The role of foot posture and motion on external knee adduction moment: implications for the effectiveness of lateral wedge insoles.

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Abstract

The knee joint is the most common joint affected by osteoarthritis (OA). The medial compartment of the knee is more commonly afflicted with OA than the lateral compartment. Lateral wedge insoles (LWI), a common treatment approach for the conservative management of medial compartment knee OA, have previously been considered effective in reducing external knee adduction moment (EKAM). LWI aim to shift a proportion of knee load from the medial compartment to the lateral compartment of the knee joint, providing some symptomatic relief. Foot posture may influence the efficacy of LWI in reducing the EKAM due to its effect on the dynamic function and mechanical alignment of the lower limbs. This thesis investigated the role of foot posture on the magnitude of EKAM and impact on the effectiveness of LWI for the treatment of medial compartment knee OA. Firstly, a repeatability trial was conducted to ensure investigator competency, and reliability of the methods and outcome measures utilised. Secondly, a trial using healthy subjects assessed rearfoot posture using the Foot Posture Index (FPI) to determine if a relationship existed between static foot posture and biomechanical rearfoot motion and their effects on EKAM when wearing LWI, to determine whether clinical foot parameters have a role in the magnitude of EKAM. The role of foot posture in response to LWI, the effects of foot posture on the efficacy of LWI, and effects and impact on EKAM in patients with medial compartment knee OA were assessed. No relationship was identified between clinical static foot posture, biomechanical rearfoot motion, and EKAM. However, a relationship existed between rearfoot motion and EKAM. Rearfoot range of motion can therefore predict the response to LWI. The thesis then examined research questions in regards to the collection of rearfoot motion using different methods (a heel cup cluster and a heel pin cluster) demonstrating that heel pin cluster marker sets are an acceptable method of determining rearfoot motion in barefoot and shod walking. Due to changes in walking speed with lateral wedge insoles the role of increased walking speed on the magnitude of EKAM when wearing LWI was assessed. Increasing walking speed with LWI reduced biomechanical response. The thesis has demonstrated a further understanding of foot posture and ankle motion in healthy subjects and in individuals with medial compartment knee OA. Further clinical studies investigating the role of rearfoot motion and biomechanical response to lateral wedge insoles are indicated.

Chapter One

Introduction

Osteoarthritis (OA) is the most common form of arthritis (Bakken *et al*., 2007) causing pain and stiffness in joints as a result of the degeneration of joint cartilage and underlying bone (Wieland *et al*., 2005). More than 8.5 million people in the UK alone were diagnosed as having OA in the year 2002 (Arthritis Care, 2004). OA is a leading cause of functional disability among older adults (Felson *et al*., 1987) affecting approximately 10% of males and 18% of females aged over 60 years (Murray and Lopez, 1997).

Knee osteoarthritis is a common chronic musculoskeletal condition affecting the entire knee joint, causing severe pain and functional limitation, with the knee joint being the most common joint affected by OA (Felson, 1990, Brandt *et al*., 2003, Parkes *et al*., 2013). In knee OA, the thickness of the articular cartilage decreases and fibrillates, and the bones concerned with the joint alter, including the development of osteophytes and subchondral thickening, the joint capsule also increases in thickness and synovitis is present (Burr, 2003, Abramson, 2004). Knee osteoarthritis affects approximately 12% of people aged 60 and over (Brandt *et al*., 2003), and 10% of individuals aged 55 and over in the UK (Peat *et al*., 2001), and is estimated to be the eighth leading cause of disability in men, and the fourth most common in women globally. As much as a third of the population within the United Kingdom over the age of 40 years complain of symptoms associated with knee OA (such as knee pain), of which 50% will develop knee OA (Peat *et al*., 2001).

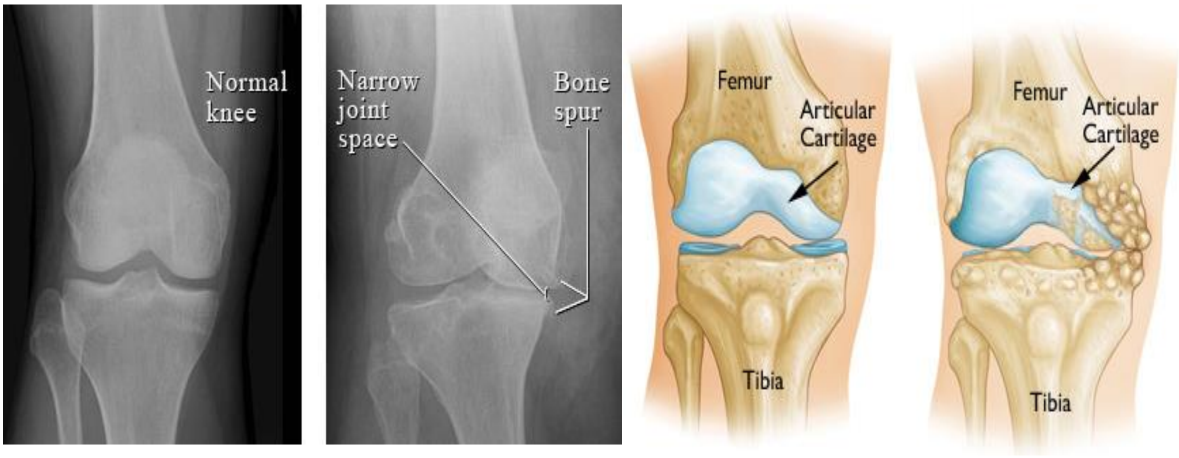

Figure 1.1: X-Rays and diagrams depicting the differences between normal knee joints (left) and osteoarthritic knee joints (right) (Sydneykneecomau, 2016).

Knee osteoarthritis causes considerable burden to society, and is a leading health concern within the UK, in addition to the consequences experienced by patients (pain and loss of dynamic function) due to the high financial cost of existing interventions and because of knee OA's chronic course (Healey *et al.*, 2002, Bitton, 2009). Approximately 24% of the UK population aged 65 years or above present osteoarthritic changes in one or both knee joints, resulting in considerable economic costs. OA of the knee and hip carry a great social impact and additional disability compared to OA of other joints, with the knee causing the greater of the two, resulting in significant economic impacts. (Jinks *et al.*, 2004, Bijlsma and Knahr, 2007).

Knee OA significantly contributes to functional limitations and disability in those affected, and is characterised by pain in the knee (which increases with activity and is relieved with rest), knee joint swelling, stiffness, decreased quadriceps femoris muscle strength, and a decrease in joint range of motion (ROM) (Bijlsma and Knahr, 2007).

The main factors affecting the development of knee OA are body mass (obese people with a high Body Mass Index (BMI) are more likely to develop knee OA due to increased load on the knee joint, and therefore increased weight bearing by the knee joint), age, gender, racial characteristics, abnormal biomechanics of the lower limbs, previous lower limb injury and genetic predisposition (Felson *et al.*, 2000).

The medial compartment of the knee is four times more likely to be affected with knee OA than the lateral compartment (Ledingham *et al*., 1993). During walking, the knee joint is subject to a continual system of forces and moments which work in equilibrium when no pathologies of the lower limbs are present. However, individuals with knee OA exhibit alterations from the normal gait of healthy individuals, including greater mid stance knee adduction moments, decreased stance phase sagittal plane peak flexion moments, reduced peak hip adduction moments, and decreased peak hip extension moments (Lewek *et al*., 2004, Astephen *et al*., 2008). Previous investigations have observed secondary gait alterations in patients with medial knee OA indicating an adaptive strategy to shift load from the medial side of the knee to the lateral side in an attempt to reduce pain, including walking at slower speeds (Winter, 1991, Kaufman *et al*., 2001, Al-Zahrani and Bakheit, 2002, Baliunas *et al*., 2002, Mundermann *et al*., 2005, Messier *et al*., 2005).

A reliable indicator of medial compartment knee loading is the external knee adduction moment (EKAM), which can be measured during walking to determine alterations in load (Schipplein and Andriacchi, 1991) and has previously been described as an accurate way of determining knee OA disease presence, severity and progression (Sharma *et al*., 1998, Baliunas *et al*., 2002, Miyazaki *et al*., 2002). The EKAM is created during walking, where the resultant ground reaction force (GRF) passes medial to the centre of the knee joint, applying an EKAM about the knee joint throughout stance, causing a turning effect, resulting in the tibia rotating medially with respect to the femur, and therefore a large proportion of the load on the knee joint is transferred through the medial compartment of the knee (Shelburne *et al*., 2008).

The magnitude of the peak adduction moment during normal walking is associated with medial and lateral cartilage thickness in the load bearing regions of the knee joint during walking. Medial knee joint cartilage thickness increases with the magnitude of the adduction moment in healthy cartilage, suggesting that healthy cartilage adapts to higher loads during walking by increasing cartilage thickness in different regions. Knee OA patients have a relative decrease in cartilage thickness in the load-bearing regions of the medial compartment of the knee joint, and a higher adduction moment. Load on the knee joint can lead to an adaptive response (thickening and enhanced mechanical properties) within the knee joint cartilage, and degraded cartilage cannot adapt to repetitive loads during walking on a cellular level, and therefore degrades at a higher rate, caused by higher loads of the knee joint during walking. Altered contact mechanics in the newly loaded regions of the knee joint may lead to local degenerative changes in the articular cartilage. Alterations in mechanics could therefore cause the shifting of loads on to areas of cartilage that may respond poorly and fail to adapt well to increases in load, leading to degenerative changes in the knee joint. However, Griffin and Guilak (2005) state that 'the degeneration of articular cartilage leading to knee osteoarthritis is complex, involving interconnected biological, mechanical, and structural pathways, including a kinematic change in loading patterns during walking, of sufficient magnitude (due to injury, increased laxity, neuromuscular changes, or obesity) to transfer load to areas of knee cartilage that are not conditioned to chronic loading during walking, causing degradation and negative response to load, resulting in the rapid progression of knee OA' (Griffin and Guilak, 2005).

The magnitude of the EKAM is influenced by the magnitude of the GRF (Reeves and Bowling, 2011). Reducing the EKAM has therefore become the objective of knee OA treatment in an attempt to reduce pain, maintain function and slow and possibly prevent disease progression (Jones *et al*., 2012). Changes in certain kinematic or kinetic factors during gait could possibly reduce medial knee load and therefore the EKAM (Chang *et al*., 2007), and understanding and managing those factors could lead to a reduction in knee OA disease progression over time.

Walking with a greater toe out angle, walking with a narrow gait, increasing mediolateral trunk sway, barefoot walking, modifying foot posture, and reducing walking speed have previously been suggested as gait altering strategies to reduce the EKAM and therefore medial knee loading (Shabook and Block, 2006, Chang *et al*., 2007, Reilly *et al*., 2009, Levinger *et al*., 2010, Lidtke *et al*., 2010, Hunt *et al*., 2011, Wilson, 2012, Street and Cage, 2013).

Many differing interventions can be used in the management of knee OA, including pharmacological, surgical and conservative treatment methods (Fang *et al*., 2006).

Pharmacological interventions such as analgesics and non-steroidal anti-inflammatory drugs (NSAID's), used to relieve pain and inflammation are the most commonly used intervention, and are effective in reducing pain, however may lead to an increase in pain free activity and therefore joint loading and possibly disease progression (Schnitzer *et al*., 1993, Huskisson *et al*., 1995, Jones *et al*., 2012), and often carry severe side effects with prolonged use, including gastrointestinal ulceration and bleeding (Bradley *et al*., 1991, Richy *et al*., 2004, Hippisley-Cox *et al*., 2005). Additionally, pharmacological interventions for knee OA fail to address the biomechanical causes of the disease and only manage its symptoms (Walsh and Hurley, 2009). Additional non-pharmacological interventions include hot and cold treatment, weight loss, patient education, walking aids, exercise, physiotherapy and splints (Warsi *et al*., 2003, Christensen *et al*., 2007, McAlindon *et al*., 2014, NICE, 2014).

Surgical intervention is often required in severe cases of knee osteoarthritis, and includes; arthroscopic lavage and knee joint replacements. Surgical intervention, although the most effective treatment method, is extremely costly, and so it is only offered as a last treatment in severe cases where quality of life is seriously affected and other core treatments have been exhausted, in an attempt to reduce pain and restore normal biomechanics of the knee joint (Dieppe *et al*., 1999, Griffin *et al*., 2007). Surgery can also lead to complications, and requires considerable recovery time (Griffin *et al*., 2007). Thus, research into more conservative methods of treatment for knee OA is needed.

Knee OA is a biomechanical disease which is affected by loading on the knee joint (Brandt *et al*., 2008). Therefore, recent research aims to devise suitable conservative interventions which aim to decrease the amount of loading on the knee joint, in an aim to relieve symptoms and slow disease progression. Current interventions aim to relieve a proportion of the load off of the medial side of the knee. Interventions such as lateral wedge insoles (LWI) and valgus knee braces have been suggested in previous investigations as reliable interventions in reducing the EKAM and therefore altering medial compartment knee loading (Jones *et al*., 2012).

Lateral wedge insoles (LWI) are inexpensive, self-administered, conservative mechanical interventions utilised in the treatment of medial compartment knee OA, and comprise of an insole shoe insert with a thicker border on the lateral side, compared to the medial side (Zamosky, 1964, Jones *et al*., 2013, Chapman *et al*., 2015). LWI are a simple intervention and therefore they can be easily and safely used by the knee OA population (Kerrigan *et al*., 2002, Baker *et al*., 2007, Jones *et al*., 2013).

Research has indicated LWI are a successful approach in reducing the EKAM (Jones *et al*., 2012) and therefore alleviate a proportion of the force transmitted by the medial compartment of the knee joint by causing slanting of the calcaneus into an everted position, allowing the centre of pressure in the foot to shift laterally, and therefore modifying load at the knee joint by altering the kinematics and kinetics of the subtalar ankle joint (Sasaki and Yasuda, 1987, Abdallah and Radwan, 2011, Chapman *et al*., 2015), aiming to minimise pain and increase or maintain activity levels (Butler *et al*., 2007, Hinman *et al*., 2008, Shelburne *et al*., 2008).

Results from trials using LWI in knee OA patients have provided inconsistent results in regards to reduction of the EKAM (Jones *et al*., 2014) and pain improvement (Hinman *et al*., 2008), with a number of studies reporting no improvement in pain (Pham *et al*., 2004, Parkes *et al*., 2013, Jones *et al*., 2013) suggesting that lateral wedge insoles are not effective for the treatment of knee pain in individuals with medial compartment knee osteoarthritis (Parkes *et al*., 2013). Interestingly, a substantial reduction in EKAM generated with the use of a lateral wedge insole does not correlate at all with immediate pain reduction (Jones *et al*., 2013).

Additional investigations have identified no symptomatic or structural benefits or effects on disease progression after wearing LWI for 12 months (Bennell *et al*., 2011). A number of LWI trials have reported an incidence of biomechanical non-response to LWI intervention (Kakihana *et al*., 2007, Chapman *et al*., 2015), meaning a number of individuals within the trial did not demonstrate a reduction in knee loading when wearing a LWI. Reilly *et al*., (2009) identified foot posture as a possible influence on the effectiveness of orthotic interventions in patients with medial knee OA, perhaps explaining the incidence of non-response within the Kakihana and Chapman trials. Reilly *et al*., (2009) and Levinger *et al*., (2010) state that foot posture may contribute to a number of lower limb musculoskeletal conditions, and altering of the mechanical alignment and dynamic function of the lower limbs, therefore possibly affecting the efficacy of certain interventions designed for the treatment of knee OA, such as LWI. Therefore, foot posture and its effects on knee loading and also on the efficacy of certain orthotic interventions, specifically LWI requires further investigation, of which this thesis aims to attain.

Levinger *et al.,* (2010) recommends an in depth knowledge of foot posture to be paramount in fully understanding the effect of interventions on the knee and lower limb joints, also allowing the identification of participants who will most likely benefit from intervention. OA patients within a trial by Levinger *et al*., (2012) demonstrated altered foot kinematics during gait that were symptomatic of a less mobile more everted foot type. Additionally, Reilly *et al*., (2009) also infers that accurate foot assessment can provide an appreciation into how foot postures influence or can be influenced by reducing the load on the medial compartment. Furthermore, Chapman *et al*., (2015) concluded that coronal plane foot and ankle biomechanical measures are key mechanisms in influencing the magnitude of the EKAM.

Further investigation is therefore needed in order to determine whether foot posture may influence the incidence of biomechanical non-response to LWI, and will be conducted within this thesis.

The literature concerning the use of LWI for the treatment of medial compartment knee OA in relation to foot posture, rearfoot posture and motion is limited, and a number of articles infer that foot posture should be investigated within future research (Hinman *et al*., 2008, Butler *et* *al*., 2009). A recent study by Chapman *et al*., (2015) concluded that coronal plane foot and ankle biomechanical measures play a key role in the reduction of the EKAM when wearing LWI. However, the exact mechanism of this relationship remains unclear, and therefore this will be investigated within this thesis.

The overall research question of this thesis is to determine the role that foot and ankle motion have on EKAM and to evaluate the efficacy of LWI on EKAM in both patients with medial compartment knee osteoarthritis and also in healthy subjects. Furthermore, to understand what foot and ankle factors could explain biomechanical response to LWI.

<u>Thesis contents</u>

The structure of the thesis will firstly review the existing literature linked to knee OA, the EKAM, and treatments of knee OA, particularly LWI in order to demonstrate the novelty of the investigations within the thesis, and the investigation aims of exploring and satisfying gaps within previous literature (chapter two).

Secondly, the biomechanical methods that define the 3D motion data capture, force measurement and segment modelling and computation are presented, additionally, the full methodology for all studies is detailed (chapter 3). A test-retest study that was conducted by the investigator to ensure repeatability of the investigators reflective marker placement to determine the error within the planned studies is also demonstrated (chapter 3).

The thesis continues by presenting an investigation into static foot posture in 30 healthy limbs using the Foot Posture Index in order to identify any relationship between rearfoot motion and foot posture relative to the magnitude of the EKAM, aiming to provide an understanding of foot posture in barefoot and whether there is a relationship to the EKAM. This was further examined through a larger retrospective data set to establish any relationship between the FPI scores, FPI eversion and inversion static and dynamic rearfoot motion, related to the magnitude of the EKAM, in order to determine the association between the outcome parameters of clinical examination and the magnitude of the EKAM (chapter 4).

A clinical trial was then conducted that assessed the role of foot posture in response to the wearing of LWI, the effects of foot posture on the efficacy of LWI, and also the effects and impact on the EKAM in patients with medial compartment knee OA with the objective of categorising any relationship between clinical static foot posture and biomechanical dynamic foot posture, in biomechanical responders and biomechanical non-responders to LWI (chapter 5).

Rearfoot motion was identified as a possible influence on the biomechanical response and non-response to LWI in medial compartment knee OA patients within investigations conducted in chapter 5. The previous clinical trial did not collect in-shoe rearfoot motion and further examination of the rearfoot was assessed through novel methods for both barefoot and shod data collections. Finally, with changes in speed commonly seen when interventions are worn, a further examination of speed effects on the reduction of the EKAM was investigated (chapter 6).

Finally, the thesis concludes with demonstration of the thesis novelty and potential future studies are presented (chapter 7).

Chapter Two

Literature Review

2.1 Osteoarthritis

Osteoarthritis (OA) can be defined as, 'the degeneration of joint cartilage and the underlying bone' and is a common progressive musculoskeletal disorder (Fang *et al.*, 2006) associated with ageing (Maly *et al.*, 2002), accounting for a large proportion of disability in the UK and globally due to its major effect on joint function as a result of its clinical symptoms, including: pain, joint stiffness, swelling, and a decline in joint range of motion (Kean *et al.*, 2004, Fang *et al.*, 2006, Jones *et al.*, 2015). OA is characterised by the progressive breakdown of articular cartilage, apoptosis of chondrocytes (death of chondrocyte cartilage cells), new growth of cartilage and bone at the joint margins (osteophytes) and increased bony envelope thickness (bony sclerosis) (Brandt *et al.*, 1998, Fang *et al.*, 2006). Further features include: joint space narrowing which contributes to capsular and ligamentous laxity and muscle weakness around the affected joint, leading to joint instability and deformity (Cooke *et al.*, 1994).

OA affects a number of joints within the human body, including joints of the hand, the spine and weight-bearing joints, such as the hip, knee and ankle. It is much more common in the joints of the fingers, hip, knee and spine than in the elbow, wrist and ankle. The knee joint is the most commonly affected weight bearing joint (Oliveria de Almeida *et al.*, 1995).

