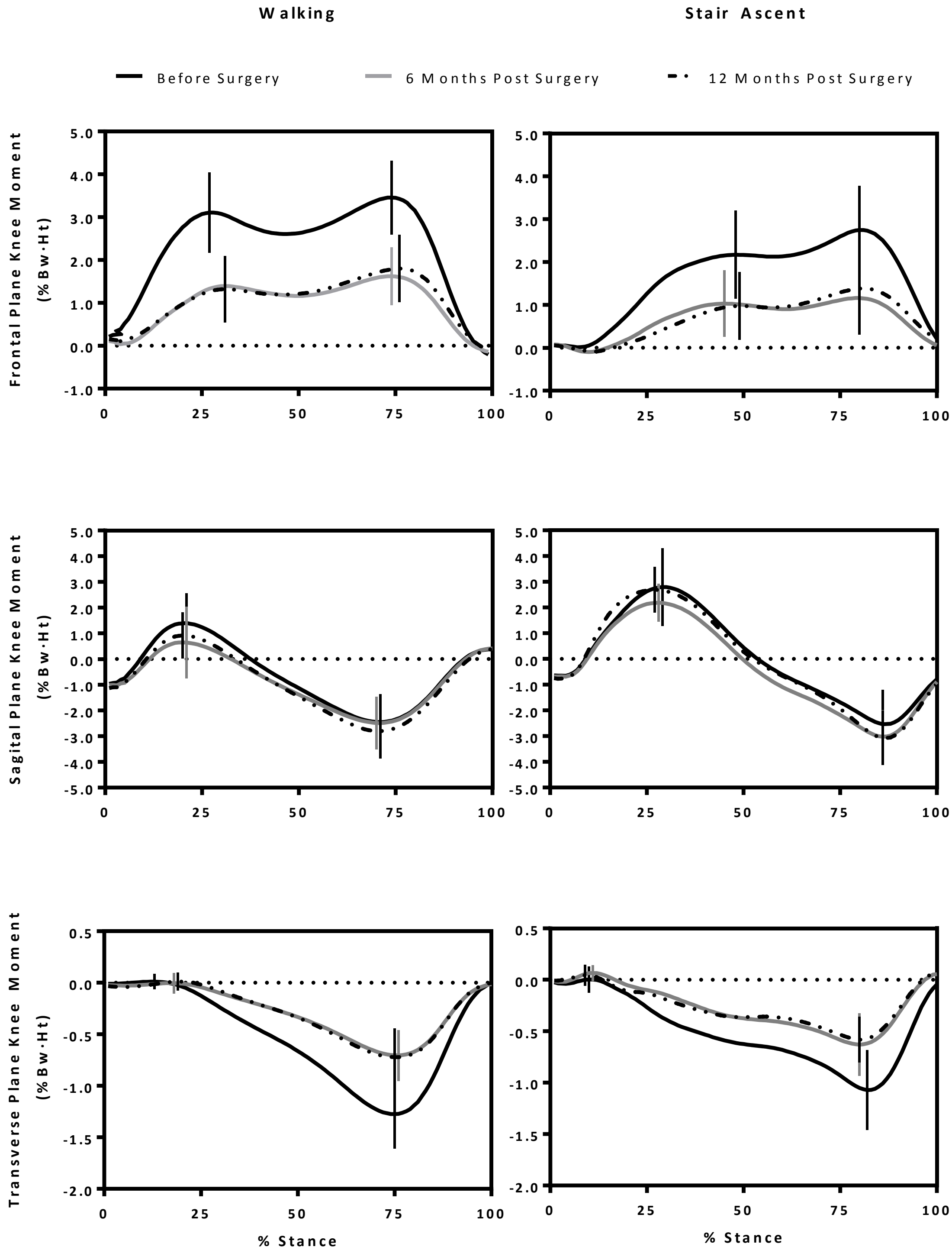

Figure 3.2: Ensemble averages (n=14) for external knee moments in all three orthogonal planes of movement plotted over 100% stance for level walking (left) and stair ascent (right) before, and 12 months after surgery. Vertical bars represent 95% confidence intervals for peak values.

Table 3.2: Descriptive statistics (mean, standard deviation, and mean change with 95% confidence interval) for knee moment variables and selected covariates.

	Before Surgery		**6 Months After Surgery**		**12 Months After Surgery**		**Overall Change**	
Peak External Knee Moments [n=14] (%Bw·Ht)	**Level Walking**	**Stair Ascent**	**Level Walking**	**Stair Ascent**	**Level Walking**	**Stair Ascent**	**Level Walking**	**Stair Ascent**
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (95% CI)	Mean (95% CI)
Adduction moment	3.60 (0.85)	3.00 (0.95)	1.88 (0.71)	1.41 (0.68)	1.93 (0.68)	1.66 (0.93)	-1.67 (-2.05, -1.29)	-1.34 (-1.94, -0.75)
Flexion moment	1.50 (1.11)	3.08 (1.52)	0.76 (1.27)	2.33 (0.74)	0.98 (0.93)	2.86 (0.83)	-0.52 (-1.00, -0.04)	-0.22 (-1.11, 0.66)
Extension moment	-2.60 (1.04)	-2.82 (1.22)	-2.63 (1.03)	-3.30 (1.01)	-2.87 (1.00)	-3.32 (0.86)	-0.27 (-0.78, 0.25)	-0.50 (-1.37, 0.37)
External rotation moment	0.06 (0.05)	0.07 (0.13)	0.05 (0.08)	0.11 (0.10)	0.05 (0.07)	0.13 (0.16)	-0.01 (-0.05, 0.03)	0.06 (-0.02, 0.13)
Internal rotation moment	-1.30 (0.33)	-1.12 (0.38)	-0.73 (0.25)	-0.66 (0.26)	-0.74 (0.27)	-0.63 (0.23)	0.56 (0.42, 0.70)	0.49 (0.34, 0.65)
Covariates								
Gait Speed (m/s)	1.13 (0.12)	0.46 (0.05)	1.11 (0.11)	0.46 (0.01)	1.19 (0.11)	0.50 (0.04)	0.06 (0.01, 0.10)	0.04 (0.02, 0.06)
Lateral Trunk Lean (º)	1.60 (2.19)	3.49 (2.34)	1.20 (1.75)	3.71 (2.74)	0.75 (1.35)	1.89 (1.76)	0.85 (0.01, 1.68)	1.60 (0.69, 2.50)

CI, Confidence interval

For the peak extension moment, there was a significant main effect for ambulation ($p=0.03$), but not for time ($p=0.31$). There were no effects on the peak external rotation moment ($p>0.1$). There were no significant interactions for all moments ($p>0.19$). The peak knee adduction ($p=0.001$) and extension moments ($p=0.028$) were lower during stair ascent than during level walking, while the peak knee flexion ($p<0.01$) and internal rotation moments ($p=0.003$) were higher (pre- and postoperatively). The peak knee adduction, flexion and internal rotation moments all significantly decreased 6 months after HTO during walking and stair ascent ($p<0.05$). There were no differences between 6 and 12 months postoperative ($p>0.3$); however, the peak flexion moment was only significantly different between the preoperative and 6-months postoperative conditions. The SRMs suggested overall large decreases in peak knee adduction moments (walking, SRM=2.54; stair ascent, SRM=1.30) and peak internal rotation moments (walking, SRM=2.36; SRM=1.84 stair ascent) from preoperative to 12 months postoperative.

For walking speed, there was a significant main effect for type of ambulation ($p<0.001$), with speed faster during walking than stairs. There was also a main effect for time ($p=0.005$), with speed increasing significantly at 12 months postoperatively for both walking and stairs ($p<0.005$). There was no interaction. For lateral trunk lean, there was a significant interaction between type of ambulation and time ($p=0.009$). There was a very small but statistically significant decrease in lateral trunk at 6 months for walking ($p<0.001$), but not for stairs ($p=0.9$). There were small decreases in trunk lean for both walking and stairs at 12 months postoperatively ($p<0.01$).

3.4 Discussion

Medial opening wedge HTO altered the external moments about the knee, in three planes, decreasing the peak adduction, flexion and internal rotation moments during walking. Although the observed changes in the sagittal and transverse planes are novel, the present knee adduction moments during walking, and their reductions after surgery, are comparable to other studies investigating the effects of medial opening wedge HTO

(Birmingham *et al.*, 2009; Leitch *et al.*, 2013; Wada *et al.*, 1998; Ramsey *et al.*, 2007; DeMeo *et al.*, 2010; Lind *et al.*, 2011; Prodromos *et al.*, 1985; Wang *et al.*, 1990; Weidenhielm *et al.*, 1995). When expressed as an overall change 12 months after surgery, these results indicate a large reduction in the knee adduction moment, with even the smallest change suggested by the 95% CI >35% (Table 3.2). Interestingly, there was also a relatively large decrease in the internal rotation moment, with even the smallest change suggested by the 95% CI >30%. The calculated SRMs also suggest that these are large effect sizes.

The present findings also expand on previous results by examining the change in knee moments during stair ascent. The preoperative peak knee adduction moments in this study during stair ascent (and during walking) were higher than those reported by Kaufman *et al.*, (2001) who also compared walking and stair ascent in individuals with knee OA. Differences between studies may due to differences in disease severity of the patients, with the present patients (awaiting surgery) presenting with more severe radiographic disease. When expressed as an overall change 12 months after surgery, these results for stair ascent indicate a relatively large reduction in the knee adduction moment, with even the smallest change suggested by the 95% CI >25% (Table 3.2). Similar to walking, there was also a relatively large decrease in the internal rotation moment during stair ascent, with even the smallest change suggested by the 95% CI >30%. Although smaller than those observed for walking, the SRMs also suggest these changes are large.

The present preoperative sagittal plane moments were similar to those reported in previous studies for level walking (Lind *et al.*, 2011; Kaufman *et al.*, 2001) and stair ascent (Kaufman *et al.*, 2001). The peak flexion moment 12 months postoperative was not significantly greater than preoperative values in the present patients. Although this is contrary to the findings reported by Lind *et al.*, (2011), those authors suggested dissimilarity between studies might be attributed to differences in the observed changes in walking speed after surgery.

Importantly, changes in sagittal and transverse planes observed after surgery, during walking and stair ascent, suggest a change in the distribution of loads on the knee beyond what is indicated by the knee adduction moment alone. Sagittal plane moments about the knee during walking also contribute to changes in directly measured medial compartment loading at the knee (Walter, 2010; Schipplien and Andriacchi, 1991). Patients in the present study experienced a statistically significant decrease in the peak knee flexion moment 6 months postoperatively, indicating a possible decrease in medial compartment loading. However, the peak knee flexion moment returned to almost the preoperative level by 12 months postoperatively for both walking and stair ascent. Therefore, medial opening wedge HTO may not have an effect on sagittal plane moments other than during rehabilitation after surgery. The potential longer-term effect of medial opening wedge HTO on knee flexion moments requires further research.

In addition to changes in the frontal plane, the changes in transverse plane moments observed after surgery, during stair climbing and walking, also suggest a change in the distribution of loads on the knee. Changes in the transverse plane moments may result in changes in the knee’s load-bearing region (Andriacchi *et al.*, 2004). Moreover, transverse plane moments about the knee may also be associated with articular cartilage degeneration (Henriksen *et al.*, 2012).

Limitations in making inferences about knee joint loads based on external moments about the knee must be acknowledged (Walter *et al.*, 2010). Other limitations in this study include the use of different force plates during walking and stair ascent. Although this may affect the comparison of moments between these two modes of ambulation, it does not affect the comparisons evaluating the changes as a result of surgery. Another limitation is the modest sample size, although the confidence intervals around the changes are quite narrow.

In summary, the results of this study suggest that medial opening wedge HTO results in long-term (12 month) changes in knee moments in the transverse plane in addition to the frontal plane. The results also suggest that these moments are decreased during both level walking and stair ascent. Overall, these results support medial opening wedge HTO as a mechanism for altering medial compartment loading.

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Chapter 4

Development of a Multi-Axis Fixation Jig for Testing High Tibial Osteotomy Plates: An Application of In-Vivo Gait Data

Overview: *The purpose of this study was to develop and test a multi-axis fixation jig placed within a materials testing machine for assessing medial opening wedge high tibial osteotomy (HTO) fixation plates in a manner more representative of walking. In-vivo gait data were used to design the jig and assign appropriate in-vitro parameters. A medial opening wedge HTO was then performed on a composite bone and the jig was used to test strain on the bone's lateral cortical hinge and on the fixation plate while applying loads of 900N and 1400N at frontal plane lever arms of 0cm and 3cm. Testing was repeated on one and two test days to determine reliability. The 3cm lever arm resulted in significantly (p<0.001) greater axial strain on the cortical hinge than all other testing conditions, when using loads of 900N and 1400N. The 3cm lever arm also resulted in significantly (p<0.012) greater axial strain on the fixation plate when using the 1400N load. Averaging multiple test sessions resulted in coefficients of variation for between-day reliability of <7%. Overall, these results suggest applying load at a lever arm should be taken into consideration in future testing of medial opening wedge HTO fixation plates*[3].

[3] A version of this chapter is under review: Leitch, K.M., Birmingham, T.B., Reeves, J.M., Giffin, J.R., Dunning, C.E., 2013. Development of a multi-axis fixation jig for testing high tibial osteotomy plates: An application of *in-vivo* gait data. J Biomech.

4.1 Introduction

Knee osteoarthritis (OA) is one of the fastest growing chronic health conditions globally (Vos *et al.*, 2010). With no treatments proven to alter the course of this disease, research efforts focusing on ways to slow OA progression are required (Hunter, 2011). Gait biomechanics plays an important role in knee OA and helps explain why the medial compartment of the tibiofemoral joint is most commonly affected (Andriacchi *et al.*, 1994; 2006). During the stance phase of gait, the line of action of the ground reaction force (GRF) typically passes medial to the knee joint, producing a lever arm in the frontal plane. This creates an external adduction moment about the joint, and greater loads on the medial compartment relative to the lateral compartment (Figure 4.1A)(Andriacchi *et al.*, 1994; Halder *et al.*, 2012; Hunt *et al.*, 2006; Schipplein and Andriacchi, 1991). Medial opening wedge high tibial osteotomy (HTO) is a biomechanically-based surgical procedure that alters how load is distributed within the tibiofemoral joint (Amis, 2013). Gait studies demonstrate that medial opening wedge HTO can produce substantial decreases in the external knee adduction moment (Prodromos *et al.*, 1985; Birmingham *et al.*, 2009). This change in load distribution is achieved by realigning the mechanical axis of the tibia, thereby decreasing the frontal plane lever arm.

The medial opening wedge HTO technique creates a gap or void in the proximal tibia during realignment of the tibia. Stable fixation of the gap, good surgical technique and patient compliance are essential to avoid loss of correction, non-union, or collapse prior to the bone healing (Amendola, 2003; Brinkman *et al.*, 2008; 2010; Magyar *et al.*, 1999). Various fixation techniques for medial opening wedge HTO have been tested *in-vitro*, whereby fixation plates applied to cadaveric or composite bone specimens have been loaded in materials testing machines (Agneskirchner *et al.*, 2006; Miller *et al.*, 2005; Hernigou *et al.*, 1987; Stoffel *et al.*, 2004; Spahn and Wittig, 2002; Pape *et al.*, 2010; Maas *et al.*, 2013). The specimen alignment and loading direction most often used in these types of studies have been based on anteroposterior (AP) radiographs and the desired shift in the location of the weight-bearing line (WBL), a measure of the mechanical axis of the lower limb (Figure 4.1B) (Fujisawa *et al.*, 1979).

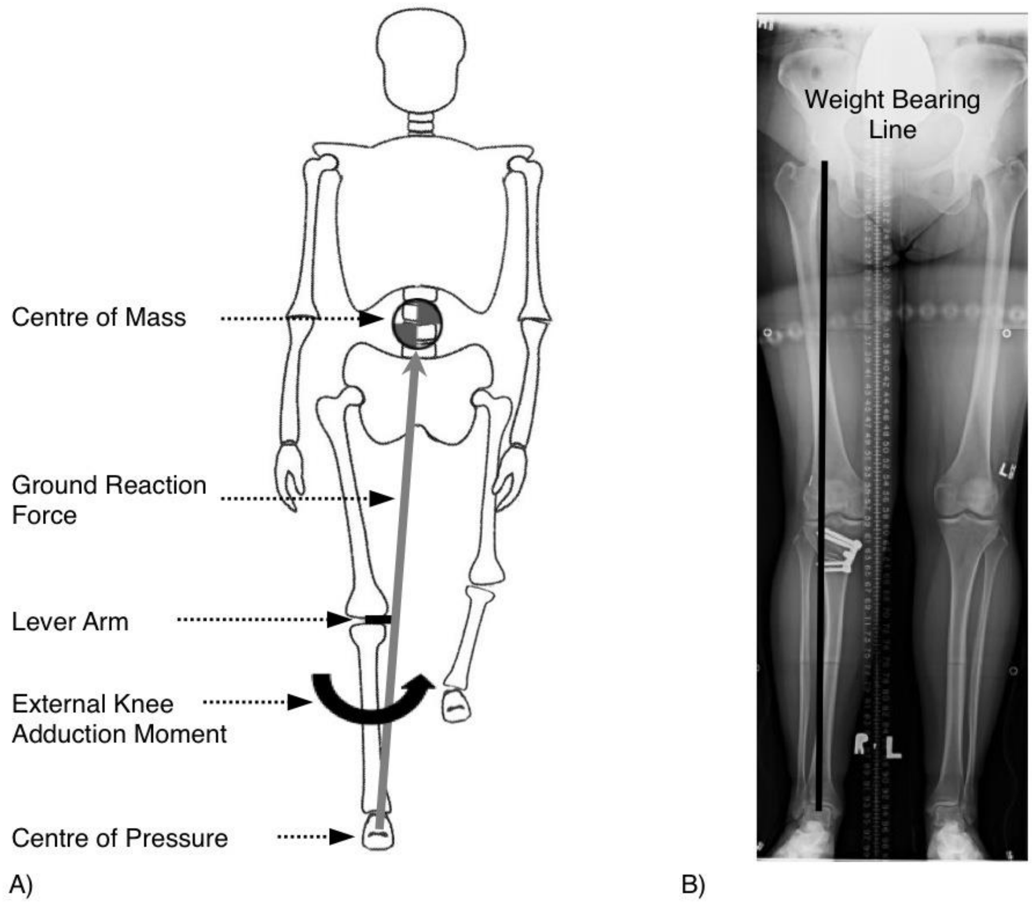

Figure 4.1: External knee adduction moment versus weight-bearing line **A)** Schematic of the external knee adduction moment. The knee adduction moment is derived using inverse dynamics (which analyzes the foot and tibia as separate segments unlike the simplified schematic) and is primarily the product of the magnitude of frontal plane ground reaction force (GRF) and the perpendicular distance between the projection vector and the knee joint center of rotation (lever arm). Adapted from Perry J, (1992). **B)** Weight-bearing line (WBL) of a lower limb after medial opening wedge HTO. The WBL is drawn from the center of the hip to the center of the ankle. The typical aim of medial opening wedge HTO is to move this line to a 62% lateral offset from the knee joint center (Fujisawa *et al.*, 1979).

Although such static measures of limb alignment are correlated with the external knee adduction moment during walking, they may not adequately represent dynamic knee joint loading (Leitch *et al.*, 2013; Specogna *et al.*, 2007; Hurwitz *et al.*, 2002; Wada *et al.*, 1998; 2001; Hilding *et al.*, 1995). Using *in-vivo* gait analysis data to establish experimental parameters for testing medial opening wedge HTO fixation devices could provide further insight for optimal fixation designs. Specifically, variables known to be primarily responsible for external loading of the knee during walking, such as the frontal plane lever arm, frontal plane GRF, and tibiofemoral angles, may affect materials testing results (Andriacchi *et al.*, 1994; Hunt *et al.*, 2006; Birmingham *et al.*, 2009; Jenkyn *et al.*, 2008).

The purpose of this study was to develop and test a multi-axis fixation jig placed within a materials testing machine for assessing medial opening wedge HTO plate fixations in a manner more representative of walking. The specific objectives of this study were to: (i) design the jig based on gait variables known to contribute to the external knee adduction moment as opposed to static alignment measures; (ii) compare strain on the lateral aspect of the tibial osteotomy (cortical hinge) and strain on the medial opening wedge HTO plate under different lever arm conditions; and (iii) to evaluate the reliability of the strain measures obtained within and between test sessions. Hypotheses were that the lateral cortical hinge and medial opening wedge HTO plate would experience more strain when load was applied at a lever arm, and that the strain measures obtained within and between test sessions would be reliable with coefficients of variation (CoVs) < 10%.

4.2 Methods

4.2.1 Overall Study Design

In-vivo gait data from an existing database were analyzed and descriptive statistics for variables of interest were calculated. Gait data were then used to design the multi-axis fixation jig to accommodate the spread in those variables and to assign appropriate *in-vitro* parameters. A medial opening wedge HTO was then performed on a varus composite bone and the strain on the lateral cortical hinge and plate were compared using the new jig under different lever arm conditions. Testing was repeated on two days to determine reliability.

4.2.2 Gait Analysis & Multi-axis Fixation Jig Design

Patients with medial compartment knee OA underwent gait analysis before and two years after medial opening wedge HTO (n=165, age = 49 ± 9 years, BMI = 30.2 ± 5.1 kg/m^2). A high resolution optical motion capture system with passive reflective markers and a floor mounted force plate were used to collect 3D kinematic and kinetic gait data while patients walked barefoot at a self-selected pace in the laboratory. A detailed description of the gait analysis methods has been previously reported (Hunt *et al.*, 2006; Birmingham *et al.*, 2009; Jenkyn *et al.*, 2008). The external knee adduction moment was calculated using inverse dynamics and transformed into the local coordinate system of the shank (Andriacchi *et al.*, 1982). At the time corresponding to the peak knee adduction moment the following variables were obtained: frontal plane GRF, lever arm (the distance between the frontal plane GRF vector and the knee joint center), and tibiofemoral angles in all three planes.

The multi-axis fixation jig was designed based on the spread of each gait variable both preoperatively and postoperatively. The jig was machined from stainless steel on a CNC machine for accuracy and designed to be integrated within a material testing machine (Model 8874; Instron, Canton, MA).

4.2.3 Bone Preparation

Fourth generation composite tibia and femur bones were used (Model: 3403, 3401-1, Sawbones®, Pacific Research Laboratories, Inc., Vashon, WA, USA). The tibia was fabricated to incorporate a 10° varus deformity. This was corrected using a medial opening wedge HTO completed by a fellowship-trained surgeon who performs over 50 of these procedures yearly. Using an oscillating saw, an oblique cut was made starting approximately 30mm below the medial surface of the tibia, and extended 5-10mm short of the lateral tibia cortex to reproduce the intact lateral cortical hinge desired in the true surgical procedure. The osteotomy was carefully opened using a graduated wedge over several minutes to avoid fracturing the lateral cortical hinge. After opening the osteotomy, a 71mm Flat Contour Lock HTO Plate (Arthrex®, Naples, FL, USA) was secured according to manufacturer guidelines. The tibia and femur composite bones where then trimmed of their distal and proximal ends, respectively, and potted in bone cement (Denstone; Heraeus, South Bend, Indiana). The tibia was laser aligned at an angle of 15° with respect to the femur (Note: This represented the median flexion angle at the time of peak external knee adduction moment from the *in-vivo* patient data.) The femur was potted vertically.

4.2.4 Strain Testing

A 45° stacked strain gauge rosette was glued to the lateral proximal tibia at the lateral cortical hinge, with the middle gauge of the rosette configuration aligned with the longitudinal axis of the tibia. A second strain gauge was glued to the HTO plate at the level of the osteotomy. The middle gauge of the rosette configuration was aligned along the longitudinal axis of the plate. Each gauge was wired independently into a quarter bridge completion circuit (Vishay Intertechnology, Inc., Malvern, PA, USA). Strains on the plate and on the bone were initially evaluated at a 0cm lever arm to represent the alignment typically used during *in-vitro* plate fixation testing. Testing was also performed with an offset lever arm, the magnitude of which was determined from the gait data to represent the median lever arm from the *in-vivo* patient data following medial opening wedge HTO. Testing was conducted at two load levels: a lower load that represented the median frontal plane vertical GRF from the *in-vivo* patient data and a higher load that represented the extreme values.

Four testing conditions were evaluated in the following order (lever arm = 0cm, offset value, 0cm, and 0cm). The 0cm lever arm condition was repeated to assess any fixation loosening, hysteresis or creep that may occur over multiple testing conditions. To replicate the proper conditions at the offset lever arm *in-vitro*, the tibia was angled and translated in the frontal plane according to the gait data (*e.g.*, for a 3cm lever arm, the tibia was angled at 3.5° of varus and translated along the linear bearing rail to a marked 1cm location). The femur was also angled by an equivalent amount to ensure congruency of the tibia and femur surfaces. A custom fabricated cast ensured consistent alignment between each test condition. Specimens were loaded using the materials testing machine, which was operated in load control and held the target load for 10s over three cycles at each lever arm condition. Axial force and stain data were collected at a sampling rate of 1kHz (National Instruments NI-PXI 1050, and SCXI 1010) using a custom data collection program (LabVIEW 2008, National Instruments, Austin, TX, USA). The experimental setup was dismantled, reassembled and repeated three times within one test day to determine within-session reliability and between-session (within-day) reliability. The setup was also reassembled and repeated the next day to determine between-day reliability.

4.2.5 Statistical Analyses

Box and whisker plots were created for each gait variable using both the preoperative and postoperative data to identify measures of central tendency and dispersion. Strain data were averaged over the central 8 seconds of the loading period for each cycle. All three cycles were then averaged together to produce strain for each loading condition. Repeated measures ANOVAs were then used to compare the different conditions. Tukey post-hoc analyses were planned following a significant main effect, with statistical significance set at 0.05. Axial strain data measured on the lateral cortical hinge during the offset lever arm condition with the median load was used to evaluate reliability. Coefficients of variation (CoVs) expressed as percentages were used to describe the within-session reliability (three repeated trials), within-day reliability (three repeated sessions in one day) and between-day reliability (first session on day 1 and day 2).

4.3 Results

4.3.1 Gait Analysis

The median, upper and lower quartiles and 1.5 the inter-quartile range for frontal plane lever arm and GRF, tibiofemoral angles in all three planes, and the angle of the tibia with respect to the GRF are shown in Figure 4.2. There was considerable spread in the gait variables examined. Variables that changed most after medial opening wedge HTO included the frontal plane lever arm, knee adduction/abduction angle and the angle of the tibia with respect to the GRF. The median lever arm post-operatively was 3cm. The median GRF post-operatively was 900N, with an extreme value of 1400N.

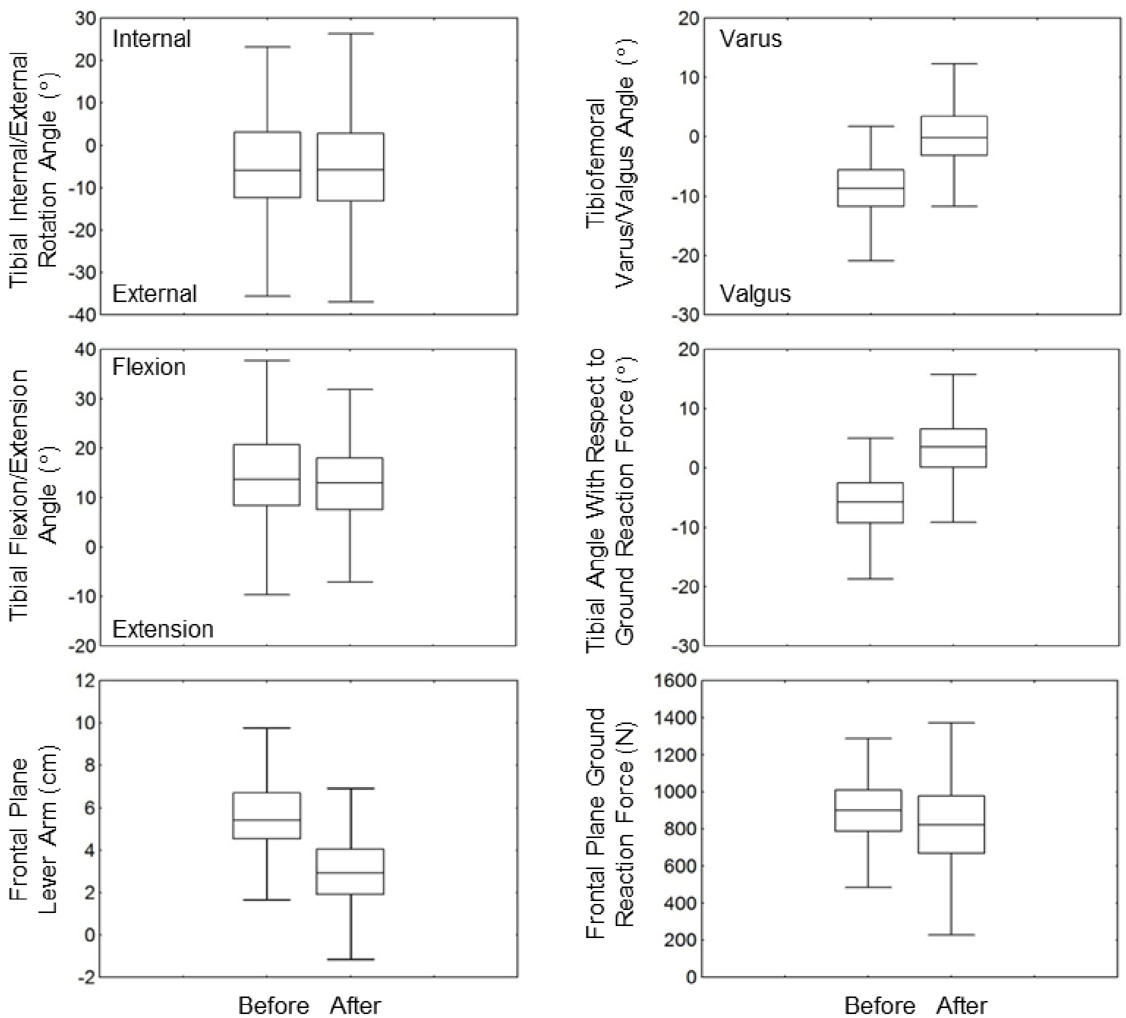

Figure 4.2: Box and whisker plots for gait variables at the time of peak knee adduction moment. The data presented on the left of each plot were collected from 165 patients before high tibial osteotomy surgery. The data on the right were collected from the same patients 2 years after surgery. The central mark represents the median, the edges of the box are the 25th and 75th percentiles, and the whiskers extend to the most extreme data points not considered outliers (Non-Outlier Region).

4.3.2 Multi-axis Fixation Jig

The multi-axis fixation jig is illustrated in Figure 4.3. It enables specimens to be rigidly fixed to the device and the table of the materials testing machine using custom machined potting mounts. To accommodate the range in the frontal plane lever arm from the *in-vivo* gait data, the device has capacity to translate up to ±10cm horizontally along a linear bearing rail in 1cm increments. The position is held by two locking pins. The device is able to rotate about its vertical and anterior-posterior axes to accommodate knee adduction/abduction and internal/external rotation angles. Desired angulations up to ±30° (0.5° increments) and rotations of up to ±10° (5° increments) are achieved with the use of precision drilled plates.

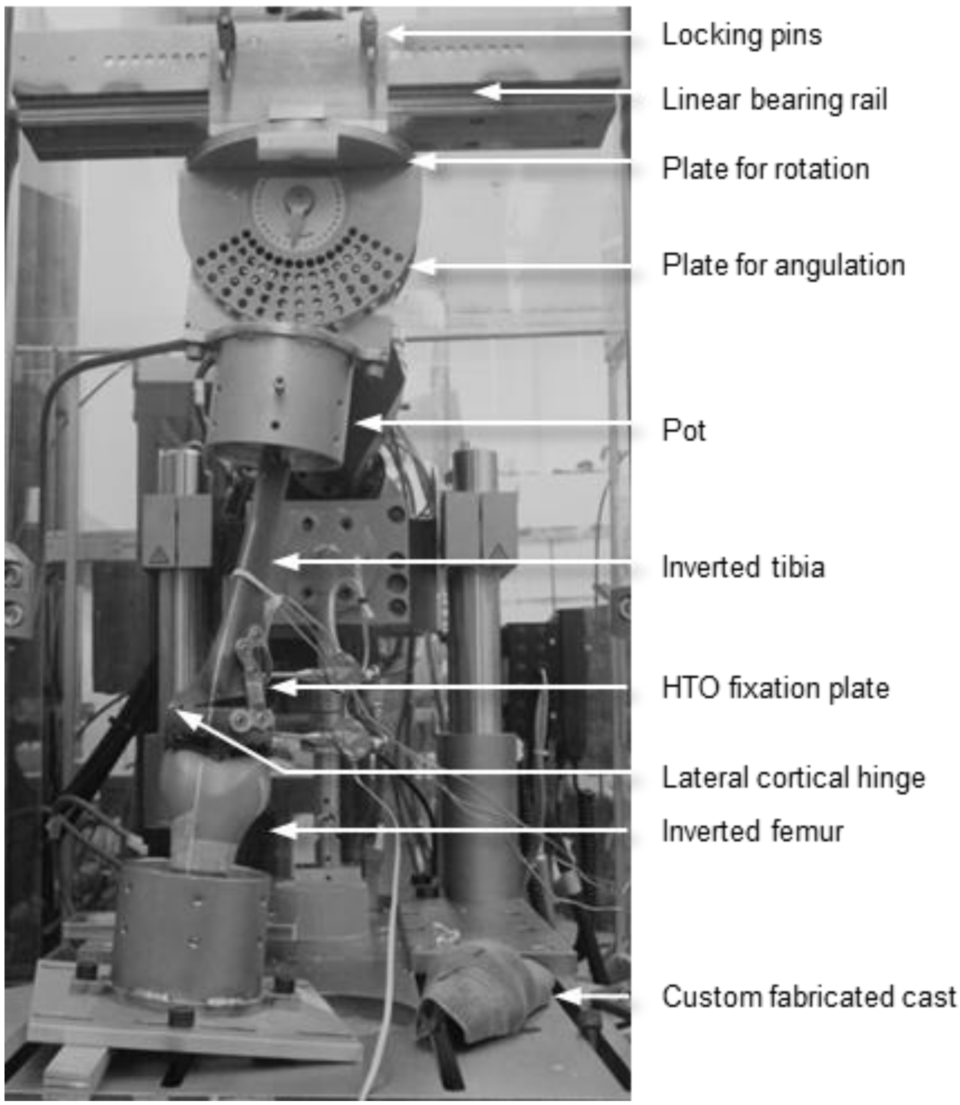

Figure 4.3: Photograph of inverted tibia and femur sawbones mounted in the multi-axis fixation jig. Strain gauges were affixed to the HTO fixation plate and to the lateral cortical hinge.