2.2 Incidence and Prevalence of Knee OA

In 1990, knee OA was found to account for 2.8% of the overall years lost to disability and therefore was considered to be the 10th leading cause of non-fatal burden (Murray and Lopez, 1997). In 2000, knee OA became the 6th leading cause of non-fatal burden as this percentage increased to 3% of overall years lost to disability (Symmons *et al.*, 2006). According to the World Health Organisation (WHO), OA is among the top ten conditions in Europe with respect to causing burdens to society (Englund, 2010).

The incidence and prevalence of OA increases with age with the most common joint affected being the knee (Vad *et al.*, 2002, Wieland *et al.*, 2005, Bakken *et al.*, 2007). It has been established that 10% of people over the age of 55 are affected by knee OA (Peat *et al.*, 2001), with it rarely occurring before the age of 40 years, but most significantly affecting populations aged 70 years and above (Petersson, 1996) with symptoms usually starting to develop between the ages of 40-60. In the UK, 20-28% of the population aged 40 years and above experience knee pain, of which 50% will develop knee OA (Peat *et al*., 2001).

In the Framingham cohort study, 27% of people aged 70 years or less had radiographic knee OA, compared with 44% in people above 80 years (Felson *et al*., 1987). Similarly, symptomatic knee OA was less frequent in people younger than 70 years (7%) compared with more elderly individuals (11.2%). Interestingly, the elderly participants without knee OA at baseline (mean age 70.5 years, range 63-92 years) were followed up for eight years, and 15.6% developed knee OA (Felson *et al*., 1997). The Framingham Osteoarthritis Study provided evidence that over twenty years, the prevalence of symptomatic knee OA increased, whereas radiographic knee OA did not (Nguyen *et al*., 2011). Conversely, the results of an additional cohort study showed the incidence of developing radiographic knee OA increased by 21.7% between 2003-2006 in subjects aged 50 years and above (Duncan *et al.*, 2011).

The incidence and prevalence of OA particularly of the knee joint, overall is higher in women compared to men (Felson *et al*., 1995, Johnson and Hunter, 2014) with 45% of women over the age of 65 having symptoms, whilst radiological evidence is identified in 70% of women over the age of 65 (Symmons *et al*., 2000), however this relationship changes with age (Oliveria de Almeida *et al*., 1995) (Felson and Zhang, 1998). Men aged below 45 years were found to have a higher prevalence of knee OA than women of the same age (Silman and Hochberg, 2001). The estimated lifetime risk for knee OA is approximately 40% in men, and 47% in women (Johnson *et al*., 2014). In the UK, the Chingford study, a 15 year follow up study, explored the incidence and prevalence of radiographic knee OA in 561 women (48-58 years) and discovered the prevalence increased from 9.5% at baseline to 38.6% after 15 years. Similarly to the Framingham study, the prevalence of radiographic knee OA was found to increase in those without the condition at baseline (86.3%), with 39.5% developing radiographic knee OA in at least one knee over a 15 year period (Leyland *et al*., 2012).

The WHO has reported knee OA to be the fourth most common cause of disability in women, and the eighth in men (Vad *et al*., 2002). Srikanth *et al*., (2005) concluded that women are more likely to have more severe knee OA after experiencing the menopause.

Prevalence rates for knee OA based on population studies in the USA are comparable to those in Europe (Litwic *et al*., 2013), however previous studies have identified a higher prevalence of knee OA in some races compared to others (Zhang *et al*., 2001). Chinese women were found to have a higher prevalence of knee OA compared with age matched white American females, and Caucasian females (Zhang *et al*., 2001). Furthermore, black females were acknowledged as having higher prevalence of knee OA than white females (Anderson and Felson, 1988). The differences in prevalence rates may be related to a number of local and environmental factors such as; genetics, anatomy, nutritional status, education, lifestyle, economics, and culture (Jordan *et al*., 2007, Jordan *et al*., 2009, Johnson *et al*., 2014).

2.3 Economic Burden of Knee Osteoarthritis

Knee OA has been found to cause major economic burdens globally, resulting in both direct and indirect costs (Bitton, 2009). In the UK alone, around 25% of the population aged over 65 years have been diagnosed as having knee osteoarthritic changes, resulting in vast economic expense (Jinks *et al*., 2004, Bijlsma and Knahr, 2007). The 2012 Osteoarthritis Nation report conducted by Arthritis Care concluded that approximately 8.5 million of the UK population have OA, which is estimated to cost around 1% of the annual Gross National Product (Arthritis Care, 2012).

Direct costs associated with OA diagnosis include physician and allied health professional visits and hospital costs, while associated indirect costs result from the inability of those afflicted with knee OA to work, despite the disease mostly affecting those who have retired from work due to age (Pincus *et al*., 1989, March and Bachmeier, 1997).

Pincus *et al*., (1989) states that individuals with knee OA experience work limitations, including loss of work days, decreased working hours, inability to find suitable employment and early retirement, all leading to reliance on the state and therefore causing an economic burden (Gabriel *et al*., 1997). In the UK, 36 million working days are lost to OA per year, which is estimated to cost £3.2 billion (Arthritis Care, 2012). This figure is expected to rise in subsequent years due to the global ageing population and increasing prevalence of obesity, and the subsequent increasing incidence of knee OA.

The rates of knee replacements in the UK alone tripled during the period between 1991 and 2006 (Culliford *et al*., 2010) and the cost for total knee replacements carried out in the US was $14.6 billion in 2004 (Kim, 2008). In Canada, the direct costs of 140 patients with OA were $5700 USD per person during the period of 1999-2000 (Maetzel *et al*., 2004). The previously mentioned costs do not take into account the expenses of pain management, loss of income due to disability and various treatments including follow up appointments, revision surgery and rehabilitation physiotherapy (Kim, 2008).

The increasing prevalence of OA worldwide means the economic burden of OA is increasing (Gabriel *et al*., 1997), with a predicted 1.4 million knee replacements expected to be required in 2015, a large increase compared with the amount of knee replacement operations carried out in 2004 (Kim, 2008).

In view of the increasing prevalence of OA and the mounting burdens on the global economies, there is a paramount need to identify and understand the causes of knee OA, in order to find effective preventative treatments and interventions to manage this debilitating disease and reduce risk factors for both incidence and progression of knee OA.

2.4 Diagnosis of Knee Osteoarthritis

OA can be categorised by identifying the joint which is affected (for example the hip or knee), and also by whether it is primary; (idiopathic) (experienced after no antecedent event or disease associated with OA), or secondary; (caused by an antecedent event, for example; metabolic, anatomical, traumatic or inflammatory conditions, congenital diseases, joint disorders, endocrine diseases, or neuropathic anthropathy). Primary (idiopathic) OA can be divided into localised OA (where one joint or region is affected) and generalised OA (where two or more joints or regions are affected) (Altman *et al*., 1987, Brandt *et al*., 1998). Generalised OA includes the following affected areas: the distal and proximal inter-phalangeal joints of the hand, the first carpo-metacarpal joint, knees, hips and the metatarsophalangeal joints (Altman, 1987).

Knee OA can be diagnosed both clinically and/or radiographically. The American College of Rheumatology (ACR) devised a clinical classification criterion which is commonly used in clinical practice to identify symptomatic knee OA. Knee pain experienced on the majority of days in the previous month is the key feature to identifying knee OA (Altman, 1987).

In addition to experiencing knee pain, the patient must also meet at least three out of six of the following criteria in order to be diagnosed with knee OA: The patient must be aged 50 years and above, must experience morning stiffness of the knee for no longer than 30 minutes, must experience crepitus sensations with movement of the knee joint, bone tenderness of the bones in the surrounding area of the joint, bone enlargement around the affected knee joint, and no palpable warmth around the knee joint.

The ACR clinical classification criterion has been shown to be a reliable method in identifying articular cartilage damage at an early stage (Wu *et al*., 2005). Some limitations surrounding the ACR clinical classification criteria can be identified however, as the criteria was established after comparing patients diagnosed with knee OA and young subjects with knee pain caused by varying musculoskeletal issues (mainly rheumatoid arthritis). Additionally, the criteria are mostly subjective and based on opinion, and are therefore open to discussion by professionals (McAlindon and Dieppe, 1989). Even so, the ACR criteria remain of use in identifying and amalgamating the characteristics of participants involved in numerous varying studies for ease of evaluation and comparison (Wu *et al*., 2005). Knee OA may also be diagnosed using both the ACR criteria and radiographic classification criteria. In order to be considered as being afflicted with knee OA, individuals should meet the ACR clinical classification criteria and should also have evidence of osteophytes (bone growths at the joint margins) surrounding the knee joint, identified using radiography (Altman, 1987).

An additional, commonly used radiographic classification method to identify knee OA and to determine its severity is the Kellgren and Lawrence (KL) grading system (Kellgren and Lawrence, 1957). The KL grading system has been developed to diagnose and classify knee osteoarthritis into five grades: KL Radiographic score - Grade 0: no features (Normal); Grade 1: (Doubtful) narrowing of joint space and possible osteophytic lipping; Grade 2: (Mild) definite osteophytes and possible narrowing of joint space; Grade 3: (Moderate) multiple osteophytes, definite narrowing of joint space, some sclerosis and possible deformity of bone contour; Grade 4: (Severe) large osteophytes, marked narrowing of joint space, severe sclerosis and definite deformity of bone contour (attrition) (Kellgren and Lawrence, 1957) (figure 1.1). Knee OA is usually classified when the KL grade is 2 or above (Felson *et al*., 1997, Leyland *et al*., 2012), however it is frequently disputed that the KL grade 1 should not be considered as OA, due to the grades features being of limited clinical significance (Thorstensson *et al*., 2004). Conversely, the KL grade 1 classification has been associated with progression of radiographic features five years after initial grade 1 classification and therefore is noteworthy, and should be treated as an early phase of the disease (Hart and Spector, 2003). Previous investigations also questions the relevance of osteophytes in the osteoarthritic process, as their role is not clear (Thorstensson *et al*., 2004).

Limited correlation exists between knee OA severity and clinical symptoms. The Framingham study identified 60% of participants with radiographic knee OA to be asymptomatic (Felson, 1990). Pain is usually the major concern for patients with knee OA as it affects quality of life, balance and knee function. Consequently, clinical management of knee OA irrelevant of the KL classification stage usually focuses on decreasing pain and therefore managing symptoms and not their cause (Felson, 1990).

Figure 2.1: Kellgren and Lawrence Knee Osteoarthritis Radiographic Grading Scale (A = KL grade 1, B = KL grade 2, C = KL grade 3, D = KL grade 4) (Link et al., 2003).

2.5 Knee Osteoarthritis Risk Factors

The current ageing population in the UK and the lack of a cure for OA mean the prevalence of OA is rising over time resulting in increased costs; both financially and also in terms of reducing the quality of life (QoL) of patients (Felson *et al*., 2000). It is therefore paramount that risk factors are identified (Felson *et al*., 2000) aiding early diagnosis of OA. An understanding of symptoms, together with early OA diagnosis, and the development of effective and reliable interventions are vital to treat and manage this debilitating condition (Felson *et al*., 2000).

A combination of systemic and local biomechanical factors contributes to OA of the knee joint (Felson *et al*., 2000). The systemic factors establish the foundation for cartilage properties and quality, whereas local biomechanical factors have a critical influence on the final qualities and properties of articular cartilage, its wellbeing, or deterioration (Cooper *et al*., 2000). Therefore, local biomechanical factors establish both the site and severity of OA (Cooper *et al*., 2000, Felson, 2000, Haara *et al*., 2003). Table 2.1 depicts common systemic and biomechanical risk factors for knee OA.

Table 2.1: Risk factors for knee osteoarthritis, modified from Felson, (2000).

Systemic Factors	Local Biomechanical Factors
Age	Obesity
Gender	Joint Injury
Ethnic Characteristics	Joint Deformity
Bone Density	Sports Participation
Oestrogen Replacement Therapy (post-menopausal females)	Muscle Weakness
Nutritional Factors	Lower Limb Mal-alignment
Genetic Predisposition	External Knee Adduction Moment (EKAM)
Osteoporosis	Coronal Plane Knee Joint Laxity
Other Systemic Factors	Proprioception deficits

2.5.1 Systemic Risk Factors

The following systemic factors are reviewed here briefly, as the majority of these are non-modifiable:

Age – Knee OA prevalence increases with age, meaning elderly people are much more likely to suffer from knee OA than younger people (Felson *et al*., 1987, Buckwalter *et al*., 2004, Heidari, 2011, Peat *et al*., 2011, Johnson *et al*., 2014).

Gender – Knee OA is overall more common in women than in men; however these trends vary with age (Kohatsu and Schurman, 1990, Felson *et al*., 1997, Johnson *et al*., 2014). Knee OA is more common in women aged over 55 years and more common in men before the age of 50 (Felson *et al*., 2000, Silman and Hochberg, 2001, Heidari, 2011).

Hormonal (oestrogen) – Deficiency of the hormone oestrogen in post-menopausal women dramatically contributes to knee OA due to oestrogens regulating effect on bone metabolism (Nevitt and Felson, 1996, Johnson *et al*., 2014). However, pre-menopausal women also have an increased risk of knee OA as the hormone oestrogen causes an increase in bone mass, therefore increasing the loading on the knee joint and the articular cartilage (Nevitt and Felson, 1996).

Osteoporosis and Bone Density – Low bone density is associated with a decreased risk of knee OA due to the reduced load on the knee joint. However, the presence of osteoporosis and bone resorption in bones surrounding an arthritic knee joint is correlated with progressive knee OA (Bettica *et al*., 2002).

Ethnicity – The risk of OA is greater among populations of African American and Chinese descent when compared to the risk faced by non-Hispanic white women (Anderson and Felson, 1988, Kington and Smith, 1997, Felson and Zhang, 1998, Zhang *et al*., 2001). The cause of this increased risk is unknown, but could be influenced by environmental factors surrounding these individuals and also local factors, such as nutritional intake and obesity (Zhang *et al*., 2001).

Genetic Factors – Genetic elements, specifically cartilage oligomeric protein genes can cause an increase in the incidence of knee OA after an injury has taken place in the knee joint (Loughlin, 2003).

Biochemical Markers – The presence of certain biochemical markers, particularly cartilage oligomeric matrix protein when present in the synovial fluid and urine identifies those at high risk of developing knee OA (Felson *et al*., 2000). Bone turnover markers (serum OC and CTX-I), cartilage and synovial tissue turnover were identified as being in decline in patients with knee OA when compared with controls. Measuring these markers is a valuable method of identifying the progression of OA (Garnero, 2001).

Nutritional Factors – Dietary intake of antioxidants, for example ascorbic acid (vitamin C), lycopene and beta-carotene have been identified as reducing the progression of knee OA due to their ability to contribute towards collagen production, however a high intake of antioxidant nutrients does not decrease the risk or incidence of developing knee OA (McAlindon *et al*., 1996).

Clinically diagnosed deficiency of vitamin K increases the risk of progressing knee osteoarthritis and cartilage lesions due to the role of vitamin K in the regulation of bone and cartilage mineralisation (Neogi *et al*., 2006, Misra *et al*., 2013).

Additionally, low dietary intake or low serum levels of calciferol (vitamin D) may have significant consequences on the development of knee OA in patients, particularly those with a low body mass index (BMI), leading to an increase in the incidence and progression of the disease, due to the role of calciferol in several aspects of bone and articular cartilage metabolism with low serum levels of calciferol predicting loss of joint space and increased osteophyte growth within the diseased knee joint (McAlindon *et al*., 1996, Felson *et al*., 2007, Johnson and Hunter, 2014). Conversely, randomised controlled trials have identified the relationship between knee OA and vitamin D to be somewhat conflicted, concluding that no cartilage loss is present in subjects with low levels of vitamin D (McAlindon *et al*., 2010). Further studies are necessary in order to achieve an enhanced understanding of the association between knee OA and dietary factors.

The majority of systemic risk factors are non-modifiable and therefore it is paramount that modifiable risk factors are investigated through biomechanical factors.

2.5.2 Local Biomechanical Risk Factors

Obesity – There is considerable evidence indicating that the increased load on the knee joint due to an obese individual's elevated body mass is a major risk factor of knee OA leading to antedated development of the disease, and causing an increased risk of radiographic knee OA progression (Cooper *et al*., 2000, Silman and Hochberg, 2001, Felson, 2004, Zhang and Jordan, 2010, Aaboe *et al*., 2011, Heather *et al*., 2012, Muraki *et al*., 2012, Johnson and Hunter, 2014, Murphy *et al*., 2016), with a single-limb stance phase of a normal gait cycle showing the force through the knee to increase by 2-3lbs for every 1lb increase in body weight (Felson *et al*., 2000). This can lead to cartilage breakdown, ligamentous malfunction and knee instability due to increased joint loading (Felson *et al*., 2000, Aaboe *et al*., 2011).

A study by Cicuttini *et al*., (1996) identified the risk of knee OA to increase by 9-13% for every 2 pound increment in body weight. Likewise, a meta-analysis by Jiang *et al*., (2012) identified a 35% increased risk of knee OA for every 5-unit increase in body mass index (BMI), additionally, Messier *et al*., (2005) identified that for each unit of weight loss, a four unit reduction in knee joint forces was observed during walking in overweight and obese individuals with knee OA, and with each 1kg of weight loss, a 1.4% reduction in the knee adduction moment was achieved, meaning a dose-response relationship can be identified between the risk of knee OA and obesity, particularly in females and weight loss resulting in a reduction of load exerted on the knee joint per step, accumulating each day gives a clinically meaningful reduction, and benefits to the individual (Messier *et al*., 2005).

Consequently, weight loss is advocated as an ideal first treatment for overweight and obese individuals with knee OA as it has been reported to yield clinically significant improvements in knee joint function and activity, and reductions in pain and inflammation, therefore reducing the disability of overweight and obese individuals with knee OA (Messier *et al*., 2000, Messier *et al*., 2004, Christen *et al*., 2005, Messier *et al*., 2005, Miller *et al*., 2006, Zhang *et al*., 2009, Messier *et al*., 2010, Richette *et al*., 2010, Aaboe *et al*., 2011, Heather *et al*., 2012).

Various methods of achieving weight loss and a subsequent reduction in the BMI of overweight and obese individuals with knee OA are available, with the most common methods involving combinations of energy deficit controlled diets, and exercise. Although, exercise can be difficult for individuals with knee OA due to pain, disability and reduced knee function, particularly if they are older and are of a higher BMI, and adherence to exercise and diet prescriptions can be difficult to control and ensure, a high number of studies have reported successful outcomes of trials using diet and exercise to reduce individuals weight for the treatment of knee OA (Messier *et al*., 2000, Messier *et al*., 2004, Christen *et al*., 2005, Messier *et al*., 2005, Miller *et al*., 2006, Zhang *et al*., 2009, Messier *et al*., 2010, Richette *et al*., 2010, Aaboe *et al*., 2011, Heather *et al*., 2012).

A study by Messier *et al.*, (2010) examined weight loss in knee joint loads during walking in participants with knee OA, and reported that a 10% reduction in weight in overweight and obese participants led to a reduction in knee joint compressive forces during walking, compared to a non-weight loss group. The difference in knee joint compressive forces is mostly due to reductions in hamstring muscle co-contraction during early stance phase, similarly, an additional study by Messier *et al*., (2004) found that modest weight loss combined with moderate exercise led to better improvements in knee function, pain, and performance compared to either intervention alone.

Likewise, Christensen *et al*., (2005) also examined the effects of a diet induced 10% reduction in body weight and concluded the 10% reduction resulted in 28% improved function of the knee joint. A 16 week intensive combination treatment consisting of a hypo-energetic diet and nutritional education conducted by Aaboe *et al*., (2011) in overweight and obese individuals with knee OA aimed to reduce body mass by at least 10%. The average weight loss achieved by participants was 13.7kg from baseline weight. Weight loss was found to significantly reduce knee joint loads during walking, however as weight decreased walking speed increased which caused an interference in the reduction of joint loads. Each kilogram of weight loss reduced the peak knee joint load by 2.2kg (a reduction factor of 2.2), and the EKAM reduced by 12% (Aaboe *et al*., 2011).

Miller *et al*., (2006) reported similar findings after conducting a trial involving intensive weight loss in older, obese and overweight individuals concluding that greater improvements were observed in those with the highest percentage of weight loss.