4.3.3 Strain Testing

Strain measurements were statistically different for the different testing conditions. There was a significant main effect for testing condition when axial strain on the lateral cortical hinge was tested under a load of 900N ($p<0.001$). Post-hoc analyses indicated the 3cm lever arm resulted in significantly greater axial strain than all other testing conditions ($p<0.001$) (Figure 4.4A). No other significant differences were detected ($p>0.05$). There was no significant main effect for testing condition when axial strain on the medial opening wedge HTO plate was tested under a load of 900N ($p=0.60$) (Figure 4.4B).

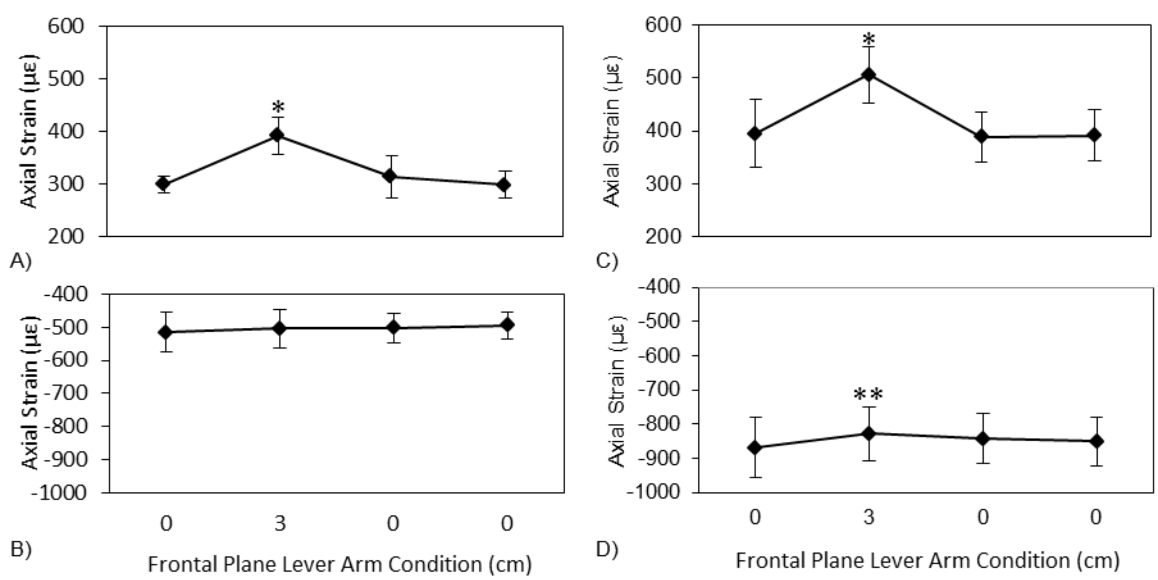

Figure 4.4: Means +/-SD for axial strain on the lateral cortical hinge (**A & C)** and on the medial opening wedge HTO plate **(B & D)** with a load of 900N **(A & B)** and 1400N **(C & D)** for each test condition.
*significant difference between the 3cm lever arm and all other lever arm condition**.**
** significant difference between 3cm lever arm and first 0cm lever arm condition only.

Increasing the load to 1400N resulted in a significant main effect for testing condition when evaluating strain on both the lateral cortical hinge ($p<0.0001$) and on the medial opening wedge HTO plate ($p<0.0216$). Post-hoc analyses indicated the 3cm lever arm resulted in significantly greater axial strain on the lateral cortical hinge compared to all other testing conditions ($p<0.001$) (Figure 4.4C), and significantly greater axial strain on the medial opening wedge HTO plate compared to the first 0cm lever arm testing condition only ($p<0.012$) (Figure 4.4D). Coefficients of variation for within-session reliability ranged from 2.80% to 17.96%, while CoVs for within- and between-day reliability were 4.81% and 6.59%, respectively (Table 4.1).

Table 4.1: Test Re-Test Reliability

	Session	**Cycle**	**Strain [με]**	**Within-Session CoV [%]**	**Strain for Each Session [με]**	**Within-Day CoV [%]**	**Between-Day CoV [%]**
Day 1	1	1	400.12	2.80	413.23	4.81	6.59
		2	421.91				
		3	417.68				
	2	1	371.92	3.33	386.70		
		2	395.48				
		3	392.71				
	3	1	364.28	6.02	391.00		
		2	400.11				
		3	408.60				
Day 2	1	1	299.90	17.96	376.43		
		2	401.37				
		3	428.01				

CoV, Coefficient of Variation
Within-Session CoV, three repeated cycles
Within-Day CoV, three repeated session in one day
Between-Day CoV, two repeated session on two days

4.4 Discussion

The present results show that *in-vivo*, 3D gait analysis can inform *in-vitro* materials testing of medial opening wedge HTO plate fixations. To our knowledge, this is the first study to incorporate such data in plate testing. Experimental protocols usually rely on static radiographic measures of bony alignment because they are used by surgeons to determine the optimal correction (Amendola, 2003; Fowler *et al.*, 2000). For that reason, the use of those measures for experimental testing is reasonable and those studies do provide useful information about HTO plate fixations. However, the best fixation device is still controversial. This study demonstrates that applying a load at a lever arm in the frontal plane to generate an adduction moment similar to what occurs during walking will result in significantly higher strain on the lateral cortical hinge and on the medial opening wedge HTO plate. Therefore, we suggest that applying a load at a lever arm when assessing medial opening wedge HTO plate fixations will provide additional, important information.

The present findings also suggest reasonable within-day (CoV< 5%) and between-day reliability using these methods (CoV<10%) (Table 4.1). It should be noted, however, that the first cycle on Day 2 was quite variable, resulting in a CoV of 18%. Overall these values suggest reasonable measurement error, yet emphasize the importance of incorporating multiple testing cycles to improve reliability of strain measurements.

Previous biomechanical investigations comparing HTO fixations have reported one of the most common points of failure to be at the lateral cortical hinge (Agneskirchner *et al.*, 2006; Stoffel *et al.*, 2004; Spahn and Wittig, 2002; Pape *et al.*, 2010). Miller *et al.*, (2005) demonstrated that a disruption of the lateral cortical hinge leads to increased micro-motion at the osteotomy site. Excessive micro-motion may contribute to delayed union or non-union (Brinkman *et al.*, 2008; 2010; Magyar *et al.*, 1999) and subsequent tendency to recurrent varus malalignment (Stoffel *et al.*, 2004; Luites *et al.*, 2009). Future testing of medial opening wedge HTO fixation plates that incorporate a lever arm in the loading protocol will provide further insight into which plates prevent the failure of the lateral cortical hinge, and which plates can produce more stability in the event of a breached lateral cortical hinge.

Maas *et al.,* (2013) demonstrated that lateral cortical breach after medial opening wedge HTO occurs at smaller loads during cyclic loading compared to static load to failure. Also, Miller *et al.*, (2005) and Stoffel *et al.,* (2004) showed decrease rigidity under torsional loading in cases where the lateral cortical hinge was disrupted. Stoffel *et al.*, (2004) further showed that failure occurs only after exceeding internal rotation moments similar to those experienced during walking. The present results add to those previous studies by demonstrating that incorporating a frontal plane lever arm will also help simulate functionally relevant conditions when testing medial opening wedge HTO plates, especially if investigating a breach of the cortical hinge.

The force across the knee represents the summation of dynamic forces, body weight and muscle forces, where the muscle force produces the major portion of the force (Andriacchi, 2013). It is currently unclear how muscle forces may affect loading of the lateral cortical hinge and the medial opening wedge HTO plate, as they are located distal to the knee and have far fewer muscles crossing them. In this study, we used both the median and extreme GRFs observed from the gait data to account for such variation. However, it is possible that dynamic loads experienced during recovery after surgery may be higher or lower than used presently. In either case, the present results suggest that incorporating a lever arm during such testing is important.

In summary, this study introduced a multi-axis fixation jig that was designed based on *in-vivo* gait data. Using this device, results demonstrated that applying load at a lever arm in the frontal plane increases strain on the tibial osteotomy lateral cortical hinge and on the medial opening wedge HTO plate. The test-retest reliability of the resulting strain measures was reasonable. Therefore, applying load at a lever arm in the frontal plane should be taken into consideration in future testing of medial opening wedge HTO fixation plates.

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Chapter 5

In-vitro Biomechanical Investigation of Plate Designs Used For Medial Opening Wedge High Tibial

Overview: The purpose of this study was to compare medial opening wedge HTO fixations performed with either a flat or toothed Contour Lock plate, during cyclic loading conditions. The osteotomies were performed on composite bones and a fixation jig was used within a materials testing machine to apply cyclic loads from 900N and 2400N until failure occurred. Motion across the osteotomy, strain on the bone's lateral cortical hinge and on the fixation plates, and load at failure were evaluated. To date, five specimens have been tested. Although the number of specimens is currently too low to allow for statistical comparison, it appears there is little difference in the load at failure for the tooth versus the flat plate. Preliminary findings suggest the flat plate may provide more stability than the tooth plate for medial opening wedge HTO during dynamic loading of the bone-implant construct in terms of maximum load at failure. However, the tooth plate is better for maintaining the osteotomy and provides more stability in the event of lateral cortical hinge rupture. Both plates provide sufficient strength, because the lateral cortical hinge in this model appears to be weaker than either plate.

5.1 Introduction

Medial opening wedge high tibial osteotomy (HTO) is a well-established procedure for the treatment of varus osteoarthritis of the knee (Fowler *et al.*, 2000; Amendola and Bonasia, 2010). The goal of the surgery is to change the mechanical axis of the lower limb by creating a gap in the proximal tibia to redistribute and lessen the load on the medial compartment of the knee. The gap created by the osteotomy requires stabilization with a surgical device to promote healing and bony union (Amendola, 2003; Brinkman *et al.*, 2008; 2010; Magyar *et al.*, 1999).

There are several options for fixation of medial opening wedge HTO, including a commonly used plate-based system known as the Contour Lock HTO plate (Arthrex, Naples, FL). This plate has multi-directional locking screws and is anatomically contoured for a precise fit both proximal and distal to the osteotomy site. There are several different design features available for this locking plate, with the main difference being the presence of a wedge insert or “tooth” on two of the three plate options (with the wedge being either rectangle or anterior/posterior sloped). The tooth is intended to help maintain the correction during plate fixation by providing some cortical load sharing to the osteotomy to help prevent collapse during healing and limit micro-motion across the osteotomy site. Although the tooth may provide advantages to both patients and surgeons, it also has some disadvantages. It leads to higher manufacturing and inventory costs due to the number of different plates that need to be produced. Moreover, despite the large number of plate sizes that are currently offered, the exact plate size for a desired correction in either the coronal or sagittal plane may not be available with the stocked incremental tooth sizing. In situations such as this, the “no-tooth” or flat plate allows for more custom, precise corrections, especially when adjusting the posterior slope of the tibia. However, without the potential cortical support/load transfer the tooth is purported to provide, it has been speculated that the flat plate maybe inferior in terms of preventing collapse of the osteotomy and limiting micro-motion that may be detrimental to long-term healing.

Therefore, the aim of this study was to compare medial opening wedge HTO fixations performed with either a flat or toothed Contour Lock plate, during cyclic loading conditions by quantifying resulting load at failure, micro-motion across the osteotomy site and strain on both the plate and the lateral cortex of the tibia. We hypothesized that there would be no difference between the two plates with respect to any of these measures (*i.e.*, load at failure, micro-motion, and plate/bone strains).

5.2 Methods

Initial testing used five fourth generation composite tibias (model: 3403, 3401-1, Sawbones®, Pacific Research Laboratories, Inc., Vashon, WA, USA) with a pre-exiting 10° varus deformity. Specimen preparation involved correcting the deformity to approximately neutral alignment using a medial opening wedge HTO, completed by a fellowship-trained surgeon who performs over 50 of these surgeries yearly. As part of the procedure, an oblique cut was made starting approximately 25-30mm below the medial surface of the tibia, and extended 5-10mm short of the lateral tibia cortex to reproduce the intact lateral cortical hinge desired in the true surgical procedure. The osteotomy was carefully opened using a graduated wedge over several minutes and applying gentle heat to the lateral cortical hinge to avoid fracturing the lateral cortical hinge. After opening the osteotomies, three osteotomies were fixed with a 71mm Flat Contour Lock HTO Plate (Arthrex®, Naples, FL, USA) and the other two osteotomies were fixed with a 9mm anterior/posterior sloped wedge (tooth) Contour Lock HTO Plate Arthrex®, Naples, FL, USA) (Figure 5.1). Both plate fixations were secured according to manufacturer guidelines. The tibia composite bones where then trimmed of their distal ends, and potted in bone cement (Denstone; Heraeus, South Bend, Indiana). The tibias were aligned at an angle of 15° with respect to vertical using a laser level. (Note: This represented the median flexion angle at the time of peak external knee adduction moment from the *in-vivo* patient data.).

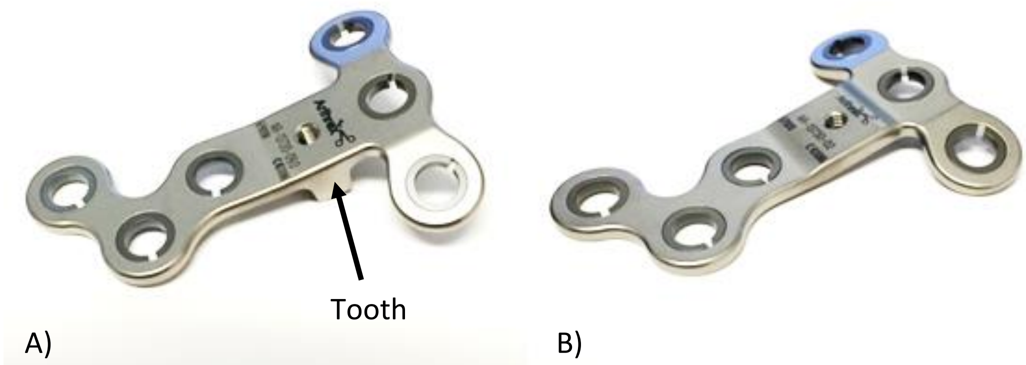


Figure 5.1: Medial opening wedge HTO plates. The **A)** 9mm A/P sloped wedge Contour Lock HTO Plate (tooth) and **B)** 71mm Flat Contour Lock HTO Plate (flat). Both plates are pre-contoured to fit the metaphysis.

A custom multi-axis fixture specifically designed to test HTO fixations in a manner representative of single limb support during walking was used with an Instron® materials testing machine (Chapter 4). The Instron® was operated in load control to apply compressive forces 3cm medial to the joint centre using a cyclic staircase load to failure protocol (Figure 5.2) based on the load levels observed in the post-operative gait data presented in Chapter 4. Using a frequency of 1.8Hz, the load was cycle between a lower bound of 200N and an upper bound that started at 800Nand was increased by 200N every 5000 cycles until failure was achieved. Failure was defined as, breakage of the plate, or breakage of the lateral cortical hinge or the propagation of the crack through the proximal tibia that resulted in the segment being separated into two pieces.

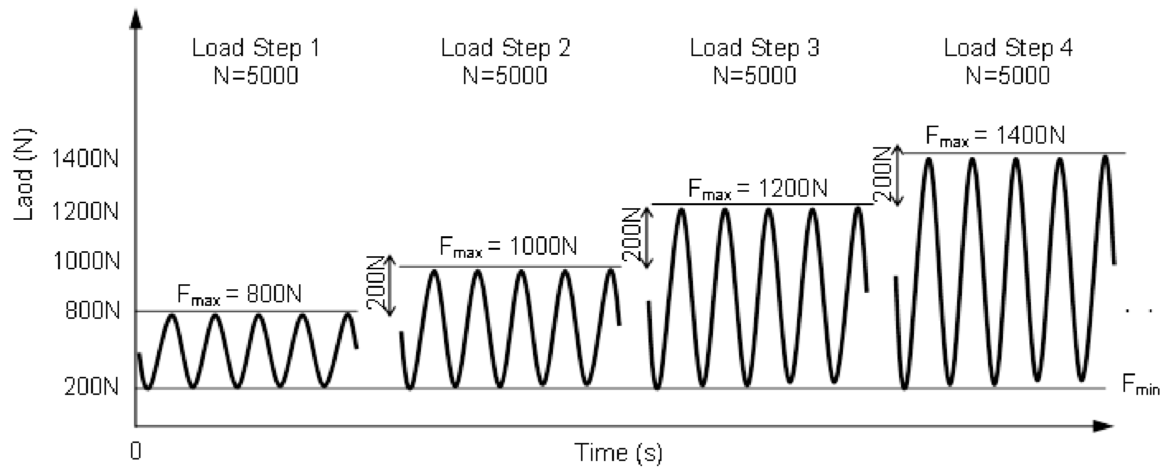
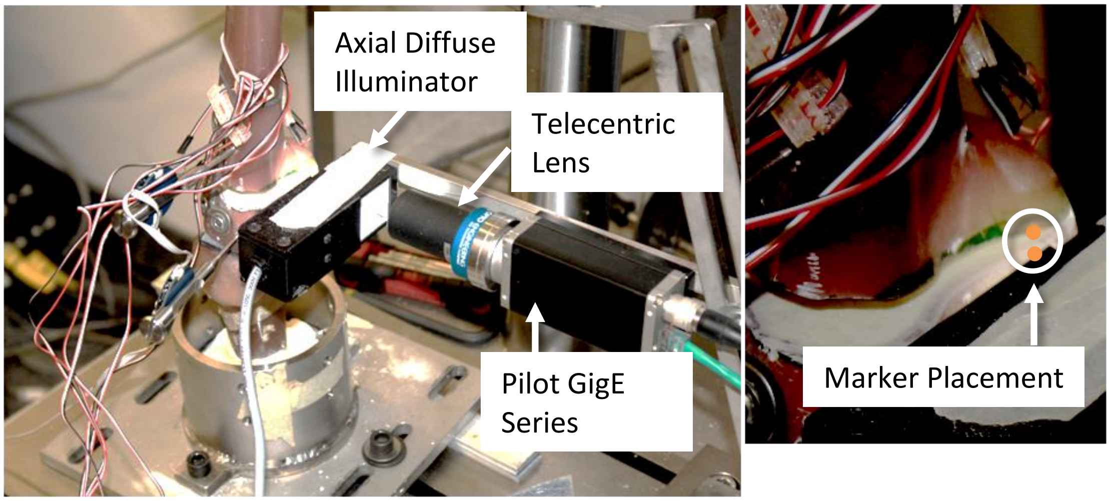


Figure 5.2: Schematic of the staircase loading protocol. After each set of N=5000 cycles, the upper force was increased stepwise by 200N until the test is stopped by specimen failure (the lower force remains constant at 200N throughout testing). The loading frequency was to 1.8Hz and the materials testing machine was operated in load control.

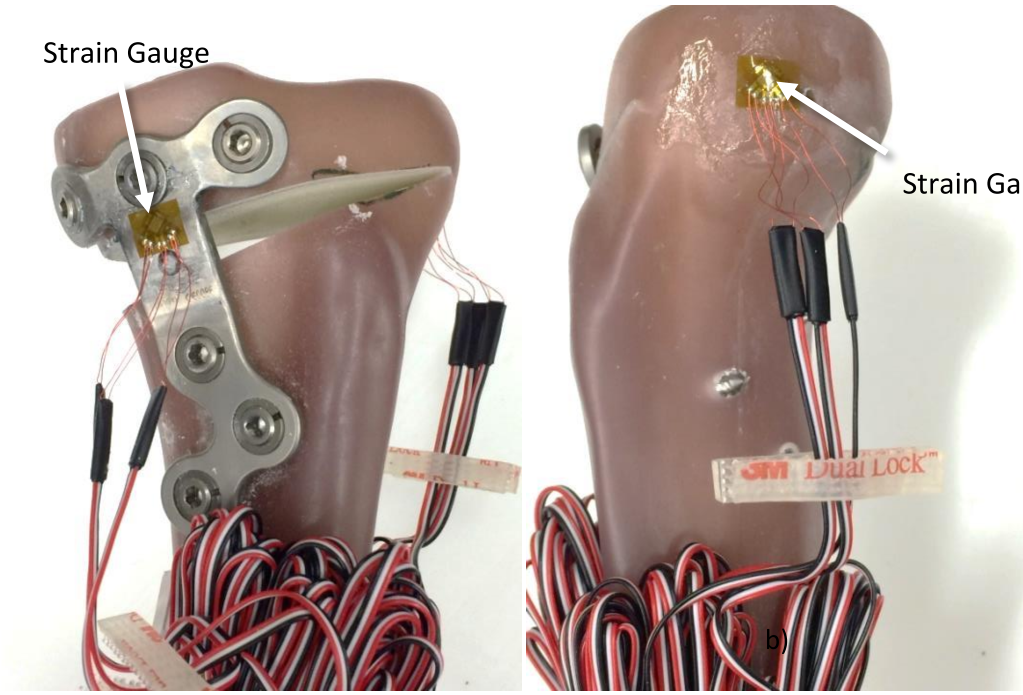
Micro-motion across the osteotomy site was quantified using a custom tracking system (Basler Pilot GigE Camera [Basler, Ahrensburg, Germany]; Opto Engineering Telecentric Lens [Opto Engineering, Mantua, Italy]; Axial Diffuse Illuminator [Advanced Illumination, Rochester, VT, USA]; and LabVIEW Vision Acquisition System [National instruments, Austin, TX, USA]) (Figure 5.3). This system incorporates a colour thresholding method to optically track the centroid of markers placed on the posterior tibia, proximal and distal to the gap created by the osteotomy, and 13.5mm medial to the cortical hinge, to determine their relative distances throughout loading. The system has a resolution of 0.003 ± 0.002mm was set to collect data at a sampling rate of 5.6Hz.



A) B)

Figure 5.3: Custom tracking system **A)** A high resolution camera with telecentric lens, and axial diffuse illuminator was used to capture motion of markers placed proximal and distal to the osteotomy (not shown). This system is controlled by a custom LabVIEW program. **B)** Example of marker placement.

Strain on the fixation plate and on the lateral cortical hinge were both measured using 45° stacked strain gauge rosettes (Vishay Intertechnology, Inc., Malvern, PA, USA). One gauge was glued to the lateral proximal tibia at the lateral cortical hinge, with the middle gauge of the rosette configuration aligned with the longitudinal axis of the tibia. A second strain gauge was glued to the HTO plate at the level of the osteotomy (Figure 5.4). The middle gauge of the rosette configuration was aligned along the longitudinal axis of the plate. Each gauge was wired independently into a quarter bridge Wheatstone Bridge completion circuit to simultaneously monitor plate strain. Strain data were collected at a sampling rate of 10Hz (National Instruments NI-PXI 1050, and SCXI 1010) using a custom data collection program (LabVIEW 2008, National Instruments, Austin, TX, USA).



A) B)

Figure 5.4: Strain gauge location.Strain gauges were applied to the **A)** plate and **B)** lateral cortical hinge.

Three outcome measures were used. From the load cell of the Instron, the loads when failure occurred were recorded and compared between plate types. Micro-motion across the osteotomy at each load step were plotted and compared descriptively between the flat and tooth plate. Finally, maximum and minimum principle strains on the plate and lateral cortical hinge where also plotted and descriptively compared.

5.3 Results

To date, five specimens have been tested to failure. Combined, specimen preparation, equipment setup and testing took on average 10 hours to complete per specimen. Table 5.1 provides the maximum load values at the time of failure for each specimen. Although the specimen numbers are currently low to allow for statistical comparison, it appears there is little difference in the load at failure for the tooth versus the flat plate. The mode of failure in all five cases was rupture of the lateral cortical hinge.

Table 5.1: Summary of load at failure for the 5 specimens initially tested

Specimen	Load at Failure [N]
Tooth Plate 1	1800
Tooth Plate 2	1600
Flat Plate 1	2200
Flat Plate 2	1800
Flat Plate 3	1600

Motion from the camera system and strain data are presented for the Tooth Plate 2 and Flat Plate 3, only. Figure 5.5 shows the progression of micro-motion observed between the centre of mass of the proximal marker and the centre of mass of the distal marker for both plate types as the load/cycles increased. Overall, the distance between the markers decreased with load (*i.e.*, the graphs have a negative average slope) until catastrophic failure occurred. Within each load step, the minimum distance between the markers is observed when the peak load is applied. For example, in Figure 5.5B for the flat plate, the minimum distance between the beads is approximately 3.7mm during the 800N load step, and decreases to approximately 3.5mm during the 1000N load step. That is, the osteotomy collapses by approximately 0.2mm during this portion of the loading cycle. These data are summarized in Figure 5.6, which shows that, in general, there was less collapse of the osteotomy with the tooth plate then the flat plate.

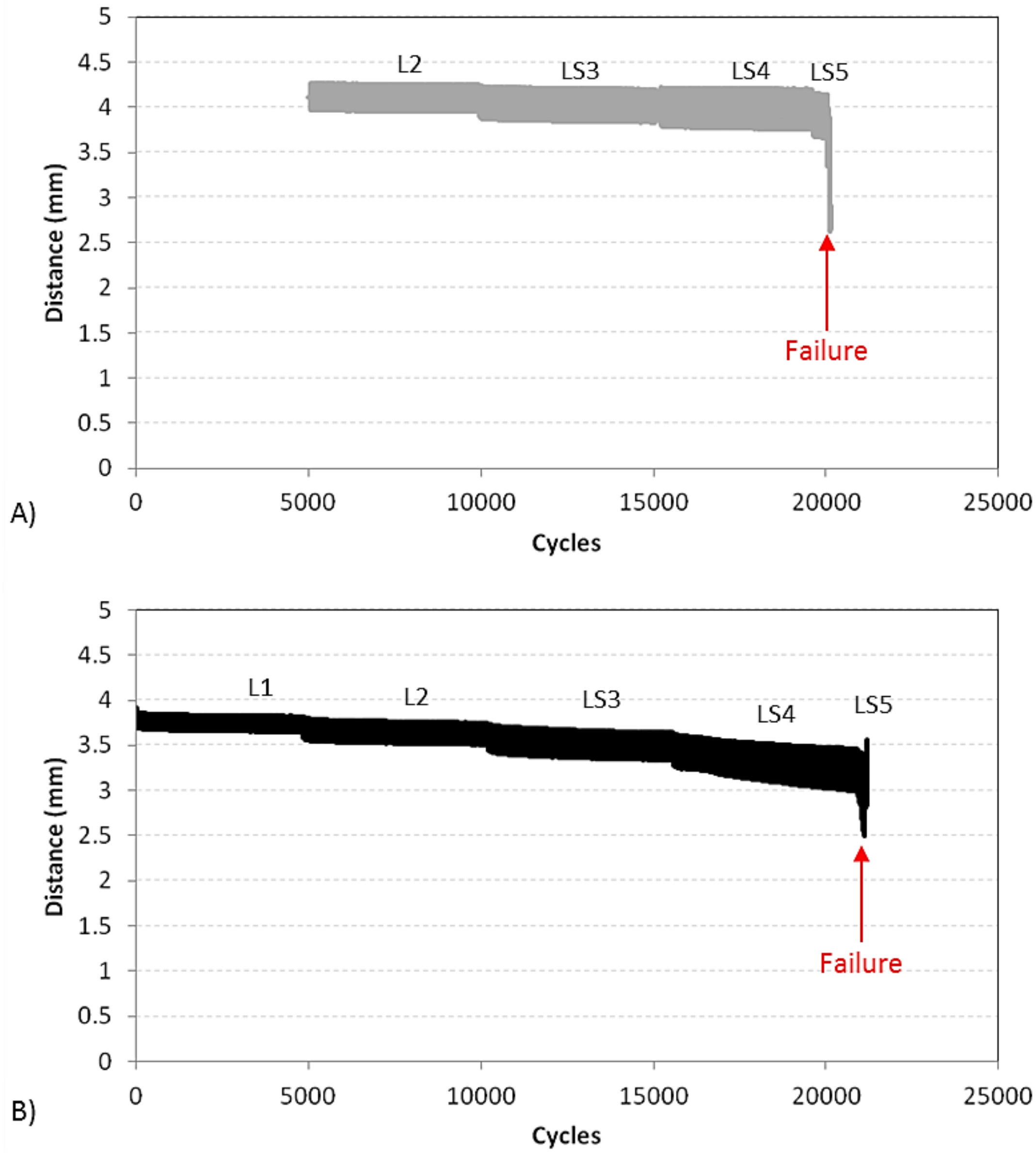


Figure 5.5: Typical evolution of the distance between the centre of mass of the proximal tibia marker and the distal tibia marker during fatigue to failure testsfor **A)** tooth plate and **B)** flat plate.

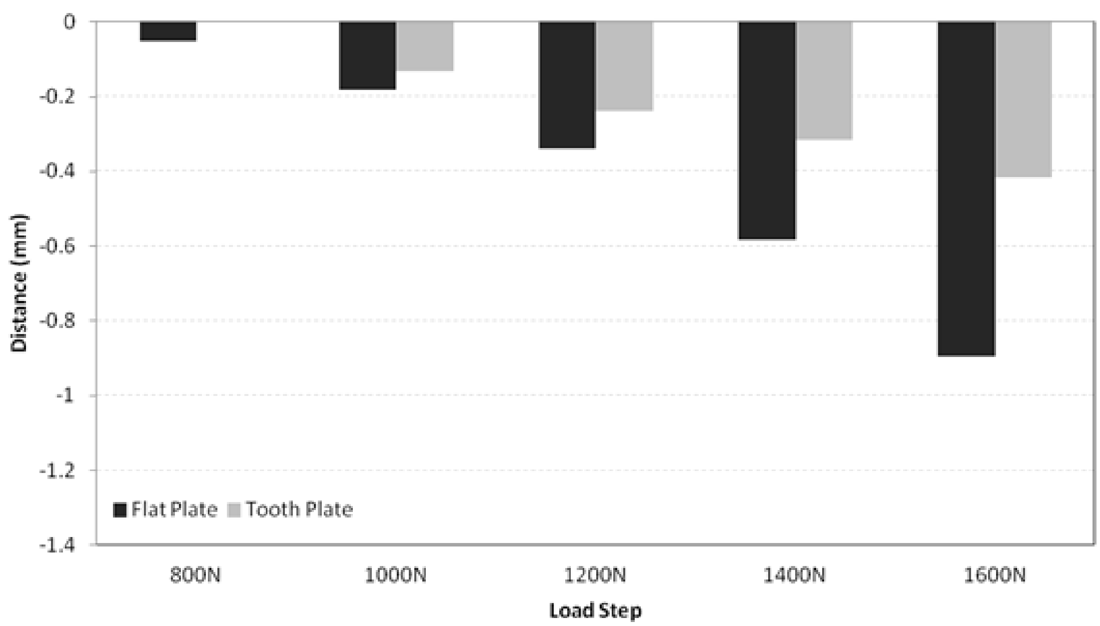


Figure 5.6: Summary plot of the magnitude of the osteotomy collapse at each load step during the fatigue failure tests, where a negative number indicates the proximal tibia marker moves closer to the distal tibia marker (*i.e.*, collapse). Data for the 800N case for the tooth plate was unavailable.