A reduction of two units of BMI in obese women with symptomatic knee OA was found to decrease the risk of developing knee OA by 50% (Felson *et al.,* 1992). Similarly, the Framingham study states a weight loss of 5kg delivers a 50% reduction in the risk of developing knee OA (Felson *et al*., 1992).

Weight loss is therefore an excellent short term investment in terms of biomechanical joint loading, knee function and pain for patients with knee OA and obesity (Aaboe *et al*., 2011). Obesity is increasing in prevalence and therefore it is likely that a large number of individuals will be affected by knee OA in the future (Johnson and Hunter, 2014). Heather *et al*., (2012) advocates the screening of individuals who are at risk of developing knee OA at an early age, and the education of individuals and their family members, as weight loss and maintenance can reduce the exposure of load bearing joints to obesity induced stress to ensure successful long term disease prevention.

Joint Injury and Previous Lower Limb Injury – The knee joint is one of the most commonly injured joints, and those who have a history of knee injury have a moderate to strongly increased risk of knee OA symptoms, and radiographic symptoms (Silman and Hochberg, 2001, Zhang and Jordan, 2010, Muraki *et al*., 2012, Johnson and Hunter, 2014, Murphy *et al*., 2016). Previous lower limb injury, such as anterior cruciate ligament (ACL) rupture (often considered the most significant lower limb injury concerning knee OA) may cause synovitis and knee joint instability, and is often accompanied by damage to subchondral bone, articular cartilage, the menisci, and collateral ligaments (Slauterbeck *et al*., 2009). An injured and non-functional ACL causes alterations in the static and dynamic loading of the affected knee joint initiating changes in the joint cartilage and therefore impacting joint loading (Chaudhari *et al*., 2008).

An increased incidence of radiographic knee OA was identified in women who had experienced an ACL tear through sport injury (Lohmander, 1994). The tissue damage leading to knee OA is thought to be due to the large forces required to injure the ACL (Buckwalter, 2002). Unfortunately, most patients with ACL tears are aged 30 years or less, leading to an early onset of knee OA, usually between the ages of 30-50 years of age, which in turn leads to a reduced quality of life (Lohmander *et al*., 2007, Friel and Chu, 2013). Knee joint changes indicative of knee OA and functional disability can be identified as early as ten years after the initial injury to the knee joint (Lohmander *et al*., 2007, Slauterbeck *et al*., 2009).

Traumatic meniscal tears and articular cartilage damage as a result of injury are strongly correlated with the onset and development of knee OA (Johnson and Hunter, 2014), and therefore it can be stated that knee and other lower limb injuries often lead to an increased risk of early onset knee OA in individuals (Johnson *et al*., 2002, Friel and Chu, 2013).

Muscle Weakness – The quadriceps femoris works to decelerate the lower limbs during movement, provide dynamic joint stability, and absorb limb loading. Consequently, it has been hypothesised that quadriceps femoris weakness could play a role in the onset and progression of knee OA (Bennell *et al*., 2013, Johnson *et al*., 2014). Discrepancies in muscle strength, activation and proprioception of the quadriceps and gluteus medial muscles often occur as a result of knee OA and are continuously identified in individuals afflicted with knee OA within the literature, postulated to be due to pain avoidance disuse of the lower limbs (Slemenda *et al*., 1998, Lewek *et al*., 2004, Segal and Glass, 2011, Johnson *et al*., 2014,), thought to be due to the failure of voluntary activation of muscles, with knee OA patients demonstrating significantly lower quadriceps strength relative to body mass index (BMI) than a group of control subjects (Lewek *et al*., 2004).

A study by Slemenda *et al*., (1998) concluded that reduced quadriceps strength relative to body weight could possibly be a risk factor for knee OA in women. Likewise, Ikeda *et al*., (2005) identified significant reductions in the size of the quadriceps cross-sectional area in women with knee OA, compared with age and body mass matched healthy women. Muscle atrophy was identified in individuals with knee OA in a number of studies (Slemenda *et al*., 1997, Fink *et al*., (2007), Petterson *et al*., (2008) and therefore it can be assumed that muscle weakness associated with knee OA may be due to the loss in the muscle cross sectional area (Fink *et al*., 2007, Petterson *et al*., 2008).

Quadriceps muscle weakness has been reported as possibly causing the risk of structural damage to the lower limbs to increase, with a study by Slemenda *et al*., (1997) finding a 29% and 20% reduction in the risk of developing both symptomatic and radiographic knee OA for every 5kg increase in extensor strength respectively. Exercise is advocated as a means of improving muscle function, particularly strength, and has been reported to result in reduced pain and improved function in individuals with knee OA (Bennell *et al*., 2013). Exercise can be difficult to adhere to however, due to the symptoms experienced by individuals with knee OA and also due to the fact that those who suffer from knee OA are usually of an older age.

Abnormal Lower Limb Biomechanics – Lower limb mal-alignment, joint laxity, reductions in proprioception (often due to old age), and increased load on the knee can lead to alteration of normal knee biomechanics (Miyazaki *et al*., 2002, Johnson and Hunter, 2014). Sharma *et al*., (2001) identified a strong association between varus and valgus mal-alignment of the lower limbs and knee joint and the increased risk of developing medial and lateral knee OA, leading to progression. Medial progression of knee OA was identified to be four times more likely in individuals with varus alignment, whereas lateral progression of knee OA was found to be five times more likely in individuals with valgus alignment (Cerejo *et al*., 2002, Johnson and Hunter, 2014). Although some subjects with healthy knees have displayed varus mal-alignment in their lower limbs, varus knee alignment is considered to be one of the most useful factors in determining a high knee adduction moment (Barrios *et al*., 2011). Varus malalignment can increase a person's risk of developing knee OA (Moreland *et al*., 1987, Sharma *et al*., 2001), and no study to date has reported the slowing of knee OA disease progression when the malalignment is corrected (Johnson and Hunter, 2014).

Repetitive Joint Stress – Various activities involving continuous squatting, kneeling, and bending positions and the lifting of heavy loads can increase a person's risk of development knee OA (Croft *et al*., 1992, Cooper *et al*., 1994, Messier *et al*., 2009). These activities are often related to occupation, or sports participation (for example skiing and football) (Kujala *et al*., 1995, Coggon *et al*., 2000, Gaudreault *et al*., 2012).

Hansen *et al*., (2012) states physical activity may be detrimental if it places excess load on the knee joint, despite the recognised benefits of conditioning and strengthening the periarticular muscles to aid joint stabilisation, leading to disease progression. The recent review by Hansen *et al*., (2012) acknowledged that no relationship existed between running, high volume running and knee OA in the general population, suggesting that without injury in the knee joint, there is no increased risk of developing knee OA due to running. In contrast, an association was found to exist between elite level athletes and knee OA development, due to the highly repetitive nature of certain sports, intense training demands, and the high impact on the knee joints, when compared to non-elite sports participants (Hunter and Eckstein, 2009). The elite athletes had a higher incidence of knee joint and lower limb injury, so it is unknown if the association is due to sports participation, or injury, with studies by Von Porat *et al*., (2004) and

Lohmander *et al*., (2004) establishing the onset of knee OA in football players to be caused by knee injury, rather than due to repetitive stress caused by training loads.

These systemic and local biomechanical factors can result in a deleterious varus angulation deformity present in patients with medial compartment knee OA which increases or changes loading patterns on the medial compartment of the knee causing damage to the articular cartilage and subchondral bone (Fang *et al*., 2006). The progression of knee OA may also be exacerbated by previous injuries to the knee joint and ligaments, varus malalignment and proximal muscle weakness, all of which are considered to increase the force transmitted by the medial compartment of the knee (Shelburne *et al*., 2008). Knee OA poses a substantial burden on public health, and of the modifiable risk factors discussed above, to date, only obesity and the avoidance of knee joint injury are accompanied by sufficient evidence to support intervention (Johnson and Hunter, 2014). Therefore, there is a requirement for further epidemiological studies in order to prevent the onset and progression of knee OA, and also pain and function related to knee OA.

2.6 Pathogenesis of Knee Osteoarthritis

Knee OA affects both the articular cartilage and underlying bone of the knee joint. Articular cartilage is produced by cartilage cells (chrondrocytes), which form a thin layer consisting of collagen and proteoglycans which covers the surface of all joints. The integrity of this layer is imperative for the cartilage to correctly perform its function of distributing the load across the knee, and reducing friction (Ryu *et al*., 1984).

Knee OA instigates in areas of the joint which are continuously exposed to high and repetitive loading (Miyazaki *et al*., 2002, Amin *et al*., 2004), such as areas of the tibial condyle which are not protected by the menisci and the vertical ridge of the patella (Ryu *et al*., 1984). In knee OA patients, proteolytic degradation of the layer of collagen and proteoglycans occurs and chondrocyte activity increases, therefore resulting in morphological changes to the cartilage, such as softening, fibrillation, fissuring, ulceration and finally loss of the femoral and tibial articular cartilage (Wluka *et al*., 2002, Heinegard *et al*., 2003).

Knee OA patients lose approximately 5% of their tibio-femoral articular cartilage annually (Wluka *et al*., 2002, Johnson and Hunter, 2014). The medial compartment of the knee is most commonly affected by OA, more so than the lateral compartment by 10-fold (Ahlbäck, 1968, Felson *et al*., 2002, Mundermann *et al*., 2008, Jones *et al*., 2015) perhaps due to the decreased thickness of the articular cartilage on the medial compartment compared to the lateral compartment, but mainly because of its high load bearing capacity, with the peak load on the medial compartment almost 2.5 times higher than the peak load on the lateral compartment (Prodromos *et al*., 1985, Schipplein and Andriacchi, 1991, Cicuttini *et al*., 2002, Mundermann *et al*., 2008, Jones *et al*., 2015) and also, due to the line of gravity and the ground reaction force passing medially to the knee joint in the frontal plane during walking, creating a moment causing adduction of the tibia relative to the femur (Schipplein and Andriacchi, 1991).

Knee OA has no sudden onset, and is characterised by a gradual process of joint changes and symptoms, often making it difficult to diagnose (Barrios *et al*., 2009). The pathogenesis of knee OA requires further investigation and currently the disease is usually only detectable after irreversible joint damage of both cartilage and bone has taken place (Fang *et al*., 2006). This is evident in morphological joint changes, such as; loss of knee joint (hyaline) cartilage, meniscal maceration, loss of joint space (joint space narrowing), thickening of subchondral bone and osteophyte growth indicating extrusion (Brandt, 2003, Burr, 2003, Englund, 2010). Knee joint space narrowing contributes to capsular and ligament laxity which is characterised by progressive softening and breakdown of articular cartilage and eventually bone at knee joint margins, apoptosis of chondrocytes (breakdown of cartilage cells), muscle weakness around the joint leading to joint instability and deformity, and bony sclerosis (Cooke *et al*., 1994, Brandt *et al*., 1998, Kean *et al*., 2004).

Knee OA also leads to inflammation of the joint, caused by repetitive stresses (synovitis) where the synovium and chrondrocytes produce cytokines that degrade the activity of the chrondrocytes (Abramson, 2004). Figure 2.2 illustrates the changes in the knee joint in patients with knee OA.

Figure 2.2 OA Knee Joint (Schultz, 2011).

Knee OA is characterised by knee pain, which is known to increase with activity and reduce with rest. Joint swelling and stiffness after rest (especially in the mornings) and reduced ROM are also typical symptoms of knee OA (Bijlisma and Khahr, 2007). It is not the breakdown of the joint cartilage that causes pain in OA, as cartilage does not have a nerve supply, but rather pain is caused by repetitive stresses resulting from the reduction in cartilage, affecting the other structures of the joint, including the subchondral bone, ligaments, joint capsule, periosteum and synovium (Kidd *et al*., 2004). Therefore, the increased repetitive stress and load on these structures (other than the cartilage) cause the pain, and not the reduction in cartilage itself (Kidd *et al*., 2004).

Pain is considered the source of functional decline in knee OA, often leading to muscle weakness and atrophy (Baker *et al*., 2004). Pain commonly increases as the disease progresses (Miyazaki *et al*., 2002) and often leads to a decrease in the patients activity levels (Fransen *et al*., 2001) causing them to become more dependent on others in their daily life (Felson *et al*., 1987).

A number of approaches can be utilised in order to reduce pain experienced as a result of knee OA, but firstly an understanding of the factors and changes which initiate pain resulting from knee OA must be gained. Alterations in the biology and biomechanics of the lower limbs can cause and be caused by medial compartment knee OA (Andriacchi *et al.*, 2009, Hsu *et al*., 2015).

2.7 Biological Consequences of Medial Compartment Knee OA

A number of biological variations can be identified between healthy knee joints and knee joints affected by knee OA. It is well known that OA occurs when the dynamic equilibrium between the breakdown and repair of joint tissues cannot be maintained. The treatment of OA therefore requires knowledge and understanding of the conditions and events that contribute to the development of OA, as well as the structure and function of synovial joints (Garstang and Stitik, 2006).

The effects of walking mechanics are an important factor in the initiation and progression of osteoarthritis, and have been widely reported within the literature. Knee cartilage is conditioned to loading and also to the large number of repetitive cycles of loading that occur during activities such as walking, as identified by Andriacchi *et al*., (2009) after investigating the effects of walking mechanics on healthy and diseased knee cartilage using magnetic resonance imaging (MRI). Andriacchi *et al*., (2009) compiled 3D thickness models of knee joint cartilage, investigating the relationship between kinematics and kinetics of the knee during walking, and the maintenance of cartilage health. Andriacchi *et al*., (2009) reports that from a biological context, healthy cartilage homeostasis is achieved as long as there are no changes to normal mechanics (including load variance and kinematics), the structure of the knee joint, and cartilage biology, which can be caused by the incidence of injury and other conditions, such as an increase in body mass index (BMI) (Andriacchi *et al*., 2009).

Healthy cartilage is thickest is in the load bearing areas of the tibiofemoral articulation, which are usually in contact during the stance phase of the gait cycle, with the knee positioned near full extension. MRI of healthy knees indicates that the tibial and femoral condyles are thicker in the posterior load-bearing regions of the lateral compartment, which are in contact during walking (Andriacchi *et al*., 2009). The tibial cartilage and femoral cartilage are thicker in the anterior load-bearing regions in the medial compartment of the knee. The variation in cartilage thickness on the tibia was found to mirror the variation of cartilage thickness on the femoral condyles in each compartment of regions where the knee is in contact during walking. Additionally, Andriacchi *et al*., (2009) identified that the anterior to posterior asymmetry in cartilage thickness between the lateral and medial compartments of the knee joint was consistent with typical patterns of internal-external rotation motion of the knee during walking. Therefore, load patterns during walking have a considerable effect on the general characteristics and health of cartilage and also on the regional variation of cartilage thickness in the thickest load bearing areas of the knee joint. Furthermore, individual differences in local load magnitudes can influence cartilage thickness within a specific load bearing region of the joint (Andriacchi *et al*., 2009). Cartilage thickness variation throughout regions of the knee joint has recently been related to the collagen organisation and chondrocyte morphology present in the central (not covered by the meniscus) and peripheral (covered by the meniscus) regions of the superficial zone of the tibial plateau of the articular cartilage, which vary significantly between regions (Andriacchi *et al*., 2009).

The magnitude of the peak adduction moment during normal walking has been associated with medial and lateral cartilage thickness in the load bearing regions of the knee joint during walking. The thickness of the medial knee joint cartilage increases with the magnitude of the adduction moment in healthy cartilage, suggesting that healthy cartilage can adapt to higher repetitive loads during walking by increasing cartilage thickness in different regions. Knee OA patients have a relative decrease in cartilage thickness in the load-bearing regions of the medial compartment of the knee joint, and a higher adduction moment. The relationship between the higher adduction moment and thinner cartilage in patients with knee OA is consistent with the literature, suggesting that the adduction moment during walking can be predictive of the clinical outcome of treatment, disease severity, and disease progression of medial compartment knee OA (Andriacchi *et al*., 2009).

Load on the knee joint can lead to an adaptive response (thickening and enhanced mechanical properties) within the knee joint cartilage. Considering the negative response of osteoarthritic cartilage to load compared to the positive response of healthy cartilage to load, it seems that degraded cartilage cannot adapt to repetitive loads during walking on a cellular level, and therefore degrades at a higher rate, caused by higher loads of the knee joint during walking. Altered contact mechanics in the newly loaded regions of the knee joint may lead to local degenerative changes in the articular cartilage. Cartilage in highly loaded areas of the knee joint indicates mechanical adaptations when compared to underused areas, in which signs of fibrillation can be observed even in healthy knees in relatively young subjects. Alterations in mechanics could therefore cause the shifting loads on to areas of cartilage that may respond poorly and fail to adapt well to increases in load, leading to degenerative changes in the knee joint. However, Griffin and Guilak (2005) state that ‘the degeneration of articular cartilage leading to knee osteoarthritis is complex, involving interconnected biological, mechanical, and structural pathways, including a kinematic change in loading patterns during walking, of sufficient magnitude (due to injury, increased laxity, neuromuscular changes, or obesity) to transfer load to areas of knee cartilage that are not conditioned to chronic loading during walking, causing degradation and negative response to load, resulting in the rapid progression of knee OA' (Griffin and Guilak, 2005).

Griffin and Guilak (2005) suggest that an imbalance between the anabolic and catabolic activities of chondrocytes is a key characteristic of knee OA, and therefore, alterations in cellular metabolism may contribute to the onset and progression of the disease. Articular cartilage can alter its structure and composition to accommodate the physical demands of the body, however has a limited ability for self-repair, due to the avascular nature of the tissue, which is also aneural, alymphatic, and with sparse cell population. The components of the extracellular matrix (ECM) slowly regenerate, and homeostasis is maintained by the catabolic and anabolic events of chondrocytes. Such activities are controlled by both genetic and environmental information and factors (for example, growth factors, cytokines, and ECM composition) (Griffin and Guilak, 2005).

The normal synovial joint consists of subchondral bone, articular cartilage, the synovial membrane, synovial fluid, and the joint capsule, supported by the periarticular muscles, tendons, and ligaments, ensuring proper joint function (Garstang and Stitik, 2006). Articular cartilage, supported by subchondral bone and metaphyseal trabecule forms the articular surface. Articular cartilage has a number of roles in the normal joint, including friction reduction, shock absorption, and the spread and transmission of weight loads to the underlying bone. Articular cartilage is composed of an extracellular matrix and chondrocytes. The extracellular matrix is composed mainly of water (65–80% by weight), collagen, and proteoglycans. The other constituents of cartilage are type 2 collagen (10–20%), proteoglycans (4–7%), and cellular elements and proteins (1–10%) (Garstang and Stitik, 2006).

Proteoglycans have a protein core and one or more glycosaminoglycan side chains. Chondrocytes are the only cells of the articular cartilage, located throughout the extracellular matrix. Cartilage is avascular, and therefore the chondrocytes receive nutrients and eliminate waste by diffusion through the synovial fluid and by facilitated imbibition. The subchondral bone also plays a role in normal joint protection. The deepest layer of cartilage is calcified and attached to the subchondral bone plate (cortical end plate). The cartilage and bone are interdigitated at their interface, which serves to transform shear forces into tensile and compressive stresses. Subchondral bone can attenuate about 30% of the loads through the joint, whereas articular cartilage attenuates only 1–3% of load forces (Garstang and Stitik, 2006). In addition to its shock-absorbing function, the subchondral bone plays a supportive role in maintaining the joint environment, containing bone marrow and trabecular bone, end arteries and veins. The subchondral bone has marked porosity, with vessels penetrating the calcified cartilage zone, which helps provide nutrients to the cartilage, and facilitates the removal of metabolic waste products. The synovial membrane also provides protection to the joint, consisting of a thin synoviocyte layer, which forms synovial fluid by plasma ultrafiltration, producing hyaluronate. Synovial fluid is viscoelastic (providing shock absorption and friction reduction), provides a barrier for inflammatory cell and debris movement within the joint, and shields articular nociceptors from inflammatory mediators (Garstang and Stitik, 2006).