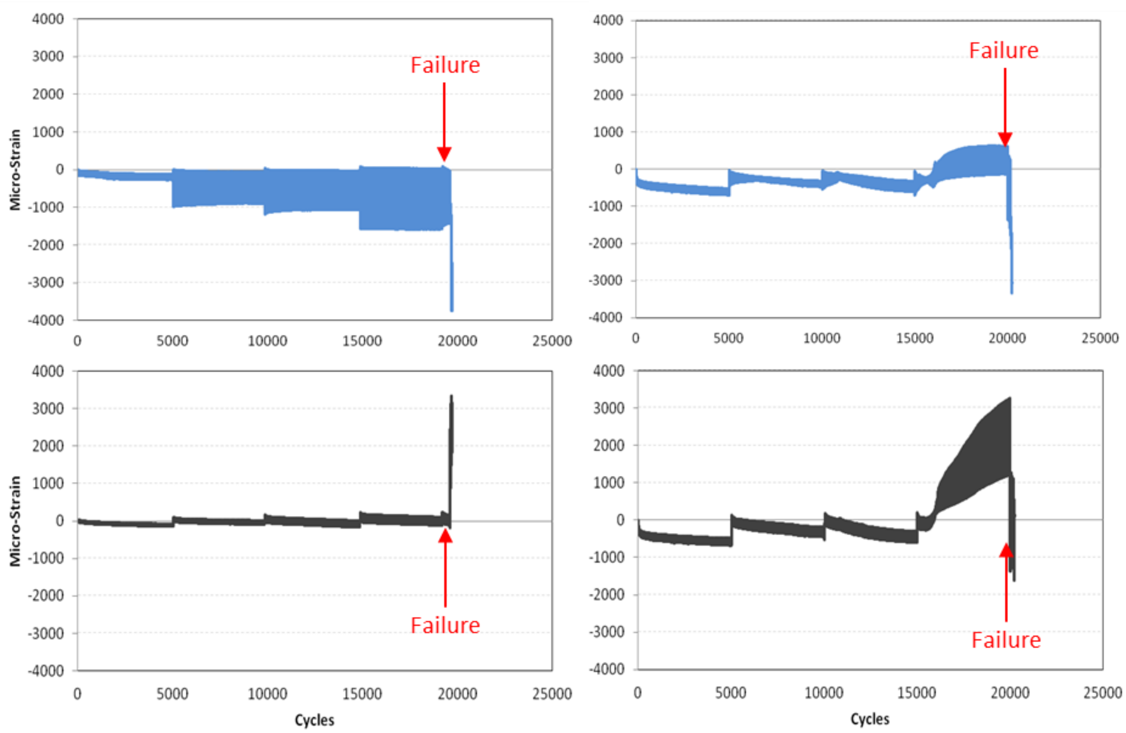


Figure 5.7: Typical evolution of strain on the lateral cortical hinge for (left) Tooth Plate and (right) Flat Plate. The plot on the top (blue) is for maximum principal strain and the plots on the bottom (grey) is for minimum principal strain 2

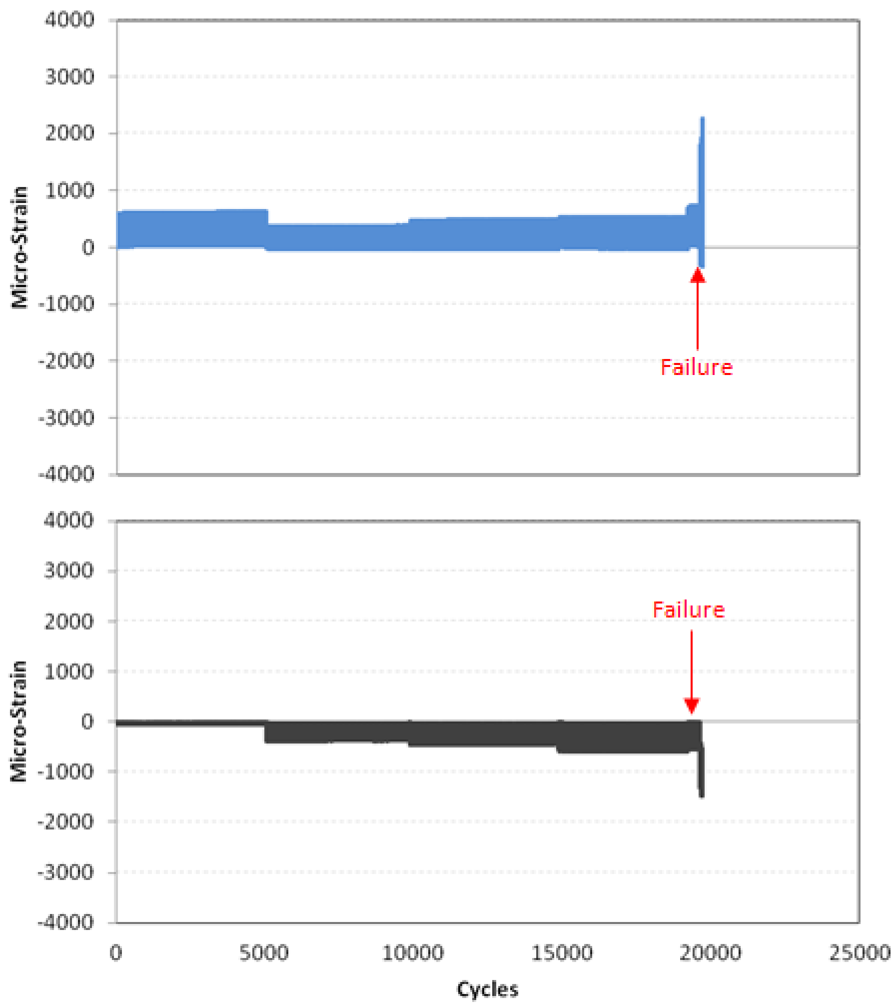


Figure 5.8: Typical evolution of strain the tooth plate during fatigue to failure test. The plot on the top (blue) is for maximum principal strain and the plot on the bottom (grey) is for minimum principal strain.

The evolution of strain on the lateral cortical hinge for both plate types throughout the testing period is shown in Figure 5.7. The strain on the lateral cortical hinge is greater with the tooth plate than the flat plate. Figure 5.8 shows the strain on the tooth plate. Due to malfunction of the strain gauge, strain on the flat plate is not presented.

5.4 Discussion

The goal of this study was to compare the stability of medial opening wedge HTO fixations specifically, the toothed and the flat Contour Lock plates during cyclic loading. Although testing continues, the preliminary findings from the maximum load at failure data suggest the flat plate offers a higher stability in case of maximum dynamic loading of the bone-implant construct; however, the tooth plate may prevent collapse of the osteotomy and provide more stability if failure of the opposite lateral cortical hinge occurs based on the motion data. However, one should be cautious when interpreting these results due to low number of specimens.

In all cases, failure initiated at the opposite cortex, however the crack did not always propagate along the lateral cortex as expected. In one case there was failure of the lateral cortical hinge, in three cases the crack propagated through the lateral tibia plateau and in one case failed distally toward the tibial shaft. The location of failure at this point did not seem to be associated with either plate type. Other biomechanical studies comparing stability of fixation constructs report the fracture of the lateral cortical hinge being the typical point of failure, which is similar to what is seen clinically (Agneskirchner *et al.*, 2006; Spahn *et al.,* 2002; Stoffel*et al.,* 2004; Zhim *et al.*, 2005; Maas *et al.,* 2013). No failure of the plate fixation was detected. Possible reasons for the different types of failure seen in the present study could be attributed to the opening of the osteotomy, rather than the cutting the wedge out, screw placement, loading without soft tissue.

The main goal of the cyclic testing was to simulate repetitive loading of the osteotomy during activities of daily living and thus investigate the stability of the osteotomy plates during functionally relevant conditions. Although the failure modes were similar between the plate types the tooth plate typically failed earlier (average maximum load 1700N) than the flat plate (average maximum load 1860N). Furthermore, the loads at failure were lower than one might expect. Knee modeling and instrumented knee implant studies suggest that load within the knee are 2-3 time body weight during walking. With load to failure values 1-2 times body weight in this study, one would expect these fixation plates to be failing in people. Possible reasons for the discrepancy could be a limitation in the sawbone model itself, or perhaps more plausible, the fact that there are no soft tissues in this model for any load sharing to occur.

Maas *et al.*, (2013) performed cyclic staircase load tests and found the Contour Lock plate typically failed at 2400N. The maximum load at failure for this plate in the present study was an average of 1700N. The most likely reason for the differences is the load application. In the present study, load was applied at a lever arm, resulting in an adduction moment. The type of osteotomy performed between studies could also attribute to the differences observed. Although both studies used sawbones for the specimens, the present study corrected a pre-existing 10° varus alignment rather than removing a wedge from a neutrally aligned tibia. The present method required gradual opening of the osteotomy while applying gentle heat to the lateral cortical hinge. Although the present method is more like the actual surgery, heating the sawbone may have caused weakening in the lateral cortical hinge before dynamic testing.

The motion on the posterior aspect of the osteotomy may suggest that the tooth plate does not allow as much motion (*i.e.*, collapse) to occur as the flat plate. Although it is not possible to compare strain on the plate directly, the tooth plate appears to induce more strain on the lateral cortical hinge and possibly cause earlier failure of the hinge than the flat plate. However, more specimens need to be tested to confirm these preliminary findings.

While considering the findings of this study, one should take into account the small number of specimens used. Based on the data collected to date, sample size calculations suggest that testing should continue until a total of 16 specimens (8 for each plate type) have been tested. This will provide 80% power to detect a difference in load at failure of at least 343N between plate types (Appendix A). Limitations in the present study include the lack of soft tissues and muscle contraction during the loading. Although using *in-vivo* gait data to design the present methods may provide more applicable testing conditions than previous loading studies, caution is still recommended when interpreting these results.

Preliminary findings suggest the flat plate may provide more stability than the tooth plate for medial opening wedge HTO during dynamic loading of the bone-implant construct in terms of maximum load at failure. However, the tooth plate is better for maintaining the osteotomy and provides more stability in the event of lateral cortical hinge rupture. Both plates provide sufficient strength, because the lateral cortical hinge is weaker than either plate.

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Chapter 6

Micro-motion in the Tibia After Medial Opening Wedge High Tibial Osteotomy Using Dynamic Single-Plane Flat-Panel Radiography: A Proof-of-Concept Study

Overview: The purpose of this study was to provide the "proof-of-concept" as to whether or not dynamic FP radiography could detect micro-motion in the proximal tibia after medial opening wedge HTO during standing tests that loaded and unloaded the surgical limb. Two patients participated. Patient #1 had undergone surgery approximately 7 years prior to testing, while patient # 2 had undergone surgery 2 weeks prior to testing. A floor-mounted C-arm unit equipped with a flat-panel detector was used for image acquisition, while patients performed standing, weight-shift tests. Although some motion was observed in all trials, the direction of motion was not always consistent with what one would expect when loading and unloading the limb after medial opening wedge HTO. The present results support the concept that dynamic flat-panel single-plane radiography can detect micro-motion after medial opening wedge HTO. However, the findings also suggest that further modification of the registration software is required to increase confidence in distinguishing true motion from registration error. The present results will support the development of the next stages of research of what are admittedly preliminary, yet encouraging, proof-of-concept investigations.

6.1 Introduction

Stable fixation is essential to prevent collapse and maintain the angle of correction achieved after medial opening wedge high tibial osteotomy (HTO) (Claes *et al.*, 1998; Brinkman *et al.*, 2008; 2010) after medial opening wedge high tibial osteotomy (HTO). Ideally, the fixation technique should be strong enough to promote weight-bearing early (*i.e.*, weeks) after surgery, yet still allow micro-motion in the bone to enable proper healing. Although the amount of micro-motion required for healing of the osteotomy wedge is unclear, too much micro-motion may inhibit bone union (Kenwright and Goodship, 1989; Goodship *et al.*, 1985). Rehabilitation after medial opening wedge HTO varies considerably depending on the method of fixation used, with full weight-bearing being delayed anywhere form 2-to-12 weeks postoperatively. The decision regarding how much weight the patient can place on the limb is based largely on the extent of bone healing assessed on standard x-rays.

Although standard x-rays may provide an indication of the extent of union that has occurred, it provides limited, indirect information about the stability of the fixation. Previous studies have typically evaluated the stability of various types of HTO fixations using cadavers or artificial bone models (*e.g.,* Sawbones) (Agneskirchner *et al.*, 2006; Miller *et al.*, 2005; Hernigou *et al.*, 1987; Stoffel *et al.*, 2004; Spahn and Wittig, 2002; Pape *et al.*, 2010; Maas *et al.*, 2013). While these studies have provided useful information that has led to improved plate fixation designs, their clinical applicability might be questioned. Fewer studies have evaluated the stability of HTO plate fixations in patients, and these studies have been limited to static testing situations (Brinkman *et al.* 2010; Gaasbeek *et al.*, 2005; Luites *et al.*, 2009; Magyar *et al.*, 1999; Pape *et al.*, 2013).

Dynamic radiography may help test HTO fixation stability under more functional conditions. Dynamic single-plane flat-panel (FP) radiography uses principles of radiostereometric analysis (RSA), an x-ray technique that requires the implantation of at least three non-collinear marker beads into the skeletal segment of interest to enable the localization of the segment in 3-dimensional (3D) space (Valstar *et al.*, 2005; Hurschler *et al.*, 2009). Although RSA offers great accuracy, the analysis can only be done during static or quasi-static activities. Alternatively, dynamic FP radiography uses the principles of RSA to track the 3D motion of bone segments during dynamic activities. To compensate for the limited amount of information available from a single-perspective view, the 3D arrangement of the implanted marker beads must be known in advance. The 3D position of the bone segments in the image sequences are determined by performing a 3D-to-2D registration between the known 3D arrangement of beads and their corresponding projections in the 2D image sequences (Yuan *et al.*, 2002; Garling *et al.*, 2005).

If dynamic FP radiography is an appropriate method to test the stability of HTO fixations postoperatively, it must first demonstrate the ability to detect micro-motion during dynamic loading. Therefore, the purpose of this study was to provide the "proof-of-concept" as to whether or not dynamic FP radiography could detect micro-motion in the proximal tibia after HTO during weight-shifting tests. We hypothesized that dynamic FP radiography could detect micro-motion in a fully healed tibia, as well as changes in micro-motion during bone healing, after medial opening wedge HTO.

6.2 Methods

This proof-of-concept study was approved by the institutional research ethics board. After giving informed consent, two patients participated. Patient #1 (Female, Age: 49yrs, Height: 160cm Weight: 85kg) had undergone medial opening wedge HTO approximately 7 years prior to testing. Patient #2 (Male, Age: 44yrs, Height: 172cm, Weight: 123kg) was scheduled to undergo medial opening wedge HTO.

6.2.1 Surgery

For both patients medial opening wedge HTO was carried out under fluoroscopy. An oblique cut was made approximately 30mm below the joint line, and extended toward the tibiofemoral joint, stopping approximately 5mm shy of the lateral tibia cortex. A wedge was created, based on the degree of malalignment and the presence and severity of cartilage degeneration (visualized arthroscopically) in the lateral compartment. The wedge created was then stabilized with a fixation plate. The size of correction was 12.5mm for patient #1 and 17.5mm for patient #2. For both patients the osteotomies were filled with cancellous allograft bone. Five-to-nine tantalum beads (patient #1: 0.8mm diameter, patient #2: 1.0mm diameter) were implanted into the proximal and distal parts of the osteotomy (Figure 6.1) with a special insertion instrument. To avoid bead loosening, the tantalum beads were placed at least 1cm away from the osteotomy line.

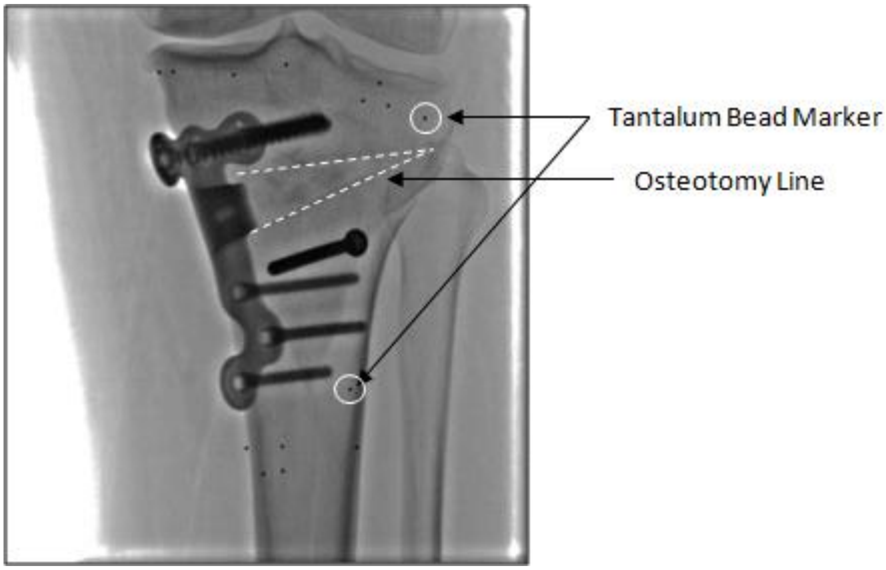

Figure 6.1: Tantalum bead placement. Fluoroscopy image of the tantalum marker beads inserted into the tibia proximally and distally to the osteotomy.