Pathological changes present in knee OA include fibrillations and loss of the articular cartilage, and thickening and remodelling of the subchondral bone, also, loss of joint space. It is still unclear whether cartilage and bony changes occur concomitantly or whether one tissue is involved before the other. However, OA typically progresses to involve many or all the of tissues that form the synovial joint, including the articular cartilage, subchondral bone, synovial tissue, ligaments, joint capsule, and muscles that act across the joint. In the early stages of OA, fibrillation and irregularities of the superficial zone of the articular cartilage develop and extend into the transitional zone. After this, focal regions of cartilage loss with clefts and fissure develop, along with changes in the deepest layer of cartilage, the calcified cartilage layer. In late-stage OA, the loss of articular cartilage may be of full thickness, and the bone may become exposed. One of the first pathologic signs of bony involvement in OA is the formation of new extra bone on trabeculae in the subchondral bone. Articular cartilage degeneration is accompanied by subchondral sclerosis, formation of cyst like bone cavities, and development of osteophytes. The growth of osteophytes accompanies changes in the articular cartilage and in subchondral bone in most synovial joints. These fibrous, cartilaginous, and osseous prominences usually develop around the periphery of the joints, but may also occur along insertions of the joint capsule or protruding from the degenerating joint surfaces. Subchondral bone alterations are thought to be a result of abnormal osteoblast function (Garstang and Stitik, 2006).

The loss of articular cartilage leads to secondary changes in synovial tissue, ligaments, and the muscles that surround the involved joint. Thus, the normal protective role played by muscles can be diminished by these secondary effects because decreased use of the joint and decreased range of motion may lead to muscle atrophy, with concomitant loss of joint protection. On a cellular level, OA is thought to represent an imbalance between the destructive and reparative or synthetic processes of the articular cartilage (Huber *et al.*, 2000, Garstang and Stitik, 2006).

The mechanisms responsible for progressive loss of cartilage in OA include alteration of the cartilage matrix, decline of the chondrocytic synthetic response, and progressive cartilage loss. Early changes in the cartilage include an increase in the water content, and progressive disease is marked by loss of the extracellular matrix (Huber *et al*., 2000). Initially, chondrocytes multiply and become metabolically active. They also produce increased quantities of collagen and proteoglycans, but the quality is abnormal. The type II collagen fibers in the osteoarthritic cartilage are smaller than normal, and the normally tight weave in the midzone becomes distorted (Huber *et al*., 2000). In addition, with advancing disease, the proteoglycan concentration decreases to 50% or less. As the disease worsens, less aggrecan is present and the glycosaminoglycan chains become shorter. These cartilage matrix changes lead to increased matrix permeability and decreased matrix stiffness, which then predisposes the joint to further damage. Failure of chondrocytic responses to restore or maintain tissue leads to loss of articular cartilage accompanied or preceded by a decline in chondrocytic response. This decline leads to the last step in the development of OA. OA is considered a non inflammatory arthritis, but there is evidence that as the cartilage destruction proceeds, changes in the joint occur that are associated with inflammation. The synovial membrane may have mild to moderate inflammatory reaction, which is thought to be partly attributable to the inflammatory effects of loose fragments of articular cartilage in the synovial fluid Meyers *et al*., 1992, Huber *et al*., 2000, Garstang and Stitik, 2006). Once the synovium is inflamed, the synoviocytes produce cartilage-degrading enzymes, such as matrix metallotoproteins, and cytokines, including interleukin-1, interleukin-6, and tumor necrosis factor alpha. These stimulate the chondrocytes to produce more degrading enzymes. Enzymatic degradation contributes to further decreased cartilage volume (Guilak *et al*., 2004). In addition to the catabolic processes described above, potent inflammatory mediators are also released into the joint. Additionally, joint impact has been shown to cause upregulation of arachadonic acid, interleukin-1, tumor necrosis factor-alpha, and matrix metallotoprotein-3, even in the absence of fracture (Pickvance *et al*., 1993). Thus, it is likely that a variety of stimuli trigger the events that lead to joint destruction after trauma and to OA in general (Garstang and Stitik, 2006).

Vincent *et al*., (2012) Alterations in patterns of knee kinematics cause a shift from normal articular contact areas to articular areas that are infrequently loaded. Aberrant loading of these areas causes fibrillation of the collagen network, loss of matrix proteoglycans, increased surface friction, increased shear stress, upregulation of catabolic factors (e.g., matrix metalloproteinases and interleukins), and ultimately cartilage degradation (Andriacchi *et al*., 2004, Andriacchi *et al*., 2006, Andriacchi *et al*., 2009). ACL injury, ligament laxity or stiffness, decreased muscle strength, and altered muscle activation patterns can alter normal joint kinematics (Andriacchi *et al*., 2004, Andriacchi *et al*., 2006, Andriacchi *et al*., 2009, Vincent *et al*., 2012).

The pathogenic role of biomechanical dysfunction in OA is well established (Egloff *et al*., 2012). For weight-bearing joints altered loading mechanisms, increased mechanical forces and changed biomechanics are significant contributing factors for initiation and progression of OA. Thus, OA is a disease of the whole joint, including muscles, tendons, ligaments, synovium and bone, with a multifactorial etiology, including increased mechanical stress, ligament derangements, cartilage degradation, subchondral bone changes and muscular impairments. Furthermore, secondary synovial inflammation plays a role in OA, notably in the early stage. Epidemiological studies of the last decades tried to define risk factors such as age, genetic predisposition, obesity, joint congruency, increased mechanical stress and greater bone density. OA may evolve as a consequence after an antecedent incidence, such as intraarticular fractures and ligament lesions, systemic diseases like rheumatoid arthritis, hemochromatosis, haemophilia, or post infectious arthritis, or as a result of a congenital or developmental anatomic abnormality. OA occurs when the dynamic steady state between destructive forces and repair mechanisms destabilises the joint homeostasis (Andriacchi *et al*., 2004, Andriacchi *et al*., 2006, Andriacchi *et al*., 2009, Vincent *et al*., 2012, Egloff *et al*., 2012).

Muscle atrophy can cause OA, but is also seen as a consequence of OA. Synovitis with secretion of proinflammatory cytokines into the joint space correlates with pain and radiological progression. Cartilage degradation is the hallmark of OA. Subchondral bone pathology is also observed in OA, ultimately leading to osteosclerosis. Currently it is not clear whether subchondral bone changes occur as cause or consequence of cartilage damage (Andriacchi *et al*., 2009, Vincent *et al*., 2012, Egloff *et al*., 2012). Other contributing factors are muscle weakness and somatosensory deficits which are consistently accompanied by OA. Muscle weakness is one of the first and most frequent symptoms in OA. However, while muscle weakness and atrophy accompanies OA it is still not clear whether it is caused by OA or precedesit. Muscle weakness is linked to to narrowing of joint space, increased knee pain and elevated development of OA in elderly women. Furthermore, decreased isokinetic quadriceps muscle strength in women have been found to be an indication of increased lower limb loading during the gait cycle. Joint inflammation is a well-recognised feature of OA, notably in the early stage. Inflammation in OA can be triggered by malalignment, overuse, trauma, crystal formation, trauma or idiopathy. Pathobiologically, synovitis leads to the secretion of pro inflammatory cytokines such as tumor necrosis factor (TNF) –alpha, interleukin (IL)-1 or 6. This impaired cytokine balance in the synovial fluid leads to the induction of proteinases such as metalloproteinases or aggrecanase with subsequent cartilage degradation and an inflammatory reaction once the fluid has contact with the subchondral bone, for example, by subchondral cyst formation. The current consensus based on in-vitro mechanical loadings experiments is that injurious compression leads to proteoglycan depletion, destruction of the collagen network and cartilage degradation (Punzi *et al*., 2010). In response, proinflammatory products are released and are postulated to activate the synovium and to cause synovitis (Selam and Berenbaum, 2010, Goldring *et al*., 2011, Egloff *et al*., 2012).

Biology and biomechanics of knee OA are related, and the contribution of biomechanical factors to aetiology, pathogenesis and to disease progression require further research in order to reduce the enormous socioeconomic and personal impact of this disease (Vincent *et al*., 2012, Egloff *et al*., 2012). Similarly, Andriacchi *et al*., (2009) states that the mechanics of walking can play an important role in the consideration of new methods for prevention and treatment of osteoarthritis.

Biological changes present in knee OA are linked to the biomechanics of knee OA (Vincent *et al*., 2012), new methods of treatment and research are therefore needed. MRI is the most accurate and therefore ideal method of viewing biological changes associated with knee OA, as utilised within the literature. However, MRI is costly and not accessible to all patients. Furthermore, MRI is not widely available for use within clinical or research purposes. X-ray is perhaps therefore a more suitable and consequently a more widely used option for the investigation and assessment of the presence and severity of knee OA, despite presenting some limitations.

2.8 Biomechanical Changes in Medial Knee OA

The term ‘biomechanics’ literally means ‘life mechanics’, and describes the science of movement of a living body and the effect of forces and motion on bones, muscles, tendons and ligaments within that body to produce movement when Newtonian mechanics are applied (Rau *et al*., 2000, Rose and Gamble, 2006).

Before an understanding of altered biomechanics due to knee OA can be gained, it is imperative to firstly understand typical biomechanical features of the normal lower limbs and the normal gait cycle.

2.8.1 The Normal Gait Cycle

The term 'gait cycle' describes the period of time and events between two footsteps, and commences from the heel strike of one foot, ending at the subsequent heel strike of the same foot (Perry, 1992). The gait cycle comprises of two phases; phase one consists of stance, where the foot is in contact with the supporting surface and phase two, known as swing describes the forward swinging motion of the limb losing contact with the supporting surface. The gait cycle is divided into four sections: early-stance (0-20% of the gait cycle), mid-stance (21-40% of the total gait cycle), late-stance (41-60% of the total gait cycle) and swing phase (61-100% of the total gait cycle) (Mundermann *et al*., 2004).

The stance phase of gait comprises of approximately 60% of the total gait cycle and allows weight bearing and provides stability. There are five individual actions which occur during the stance phase: heel strike, foot flat, mid stance, heel rise and toe off (Mary, 1988). The swing phase prepares and aligns the foot for the heel strike, ensures the swinging foot clears the floor, and provides forward momentum of the leg. The swing phase comprises of approximately 40% of the total gait cycle (Mary, 1988). Ground contact commences with the heel strike and continues to foot flat during the single limb support and forefoot contact phase (Mary, 1988, Perry, 1992). The double support phase concludes with toe-off (Mary, 1988).

Stance phase and swing phase can be separated into eight phases. These eight phases are as follows: Weight acceptance, which allows initial contact and loading response to take place, mid and terminal stance, which occur during the single limb support phase, the final phase of the stance is pre-swing, which allows the limb to commence the forward motion (Perry, 1992, Perttunen, 2002). This forward motion of the limb continues and forms three swing phases. The leg accelerates forward due to hip and knee flexion and dorsiflexion takes place at the ankle joint during initial swing. The swinging leg is then aligned with the stance limb which is at the mid stance phase, during the mid-swing. During terminal swing, the foot is prepared for controlled, smooth ground touch using the support of eccentric hamstring muscle activity (Mary, 1988, Perry, 1992, Perttunen, 2002).

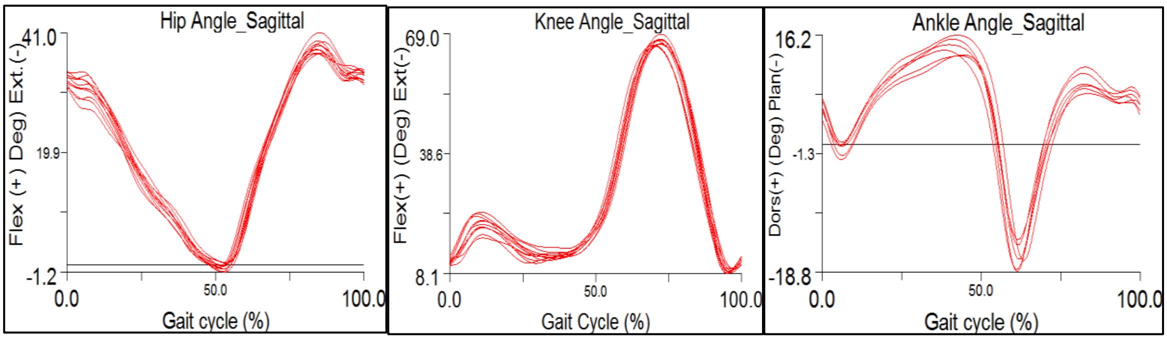

Figure 2.3 – Graphs showing sagittal angle displacement for the hip, knee and ankle joints during the normal gait cycle.

During a typical gait cycle, external ground reaction forces act on the lower limbs due to the foot striking or pushing off from the ground and acceleration or deceleration of the body creating moments. A moment can be defined as a turning force created by a force applied at a distance from a turning point (Richards, 2008). The use of 3D gait analysis allows better understanding of biomechanics and any alterations that may take place in the presence of knee OA or other lower limb pathologies (Zeni and Higginson, 2009). Gait speed is an important consideration when measuring gait parameters based on the magnitude of the GRF and segmental accelerations. More rapid accelerations of the centre of mass of the body may result in a higher GRF and higher joint moments, and both healthy and knee OA individuals experience increases in joint moments when walking at faster speeds. Similarly, reductions in walking speed lead to reductions in knee joint loads (Munderman *et al*., 2004). Larger joint moments are indicative of increased joint loads, and increased joint loads are often implicated in the disease progression of medial compartment knee OA (Miyazaki *et al*., 2002, Lelas *et al*., 2003, Mockel *et al*., 2003, Bejek *et al*., 2006, Zhao et al., 2007, Zeni and Higginson, 2009).

Numerous biomechanical alterations are present in knee OA patients, meaning several significant changes to the normal gait cycle can be observed. Medial knee OA is associated with adjustments to normal biomechanics in gait, balance, muscle strength, and muscle co-contraction in an attempt to accommodate the condition and decrease pain (Rau *et al*., 2000). The following sub-sections describe and discuss biomechanical alterations in gait, knee joint loading, muscle strength, balance and muscle co-contraction, which are evident in knee OA patients.

2.8.2 Medial Knee Osteoarthritis and Gait

As mentioned previously, certain alterations exist between the normal gait of healthy individuals and the gait of individuals with medial compartment knee OA. Individuals with knee OA across varying radiographic severities of the disease have been reported in the literature to adopt slower walking speeds. This is associated with; shortened step lengths, larger double support times, decreased hip and knee ROM angles, reduced cadence and stride length and increased stance times when compared to age matched healthy (non-arthritic) populations (Andriacchi *et al*., 1977, Kaufman *et al*., 2001, Al Zahrani and Bakheit, 2002, Baliunas *et al*., 2002, Messier *et al*., 2005, Landry *et al*., 2007). Mundermann *et al*., (2004) implies that the reduction in walking speed observed in knee OA populations to be an adaptation in order to reduce the load on the knee joint.

Individuals with medial compartment knee OA exhibit greater mid stance knee adduction moments, decreased stance phase sagittal plane peak knee flexion moments (Lewek *et al*., 2004) reduced peak hip adduction moments, and decreased peak hip extension moments when compared to individuals in the same age groups (Lewek *et al*., 2004, Astephen *et al*., 2008). Mundermann *et al*., (2005) observed secondary gait alterations among knee OA patients indicating an adaptive strategy to shift the body's mass more hastily from the contralateral limb to the support limb. This alteration appears successful in reducing the load at the knee in patients with mild to moderate knee OA. The overloading of lower extremity joints could possibly lead to rapid progression of OA symptoms and the onset of OA in joints contiguous to the knee joint (Mundermann *et al*., 2005). This finding indicates the importance of thorough research into possible knee OA interventions. Interventions should be assessed not only on their ability in the treatment of OA, but for their effects on surrounding lower limb joint mechanics (Mundermann *et al,* 2005).

In patients with knee OA, both early stance knee flexion and external rotation moment are decreased (Lewek *et al*., 2004, Childs *et al*., 2004, Rudolph *et al*., 2007, Landry *et al*., 2007, Astephen *et al*., 2008) perhaps due to a more fixed position during heel strike (Childs *et al*., 2004), an increase in stiffening assumed in the presence of knee instability (Schmitt and Rudolph, 2007), a highly flexed position at initial contact (Childs *et al*., 2004), quadriceps weakness (Fisher *et al*., 1997), and finally pain (Kaufman *et al*., 2001). Both early and late stance peak knee flexion moments have also been observed as decreasing (Kaufman *et al*., 2001, Baliunas *et al*., 2002, Astephen *et al*., 2008). In unilateral knee OA, early stance peak knee and hip flexion angles on the OA limb were significantly lower than the angles observed on the contralateral side (Briem and Snyder-Mackler, 2009).

The strategy of reducing knee flexion moments is most likely adopted by knee OA patients as a way of reducing forces on the knee joint and therefore reducing pain (Costigan *et al*., 2002, Astephen *et al*., 2008). The reduction in pain can be attributed to fewer eccentric contractions, as decreasing knee flexion moments requires less eccentric contractions during knee extension (Kaufman *et al*., 2001, Mundermann *et al*., 2005). Astephen *et al*., (2008) identified the maximum knee flexion angle in knee OA patients to be 49.9°, whereas the maximum knee flexion angle for healthy subjects was found to be 68.5°, indicating a large variation. Nevertheless, mid-stance knee extension moments have presented conflicting outcomes in studies of knee OA populations given that they were found to increase (Al Zahrani and Bakheit, 2002) decrease (Huang *et al*., 2008) and remain constant (Messier *et al*., 2005, Mundermann *et al*., 2005) when compared with healthy subjects. Possible explanations for these differences in findings could be; variances in walking speed, pain levels experienced and muscle strength.

The findings of increased mid stance knee extension moments, coupled with an observed prolonged biceps femoris activity may be an attempt by knee OA patients to increase stability during gait (Al Zahrani and Bakheit, 2002). Knee flexion aids in shock absorption during early stance. An increase in walking speed results in surplus forces acting on the knee joint and therefore requiring a higher amount of shock absorption in the knee, shifting the knee into greater flexion (Winter, 1991). Therefore, lower knee flexion is an adaptive strategy adopted by knee OA patients in order to reduce pain and maintain functional activity (Kaufman *et al*., 2001). The drawn out mid stance knee extension moment may increase stability during gait due to amplified biceps femoris activity (Al-Zahrani and Bakheit, 2002). Conflicting results have emerged regarding mid stance knee extension moments, with Huang *et al*., (2008) stating a decrease, Al Zahrani and Bakheit (2002) implying an increase, and Messier *et al*., (2005) declaring the mid stance knee extension moment to remain constant in comparison to healthy subjects (Mundermann *et al*., 2005). Interestingly, early stance peak knee and hip flexion angles on the limb affected by knee OA were considerably less than those on the contra-lateral side in unilateral knee OA (Briem and Snyder-Mackler, 2009). Al Zahrani and Baheit, (2002) identified knee OA patients to display a decreased ROM at the hip, knee and ankle joints during walking. Gok *et al*., (2002) reported knee varus in stance to increase, and knee valgus during swing to also increase.

Muscle Co-contraction

Muscle co-contraction involves the co-ordinated activity of synergistic muscles (agonist and antagonist) (Sirin and Patla, 1987) which are involved in the creation of force moments around joints during movement (Nigg *et al*., 2003). Knee OA patients experience increased co-contraction of both the medial and lateral (quadriceps to hamstring) muscles surrounding the knee joint when walking compared to healthy individuals (Lewek *et al*., 2004, Childs *et al*., 2004), and co-contraction of the knee muscles allows alteration of stability, knee joint stiffness, and increased articular joint loading on the medial compartment of the knee (Fisher *et al*., 1997, Lewek *et al*., 2004, Hubley-Kozey *et al*., 2006, Hubley-Kozey *et al*., 2008). The increased co-contraction affects varying muscles surrounding the knee joint, and it is believed that patients with knee OA adopt variable strategies in order to stiffen the leg and reduce pain (Childs *et al*., 2004, Hortobagyi *et al*., 2005, Schmitt and Rudolph, 2007, Ramsey *et al*., 2007, Hubley-Kozey *et al*., 2009). Muscle co-contraction occurs between; Vastus Lateralis (VL) and lateral hamstring (LH), VL and medial hamstring (MH), VL and semimembranosus (SM), VL and biceps femoris, medial quadriceps and MH, and vastus medialis (VM) and MH (Childs *et al*., 2004, Schmitt and Rudolph, 2007, Ramsey *et al*., 2007, Hubley-Kozey *et al*., 2009).