6.2.2 Dynamic Single-plane Flat-panel Radiography

A floor-mounted C-arm unit equipped with a flat-panel detector was used for image acquisition (Innova 4100, General Electric, WI, USA). A platform was designed to fit within the C-arm of the GE Innova 4100 and built to accommodate a single patient performing dynamic loading activities (Figure 6.2). Projections were acquired using a 20cm field-of-view (FOV).The source-to-detector distance was set to 120cm for all examinations. Acquisitions were at 30fps, energy of 60KVp, current of 3mA, with exposures of 3-4ms.

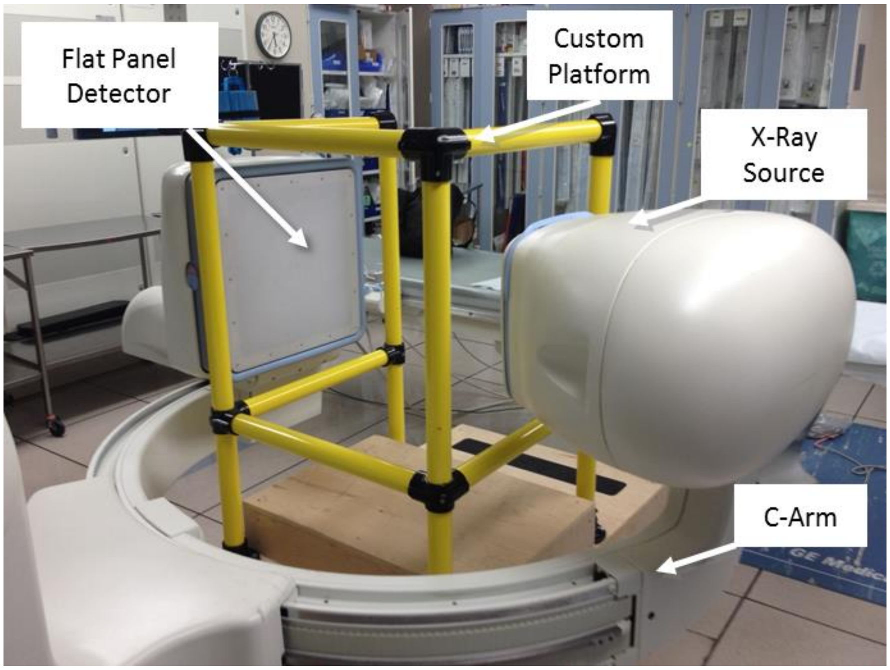

Figure 6.2: Experimental setup of the GE Innova system.

The dynamic single-plane radiography technique required two components for the registration: first, a local coordinate system that described the arrangement (*i.e.*, the locations) of the beads within the tibia for each patient, and second, the perspective geometry of the radiography system in a common frame of reference. To generate the coordinate system, a computed tomography (CT) scan was acquired for each patient. For patient #1, the CT was taken on the day of the dynamic radiography examination. For patient #2 the CT was taken two days after surgery. The prospective geometry of the GE Innova 4100 was reconstructed by acquiring images of a commercially available RSA calibration cage (Lund Knee Box, RSA Biomedical, Umea, Sweden) and custom-written calibration software (Seslija *et al.*, 2012). The 3D-to-2D registration process determined the centroids of each tantalum bead in the 2D radiograph, and defined projection lines between the centroids of the beads and the x-ray focus. It then took the 3D location of the beads, determined from the CT scan, and fit it to the projections lines, iteratively modifying the position and orientation of the sparse model until the perpendicular distance between each bead and its corresponding projection line was minimized. The accuracy of this single-plane radiography technique has been reported to be less than 0.1mm and 0.25mm for translations in-plane and out-of-plane, respectively and less than 0.6° for rotations about all axes (Seslija *et al.*, 2012). The custom software was used to calculate the motion of the tibia segments from acquired image sequences (Seslija *et al.*, 2012).

6.2.3 Examination Protocol

Dynamic imaging sequences were acquired while patients performed the following activities. Three Weight-Shift Onto HTO Limb trials were completed first, followed by three Weight-Shift Off HTO Limb trials. Follow-up dynamic single-plane radiography examinations were done at 2, 4 and 6 weeks postoperative for patient #2.

1. Weight-Shift Onto HTO Limb – the patients stood between the x-ray source and flat-panel detector, facing the flat-panel detector, with the centre of the knee of their HTO limb aligned with the centre of the detector. To perform this activity the patients started with all of their weight on the non-HTO limb and then shifted their weight onto the HTO limb.

2. Weight-Shift Off HTO Limb – the patients were aligned in the same manner as described above. To perform this activity the patients started with all of their weight on the HTO limb and shifted their weight onto the non-HTO limb.

6.2.4 Data Analysis

The sparse model of the 3D coordinates of each marker bead was created using each patient CT (CT-defined sparse model). Two sparse models were created: one for the distal segment of the tibia, below the osteotomy, and one for the proximal segment of the tibia (above the osteotomy). The centre of mass for each marker bead was computed from the selected voxels of a region-grow algorithm (Microview, Parallax Innovations). Once the model was created, each trial was processed using custom 3D-to-2D registration software to obtain motion of the centre of mass of the proximal segment of the osteotomy and centre of mass of the distal segments of the osteotomy.

A bone coordinate system was then established in order to determine movement of the proximal tibia segment relative to the distal tibia segment.

6.2.4.1 Creation of Bone Coordinate System

The bone coordinate system was established using four landmarks on the tibia in the original CT image to create a transformation matrix that transformed the CT coordinate system into a bone coordinate system. The medial-lateral (ML) axis was transformed to be parallel to the CT's x-axis, the anterior-posterior (AP) was transformed to be parallel to the y-axis and the proximal-distal (PD) was transformed to be parallel to the z-axis.

The four landmarks were chosen as follows. First, a point on the distal end of the tibia was selected by calculating a centre of mass of the cortical ring in the CT. The centre of mass was computed from the selected voxels of a region-grow algorithm (MicroView, Parallax Innovations) (Figure 6.3), using a region of interest to limit the selection of the cortical ring to span only five CT slices. A second point was selected, using the same region grow methods, along the tibia shaft approximately 30 mm proximal to point 1 but below the HTO fixation. The vector connecting these two points was defined to represent the PD axis.

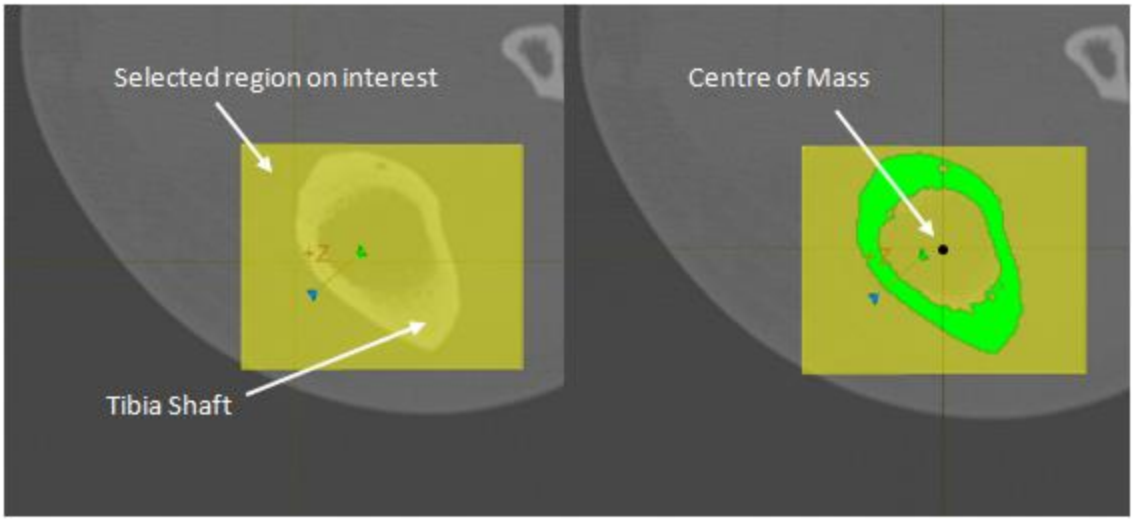

Figure 6.3: Bone coordinate system points 1 &2.The figures depict the process used to determine points 1 and 2 in creating the PD axis of the bone coordinate system from a patient CT. The figure on the left shows the selection of the region of interest around the tibial shaft. The figure on the right shows the selected region and centre of mass location after using the region grow algorithm.

A line connecting the medial (point 3) and lateral (point 4) posterior tibial condyles was used to calculate the initial ML axis (Figure 6.4). This line was translated to intersect the PD axis. The final ML axis was then computed to be a vector that passes through a point on this translated line (not the intersecting point), and the orthogonal projection of this point onto the PD axis. Finally, the AP axis was computed as the cross product of the PD axis and the ML axis.

The transformation matrix from the CT coordinate system to the bone coordinate system (TCTBCS) was then constructed. The translation matrix was defined as the difference between the bone coordinate system origin (the point where ML, AP, and PD intersect), and the CT origin (0, 0, 0). The rotation matrix was constructed by setting the 3 matrix rows to be the normalized ML, AP, and PD axis (centred at 0, 0, 0), respectively.

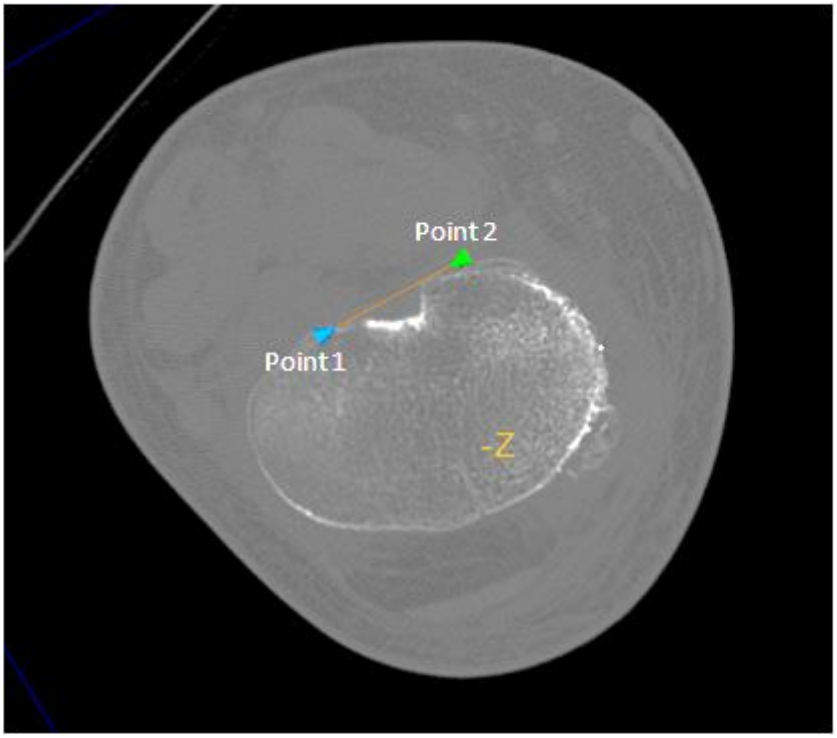

Figure 6.4: Bone coordinate system points 3 & 4. The figure depicts the selection of point 3 and 4 from the patient CT.

6.2.4.2 Anatomical Movement

Along with the position information of the centre of mass of proximal and distal segments of the tibia, the custom 2D-to-3D registration software resulted in a fluoroscopic transformation matrix, per fluoroscopic frame, that mapped the CT-defined sparse model into fluoroscopic imaging space. Two separate transformation matrices were created, one for the distal tibia sparse model and the other for the proximal tibia sparse model.

To compare the motion of one model relative to the other's frame of reference, the inverse fluoroscopic transformation matrix, per frame, of the distal tibia sparse model was applied to both the distal and proximal tibia sparse models' dataset in the fluoroscopic imaging space. This resulted in the sparse models' positions, per frame, being back in the original CT coordinate system, where the distal sparse model's frame of reference was fixed. One final transformation matrix was applied (TCTBCS) to the distal and proximal sparse models, per frame, resulting in a temporal dataset in the bone coordinate system defined earlier. The centre of mass of each sparse model was then compared to each other in the bone coordinate system to determine the motion of the centre of mass of the proximal tibia segment relative to centre of mass of the distal tibia segment.

To evaluate the hypotheses, the positions of the centre of mass of the proximal tibia segment relative to the fixed distal segment centre of mass were plotted during each of the weight-shifting tests for patient #1, and during each of the repeated testing sessions completed 2, 4, and 6 weeks postoperatively for patient #2. All trials were examined, but only the trial that required the least amount of user intervention, to reinitialize the positions of the marker projections in order for the tracking algorithm to continue, was selected for presentation. A moving average filter with a window size of 10 was used to help visualize trends in the change in position of the centre of mass of the proximal tibia segment.

6.3 Results

All testing was completed without incident. Equipment setup, data acquisition, and disassembly of equipment required approximately 1 hour per test session. Data analysis typically required between 3-to-5 hours, per trial, with the data often requiring reprocessing. The individual trial results are presented in Figures 6.5 and 6.6. Overall, approximately 1 mm of motion was observed over the length of a trial with larger "spikes" in position data frequently appearing. Although some motion was observed in all trials, the direction of motion was not always consistent with what one would expect when loading and unloading the limb after medial opening wedge HTO. Figure 6.5 shows the position of the centre of mass of the proximal tibia sparse model relative to the fixed centre of mass of the distal tibia sparse model for patient #1 (fully healed osteotomy). Those data indicate that there was motion in the fully healed tibia, with the trend line suggesting the proximal tibia moved closer to the distal tibia as weight was shifted onto the HTO limb, with less motion occurring when weight was shifted of off the HTO limb. Figure 6.6 shows the position of the centre of mass of the proximal tibia sparse model relative to the fixed centre of mass of the distal tibia sparse model for the patient #2 at 2, 4, and 6 weeks after HTO surgery. The data from 2- and 4-week tests indicate that there was separation between the proximal and distal segments as the HTO limb was loaded. The same separation was not present in the figure showing the 6-week tests, consistent with the progression of healing of the osteotomy.

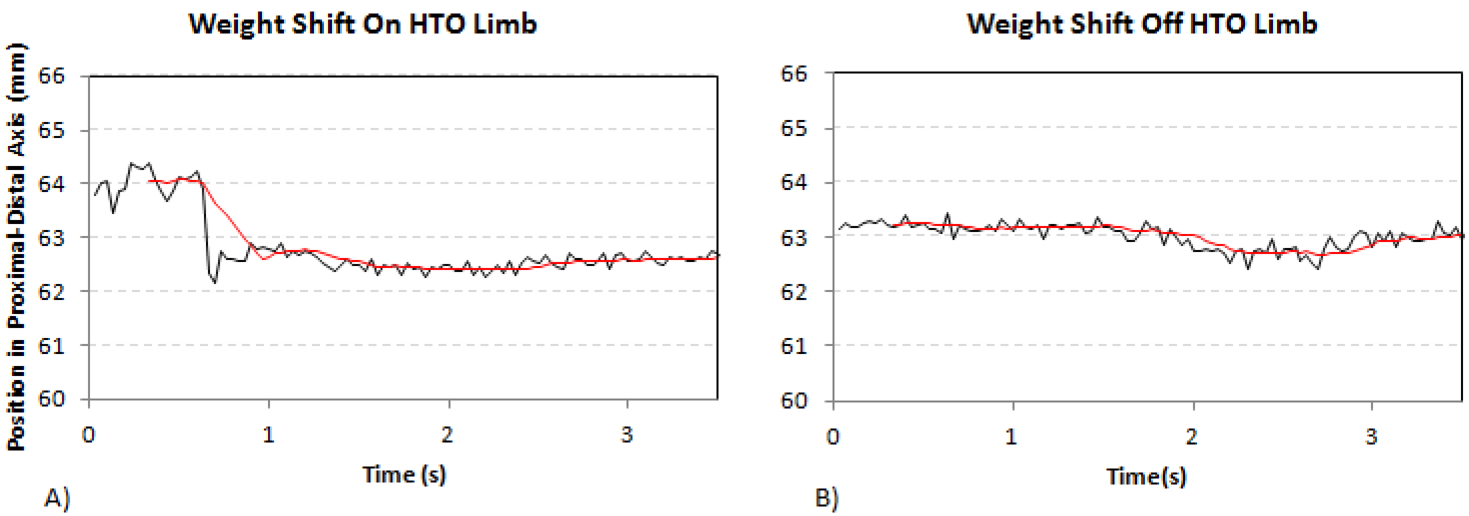

Figure 6.5: Motion in fully healed tibia. To depict motion across the osteotomy wedge, the plots show the position of the proximal tibia segment relative to the fixed distal segment for the duration of the trial. The black line is the actual position of the centre of mass of the bead cloud and the red line is a moving average trend line. In the left figure the patient shifted all of her weight from the non HTO limb to the HTO limb. In the figure on the right the patient shifted all of her weight from the HTO limb to the non HTO limb.

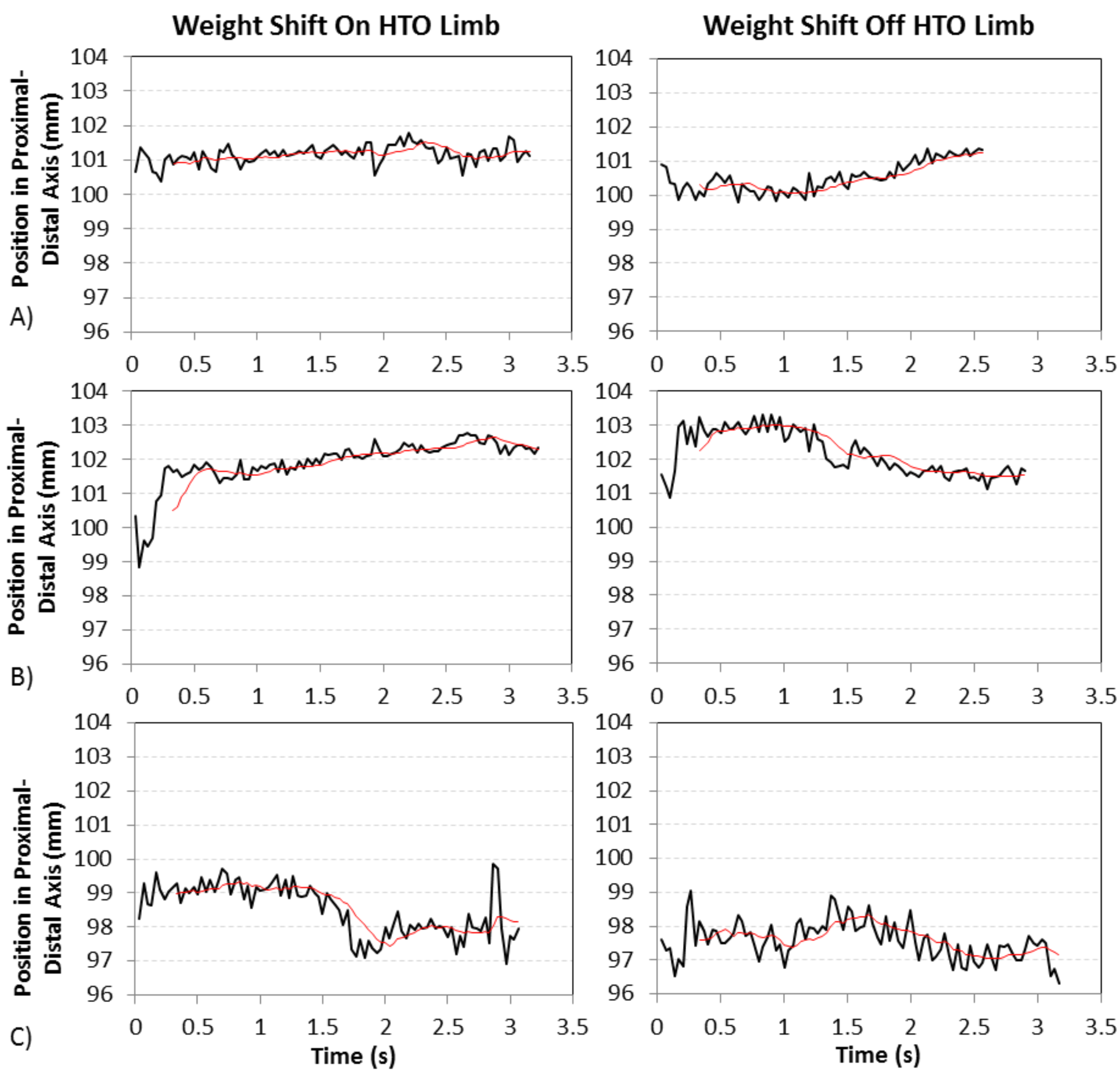

Figure 6.6: Motion in a healing tibia. To depict motion across the osteotomy wedge, the plots show the position of the proximal tibia segment relative to the fixed distal segment, in the proximal-distal axis, for the duration of the trial at 2 weeks **A)**, 4 weeks **B)**, and 6 weeks **C)**. The black line is the position of the proximal tibia and the red line is the moving average trend line. In the figures on the left, the patient shifted all his weight from the non HTO limb to the HTO limb. In the figures on the right the patient shifted all his weight from the HTO limb to the non HTO limb.

6.4 Discussion

The present findings suggest that dynamic FP radiography can detect motion between the proximal and distal segments of the tibia during weight-shifting tests completed after medial opening wedge HTO. Although generally consistent with proof of concept, one needs to be very cautious when interpreting these preliminary results. Specifically, given the size of the observed motion (>1mm), and the fact that its direction was not always consistent with what was expected with loading and unloading the limb, an alternative interpretation of these results is that considerable error exists with the current methods, and further refinements are required.

We are unaware of previous imaging studies that have evaluated motion in the tibia during weight-bearing activities after HTO. Therefore, it is not possible to directly compare the present results with other existing data. There have been, however, previous studies that evaluated the stability of HTO fixations using RSA by measuring micro-motion defined as the change in position, between the proximal and distal tibial segments, observed over 6 months to 2 years after surgery (Magyar *et al.*, 1999; Brinkman *et al.*, 2010; Pape *et al.*, 2011). Those studies suggest that in a stable osteotomy, sub-millimeter motion is observed between those time periods (Luites *et al.*, 2009). Assuming that the present patient 7 years after HTO has a stable osteotomy, the data in Figure 6.5 may suggest that considerable micro-motion exists even in a well-healed osteotomy when loaded with full body weight. Alternatively, another explanation is that the apparent, relatively large change in position is due to errors in the present methods. For patient #2, with a healing osteotomy, at 2 and 4 weeks it appears there is a separation in the proximal and distal segment and by week 6 the distance between the segments decreases suggesting healing of the osteotomy. Possible reasons for this observed separation at 2 and 4 weeks could be due a rotation of the tibia plateau. Pape *et al.*, (2011), and Brinkman *et al.*, 2009 both reported a dorsal tilt of the tibia plateau in patients after early weight-bearing using RSA. By 6 weeks it has been reported, based on MR scans, connective tissue forms within the gap of the osteotomy (Brinkman *et al.*, 2008). It may be possible the connective tissue helps stabilize the osteotomy and prevent the dorsal tilting. However, caution is still recommended when observing these trends, as changes in position of the tibia segment are still considerably larger than expected.

Potential errors may stem from several sources, such as the registration process (automated tracking algorithm or the correspondence algorithm, 3D-to-2D point-based registration) (Seslija *et al.*, 2012), image contrast, calibration process or the creation of the bone coordinate system, and further research is required to confirm the accuracy of these techniques when used under the present testing conditions.

Previous work has been done to determine the accuracy of the present registration method. The previous tests were performed using a robotic controlled, tibiofemoral knee phantom, that was programmed to mimic a patient performing a step up (Seslija *et al.*, 2012). An important difference between that study and the present study is fact that the knee phantom is without soft tissue. Images that are taken *in-vivo* have reduced contrast because of the surrounding soft tissue. Furthermore, the movements in the previous test were likely more fluid than human movement and therefore may have been easier for the tracking algorithm to predict the location of the marker bead in subsequent frames. Seslija *et al.* (2012) suggested "jerky" or sudden movement makes it more difficult for the tracking algorithm to predict movement. These factors should be considered when interpreting the present data. Errors in the estimated positions and orientations of the marker beads and the overall centre of mass of the sparse model may have resulted in the relatively large spikes shown in Figures 6.5 and 6.6 and could have conceivably affected the observed change in position.

Although the data analysis method described in this paper has the potential to process a complete weight-shift trial in less than 30 minutes, it currently requires approximately 5 hours per trial, primarily due to the need to select marker bead location frame by frame and supervise the process. As the procedure develops, it should be possible to develop methods to improve the prediction method, improve the contrast of the images and reduce processing time.

To help improve the registration process and decrease analysis time in the present study the bead size was increased from patient #1 to patient #2 to allow for easier detection of the marker beads. However, the marker size did not appear to improve the ability of the software to detect the marker bead. Therefore, the inability to determine marker bead position and orientations was more likely a result of image contrast and patient movement.

The present results suggest that it will be possible to measure motion in the tibia during a weight-bearing activity using dynamic FP radiography for the purpose of evaluating fixation stability in a healing osteotomy. However, the present results also suggest that further modification of the tracking algorithm and registration software is required to increase confidence in distinguishing true motion from registration error. The present results will support the development of the next stages of research (*e.g.,* more accurate registration process, improved image quality, improved segment coordinate system) of what are admittedly preliminary, yet encouraging, proof-of-concept investigations.

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Chapter 7

General Discussion

Overview: *This chapter summarizes the main finding of the thesis, emphasizing links between the different studies, and specifically revisiting the objectives and proposed hypotheses set out in Chapter 1. Limitations are also discussed, along with potential future directions for the biomechanical evaluation of medial opening wedge HTO.*

7.1 Thesis Summary

Medial opening wedge HTO is a treatment for the management of varus gonarthrosis. The ability to measure the stability of the HTO fixation, healing of the osteotomy and the effect of HTO on patient function *in-vivo* are all important goals for research into fixation design, and ultimately for the clinical well-being of the patient. This thesis was designed to develop and test biomechanical methods to assist in the assessment of medial opening wedge HTO.

Chapter 1 provided the background knowledge and basic concepts that were used in the design of the studies in subsequent chapters of this thesis. This chapter introduced osteoarthritis of the knee, some of the major risk factors for the initiation and progression of the disease, medial opening wedge HTO surgery, the importance of plate fixation in HTO, and current biomechanical methods used for assessing HTO, including their limitations. The chapter concluded with specific objectives and hypotheses for this thesis.

The initial focus of the thesis was on lower limb alignment, gait biomechanics and changes in the external moments about the knee after HTO. The objective of the study described in Chapter 2 was to compare knee joint moments and frontal plane angular impulse before and after varus or valgus producing osteotomy in patients with lateral or medial compartment osteoarthritis, and in healthy participants with neutral alignment.

Patients underwent 3D gait analysis and radiographic assessment of alignment (mechanical axis angle; MAA) before and 6 months after surgery, and were compared to controls. Overall, there was a 53% increase from preoperative values in the adduction impulse in patients after varus osteotomy, and a 45% decrease from preoperative values in adduction impulse in patients after valgus osteotomy. Differences observed between patients and controls preoperatively were not observed postoperatively. The cross-sectional data suggested that frontal plane angular impulse was very highly correlated to MAA before surgery and that an adduction impulse predominated until 7º of valgus, at which point an abduction impulse predominated. The prospective surgical realignment data indicated that for every 1º change in MAA toward varus, there was a 0.1%BW·Ht·s (or 1.6N·m·s) change in frontal plane knee angular impulse toward adduction, and vice versa. These overall findings *support both of the study hypotheses* and highlight the importance of changes in frontal plane alignment on gait biomechanics.

The objective of the study described in Chapter 3 was to compare the 3D external knee moments before and after medial opening wedge HTO during level walking and during stair ascent. Three-dimensional motion analyses during level walking and stair ascent were evaluated using inverse dynamics before, 6 and 12 months after surgery. There were significant decreases in the peak knee adduction, flexion and internal rotation moments, with only the adduction and internal rotation moments remaining decreased at 12 months for both walking and stair ascent. Standardized response means ranging from 1.3 to 2.5 indicated large effect sizes. Both pre- and postoperatively, the peak knee adduction moment was significantly lower during stair ascent than during level walking, while the internal rotation moment was significantly higher. These findings *partially support the proposed hypotheses*. Specifically, the study suggests that medial opening wedge HTO results in long-term changes in knee moments in the transverse plane in addition to the frontal plane, but not in the sagittal plane, during both level walking and stair ascent. Additionally, contrary to the hypothesis, both pre- and postoperatively, the peak knee adduction moment was lower (not higher) during stair ascent than during level walking.

Results from Chapters 2 and 3 emphasized the importance of lower limb alignment on external knee moments during ambulation, and therefore the distribution of dynamic loads between medial and lateral tibiofemoral compartments. The results also support HTO as a mechanism for altering medial compartment loading. Importantly, gait biomechanics data also contributed to the methods used in the next two studies.

Considering the results of Chapters 2 and 3, the main objective of the study described in Chapter 4 was to develop and test a multi-axis fixation jig placed within a materials testing machine for assessing medial opening wedge HTO fixation plates in a manner more representative of walking. Another objective of this study was to compare strain on the lateral aspect of the tibial osteotomy (cortical hinge) and strain on the medial opening wedge HTO plate under different loading conditions, by altering the distance in the frontal plane between the load vector and the centre of the knee (*i.e.*, the frontal plane lever arm). Furthermore, the reliability of the strain measures obtained within and between test sessions was evaluated. A medial opening wedge HTO was performed on a composite bone and the jig was used to test strain on the bone's lateral cortical hinge and on the fixation plate while applying loads of 900N and 1400N (lower load represented the median frontal plane vertical GRF from the *in-vivo* patient data, and a higher load that represented the extreme values) at frontal plane lever arms of 0cm and 3cm. The 3cm lever arm resulted in significantly greater axial strain on the cortical hinge than the 0 cm lever arm condition, when using loads of 900N and 1400N.

The 3cm lever arm also resulted in significantly greater axial strain on the fixation plate when using the 1400N load. Averaging multiple test sessions resulted in coefficients of variation for within-session reliability ranging from 3-18% and between-day reliability of < 7%. These findings *support both the study hypotheses*. Importantly, gait analysis data influenced the operating capabilities of the jig. The results of this study highlight the importance of incorporating gait data into materials testing studies and suggest applying load at a lever arm should be taken into consideration in future testing of medial opening wedge HTO fixation plates.

Using the multi-axis fixation jig developed in Chapter 4, and considering the results of Chapters 2 and 3, the objective of the study described in Chapter 5 was to compare medial opening wedge HTO fixations performed with either a flat or toothed Contour

Lock plate. The plates were compared during cyclic loading conditions by quantifying the resulting load to failure, micro-motion across the osteotomy site and strain on both the plate and lateral cortex of the tibia. Five specimens have been tested to date. Loads at failure ranged from 1600N to 2200N. Given the low number of specimens, no statistical comparisons were made. Preliminary results suggest that there was little difference in the load at failure for the tooth versus the flat plate. There was less compression of the osteotomy with the use of the tooth plate. The strain on the lateral cortical hinge was greater with the use of the tooth plate. The preliminary findings *partially support the hypotheses*. Although there was little difference in the load at failure between the two plates, contrary to the hypothesis, there was less motion across the osteotomy site and more strain on the lateral cortical hinge, with the tooth plate than the flat plate. Based on the data collected, sample size calculations suggest testing should continue until a total of 16 specimens have been tested to provide 80% power to detect a difference of at least 343N between the plate types.

Considering the inherent limitations in the methods described in the previous chapters, the aim of the study described in Chapter 6 was to provide the proof-of-concept as to whether or not dynamic single-plane flat-panel radiography could be used to assess micro-motion after medial opening wedge HTO. Micro-motion in a fully healed tibia (7 years postoperative), as well as changes in micro-motion during bone healing (2, 4 and 6 weeks postoperative), were measured after medial opening wedge HTO. Dynamic imaging sequences were acquired while patients performed weight-shift tests. Custom 3D-to-2D registration software was used to obtain motion of the proximal and distal sparse models around the osteotomy. A bone coordinate system was established to relate motion of the proximal tibia sparse model relative to the fixed distal tibia sparse model. The data indicated that there was motion in the fully healed tibia, with the trend line suggesting the proximal tibia moved closer to the distal tibia as weight was shifted onto the HTO limb, with less motion occurring when weight was shifted of off the HTO limb. The data from 2- and 4-week tests indicated that there was separation between the proximal and distal segments as the HTO limb was loaded. The same separation was not present at the 6-week tests, which may suggest the progression of healing of the osteotomy. However, these data need to be interpreted with caution, given the size of the observed motion (>1mm), and the fact that its direction was not always consistent with what was expected with loading and unloading the limb. An alternative interpretation of these results is that considerable error exists with the current methods and further refinements are required. The overall finding *support the hypothesis* that dynamic single-plane flat-panel radiography has the potential to assess healing of the osteotomy, however modifications of the registration algorithms is required to increase confidence in distinguishing true motion from registration error.