Knee joint internal moments on the lateral aspect of the joint deliver a valgus resistance against the EKAM, which attempts to move the knee into a more varus position. The activity of antagonist muscles alone (for example the quadriceps) is not great enough to resist the EKAM, and therefore the co-contraction between agonist and antagonist muscles (for example the hamstring and the quadriceps) allows the joint to be stabilised (Schipplein and Andriacchi, 1991). This theory is supported by a study by Hubley-Kozey *et al*., (2009) which identified early stance muscle co-contraction between VL-LH increased in patients with moderate to severe knee OA, when compared to asymptomatic individuals. Results may have been affected by overlapping of the Kellgren and Lawrence grading scale within the study groups (moderate OA K/L grade 1-3, severe OA K/L grade 3-4, and asymptomatic individuals), which may have concealed some present differences between the groups. Furthermore, the asymptomatic group were not assessed using radiography, and therefore some undiagnosed degenerative changes may have been present within the knee joint, possibly affecting results obtained. Additionally, a study by Schmitt and Rudolph, (2007) identified co-contraction between the lateral quadriceps and LG to be considerably higher in patients with knee OA with a Kellgren and Lawrence grading of 2-4 (moderate to severe) compared to healthy study participants. Similarly, co-contraction of the medial aspect of the knee joint was found to increase in mild, moderate and severe knee OA patients when compared to healthy age and gender matched individuals (Lewek *et al*., 2004, Schmitt and Rudolph, 2007, Hubley-Kozey *et al*., 2009). Furthermore, higher co-contraction was identified during early stance between VM and MH in the medial aspect of the knee joint, compared with the lateral aspect of the knee joint in patients with severe knee OA, allowing a distinction to be made between moderate and severe knee OA (Hubley-Kozey *et al*., 2009). The increased co-contraction causes the knee joint to be exposed to more compressive forces (Lewek *et al*., 2004) and may be caused by knee joint instability in the OA afflicted knee due to medial knee joint laxity, suggested as a main contributor to the increased co-contraction, which is present in OA groups significantly more than in healthy participants, leading to a decreased ROM in the osteoarthritic knee (Lewek *et al*., 2004, Schmitt and Rudolph, 2007, Rudolph *et al*., 2007).

An effective method to reduce knee joint laxity involves increasing the strength of the muscles surrounding the knee joint, providing knee joint stability (Slemenda *et al*., 1997). The GRF rate of loading may be increased during gait in the presence of quadriceps weakness (Mikesky *et al.*, 2000) due to alteration of the load distribution across the knee, leading to changes in the mechanical axis of the knee joint and consequently, the development and progression of knee OA (Andriacchi *et al*., 2004, Shelburne *et al*., 2006). Conversely, enlarged quadriceps muscle may lead to the presence of an abduction moment that reduces the EKAM by providing a counteracting force (Shelburne *et al*., 2006). The knee adduction moment (KAM) is the primary outcome measure used in biomechanical intervention studies and needs further consideration and investigation within the literature.

2.8.3 *Knee OA, Loading and the External Knee Adduction Moment (EKAM)*

Knee OA is a mechanical disease which is highly influenced by the extent of load placed on the knee joint (Brandt *et al*., 2008). The medial compartment of the knee joint is four times more frequently afflicted with OA than the lateral compartment (Ledingham *et al*., 1993, Jones *et al*., 2014). Dynamic knee joint loading is associated with the pathogenesis of medial knee OA, and is the central biomechanical factor (Sharma *et al*., 1998, Miyazaki *et al*., 2002, Andriacchi *et al*., 2004, Mundermann *et al*., 2005) therefore, observation and treatment of medial knee OA must appraise dynamic loading of the knee joint (Hurwitz *et al*., 2002), and treatment methods should aim to decrease the load on the joint to potentially slow disease progression and lessen symptoms experienced.

The knee joint is subjected to both internal and external moments, and knee implants are an accurate and reliable method of measuring knee forces, however they are invasive. Therefore, the external knee adduction moment (EKAM) has been identified as a valid and reliable predictor of medial load distributions (Schipplein and Andriacchi, 1991, Zhao *et al*., 2007, Trepczynski *et al*., 2014, Jones *et al*., 2015) and the presence (Baliunas *et al*., 2002), severity (Sharma *et al*., 1998) and rate of progression (Miyazaki *et al*., 2002, Kean *et al*., 2012, Chehab *et al*., 2014, Hatfield *et al*., 2015, Arnold *et al*., 2015, Chang *et al*., 2015, Hatfield *et al*., 2016) of medial knee OA, and also the reduction in cartilage thickness (Erhart *et al*., 2011, Jones *et al*., 2014). Additionally, the EKAM has been correlated with higher levels of pain in individuals with medial compartment knee OA, and reduction of medial loading may result in pain relief (Sharma *et al*., 1998, Miyazaki *et al*., 2002, Thorp *et al*., 2006, Maly, 2008, Kito *et al*., 2010, Erhart *et al*., 2011, Arnold *et al*., 2015). The EKAM is the principal mechanism causing compressive load on the knee joint (Zhao *et al*., 2007, Trepczynski *et al*., 2014, Jones *et al*., 2015) and may be calculated using the external forces acting on each body segment (for example ground reaction force (GRF)), and is measured using force platforms, joint motion of the specific segment using kinematic data and from anthropometric data in order to calculate the inertial and mass properties of the segment.

The detrimental consequences of increased medial knee loading are most evident during the mid-stance phase of gait, where 70-80% of the total knee load is distributed through the medial compartment of the normal knee (Schipplein and Andriacchi, 1991, Barrios *et al*., 2009, Segal, 2012, Jones *et al*., 2014). The incidence of asymmetric load distribution is due to the EKAM throughout stance (Jones *et al.*, 2012) with increasing emerging evidence illustrating the EKAM during walking (assessed using motion analysis tools and force plates) to be a reliable predictor of OA onset, severity and progression (Miyazaki *et al*., 2002, Baliunas *et al*., 2002, Mundermann *et al*., 2004, Birmingham *et al*, 2007, Henriksen *et al*., 2010). Assessing the magnitude of EKAM peaks can therefore be used as an indirect measure of medial compartment joint loading and is measured during activities (Schipplein and Adriacchi, 1991, Miyazaki *et al*., 2002, Amin *et al*., 2004, Bennell *et al*., 2011, Chang *et al*., 2015, Arnold *et al*., 2015). The EKAM characteristically displays an early stance peak (first), and a late stance peak (second). The first peak of the EKAM in individuals with knee OA is constantly higher compared with healthy controls, regardless of knee OA disease severity, however the second peak EKAM is only higher in those individuals with more severe knee OA (Mundermann *et al*., 2005, Jones *et al*., 2015).

Conservative management techniques of medial knee OA are most suitable and effective when used on individuals with mild to moderate medial knee OA, and therefore the first peak in the EKAM is of interest, and has been identified as relating to disease severity and progression, and also structural features of medial knee OA and could therefore mean reducing the EKAM leads to a delay in medial knee OA progression (Stefanyshyn *et al*., 2006, Kito *et al*., 2010, Creaby *et al*., 2010, Bennell *et al*., 2011, Jones *et al*., 2015).

Similarly, Shelburne *et al*., (2008) stated that the high incidence of medial compartment knee OA in patients with knee OA was due to an existing adduction moment and therefore a concomitant increase in load in the medial compartment of the knee. Contrariwise, several studies have reported early-stance peak EKAM to be comparable in patients with varying severities of knee OA compared to healthy individuals of matching age and gender, perhaps due to compensatory mechanisms such as trunk lean or pelvic list towards the stance leg in an attempt to lower the EKAM by decreasing the moment lever arm (Landry *et al*., 2007, Huang *et al*., 2008). Furthermore, in mild knee OA (Kellgren and Lawrence grade 1-2), conflicting results have emerged concerning late-stance peak EKAM, with Mundermann *et al*., (2005) reporting it to be significantly smaller when compared with both age and gender matched patients with severe knee OA, and healthy individuals. Additionally, Huang *et al*., (2008) observed the EKAM to be similar between OA patients and healthy participants.

The majority of investigations have identified an increase in the EKAM in patients with knee OA compared to healthy participants, and therefore the EKAM can be considered a reliable indication of knee OA (Henriksen *et al*., 2010). Results should be carefully considered however, as error can be present within investigations, particularly during the use of gait analysis, and varying biomechanical models and techniques, where markers are placed on certain anatomical landmarks and error can be present in the form of skin and soft tissue movement artefacts, often introducing some small variability to the results.

The EKAM is created during normal walking, where the resultant ground reaction force (GRF) passes medial to the centre of the knee joint, applying an external adduction moment about the knee joint throughout stance, creating a turning effect (Shelburne *et al*., 2008, Jones *et al*., 2014). The perpendicular distance from the line of action of the GRF is the lever arm for this force. This lever arm, along with the product of this force produces a moment which causes the knee joint to adduct (Kim *et al*., 2004). The EKAM results in the tibia rotating medially with respect to the femur in the frontal plane and therefore, a large proportion of the force is transferred by the medial compartment of the knee (Shelburne *et al*., 2008, Reeves and Bowling, 2011).

The magnitude of EKAM is influenced by the magnitude of the GRF (Reeves and Bowling, 2011). Andriacchi, (1994) implied that EKAM increases the load on the medial compartment of the knee, therefore stretching soft tissues on the lateral side of the joint to balance the load. Continuous stretching of the soft tissues can result in lateral laxity, which affects the lateral compartment, causing unloading due to lifting of the lateral epicondyle. This therefore causes increased loading on the medial compartment relative to the lateral compartment (Andriacchi, 1994, Baliunas *et al*., 2002). Reducing the EKAM has therefore become the objective of early conservative treatment of medial knee joint OA in an attempt to reduce pain, maintain function and to slow and possibly prevent disease progression (Jones *et al*., 2012). Coronal plane external moments, such as the EKAM, along with additional external forces acting on the knee can be calculated using a motion analysis system and a force platform, using the external forces acting on each body segment (for example; GRF), the joint motion of the segment using kinetic data and anthropometric data, used to calculate the inertial and mass properties of the segment. To achieve stability and equilibrium during movement, the EKAM must be balanced by an equal internal moment (Shelburne *et al*., 2006). Consequently, the net internal moment in the knee joint, produced predominantly by muscle, soft tissue and contact forces is equal and opposite to the EKAM (Shelburne *et al*., 2006). In the absence of reduced antagonist muscle activity, a larger EKAM can be attributed to a larger contact force (Baliunas *et al*., 2002). A large EKAM is suggestive of increased loads on the medial compartment of the knee, relative to the lateral compartment, with EKAM being the primary factor in determining both medial and lateral load distribution on the joint (Baliunas *et al*., 2002, Kim *et al*., 2004).

The EKAM is made up of two peaks and one trough. The first and second peaks arise in the early and the late stance phase of the gait cycle, (0-20% and 41-60% respectively), while the trough occurs in mid stance (21-40%) (Hurwitz *et al*., 2002) (figure 2.4).

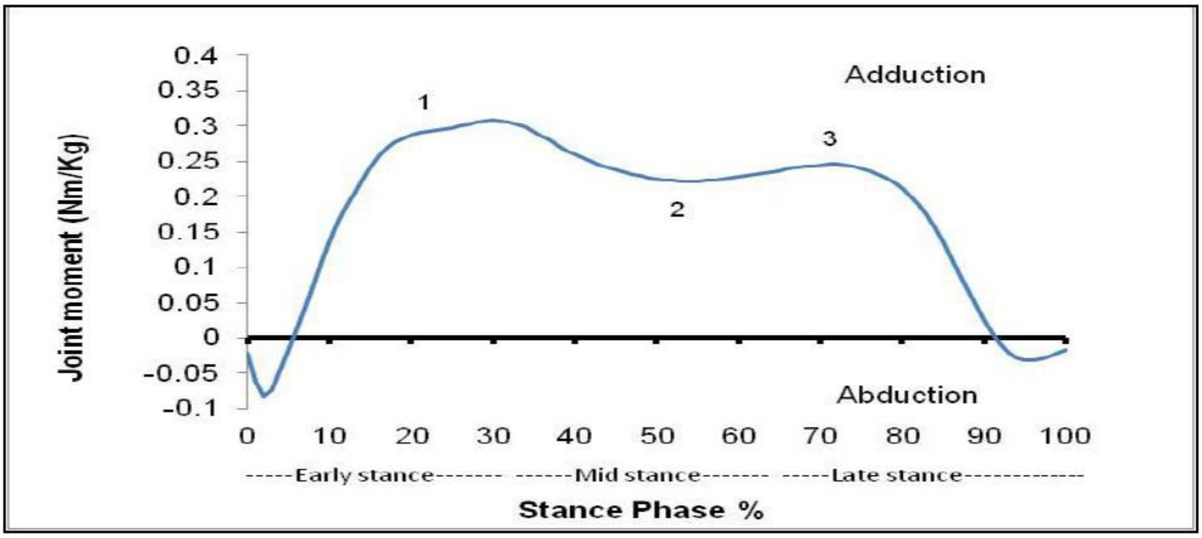

*Figure 2.4: Knee moment in the coronal plane: 1 = early stance peak external knee adduction moment (EKAM); 2 = mid-stance trough EKAM; 3 = late stance peak EKAM. *Early, mid and late stance phases are represented as a percentage of stance phase.*

Both cartilage defects and subchondral bone area are related to peak EKAM in medial knee OA patients, signifying that enlarged mechanical loading may lead to pathological changes to knee joint articular cartilage and subchondral bone in medial knee OA (Creaby *et al*., 2010).

Knee OA patients displaying radiographical medial joint space narrowing have been identified as demonstrating greater peak knee adduction moments (Baliunas *et al*., 2000). Varying relationships have been observed in medial knee OA patients with regards to dynamic knee joint loading and pain intensity during walking; this differs further when patients altering knee OA disease severity classifications are considered (Henriksen *et al*., 2012). Sharma *et al* (1998) identified a substantial relationship between the size of the EKAM and medial knee OA disease progression. Furthermore, Miyazaki *et al*., (2002) concluded that the disease progression of medial compartment knee OA could be predicted from the size of the EKAM at baseline, with logistic regression analysis showing that the risk of knee OA disease progression increased 6.46 times with every 1% increase in the EKAM. Varus alignment was identified as increasing both the risk of medial compartment knee OA, and the progression of the disease (Sharma *et al*., 2001), which suggests that the size of the EKAM can be associated with radiographically identified joint space narrowing of the medial compartment of the knee (Sharma *et al*., 2001). Not surprisingly therefore, extensive previous investigations have reported the EKAM to be larger in medial compartment knee OA patients, when compared with healthy subjects during early stance. Similar results were identified during mid-stance, and also throughout late stance, where the EKAM was found to be significantly higher. These findings were identified across all severities of knee OA and investigation was carried out on age and gender matched, healthy subjects (Wiedenhielm *et al*., 1994, Kaufman *et al*., 2001, Hurwitz *et al*., 2002, Mundermann *et al*., 2005, Thorp *et al*., 2006, Landry *et al*., 2007, Rudolph *et al*., 2007, Huang *et al*., 2008, Astephen *et al*., 2008).

The findings of greater EKAM in medial compartment knee OA patients has been suggested to perhaps be due to increased lateral trunk sway or pelvis lean alterations towards the stance leg as an adaptive mechanism in order to reduce the moment level arm and therefore the EKAM, providing some symptom (pain) relief (Landry *et al*., 2007, Huang *et al*., 2008). Conversely however, a number of contradictory findings concerning EKAM and late stance exist (Chapman *et al*., 2015) and some report EKAM in medial compartment knee OA patients to be similar to healthy subject groups (Mundermann *et al*., 2005, Huang *et al*., 2008). However, reducing the EKAM has become the main objective of early conservative treatment of medial knee joint OA (Jones *et al*., 2012) with many researchers using this surrogate measure as a target for biomechanical treatments. The following section will discuss varying options for the treatment and management of medial compartment knee OA.

2.9 Treatment Strategies and Management of Medial Knee OA

Current treatment of medial compartment knee OA aims to relieve symptoms enabling quality of life to be maintained, focusing on minimising pain, maintaining joint ROM and mobility and decreasing functional impairment (Fang *et al*., 2006). Treatment options include conservative, surgical and pharmacological methods.

2.9.1 Pharmacological

The most common management method for knee OA is pharmacological (Urwin *et al*., 1998), with the most frequently prescribed treatment being analgesics (for example Acetaminophen, more commonly referred to as Paracetamol), non-steroidal anti-inflammatory drugs (NSAIDs) (for example Ibuprofen and Naproxen) and COX-2 inhibitors which are fairly effective in reducing mild to moderate pain (Bradley *et al*., 1991) (NICE, 2008). Long term use of these drugs can cause severe side effects in some patients, such as gastrointestinal ulceration and bleeding, electrolyte imbalances, abnormal results in liver function tests, and hypertension (Richy *et al*., 2004, Hippisley-Cox *et al*., 2005, Machado *et al*., 2015). Care should therefore be taken by health professionals in the use of pharmaceuticals for pain reduction (Sum *et al*., 1997). However, the evidence base supporting the recommendations of paracetamol when used as a first line analgesic method for osteoarthritis in clinical guidelines has recently been called into question, with a recent study by Machado *et al*., (2015) concluding that paracetamol provides a small but not clinically significant reduction in pain and disability in patients with knee OA. Results of the Machado *et al*. (2015) study have prompted the National Institute for Health and Clinical Excellence (NICE) to review their advice regarding the use of paracetamol as an analgesic for the treatment of knee OA in the form of a planned full review of evidence on the pharmacological management of OA (NICE, 2014).

Intra-articular injections using steroids such as corticosteroids provide effective, however short term pain relief. Similarly, intra-articular injections of hyaluronan (a component of healthy joint fluid) provide significant pain relief and increases in function in patients with knee OA (Arroll and Goodyear-Smith, 2004, Goldberg and Buckwalter, 2005), however the effects are temporary (Bradley *et al*., 1991). Nevertheless, the most recent guidance published by NICE states that intra-articular injections of hyluronan should be avoided (NICE, 2014).

The above medications provide pain reduction, an increase in quality of life and allow an increase in activity level (Hurwitz *et al*., 2000). However, they fail to address the biomechanical causes and only manage symptoms of the disease (Walsh and Hurley, 2009) possibly leading to increased joint loading (Schnitzer *et al*., 1993) and accelerated disease progression (Huskisson *et al*., 1995) due to an increase in pain free activity (Jones *et al*., 2012).

Disease modifying osteoarthritis drugs (DMOADs), more commonly known as food supplements are a further pharmacological treatment method for knee OA, such as glucosamine (taken in the form of a food supplement and usually self-prescribed by knee OA patients) which do not have negative side effects (Towheed *et al*., 2005, Qvist *et al*., 2008). Other DMOADs currently under investigation for suitability when used for the treatment of OA include; compounds inhibiting matrix-metalloproteinases (MMPs), bisphosphonates, cytokine blockers, inhibitors of inducible nitric oxide synthase (iNOS), doxycycline, calcitonin, and diacereine (Qvist *et al*., 2008). However, evidence supporting the use of DMOADs to change the metabolism of bone and cartilage on the progression of knee OA is conflicting (Towheed *et al*., 2005) with a meta-analysis concluding that diet supplementing with glucosamine did not have a significant effect on knee joint space, when compared with a placebo. Nevertheless, a statistically valid, however small consequence on pain was identified using visual analogue scales. This finding was considered clinically insignificant however; with a mean different of only 0.4cm (Wandel *et al*., 2010) prompting NICE and the American College of Rheumatology

(ACR) to produce guidelines discouraging their use for the treatment of OA (Zhang *et al*., 2008, NICE, 2014). Conversely, Osteoarthritis Research Society International (OARSI) published guidelines recommending the use of DMOADs for six months, with consumption ending if no clinical symptom improvement is identified after this time (Zhang *et al.,* 2008).

Knee OA causes severe pain, disability and a decrease in the patient's quality of life due to irreversible joint damage and alterations to normal biomechanics of the lower limb. Therefore after more conservative methods of treatment have possibly delayed the onset or progression of OA as much as possible, or when both pharmacological and non-pharmacological treatment strategies prove ineffective, surgery is performed as a last resort to decrease pain and disability, aiming to restore normal biomechanics of the knee joint (Dieppe *et al*., 1999).

2.9.2 Surgical Treatment for Medial Compartment Knee Osteoarthritis

Surgical intervention of knee OA is costly, and of great expense to the NHS. Surgery also impacts on the individual in terms of recovery time and functional independence (Griffin *et al*., 2007). Numerous methods exist in providing surgical intervention for knee OA. These include: arthroscopic lavage, high tibial osteotomy (HTO), surgical wedge osteotomy, and knee joint replacement (knee arthroplasty – replacing the knee joint with a prosthetic joint) surgeries (Bert, 1993, Dieppe *et al*., 1999, Felson *et al*., 2000, Griffin *et al*., 2007). Uni-compartmental knee arthroplasty (UKA) and HTO are both forms of realignment surgery to correct medial compartment knee OA, and total knee arthroplasty (TKA) is used to replace a knee joint that is affected by OA on both the medial and lateral sides.

HTO is a well-established and effective treatment option for medial compartment knee OA, and is used to redirect the mechanical axis from the degenerated area of the joint to the well preserved compartment in order to decrease the stresses and relieve a proportion of the load (Griffin *et al*., 2007). Clinicians have used surgical wedge osteotomy as a method of correcting varus angulation deformity by altering load away from the diseased knee compartment and therefore providing symptom relief (Fang *et al*., 2006). HTO has led to significant improvement in knee OA symptoms and function, instability, medial laxity, with the adduction moment of the knee decreasing in magnitude up to 6 months post-surgery, however this was found to increase again after 6 months (Wada *et al*., 1998, Ramsey *et al*., 2007, Briem *et al*., 2007, El-Azab *et al*., 2011).

The disease process and progression of knee OA can result in joint debris, caused by the fibrillation of knee joint cartilage, tears and degeneration to the menisci, and proliferation of the synovium which lead to pain and inflammation, and minor mechanical obstructions. Arthroscopy is a minimally invasive surgical procedure where a small incision is made in the knee, and a fibre optic endoscope is inserted into the knee joint space. A second incision is then made and surgical instruments are inserted into the joint in order to carry out the lavage (joint washing) (Kirkley *et al*., 2008, Felson, 2010, Koh *et al*., 2015). The minimally invasive nature of arthroscopic surgery as an approach to treating knee OA has meant much research has been conducted in the area. A number of procedures may be carried out during arthroscopy of the knee, including; washing of the joint with saline to remove debris and crystals which are thought to be a cause of pain and inflammation, debridement of damaged menisci and the removal of joint fragments and torn ligaments, the repair of a proliferative synovium, removal of loose articular cartilage and smoothing of cartilage lesions, grinding, smoothing and removal of osteophytes that impede joint ROM, and drilling of osteochondral lesions (Felson, 2010). The removal of joint debris and other irregularities attempts to reduce pain and discomfort (Felson, 2010, Koh *et al*., 2015) with previous research reporting symptomatic relief reported after arthroscopic lavage, although it is unclear exactly how this is achieved (Moseley *et al*., 2002).

Recent research has however casted doubts over the effectiveness of knee joint arthroscopic lavage, and the most recent NICE clinical guidelines do not recommend arthroscopic lavage of the knee joint as treatment for knee OA unless joint locking is present (NICE, 2014). Similarly, a study by Kirkley *et al*., (2008) concluded that arthroscopic lavage and debridement provided no additional benefit to patients than physical and medical therapy when used for treatment of knee OA. Additionally, a randomised placebo controlled trial of 180 patients carried out by Moseley *et al*., (2002) divided patients into three groups; simulated placebo surgery, arthroscopic lavage, and arthroscopic debridement. Outcomes (pain and function) were assessed over a 24 month period, and it was established that surgery outcomes were no better than the placebo simulated surgery procedure. Furthermore, Felson (2010) states that knee joint arthroscopy only has a limited role as treatment for knee OA. Interestingly however, a study by Koh *et al*., (2015) used adipose derived stem cell therapy consisting of intra-articular injection of stem cells collected via liposuction from the buttocks in conjunction with arthroscopic lavage for the treatment of knee OA. Improvement in clinical outcomes in the two year final follow up exam was reported in almost all patients, with only 5 out of the 30 patients showing worsening of the KL grade. The study concluded that the treatment was effective in cartilage healing and decreased pain and improved knee function. Results indicated that the more fat cells injected into the knee joint, the greater the positive outcome of the treatment was. The treatment is however very invasive, requiring both liposuction and arthroscopic surgery, and is also costly (Koh *et al*., 2015). Likewise, a study by Smith *et al*., (2002) also identified improvement in outcomes of arthroscopic lavage when used in conjunction with other treatments after administering intra-articular corticosteroids alongside the arthroscopic lavage surgery. The improvement in pain and function was short lived however, and benefits only lasted for 2-4 weeks in all patients.

Unicompartmental knee arthroplasty (UKA) is widely recognised as an effective treatment for unicompartmental knee OA, and allows the preservation of joint components in the unaffected side of the knee joint, including articular cartilage, menisci, bone, and cruciate ligaments, therefore allowing more normal joint range of motion, function, proprioception and kinematics compared to a TKA. Weidenhielm *et al*., (1993) reported improvements in step frequency, walking speed, single support stance phase ratio (indicating increased symmetry of gait) and step length after treating medial knee OA patients with a UKA. A faster weight transfer was identified during walking due to double support stance phase of both legs decreasing. UKA is often considered for use before TKA wherever possible, and may be offered to patients until a TKA becomes necessary (Lonner *et al*., 2009).

A systematic review by Griffin *et al*., (2007) compared the safety and efficacy of UKA, HTO, and TKA in patients with knee OA. The results of two controlled trials, three randomised controlled trials and three cohort studies were reviewed for function, complications, postoperative pain, and revision rates. Outcomes concerning function following HTO, UKA, and TKA were similar, however fewer complications (such as infection and deep vein thrombosis) were experienced by patients who received UKA, and UKA was associated with a lower incidence of revision than HTO (Griffin *et al*, 2007).

Surgical procedures are invasive, and have multiple disadvantages. Complications of surgery can arise such as deep venous thrombosis and wound and infection complications following high HTO and knee replacement surgeries (Griffin *et al*., 2007). Surgery also requires constant revision depending on the age and activity level of the patient. Therefore, knee OA surgery is expensive and as mentioned previously, is only used as the last line of treatment (Griffin *et al*., 2007); therefore more conservative methods of treatment are needed.

Some knee OA patients are often not suitable for surgery (too young, for medical reasons, or no access to NHS funding), or do not want surgery. For these reasons, considerable research has been invested into more conservative treatments of knee OA as non-invasive methods are considered valuable approaches. It is important to understand which conservative techniques bring the most benefits and improvements in knee OA symptoms to the most patient types both in terms of pain reduction and improvements in functional independence. If patients report improvements in pain and functional improvement with the use of conservative techniques, they may delay or negate the need for surgery altogether.

A number of conservative management techniques exist for the treatment of medial knee OA. A brief overview of each of these treatments will be discussed below.

2.9.3 Conservative (Non-Pharmacological) Treatment for Medial Compartment Knee Osteoarthritis

Different conservative approaches exist for treating medial knee OA including; exercise, alterations to gait, knee bracing and footwear modification to realign the weight-bearing load, providing symptom relief (Fang *et al*., 2006). Advantages of conservative treatment include cost and recovery duration benefits, meaning costly surgery is delayed due to slowing of disease progression and recovery times are rapid due to the non-invasive approach.

NICE clinical guidelines recommend numerous non-pharmacological core treatments to manage knee OA, including exercise and activity (including local muscle strengthening and aerobic fitness), weight loss (where patients are overweight or obese), and patient self-management and education (NICE, 2008, NICE 2014). NICE guidelines are based on the evidence available from reliable systematic reviews demonstrating the non-pharmacological treatments effectiveness and safety as treatments for knee OA (Warsi *et al*., 2003, Christensen *et al*., 2007, NICE, 2008). Additional non-pharmacological treatments are recommended in adjunct to the core treatments advocated by NICE, these include; local thermotherapy, manipulation and stretching, the use of transcutaneous electrical nerve stimulation (TENS), assistive devices, and in the case of joint pain and instability; braces, footwear, insoles, supports and orthoses (Brosseau *et al*., 2003, Brouwer *et al.*, 2005, Reilly *et al.*, 2006, NICE 2008, Rutjes *et al*., 2009, NICE 2014).

2.9.3.1 Exercise

Evidence based clinical guidelines for the management of OA recommend exercise as a core treatment for knee OA (Scott *et al*., 1998, Zhang *et al*., 2008, NICE, 2008, Arthritis Research UK, 2010). The types of exercises recommended to knee OA patients are walking, tai chi, gentle exercise classes, strengthening, balance and proprioception exercise programmes. An individual approach to exercise is recommended, with programmes ideally specifically tailored to both individual abilities and preferences, and progressed according to the individuals development (Pelland *et al*., 2004), meaning the programme is both more beneficial to the individual patient with a better adherence to home exercise programmes.

However, a systematic review carried out by Fransen and McConnell (2009) concluded that exercise has minimal effect on pain and physical function; this was attributed to the fact that participants were only in the early stages of knee OA with low pain and disability and therefore did not experience the full benefits of completing the prescribed exercise. Conversely, aerobic and strengthening exercises have been found to reduce pain and improve function in knee OA patients, and also reduce the effects of respiratory conditions (Brosseau *et al*., 2004, Focht, 2006). Brosseau *et al*., (2004) identified aerobic exercises to have improved long term effects when compared with strengthening exercises. In opposition, a systematic review by Pisters *et al*., (2007) concluded strengthening and aerobic exercises to only have short term effects on pain and physical function in knee OA patients. The included studies contained high dropout rates however which could have influenced results. ROM exercises and stretching have both been proposed as possibly being effective in pain reduction and increasing ROM, reducing soft tissue inflammation, improving cell repair, improving stability, facilitating movement, reducing stiffness, inducing relaxation, improving stability of tissues, and improving function (Deyle *et al*., 2000).

The optimal exercise type and dosage is yet to be determined, perhaps due to the fact that exercise programmes ideally should be tailored to meet the needs of individual patients based on assessment of impairments, patient preference, co-morbidities and accessibility, as it is well known that knee OA patients experience pain, disability and a decline in ROM and function which can make exercising difficult.

An individualised, supervised moderate intensity exercise program may reduce the peak knee adduction moment in patients with mild to moderate knee OA (Thornstensson *et al*., 2007). Variations in the literature of the degree of exercise effectiveness is reliant on participants' degrees of effective adherence and compliance to designated programmes, and long term continuation of nominated home exercises (Van Baar *et al*., 2001). Bennell *et al*., (2011) recommends using supervised exercise sessions, ideally in class format to ensure maximal adherence, ensuring success of exercise therapy, as home based exercises can cause programme adherence issues (Van Baar *et al*., 2001).

Variation in exercise effectiveness could possibly be linked to at home exercise compliance, and also high drop-out rates with the use of supervised exercise sessions (Van Baar *et al*., 2001). Research surrounding exercise and knee OA primarily focuses on pain and dynamic function of the knee joint, with only a small quantity of investigations exploring the effect of exercise on medial knee load, specifically the EKAM, with studies by Thorstensson *et al*., (2007), King *et al*., (2008), Lim *et al*., (2009), Sled *et al*., (2010), Thorp *et al*., (2010), Bennell *et al*., (2010), and Foroughi *et al*., (2011) reporting no major reductions in the EKAM after the observance of varying exercise programmes. Thorpe *et al*., (2010) is the only investigation within the literature that reported a reduction in the EKAM after following an exercise programme, however, Thorpe *et al* (2010) did not report a change in the strength of the hip and knee muscles, perhaps due to the short duration of the exercise programme followed, meaning the EKAM perhaps reduced due to improved motor control of the muscles of the lower limbs (Sale, 1988).

The EKAM and the axial forces on the knee may be increased following an exercise programme (Schipplein and Andriacchi, 1991, Mundermann *et al.*, 2004) due to strengthening of the muscles surrounding the knee joint taking place, particularly the quadriceps muscle, which could lead to an increase in walking speed, therefore increasing the EKAM, and an increase in the EKAM is linked to the onset and progression of knee OA (Miyazaki *et al.*, 2002, Lim *et al*., 2009). An increase in quadriceps muscle strength could however decrease the EKAM due to an abduction moment being created which counteracts the EKAM (Shelburne *et al*., 2006). In the presence of quadriceps weakness however, Mikesky *et al*., (2000) identified the GRF rate of loading to increase during walking, which could alter the distribution of load on the knee joint, leading to further progression of knee OA (Andriacchi *et al*., 2004). A systematic review and meta-analysis carried out by Lowe *et al*., (2007) concluded that physiotherapy functional exercises carried out following total knee arthroplasty can lead to minimal short term benefits in knee joint function. No long term benefits were reported however. Rooks *et al*., (2006) also investigated the effects of an exercise programme alongside total knee arthroplasty, however the exercises (strength training, cardiovascular fitness activities and flexibility exercises) were carried out prior to the TKA. Study findings reported an increase in muscle strength and function, which led to a reduction in the use of inpatient rehabilitation service post TKA, meaning recovery times were shorter. This method could lead to cost savings, and therefore reducing the burden of knee OA on public services. Furthermore, Frost *et al*., (2002) acknowledged an increase in mobility, leg extensor power and a reduction in pain following an exercise programme aimed to promote mobility and function of the knee joint post TKA.

Thus, research in favour of exercise for the treatment of knee OA has no effect on reducing the EKAM, with the previously mentioned studies providing conflicting results regarding alterations in the EKAM after exercise programmes have been followed by participants. Exercise programmes used in conjunction with surgery have provided more positive results, however further investigation is required.

Findings indicate the use of exercise based intervention for the treatment of knee OA to be difficult in terms of reducing the EKAM and whilst clinical results are positive, the long term effectiveness of these is questioned. Biomechanical load modifying, conservative treatment methods may therefore be more reliable in order to identify effective methods of reducing the public health impact that knee OA presents (Kim *et al*., 2004, Sled *et al*., 2010, Al-Khlaifat, 2012).

2.9.3.2 Patient Education and Advice

Self-management of knee OA may offer the least burdensome treatment for knee OA, especially in the early stages of the condition. NICE have recommended education of OA patients to be paramount, therefore, patient education can be considered a conservative treatment method (NICE, 2014). Patient education and advice aims to inform patients of self-management methods and also seeks to alter health behaviour, encouraging patients to partake in exercise (Holman and Lorig, 2004, Heuts *et al*., 2005, NICE, 2014).

Walsh *et al*., (2006) carried out a systematic review into the effectiveness of patient education and advice programmes on pain and knee function in patients diagnosed with hip or knee OA and concluded that integrated advice programmes significantly improved pain and function.

Dependence on healthcare systems may be decreased by making patient education and advice the first course of treatment in the treatment of OA and may reduce the economic burden of knee OA (Heuts *et al*., 2005, Hurley and Walsh, 2009).

2.9.3.3 Gait Altering Strategies in the Treatment of Medial Compartment Knee OA

Gait modifications and retraining have been investigated within the literature as a possible conservative treatment strategy for medial compartment knee OA, with an objective of reducing the EKAM (Hunt *et al*., 2011, Kuroyanag *et al*., 2012, Shull *et al*., 2013, Van den noort *et al*., 2013, Gerbrands *et al*., 2014) and therefore delaying, slowing or preventing knee OA progression, by altering the load distribution in the knee joint (Shull *et al*., 2013). Changes in certain kinematic or kinetic factors during gait could possibly reduce medial load and therefore reduce the EKAM (Chang *et al*., 2007, Gerbrands *et al*., 2014). Identifying, understanding and managing those factors may lead to a reduction in the risk of knee osteoarthritis progression over time (Chang *et al*., 2004, Chang *et al*., 2007, Shull *et al*., 2013, Gerbrands *et al*., 2014).

Biomechanical factors affecting the EKAM include walking with a greater toe-out angle (Chang *et al*., 2007), which shifts the ground reaction force (GRF) vector closer to the knee joint centre decreasing the moment arm and thereby reducing the EKAM (Gerbrands *et al*., 2014). Chang *et al*., (2007) identified greater toe-out angle was inversely related to the EKAM during the late stance of gait in subjects with both healthy and osteoarthritis stricken knees (Andrews *et al*., 1996, Hurwitz *et al*., 2002). Further biomechanical factors affecting the EKAM include walking with a narrow gait, which significantly reduces the EKAM during early stance (Street and Gage, 2013), increased mediolateral trunk sway (Hunt *et al*., 2011, Street and Gage, 2013) and walking speed (Wilson, 2012).

Walking Speed and Knee OA

Previous research has indicated that walking speed is significantly decreased in knee OA patients when compared to healthy participants (Kaufman *et al*., 2001, Al-Zahrani and Bakheit, 2002, Zeni *et al*., 2010) associated with a decreased stride length (Al-Zahrani and Bakheit, 2002), shortened step lengths, larger double support times, decreased hip and knee ROM angles (Andriacchi *et al*., 1977, Kaufman *et al*., 2001, Messier *et al*., 2005), reduced cadence, and an increase in stance time (Al-Zahrani and Bakheit, 2002, Landry *et al*., 2007, Astephen *et al*., 2008). Interestingly, this decrease in walking speed is thought to be a gait adaptation by individuals with knee OA in order to reduce symptoms of knee OA (Wilson, 2012).

During early-stance, knee flexion aids in shock absorption, consequently, an increase in walking speed results in more force travelling through the knee joint and therefore requiring more shock absorption in the knee, moving the knee into greater flexion (Winter, 1991). The increase in knee flexion requires a higher eccentric contraction of the knee extensors (Winter, 1983), however quadriceps muscle weakness, often present in knee OA patients (Slemenda *et al*., 1997) causes patients to walk at slower speeds.

Muscle co-contraction, which greatens the compressive forces acting on the knee joint, is increased in osteoarthritic knees (Lewek *et al*., 2004) and has been found to increase further when subjects increase their walking speed. Knee OA patients are therefore likely to reduce walking speed, as a slower walking speed requires lower levels of knee flexion and therefore lower levels of shock absorption are required to help reduce the load on the knee joint (Mündermann *et al*., 2004) which can be described as an adaptive mechanism, providing some symptom relief (Lewek *et al*., 2004, Foroughi *et al*., 2010).

The effect of walking speed is a fundamental concern in gait studies when measurements are based on the level of GRF and acceleration, due to the effects of walking speed on the EKAM and the subsequent impact on knee joint loading (Zeni and Higginson, 2009, Wilson, 2012). The load on the knee joint will increase due to an increase of the dynamic ground reaction forces that is proportional to the walking speed (Wilson, 2008, Zeni and Higginson, 2009, Zeni and Higginson, 2010, Foroughi *et al*., 2010). Zeni and Higginson, (2009) identified variances in gait parameters to be due to slower walking speeds, when walking speeds were freely chosen in a study, rather than a result of knee OA disease progression.

Walking at slower speeds may be an effective method of reducing knee OA symptoms, however maintaining a reduced walking speed as a treatment for knee OA could be difficult for individuals to maintain over long periods of time, due to the demands of everyday life. Walking speed is also difficult to control or interpret without gait laboratory or other specialist equipment, again making walking at a constant reduced walking speed difficult during everyday activities (Wilson, 2012).

The Foot Progression Angle

The normal gait progression angle is approximately 5º, therefore indicating that the toes point slightly outward during normal gait (Shull *et al*., 2013). The toe out angle of the foot was found to increase during walking in patients with knee OA (Hurwitz *et al*., 2002, Chang *et al*., 2007) and has been found to reduce the EKAM during walking. The toe out angle is proposed as a compensatory mechanism to unload the knee, achieved by transforming a proportion of the EKAM into a flexion moment in early stance phase and therefore partially shifting the load at the knee joint away from the medial compartment to other structures (Jenkyn *et al*., 2008). The toe out occurs with lateral placement of the centre of pressure of the foot (COP) which shifts GRF nearer to the knee joint centre. This leads to a decreased GRF moment arm length at the knee, which in turn reduces the EKAM (Hurwitz *et al*., 2002). The toe out angle reduces the overall magnitude of the EKAM in knee OA patients (Mundermann *et al*., 2008) with a greater toe out angle during walking causing a lesser second peak EKAM (Andrews *et al*., 1996).

Similarly, toe in gait has been identified as a promising non-surgical treatment option for patients with medial knee OA (Shull *et al*., 2013). Toe in gait which can be defined as, 'decreased foot progression angle from baseline through internal foot rotation' (Shull *et al*., 2013) has been found to significantly reduce the first peak EKAM during walking. A study by Shull *et al*., (2013) required patients to undertake a six week gait retraining programme and reported a decrease in the EKAM and an improvement in symptoms and pain. Similar results were observed in a further study by Shull *et al*., (2013). Furthermore, Simic *et al*., (2013) observed a reduction in early stance peak EKAM when patients walked with a modified, toe in gait. Greater results were detected in patients with more varus knees.