7.2 Limitations and Future Directions

The gait studies described in this thesis relied on the external moments about the knee to provide insight into dynamic knee joint loading. Although the external knee adduction moment is a valid measure of the distribution of load across the knee, is correlated to internal medial compartment loads, and is a risk factor for disease progression, substantial limitations in this measure must be acknowledged. Most importantly, external moments about the knee do not directly take into account how muscle contraction contributes to knee joint loading. Previous research has suggested that most of the load on the knee joint is a result of muscle contraction. Although the studies in this thesis suggest that medial opening wedge HTO decreases knee joint moments and therefore decreases the load on the medial compartment, it is theoretically possible that changes (increases or decreases) in co-contraction of muscles crossing the knee also occur long-term postoperatively. Therefore, future research may benefit by measuring muscle contraction patterns before and after HTO. For example, consistent with developments in the field, electromyography (EMG) driven computational models that estimate muscle and joint forces may aid in confirming the proposed changes in joint loading as a result of HTO.

Similar to the gait analysis studies, the materials testing studies in this thesis did not incorporate muscle or soft tissues. It is currently unclear how muscle forces may affect loading of the lateral cortical hinge and the medial opening wedge HTO plate, as they are located distal to the knee and have far fewer muscles crossing them. In the present thesis, we used different loads to at least partially account for such variation; however, it is possible that dynamic loads experienced during recovery after surgery may be higher (or lower) than used presently. Future testing comparing plate fixations may benefit from the use of cadaveric specimens, although different limitations likely exist with their use. Another possible direction could be to simulate the muscle forces with multibody-system software and apply them to a finite element model of the tibia with an osteotomy plate. The two situations could also be compared to assess the materials testing setup. Ultimately, the combination of results from these different types of studies will provide the most information about plate fixation in medial opening wedge HTO.

Another potential limitation is the use of a custom tacking system that limited the ability to capture out-of-plane motion that might be important to fixation plate stability. Future testing would benefit from incorporating a second camera or an alternative measurement method that has the ability to capture sub-millimeter motion in 3D, such as RSA or dynamic radiography.

As previously discussed, the major limitation in the Single-Plane Flat-Panel Radiography study was the lack of confidence in distinguishing true motion from measurement error. This method would likely benefit from future refinement of the registration process by improving the marker tracking algorithm and the 3D-to-2D point based registration. A test-retest reliability study should be conducted to help determine the measurement error associated with this method.

A limitation in clinical utility of this method is the requirement of implantation of marker beads into the bone to enable motion tracking. This limits research to patients who are undergoing surgery and does not allow for pre-surgical baseline measurements. Intensity-based and model-based motion tracking methods are two alternatives that could be considered in future research. These methods take advantage of bone geometry (intensity-based) or implants (model-based) to track motion and do not require marker beads.

Overall, this thesis developed and tested various biomechanical methods to assess medial opening wedge HTO. Understanding the limitations presented above, the thesis provides novel contributions to this area of research.

Appendices

Appendix A - Sample Size Calculation for Chapter 5

Sample size calculation based on data from Chapter 5

<u>Load at Failure (N)</u>

Toothed plate 1.	1800
Toothed plate 2.	1600
Flat plate 1.	2200
Flat plate 2.	1800
Flat plate 3.	1600

Mean (SD) for all 5 plates: 1800 (245)

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<u>Sample size</u>

Based on a comparison of two independent means, a two-sided alpha=0.05, power=80%, and a standard deviation of 245N, the following numbers of plates (of each type) would be required to detect the following differencesin load at failure.

Difference between plates (N)	100	200	300	343	400	500	600
Number of plates of each type	95	24	11	8	6	4	3

--

Calculation: Number per group = $2((Z_\alpha + Z_\beta)^2 (\sigma^2))/(\Delta)^2$ Where:

α = probability of making a type I error = 0.05, (thus Z_α=1.96)

$1-\beta$ = power to detect a difference if one truly exists = 0.80, (thus β = 0.20 and Z_β = 0.84)

σ = standard deviation = 245

Δ = difference between groups

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Testing will continue until a total of 16 plates (8 of each type) have been tested. Based on the information above, that will provide 80% power to detect a difference in load at failure of 343 N between plate types.

Appendix B - Ethics Approvals

Western Research

Research Ethics

Use of Human Participants - Ethics Approval Notice

Principal Investigator: Dr. Trevor Birmingham
File Number:1187
Review Level: Delegated
Approved Local Adult Participants:900
Approved Local Minor Participants:0
Protocol Title: Medial Opening Wedge High Tibial Osteotomy for the Treatment of Knee Osteoarthritis: Evaluation of Dynamic Joint Loads and Health-Related Quality of Life - 09812E
Department & Institution: Health Sciences\Physical Therapy,Western University
Sponsor: Canadian Institutes of Health Research

Ethics Approval Date: March 26, 2013 **Expiry Date:**April 30, 2017
Documents Reviewed & Approved & Documents Received for Information:

Document Name	Comments	Version Date
Revised Letter of Information & Consent		
Revised Western University Protocol		

This is to notify you that The University of Western Ontario Research Ethics Board for Health Sciences Research Involving Human Subjects (HSREB) which is organized and operates according to the Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans and the Health Canada/ICH Good Clinical Practice Practices: Consolidated Guidelines; and the applicable laws and regulations of Ontario has reviewed and granted approval to the above referenced revision(s) or amendment(s) on the approval date noted above. The membership of this REB also complies with the membership requirements for REB's as defined in Division 5 of the Food and Drug Regulations.

The ethics approval for this study shall remain valid until the expiry date noted above assuming timely and acceptable responses to the HSREB's periodic requests for surveillance and monitoring information. If you require an updated approval notice prior to that time you must request it using the University of Western Ontario Updated Approval Request Form.

Members of the HSREB who are named as investigators in research studies, or declare a conflict of interest, do not participate in discussion related to, nor vote on, such studies when they are presented to the HSREB.

The Chair of the HSREB is Dr. Joseph Gilbert. The HSREB is registered with the U.S. Department of Health & Human Services under the IRB registration number IRB 00000940.

[redacted]

Ethics Officer to Contact for Further Information

[redacted]	[redacted]	[redacted]

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[redacted]

Western Research

Research Ethics

Use of Human Participants - Ethics Approval Notice

Principal Investigator: Dr. Robert Giffin
File Number:100870
Review Level: Delegated
Approved Local Adult Participants:14
Approved Local Minor Participants:0
Protocol Title: Precision of Roentgen Single-plane Photogrammetric Analysis (RSPA) in patients after high tibial osteotomy 18228E
Department & Institution: Schulich School of Medicine and Dentistry\Surgery,Western University
Sponsor:
Ethics Approval Date: August 13, 2013 **Expiry Date:**January 31, 2014
Documents Reviewed & Approved & Documents Received for Information:

Document Name	Comments	Version Date
Revised Study End Date	The study end date has been extended to January 31, 2014 to account for a delay in the start of the project.	

This is to notify you that The University of Western Ontario Research Ethics Board for Health Sciences Research Involving Human Subjects (HSREB) which is organized and operates according to the Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans and the Health Canada/ICH Good Clinical Practice Practices: Consolidated Guidelines; and the applicable laws and regulations of Ontario has reviewed and granted approval to the above referenced revision(s) or amendment(s) on the approval date noted above. The membership of this REB also complies with the membership requirements for REB's as defined in Division 5 of the Food and Drug Regulations.

The ethics approval for this study shall remain valid until the expiry date noted above assuming timely and acceptable responses to the HSREB's periodic requests for surveillance and monitoring information. If you require an updated approval notice prior to that time you must request it using the University of Western Ontario Updated Approval Request Form.

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The Chair of the HSREB is Dr. Joseph Gilbert. The HSREB is registered with the U.S. Department of Health & Human Services under the IRB registration number IRB 00000940.

[redacted]

Ethics Officer to Contact for Further Information

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Western

Research Ethics

Use of Human Participants - Ethics Approval Notice

Principal Investigator: Dr. Robert Giffin
File Number:103427
Review Level: Delegated
Approved Local Adult Participants:5
Approved Local Minor Participants:0
Protocol Title: Early Measures of Micromotion During Dynamic Loading Following Medial Opening Wedge High Tibial Osteotomy: A pilot study using Roentgen Single-plane Photogrammetric Analysis (RSPA)
Department & Institution: Schulich School of Medicine and Dentistry\Surgery,Western University
Sponsor:
Ethics Approval Date: February 13, 2013 **Expiry Date:**April 30, 2014
Documents Reviewed & Approved & Documents Received for Information:

Document Name	Comments	Version Date
Other	Flow Chart 1: StepUp	2013/01/14
Other	Flow Chart 2: RSPA	2013/01/14
Letter of Information & Consent	Letter of Information and Consent	2013/01/14
Western University Protocol		2013/01/16

This is to notify you that The University of Western Ontario Research Ethics Board for Health Sciences Research Involving Human Subjects (HSREB) which is organized and operates according to the Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans and the Health Canada/ICH Good Clinical Practice Practices: Consolidated Guidelines; and the applicable laws and regulations of Ontario has reviewed and granted approval to the above referenced revision(s) or amendment(s) on the approval date noted above. The membership of this REB also complies with the membership requirements for REB's as defined in Division 5 of the Food and Drug Regulations.

The ethics approval for this study shall remain valid until the expiry date noted above assuming timely and acceptable responses to the HSREB's periodic requests for surveillance and monitoring information. If you require an updated approval notice prior to that time you must request it using the University of Western Ontario Updated Approval Request Form.

Members of the HSREB who are named as investigators in research studies, or declare a conflict of interest, do not participate in discussion related to, nor vote on, such studies when they are presented to the HSREB.

The Chair of the HSREB is Dr. Joseph Gilbert. The HSREB is registered with the U.S. Department of Health & Human Services under the IRB registration number IRB 00000940.

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Ethics Officer to Contact for Further Information

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Appendix C - Letter of Permission

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Feb 16, 2014

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Licensed content author	Kristyn M. Leitch,Trevor B. Birmingham,Cynthia E. Dunning,J. Robert Giffin
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Expected completion date	Apr 2014

Curriculum Vitae

Name:	Kristyn Leitch
Post-secondary Education and Degrees:	University of Western Ontario London, Ontario, Canada 2002-2006 BESc (Mechanical and Materials)
	The University of Western Ontario London, Ontario, Canada 2006-2008 MSc (Rehabilitation Science).
	The University of Western Ontario London, Ontario, Canada 2008-2014 PhD (Biomedical Engineering)
Honours and Awards:	Joint Motion Program (JuMP) – A CIHR Training Program in Musculoskeletal Health Research and Leadership (2010 - Present)
	University of Western Ontario Graduate Research Scholarship 2006-2008
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	Lecturer The University of Western Ontario - School of Physical Therapy 2008

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University of Western Ontario - Faculty of Health Science
2007-2008

Research Grants

In-vitro biomechanical investigation of plate designs used for medial opening wedge high tibia osteotomy. 2013
Arthrex
Letich KM, Birmingham TB, Dunning CE, Giffin JR
$9,135

The effect of The Masai Barefoot Technology shoe on lever arm and peak adduction moment about the knee in individuals with medial knee osteoarthritis during gait. 2008-2009
Fowler Kennedy Sports Medicine Clinic Internal Research Grant
Leitch KM, Birmingham TB, Giffin JR, Jenkyn TR
$5960

Publications:

Refereed Papers

Sischek El, Birmingham TB, **Leitch KM**, Martin R, Willits KW, Giffin JR. Staged medial opening wedge high tibial osteotomy for bilateral varus gonarthrosis: Biomechanical and clinical outcomes. Knee Surgery, Sports Traumatology, Arthroscopy. 2013 June 13.

Leitch KM, Birmingham TB, Dunning CE, Giffin JR. Changes in Valgus and Varus Alignment Neutralize Aberrant Frontal Plane Knee Moments in Patients with Unicompartmental Knee OA. Journal of Biomechanics. 2013 Apr26; 46(7), 1408-12.

Moyer RF, Birmingham TB, Dombroski CE, Walsh RF, **Leitch KM**, Jenkyn TR, Giffin JR. (2012).Combined effects of a custom-fit valgus knee brace and lateral wedge foot orthotic on the external knee adduction moment in patients with varus gonarthrosis. Archives of Physical Medicine and Rehabilitation. Arch Phys Med Rehab.2013 Jan; 94(1), 101-12.

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Leitch KM, Birmingham TB, Dunning CE, Giffin JR. Medial opening wedge high tibial osteotomy decreases peak knee internal rotation and adduction moments during level walking and stair ascent. (Under Review)

Leitch KM, Birmingham TB, Reeved JM, Giffin JR, Dunning CE. Development of a multi-axis fixation jig for testing of high tibial osteotomy plates: An application of *in-vivo* gait data. (Under Review)

II. Scholarly Publication – Non Refereed

Leitch KM, Birmingham T, Jones I, Giffin R, Jenkyn T. (2008).Test Re-Test Reliability of In Shoe Plantar Pressure Measurements During Walking. University of Western Ontario.

II. Other refereed contributions – Abstracts and Presentations

Leitch KM, Birmingham TB, Dunning CE, Jones IC, Giffin JR. (2014) Effects of medial opening wedge high tibial osteotomy on moments about the knee during walking and stair climbing. Poster Presentation at OARSI 2014 World Congress on Osteoarthritis, Paris, France, April 2014.

Leitch KM*, Birmingham TB, Dunning CE, Giffin JR. (2013) Neutralizing high and low know moments through surgical realignment. Poster Presentation at OARSI 2013 World Congress on Osteoarthritis, Philadelphia, PA, USA, April 2013.

Leitch KM*, Birmingham TB, Reeves JM, Giffin JR, Dunning CE. Development of a Materials Testing Fixture to Enable Asymmetric Loading of the Lower Limb: An Application of *In-vivo* Gait Data. Podium Presentation at 2012 Canadian Orthopaedic Association Annual Meeting, Ottawa, Ontario, Canada, June 2012.

Leitch KM*, Birmingham TB, Reeves JM, Giffin JR, Dunning CE. (2012) Development of a Materials Testing Fixture to Enable Asymmetric Loading of the Lower Limb: An Application of *In-vivo* Gait Data. Poster Presentation at OARSI 2012 World Congress on Osteoarthritis, Barcelona, Spain, April 2012.

Boulougouris A*, Birmingham TB, Oliver TD, **Leitch KM,** Lemon P, Giffin JR. (2012) Effect of Preoperative Weight Loss on Postoperative Outcomes After High Tibial Osteotomy in Patients with Obesity, Varus Alignment and Medial Compartment Knee OA. Poster Presentation at OARSI 2012 World Congress on Osteoarthritis, Barcelona, Spain.

Leitch KM*, Birmingham TB, Reeves JM, Giffin JR, Dunning CE. (2012) Development of a Materials Testing Fixture to Enable Asymmetric Loading of the Lower Limb: An Application of *In-vivo* Gait Data. Poster Presentation at Ontario Biomechanics Conference 2012, Barrie, Ontario, Canada.

Boulougouris A*, Birmingham TB, Oliver D, Lemon P, Giffin J, **Leitch K.** (2011).The Effects of Changes in Body Composition on Dynamic Knee Joint Loading. Poster presentation at OARSI 2011 World Congress on Osteoarthritis, San Diego, California, USA.

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Birmingham T*, Moyer R, **Leitch K**, Boulougouris A, Jones I. A Systematic Review of Knee Orthoses. Proceedings of the 1^{st} International Congress for Scientific Testing of Orthotic Devices, Axis les Bains, France, March 2011.

Leitch K*, Birmingham T, Jones I, Giffin R, Jenkyn T**.** (2009). Test-Retest Reliability of In Shoe Lateral Heel Pressure Measurements During Gait. Poster Presentation at the 32^{nd} Annual Meeting of the American Society of Biomechanics. State College, PA.

Zecevic A, Magalhaes, L, Cullion, C*, Theou, O, Vlachos, S, **Leitch, K**. (2009). Acting Old: Learning about Aging through Simulation and Photovoice. Bridging partnerships in aging and rehabilitation research. Poster Presentation. St. Joseph's Health Care – Parkwood Hospital and Faculty of Health Sciences, UWO Symposium. London, ON.

Zecevic A*, Magalhaes L, Cullion C, Theou O, Vlachos S, **Leitch K**. (2008). Acting Old: Students Perception of Aging Using Photovoice. Poster Presentation at the 37^{th} Annual Scientific and Educational Meeting of the Canadian Association on Gerontology. London, ON,

Leitch KM*, Jenkyn TR, Birmingham TB, Jones IC, Giffin JR. (2008). Changes in Knee Joint Mechanics as a Result of Lateral Heel Wedging in Individuals with Medial Knee OA. Invited podium presentation at the 2^{nd}Annual Foot and Lower Extremity Symposium: London, ON.