Gait pattern modifications are simple and low cost options which are easy to perform, giving immediate results when used to cause increased medialisation of the knee, however they may prove difficult for patients to adhere to, and could possibly feel unnatural and uncomfortable due to the alteration in the foot progression angle. This unnatural sensation has been reported as decreasing over time (Shull *et al*., 2013). Although fairly easy to learn and perform, individuals may need lengthy and costly training programmes in order to become accustomed to the modification from their normal gait cycle (Shull *et al*., 2013). Another factor affecting patient adherence to gait modification is individual patient's perceived appearance to others in social situations, which could affect the long term compliance of an adapted gait pattern (Shull *et al*., 2013). The effect of altering gait on other areas of the body has not been explored within the literature.

Lateral Trunk Sway

Lateral trunk sway has been investigated within the literature as a possible gait modification to reduce the load on the knee joint (Baliunas *et al*., 2002, Esfandiari *et al*., 2013, Gerbrands *et al*., 2014). By increasing lateral trunk sway towards the affected weight bearing limb (affected with knee OA) in individuals with medial compartment knee OA, the body's centre of mass (COM) shifts laterally and the GRF shifts nearer to the knee joint centre, causing the length of the GRF moment at the knee joint to decrease (Mundermann *et al*., 2005, Hunt *et al*., 2008, Mundermann *et al*., 2008, Chang *et al*., 2011). The EKAM can therefore be reduced by approximately 65% during walking in healthy subjects by increasing lateral trunk sway towards the weight bearing limb (Mundermann *et al*., 2005). Consequently, lateral trunk sway alterations have been recommended as a gait style to lower the EKAM in knee OA patients, and to therefore reduce knee instability and pain (Hurwitz *et al*., 2002, Lewek *et al*., 2004, Chang *et al*., 2011, Esfandiari *et al*., 2013, Gerbrands *et al*., 2014). Interestingly, a higher degree of lateral trunk sway has been found to be present in patients with severe knee OA compared to patients with mild knee OA, which can be described as an innate adaptation to decrease the EKAM and therefore knee joint loading, and knee OA symptoms (Hunt *et al*., 2008, Chang *et al*., 2011).

Although a fairly simple and low cost treatment option for medial knee OA, again; increasing lateral trunk sway in individuals with knee OA may require costly and lengthy training programs, may be difficult to maintain, and may lead to adherence issues due to social acceptance. Therefore, more consistent and unobtrusive treatment methods are needed.

Altering Foot Position (Foot Posture)

Individuals with knee OA display a more pronated foot type when compared to controls, (Vinicombe *et al*., 2001, Redmond *et al*., 2006, Wrobel and Armstrong, 2008, Levinger *et al*., 2010, Levinger *et al*., 2012, Abourazzak *et al*., 2014). Modifications to foot posture and position can lead to alterations in the static and dynamic alignment of the lower limbs and therefore changes in the GRF (Donatelli, 1987, Tiberio, 1987, Guichet *et al*., 2003). Knee OA patients with pronated feet have displayed a reduction in EKAM during walking (Levinger *et al*., 2010, Lidtke *et al*., 2010) meaning a strong association has been identified between the alteration of foot COP and knee OA (Reilly *et al*., 2009, Barton *et al*., 2010, Lidtke *et al*., 2010) and pronating the foot can lead to a reduction in the EKAM (Levinger *et al*., 2010).

Barefoot Gait

Walking barefoot has provided a significant reduction in joint loading in patients with medial knee OA compared to measurements obtained when patients were walking in their everyday normal footwear (shod) (Shakoor and Block, 2006, Shakoor *et al*., 2008 Jones *et al*., 2015). Using gait analysis methods, Shakoor and Block (2006) evaluated the effects that modern everyday footwear has on gait and lower extremity joint loads in knee OA, compared to barefoot. It was reported that peak joint loads on the knee were significantly reduced during barefoot walking, compared to walking wearing everyday footwear. An 11.9% reduction in EKAM was identified when individuals walked barefoot, compared to walking with their everyday footwear. Stride, cadence and ROM at lower extremity joints also changed significantly (Shakoor and Block, 2006). It can be concluded that shoes may increase the loads on lower extremity joints and therefore modern footwear may need to be re-evaluated (Shakoor and Block, 2006) as along with other factors, modern footwear may be contributing to the high incidence of knee OA within the population. It is hypothesised that the heel present on most modern footwear, and the lift that such heels create, could have caused the peak knee torques, and therefore the lack of a heel and lack of sole stiffness in the barefoot condition caused the reduction in the peak knee torques within the Shakoor and Block (2006) study. Additionally, it is thought that the increased proprioceptive input that takes place when the foot touches the ground during barefoot walking compared with the insulated foot when wearing footwear allows a reduction in peak knee loads (Shakoor and Block, 2006). This requires further investigation.

However, although an effective way of reducing the EKAM, barefoot walking is neither a convenient nor a practical treatment option for knee OA, due to the demands of everyday life and social acceptance issues. Knee OA patients could however be advised to remain barefoot wherever it is possible, in order to receive the benefits of the reduction in the EKAM.

Medial Thrust Gait

Medial thrust during gait has been identified as reducing the EKAM (Fregly *et al*., 2007, Schache *et al*., 2008, Gerbrands *et al*., 2014), and was found to be the most effective EKAM reducing gait modification in 43% of participants in a study by Gerbrands *et al*., (2014) which compared the reduction in EKAM using various gait alteration strategies (trunk lean, medial thrust, lateral trunk sway, and toe out) in 37 healthy participants.

To summarise, gait alteration and retraining methods are effective ways of reducing the EKAM and therefore knee joint loads in both healthy individuals and individuals with knee OA, however the consistency and long term benefits of gait alterations in reducing the EKAM are unknown (Hunt *et al*., 2011, Kuroyanag *et al*., 2012, Van den noort *et al*., 2013, Shull *et al*., 2013, Gerbrands *et al*., 2014). The effects of gait strategies on the EKAM also vary and are subject specific, meaning individual selection of specific strategies is required in order for benefits to be seen and for optimal reduction of dynamic knee joint loading during gait to be achieved (Gerbrands *et al*., 2014). Further investigation is therefore required, and more definitive, reliable and universal assistive devices which provide long term reductions in the EKAM may be more ideal for the treatment of medial compartment knee OA (Shelburne *et al*., 2008).

Numerous strategies exist in order to treat knee OA conservatively, and approaches can be both direct and indirect (Jones *et al*., 2013). Footwear modifications may be used for conservative therapy, and include indirect assistive devices such as shock absorbing shoes with insoles and lateral wedged insoles (LWI), designed to alter the position of centre of pressure (COP) under the foot and therefore shift the GRF laterally with respect to the knee (Yasuda *et al*., 1987, Jones *et al*., 2013). Valgus knee braces are an additional direct approach, applying a valgus force directly to the knee (Lindenfeld *et al*., 1997, Jones *et al*., 2013). All have been identified as improving pain, stiffness and function during everyday activities (Kuroyanagi *et al*., 2007, Shelburne *et al*., 2008, Pagani *et al*., 2012, Jones *et al*., 2013, Jones *et al*., 2015). Various strategies used for the conservative treatment of knee OA will be discussed in the following paragraphs.

2.9.3.4 Valgus Knee Braces

Valgus knee braces are patient administered, load modifying devices used for the conservative treatment of medial compartment knee OA. They comprise of an adjustable knee brace, worn externally around the knee joint (Reeves and Bowling, 2011, Pagani *et al*., 2012, Jones *et al*., 2013). Valgus knee braces aim to realign the knee joint, and therefore reduce a proportion of the load acting on the medial compartment, providing pain and OA symptom relief (Duivenvoordem *et al*., 2015). The reduction in load on the medial compartment of the knee joint is achieved with the application of an opposing external valgus moment about the knee brought about with the use of a three point pressure exerted on the knee joint, meaning the knee brace provides force at three locations of the knee joint (Reeves and Bowling, 2011, Pagani *et al*., 2012, Jones *et al*., 2013).

Adjustable straps fitted on to the valgus knee brace provide an external corrective force to the knee joint, allowing a shift in knee alignment which shortens the moment arm, therefore lowering the external adduction, or varus moment causing a transfer of load away from the medial compartment of the knee and dispersing load across the knee joint more evenly, alleviating stress from the medial compartment and providing some symptom relief (Ramsey *et al*., 2009).

A number of studies investigating the efficiency of valgus knee braces have identified reductions in pain (Ramsey *et al*., 2007, Gaasbeek *et al*., 2007, Russell and Ramsey, 2009, Hurley *et al*., 2012, Jones *et al*., 2013), improvements in proprioception (Birmingham *et al*., 2001), static and dynamic balance ability (Chuang *et al*., 2007), knee instability control and muscle co-contraction during gait (Ramsey *et al*., 2007) and reductions in muscle activation and co contraction levels, possibly slowing disease progression of knee OA (Fantini Pagani *et al*., (2012). The literature surrounding valgus knee braces indicates they may be responsible for improvements in knee function and an improvement in quality of life when used for the treatment of medial compartment knee OA. However, Jones *et al*., (2013) identified a reduction in the early stance EKAM with the use of a valgus knee brace, however the reduction in EKAM with the use of a valgus knee brace (7% from baseline) was significantly lower than the reduction in EKAM obtained with the use of a LWI (12% from baseline) in individuals with knee OA. An increase in walking speed was identified within the Jones *et al*., (2013) trial during the use of both valgus knee braces and LWI, indicating a reduction in pain and an increase in function in individuals with knee OA.

Conversely, the literature also provides evidence of poor patient acceptance of valgus knee braces compared to other devices, such as LWI used for the conservative treatment of medial compartment knee OA (Jones *et al*., 2013). A recent study by Jones *et al*., (2013) compared the biomechanical effects of both LWI and valgus knee braces, establishing that valgus knee braces were worn for less than 4 hours per day by 71% of users within the trial. Conversely, LWI were worn for longer than 4 hours per day by 71% of users. The LWI were deemed more comfortable, and more easily accepted by individuals within the trial, with the valgus knee braces presenting adherence issues by users. Similarly, a trial by Duivenvoorden *et al*., (2015) reported LWI as more easily accepted by participants than a valgus knee brace. Additionally, valgus knee braces have been described as uncomfortable and cumbersome, and users have reported issues with slippage of the device. Furthermore, valgus knee braces require specialist fitting, and are indiscreet, they can also often be complicated to wear, and therefore difficult to fasten by knee OA sufferers, they may also prove difficult and uncomfortable to wear with in certain social situations (Duivenvoorden *et al*., 2015).

Valgus knee braces exhibit some benefits when used for the treatment of medial compartment knee OA, however low acceptance of the device means benefits would not be seen in individuals, due to the unwillingness to wear the valgus knee brace (Jones *et al*., 2013). Furthermore, clinical outcomes of LWI and valgus knee braces are the same, however the LWI reduced the EKAM further than the valgus knee brace (Jones *et al*., 2013). Lateral wedge insoles therefore may be a more ideal solution and are therefore an attractive option for individuals with medial knee OA as they are simple, easy and quick to apply, can be worn with different footwear types, and do not require fitting, unlike valgus knee braces.

2.9.3.5 Lateral Wedged Insoles

LWI are inexpensive, discreet, self-administered mechanical interventions used as a conservative form of treatment of medial knee OA comprising of a shoe insert with a thicker border on the lateral side compared to the medial side (figure 2.5) with good adherence to treatment (Shakoor *et al*., 2008, Kean *et al*., 2013, Jones *et al*., 2013, Jones *et al*., 2014, Arnold *et al*., 2015, Jones *et al*., 2015, Hatfield *et al*., 2016). LWI are a management technique advocated by NICE for the conservative treatment of medial compartment knee OA (NICE, 2014). LWI can also be added into the sole of the shoe (lateral wedge shoe) via modification of shoe designs (Zamosky, 1964, Shakoor *et al*., 2008). The simplicity of LWI means they can be easily and safely used by medial knee OA patients, and are fairly accessible to the majority of people, due to their low cost (Kerrigan *et al*., 2002, Baker, 2006, Jones *et al*., 2015).

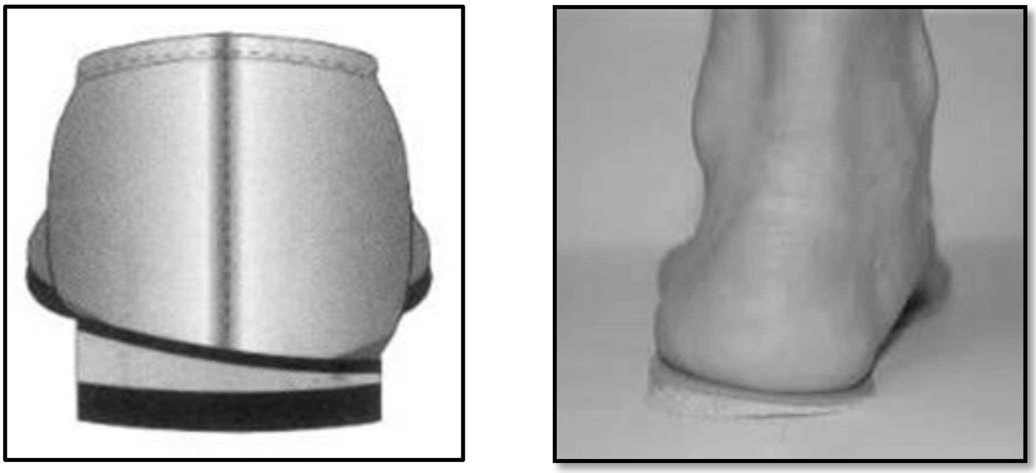

Figure 2.5: Posterior view of a lateral wedge shoe for the left foot (left). Posterior view of a lateral wedge insole for the left foot (right). Adapted from Toda et al., (2004) and Van Raaij et al., (2010).

LWI are mentioned extensively within the literature for the treatment of medial compartment knee OA (Jones *et al*., 2012, Pagani *et al*., 2012, Jones *et al*., 2013, Jones *et al*., 2014, Jones *et al*., 2014, Duivenvoorden *et al*., 2015, Jones *et al*., 2015, Yamaguchi *et al*., 2015, Arnold *et al*., 2015, Hatfield *et al*., 2016) and aim to modify load at the knee joint by altering the kinematics and kinetics of the subtalar ankle joint (Sasaki and Yasuda, 1987) with research indicating LWI to cause slanting of the calcaneus into an everted (valgus) position (Abdallah and Radwan, 2011) (figure 2.5). LWI provide a reduction in lateral knee thrust, ligamentous tension and pain and therefore increase or maintain function of the knee (Fang *et al*., 2006, Shimada *et al*., 2006, Barrios *et al*., 2009) as observed with the use of LWI in patients with mild to moderate medial compartment OA of the knee.

LWI have been suggested as an effective intervention in reducing the EKAM during early and latter stance (Butler *et al*., 2007, Hinman *et al*., 2008, Hinman *et al*., 2009, Bennell *et al*., 2011, Jones *et al*., 2012, Zhang *et al*., 2012, Skou *et al*., 2013, Jones *et al*., 2013, Arnold *et al*., 2015, Jones *et al*., 2015, Yamaguchi *et al*., 2015) and aim to minimise pain and increase or maintain activity levels by alleviating a proportion of the force transmitted by the medial compartment of the knee joint (Shelburne *et al*., 2008). This is achieved by pronating the foot to provide a valgus moment at the ankle, with the resultant valgus moment causing the centre of pressure in the foot to shift laterally up to 5mm (Shelburne *et al*., 2008), leading to a reduction in the EKAM (Kerrigan *et al*., 2002, Hinman and Bennell, 2009, Jones *et al*., 2013, Jones *et al*., 2015, Yamaguchi *et al*., 2015).

Pronation is a combination of eversion, (the calcaneus shifts into a lateral position in the frontal plane) dorsiflexion and abduction, (which aligns the femur and tibia into an upright position which subsequently leads to reduced medial loading) (Sasaki and Yasuda, 1987, Kakihana *et al*., 2005, Hinman *et al*., 2009, Levinger *et al*., 2010, Bennell *et al*., 2011, Zhang *et al*., 2012, Skou *et al*., 2013, Jones *et al*., 2013, Jones *et al*., 2015, Arnold *et al*., 2015). Shifting the centre of pressure laterally reduces the moment arm at the knee, thus it was established that EKAM and medial compartment loading reduced linearly with lateral displacement of the centre of pressure (for every 1mm lateral displacement of the centre of pressure, the peak of EKAM and medial compartment load decreased by 2% and 1% respectively (Shelburne *et al*., 2008).

LWI are designed to modify the centre of pressure under the foot by shifting the knee GRF and a proportion of the load laterally therefore reducing the EKAM and knee adduction angles (Butler *et al*., 2007, Hinman *et al*., 2008, Jones *et al*., 2013, Jones *et al*., 2014, Jones *et al*., 2015, Hatfield *et al*., 2016). Kakihana *et al*., (2005) states the wearing of full length lateral wedge insoles resulted in an enlarged ankle joint valgus moment, which was implied as a way of reducing the EKAM (figure 2.6).

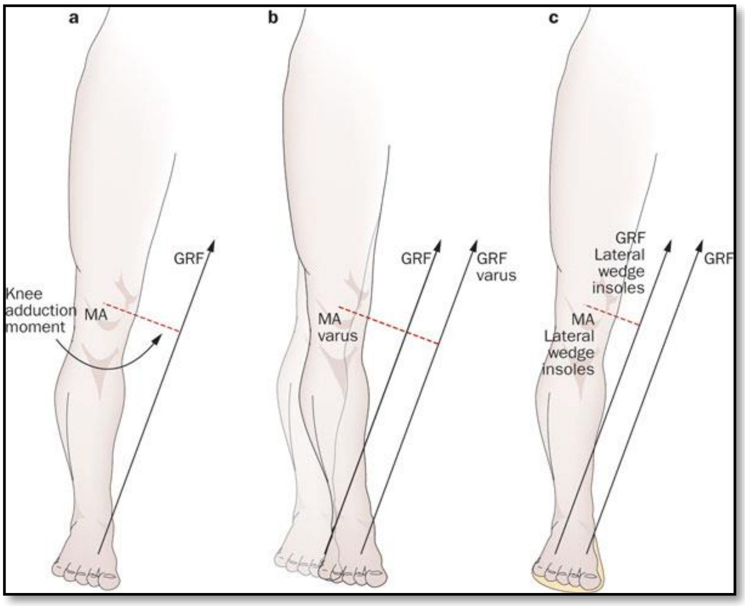

Figure 2.6: The biomechanical effects of wearing LWI during walking (GRF: ground reaction force, MA; moment arm) (Reeves and Bowling, 2011).

A number of studies report no improvement in pain (Pham *et al*., 2004, Bennell *et al*., 2011, Parkes *et al*., 2013). Baker *et al*., (2007) reported little differences between an intervention with LWI and control group with regards to pain, concluding that the effect of intervention with LWI for medial compartment knee OA produced non-significant results that proved clinically unimportant. Additionally, Bennell *et al.,* (2011) reported no symptomatic, structural benefits, or effects on disease progression after wearing LWI for a period of 12 months when compared with wearing flat control insoles. The study did however identify clear biomechanical benefits and reduced medial knee load (Bennell *et al*., 2011). Moreover, Parkes *et al*., (2013) found no consensus regarding the efficacy of LWI as a treatment for pain in medial knee OA when compared to a neutral wedge, however when assessed against baseline, positive findings were identified.

Results of previous trials have indicated there are differing biomechanical effects between individuals with regards to LWI and their effect on the EKAM, and surprisingly, individual EKAM response is varied, and as much as 30% of individuals with knee OA displaying an increase in the EKAM during walking (Chapman *et al*., 2015). A recent study by Chapman *et al*., (2015) investigated whether dynamic ankle joint complex coronal plane biomechanical measures could categorise and provide insight into medial compartment knee OA patients that experienced an increase or decrease in the EKAM whilst wearing LWI compared to control shoes. Reported findings identified 33% of participants increased their EKAM and 67% decreased their EKAM whilst wearing LWI, compared to a control shoe. Therefore it can be stated that coronal plane ankle and subtalar joint complex biomechanics influence the EKAM with the use of LWI.

Findings from the Chapman *et al*. (2015), trial may further the understanding of why some individuals respond better to LWI than others in terms of EKAM reduction, and may allow identification of individuals who would experience optimal effects from the use of LWI (Chapman *et al*., 2015). Similarly, Chapman *et al*., (2011) identified 39% of individuals taking part in a trial concerning LWI were classified as biomechanical non-responders, meaning the individual did not demonstrate a reduction in knee loading when wearing a LWI. Similarly, Kakihana *et al*., (2007) identified some variability in the results of a trial using LWI, with 18% of patients with medial compartment knee osteoarthritis not responding to the LWI (showing no reduction in the knee joint varus moment). Jones *et al*., (2014) and Chapman *et al*., (2015) concluded that coronal plane foot and ankle biomechanical measures are key mechanisms causing a reduction or increase in the EKAM when wearing LWI. Knee OA patients who demonstrated a higher peak ankle eversion angle or a higher eversion angle at peak EKAM during the control (shod) condition than the LWI condition were more likely to be classified as biomechanical responders to the LWI (Jones *et al*., 2014). Within the Jones *et al*., (2014) trial using LWI, of the 70 participants studied, 20% increased their EKAM, indicating an incidence of biomechanical non-response within the trial. Further research into the incidence of biomechanical non-response in terms of the EKAM within the literature surrounding LWI is needed. The type of LWI used may impact on the efficacy of the LWI itself.

Extensive research has been conducted concerning LWI, and a number of variations of LWI exist within the literature, including; heel only LWI, full length LWI, and full length LWI with medial arch support (Jones *et al*., 2015). Additions can be made to the LWI, such as subtalar strapping worn with a LWI. Full length LWI are the most typically used within the literature, and investigations have concluded that full length LWI are more effective in reducing the EKAM than rearfoot only LWI (Hinman *et al*., 2008).

A study by Jones *et al*., (2015) examined the differences between varying shoe types and LWI on the EKAM, pain and comfort when walking in individuals with medial knee OA. The randomised trial tested five different walking conditions; barefoot, a flat soled shoe (control), two different LWI (both full length with 5º lateral wedges, one with medial arch support and one without), and a mobility shoe (a flexible and grooved shoe). The study concluded that both LWI showed significant and comparable reductions in medial knee loading, however the medial support LWI reduced pain more, and was perceived as being more comfortable by individuals. Similarly, a previous trial by Jones *et al*., (2013) concluded that medial support LWI were better in terms of function for the foot and ankle, and also investigations by Nakajima *et al*., (2009) identified arch support to improve the biomechanical effects of LWI.

Furthermore, an additional trial by Jones *et al*., reported that both types of LWI had significant effects on the early stance peak EKAM (Jones *et al*., 2014). A further randomised cross over trial by Jones *et al*., (2013) investigated the effects of a full length LWI compared to the same LWI accompanied by the use of an off the shelf anti-pronatory device in shoes whilst walking in fifteen healthy subjects.

Both intervention conditions provided significant reductions in the EKAM, which were reported as 8.5% in the LWI with anti-pronatory device condition, and 9.1% in the LWI only condition. The LWI with anti-pronatory device was perceived to be more comfortable by participants (Jones *et al*., 2013) and therefore, the addition of an anti-pronatory device to a standard, full length LWI may lead to increased adherence of the intervention in patients with medial compartment knee OA, whilst offering an effective reduction in medial compartment joint loading and therefore could lead to slowed knee OA disease progression (Jones *et al*., 2013). Moreover, Nakajima *et al*., (2009) carried out an investigation to discover whether arch support could improve the biomechanical effects of a LWI when used simultaneously and concluded that the EKAM was reduced with the use of LWI and LWI with arch support by 7.7% and 13% respectively. The decrease was due to an alteration in the progression angle between the insoles. When used alone, LWI were identified as increasing step width, however the addition of arch support to LWI negated the increase, and therefore the use of arch support with LWI is a possible simple mechanism for further reducing the EKAM (Nakajima *et al*., 2009). Furthermore, Toda *et al*., (2004) identified LWI with 8mm or 12mm elevation, along with subtalar strapping to be the most effective in terms of reducing knee loading, and also to be the most comfortable elevation as perceived by participants. Subtalar strapping causes realignment and therapeutic effects, similar to a high tibial osteotomy by causing varus angulation of the talus, leading to correction of the femerotibial angle which causes further reduction of medial joint loads, identified when used in conjunction with LWI to be more effective than LWI alone (Toda *et al*., 2004, Hinman *et al*., 2009).

It appears as though the addition of support worn simultaneously with LWI could offer both biomechanical and perceived patient comfort benefits, working synchronously to improve the effectiveness of LWI. The addition of extra support used concurrently with LWI should therefore be investigated further within the literature.

The most common angulation of LWI used for the treatment of medial compartment knee OA is 5º (Jones *et al*., 2015, Yilmaz *et al*., 2015), with the angulation design features of the LWI influencing the biomechanical effects of the LWI on the lower limbs (Hinman *et al*., 2009, Hinman *et al*., 2012, Chapman *et al*., 2015). Although shown to be effective in reducing medial knee loads, an inclination exceeding 10º has been found to cause foot discomfort for subjects within trials, and therefore the majority of trials use the optimal comfort wedge inclination of 5º (Kerrigan *et al*., 2002, Hinman *et al*., 2009, Hinman *et al*., 2012, Chapman *et al*., 2015, Yilmaz *et al*., 2015).

A number of trials have investigated the effects of footwear based treatments as an additional option available which aim to reduce medial loads and the EKAM (Shakoor *et al*., 2008, Hinman *et al*., 2009, Shakoor and Block, 2013, Keen *et al*., 2013, Jones *et al*., 2015). Although a vast amount of research concerning LWI has reported reductions in the peak EKAM in both healthy individuals and individuals with medial compartment knee OA, surprisingly, LWI have proven ineffective at improving symptoms or slowing disease progression in some clinical trials, and reductions in the peak EKAM are occasionally not consistent across all study findings. A number of trials report that LWI had no effect on the EKAM (Pham *et al*., 2004, Baker *et al*., 2007, Hinman *et al*., 2008, Barrios *et al*., 2009, Bennell *et al*., 2011, Chapman *et al*., 2015). It has been postulated that the inconsistencies in LWI effectiveness could be due to the varying types of LWI available, and the differences in design and materials used, with a higher density manufacturing material (providing a varying sole stiffness) potentially affecting the EKAM reduction percentage, and also the length of which LWI are worn by trial participants, with 5-10 hours per day considered optimal (Hinman *et al*., 2008, Hinman *et al*., 2009).

The most apparent difference in varying types of LWI is the length (Hinman *et al*., 2008), and full length insoles (heel to forefoot) have been identified as the most effective in reducing the EKAM due to the orientation of the subtalar joint axis which is inclined upwards at an anterior angle and medially from the lateral calcaneus to the first metatarsal head. A full length LWI extends under the metatarsal head which causes an increase in the lever arm for rearfoot eversion, compared with a rearfoot (heel) only wedge which has a smaller lever arm. The reduction in EKAM is associated with an increased subtalar joint valgus moment via a more laterally shifted location of the COP of the foot. A full length LWI extends along the length of the entire foot, and the whole foot makes contact with the ground during the gait cycle, not just the rearfoot. The heel strike phase of the gait cycle makes contact with the ground for approximately 30-40% of the gait cycle. The second peak EKAM occurs at approximately 40-50% of the gait cycle. It is therefore not surprising that full length LWI are more effective at reducing the magnitude of the EKAM than heel only LWI (Inman, 1976, Crenshaw *et al*., 2000, Kerrigan *et al*., 2002, Kakihana *et al*., 2004, Kakihana *et al*., 2005). Full length LWI, rather than heel only LWI should therefore be used for the treatment of individuals with medial compartment knee OA.

Results from trials using LWI in knee OA patients have been somewhat inconsistent with regards to reduction of the EKAM and pain improvement (Hinman *et al*., 2008, Chapman *et al*., 2015), and it could be stated that the varying findings concerning reduction of the EKAM within the literature surrounding LWI could be due to the choice and utilisation of sub-optimal LWI (length, type, material and fit) and also the interaction of the individuals body type with the LWI, with Chapman *et al*., (2015) concluding that coronal plane ankle subtalar joint complex biomechanical measures influence the effect on the EKAM when wearing LWI. Further investigation is therefore paramount in order to identify individuals that may experience optimal benefits from the use of LWI for the treatment of medial compartment knee OA (Chapman *et al*., 2015). Findings of the Chapman *et al*., (2015) trial were based on shoe marker data collection, and therefore, whether barefoot walking can predict the response to LWI is unknown.

EKAM reductions when placing LWI in a person's own shoe can vary, and flat footwear or socks (although not practical) are the most ideal footwear for the use of LWI (Hinman *et al*., 2009). A study by Kean *et al*., (2013) compared a modified shoe incorporating a variable stiffness sole and lateral wedging with a standard sole shoe (control) and concluded that an individual's choice of shoe could impact the effectiveness of LWI (Kean *et al*., 2013). Moreover, concern has been reported about the compromise in shoe space when LWI are inserted into shoes, which could impact the effectiveness of the LWI, and could lead to discomfort (Bennell *et al*., 2011). Furthermore, no pain reductions have been reported with the use of typical LWI (full length and without medial support), although it has been reported that a change in EKAM is not significantly associated with a reduction in knee pain, pain reduction would be a desirable effect of LWI (Jones *et al*., 2014). Accordingly, research has been undertaken into the design of shoes which aim to reduce the mechanical loading at the knee joint (Erhart *et al*., 2002, Shakoor *et al*., 2009, Hinman *et al*., 2009).

Variable stiffness soled shoes and lateral wedged shoes (with a LWI inserted into the shoes sock-liner, integrated into the shoes design, complementing the sole) have been investigated for their ability to reduce the EKAM in patients with knee OA (Kean *et al*., 2013, Bennell *et al*., 2013). Modified shoes have been found to result in alterations to lower extremity biomechanics, specifically reductions in the knee GRF lever arm and the frontal plane GRF magnitude caused a reduction in the EKAM in people with knee OA (Bennell *et al*., 2011, Kean *et al*., 2013). Likewise, Erhart-Hledik *et al*., (2012) investigated the possible load modifying effects and clinical efficacy of variable stiffness shoes designed to reduce loading at the knee after 12 months of wearing by individuals with medial compartment knee OA, and identified that long term wearing of the specialised footwear led to a reduction in the EKAM, thereby reducing the load on the medial compartment of the knee.

Mobility shoes are another strategy designed specifically for the treatment of knee OA, surprisingly showed no effect on medial loading within the Jones *et al*., (2014) trial, however led to significant immediate knee pain reduction and improved comfort scores compared to all other walking conditions (Jones *et al*., 2015). It was hypothesised that perceived comfort of the mobility shoes may have influenced pain scores, which may change over time given that the pain scores were recorded immediately after participants first put the shoes on (Jones *et al*., 2015). Shakoor *et al*., (2013) postulate that medial loading reductions may occur over time with the mobility shoe. The same mobility shoe (designed to lower dynamic loading at the knee) was included within a trial by Shakoor *et al*., (2008), and interestingly, when compared to self-chosen (by participants) commercially available walking shoes (control) the specialised footwear effectively reduced joint loading in subjects with knee OA.

Mobility shoes are designed to mimic barefoot walking during gait, and consist of flat soled, flexible footwear. Mobility shoes have been found to lead to a reduction in knee loading in knee OA subjects and also an adaptation in gait, with sustained and long term impacts on knee joint loading identified even when the mobility shoe was removed (Shakoor *et al*., 2013). Mobility shoes may therefore may serve as a biomechanical training device to achieve beneficial alterations in gait patterns and mechanics for the treatment of medial compartment knee OA (Shakoor *et al*., 2008, Shakoor *et al*., 2013). Barefoot walking has been identified as the most effective walking style for reducing the EKAM and medial knee loading within the literature for treatment of medial knee OA (Jones *et al*., 2015), (hence the design of mobility shoes to emulate barefoot walking), however barefoot walking is neither convenient nor possible to maintain during everyday activities for the majority of the population, and therefore a more ideal intervention such as a LWI is needed. Mobility shoes have been designed with the aim of providing a safe and suitable alternative to barefoot walking, whilst still providing a reduction in knee loading (Shakoor and Block, 2006, Shakoor *et al*., 2013). Similarly, barefoot walking provided a significant reduction in medial loading during the first part of stance phase during the Jones *et al*., (2015) trial. However, Jones *et al*., (2015) identified barefoot walking to increase the medial loading during the latter period of stance and therefore stated that barefoot walking may not be the most effective solution for medial loading reduction. Therefore, LWI look to be an attractive solution for the treatment of medial compartment knee OA as reductions in medial loading were seen during both the first part of stance phase, and the late periods of stance phase (Jones *et al*., 2015).

Research comparing the effects of footwear types specifically aimed to reduce medial knee loading and the EKAM) and LWI is limited, thus further investigation is needed in order to discover which treatment is most ideal, providing the largest and longest lasting reduction in the EKAM, also which treatment reduces pain most effectively and reduces medial knee loading. To date, the literature points to LWI being the most suitable and effective method of reducing medial knee loads. Mobility shoes and other specialised footwear types are more expensive than LWI, and are also less discreet and provide varying and limited effects in terms of knee joint load modification (Hinman *et al*., 2009).

The kinetic and kinematic effects of wearing LWI have been reported as being most effective in mild to moderate medial compartment knee OA (Marks and Penton, 2004, Shimada *et al*., 2006). An investigation by Shimada *et al*., (2006) aimed to determine the efficacy of LWI on knee kinetics and kinematics during walking in subjects with knee OA, according to severity of the disease when measured using the Kellgren and Lawrence (KL) grading scale. The effects of the LWI were identified as being significant towards lowering knee joint loading in subjects with knee OA graded as I and II on the Kellgren and Lawrence grading scale. The findings of the study therefore support the recommendation that LWI are most ideal for patients with mild to moderate knee OA (Shimada *et al*., 2006).

Further investigation into LWI is needed to establish the effectiveness on biomechanical and clinical parameters in patients with symptoms of medial knee OA (Fang *et al*., 2006). Reilly *et al*., (2009) identified foot posture as a possible influence on the effectiveness of orthotic interventions in patients with medial knee OA. The study established that use of LWI to treat osteoarthritis of the knee may further increase the pronation of an already pronated foot, therefore causing further deviation from normal gait. Further investigation is needed therefore, in order to determine whether foot posture may have influenced this incidence of biomechanical non-response within trials carried out by Chapman *et al*., (2011).

The above literature fails to investigate the use of LWI in the treatment of medial knee osteoarthritis in relation to foot posture. However, a number of articles infer that foot posture would be studied in future research in their discussion (Hinman *et al*., 2008, Butler *et al*., 2009, Levinger *et al*., 2010, Levinger *et al*., 2012, Buldt *et al*., 2015, Buldt *et al*., 2015).

2.10 Foot Posture and Medial Compartment Knee Osteoarthritis

Foot posture assessment is important to consider when using LWI for the treatment of medial compartment knee OA, as foot posture variations are associated with the development of some lower limb abnormalities and musculoskeletal conditions (Reilly *et al*., 2009, Levinger *et al*., 2010, Abourazzak *et al*., 2014, Buldt *et al*., 2015, Buldt *et al*., 2015,) and altering of the mechanical alignment and dynamic function of the lower limbs (Levinger *et al*., 2010), therefore possibly reducing the effectiveness of various interventions such as LWI in the treatment of medial knee OA. For example, low arched (pes planus) and pronated (everted) feet have been associated with medial compartment knee OA within the literature (Levinger *et al*., 2010, Levinger *et al*., 2012, Buldt *et al*., 2015). However, despite this observation, the underlying mechanics linking foot posture and medial compartment knee OA are somewhat unclear. Therefore, Levinger *et al*., (2010) advocates an in depth knowledge of foot structure to be paramount in fully understanding the effect of interventions on the knee and lower limb joints in order to identify participants who will most likely benefit from intervention (Levinger *et al*., 2010). Currently however, there is a lack of research surrounding medial knee OA and foot structure and therefore greater investigation is required (Levinger *et al*., 2010, Levinger *et al*., 2012, Levinger *et al*., 2013).

Accurate foot assessment can provide an appreciation into how foot postures may influence or be influenced by reducing the loading on the medial knee compartment (Reilly *et al*., 2009, Levinger *et al*., 2012). Levinger *et al*., (2012) identified subjects with medial compartment knee OA to demonstrate altered foot kinematics during gait that are symptomatic of a less mobile, more everted foot type. Similarly, Reilly *et al*., (2009) compared navicular height in sitting and standing positions in 60 subjects with hip OA, 60 subjects with knee OA and in 60 controls. No difference was found between the knee OA and control groups; however, there was a considerable difference in frontal plane calcaneal angle, indicating a more everted (pronated) rearfoot in the knee OA group.

Foot pronation has been suggested to potentially reduce the adduction moment by shifting the centre of pressure laterally indicating an adaptation by the foot to reduce the load on the medial compartment of the osteoarthritic knee (Desal *et al*., 2007, Levinger *et al*., 2010, Levinger *et al*., 2013, Abourazzak *et al*., 2014).

It is well known LWI can alter foot motion (Levinger *et al*., 2013, Jones *et al*., 2015), specifically leading to an increase in rearfoot pronation (Nester *et al*., 2003, Kakihana *et al*., 2005, Abourazzak *et al*., 2014, Jones *et al*., 2015). Tibial malalignment and the extent of rearfoot range of motion identified within OA subjects was hypothesised to affect individual responses to load-altering interventions, such as LWI (Levinger *et al*., 2012). Accentuating pronation using a lateral wedged insole on an already pronated foot could potentially contribute to detrimental changes to lower limb kinematics and therefore the development of musculoskeletal disorders in other areas (Levinger *et al*., 2010, Abourazzak *et al*., 2014). However, there is currently a lack of research assessing foot posture and the effect on the EKAM and effectiveness of LWI concurrently (Levinger *et al*., 2012).

One of the most validated methods for assessing foot posture is the foot posture index (FPI) (Redmond *et al*., 2008). The FPI was developed to provide an efficient and reliable method for assessing static foot position, and is routinely used for clinical and research assessment (Redmond *et al*., 2008). A study compared FPI scores between 20 patients with medial knee OA and 20 controls and reported a considerably elevated average score in those with medial knee OA. This indicates a more pronated foot posture type in the medial knee OA population (Reilly *et al*., 2009, Levinger *et al*., 2010). A more recent study by Buldt *et al*., (2015) investigated the differences in the EKAM in healthy individuals with normal cavus (high medial longitudinal arch) or planus (low medial longitudinal arch) foot postures using the FPI. Results indicated that foot posture does not considerably influence the EKAM in healthy individuals whilst walking at a comfortable pace, suggesting the biomechanics of the knee are not substantially influenced by foot posture in healthy individuals. This finding proposes that foot posture may be altered by medial compartment knee OA. Also that the incidence of pronated feet within the medial compartment knee OA population presented within the literature may be a mechanism adapted by the individual to reduce disease symptoms (Buldt *et al*., 2015), instead of the presence of a pronated foot being the cause of medial compartment knee OA. Likewise, Gross *et al*., (2011) found that planus foot morphology is associated with medial compartment knee OA.

The use of the FPI may allow further detailed analysis of the EKAM primary outcome measure by grouping the subjects using these classifiers (Keenan *et al*., 2007, Redmond *et al*., 2008, Wrobel and Armstrong, 2008).

Levinger *et al*., (2012) also advocates an insight into the dynamic function of the foot during gait to be important in understanding the effect of foot kinematics on loading of the knee, thus providing an appreciation into the factors affecting the EKAM, aiding the design of knee OA treatment strategies. Several previous investigations have examined dynamic function of the foot during gait using three dimensional (3-D) motion analysis systems with infra-red cameras and force platforms in order to capture and analyse the motion of the lower limbs, ground reaction forces and also to identify gait cycle events (Landry *et al*., 2007, Levinger *et al*., 2012, Jones *et al*., 2014, Jones *et al*., 2012, Shultz and Jenkyn, 2012). The FPI and dynamic foot motion results can be used to gain an understanding into possible relationships between clinical and biomechanical foot measurements and their influences on the loading on the medial compartment of the knee.

2.11 Gaps in the Literature

Recent literature suggests that foot posture can potentially influence the magnitude of the EKAM (Levinger *et al*., 2010), and that a pronated foot can reduce the EKAM in medial compartment knee OA patients (Levinger *et al.*, 2010), although the underlying mechanisms connecting foot posture and function remain unclear within the literature (Buldt *et al*., 2015). Therefore, further research is needed to understand the role of both static and dynamic foot and ankle posture/motion on the EKAM. There is currently a lack of literature surrounding non-response to LWI intervention in knee OA patients which has been implied within the literature as possibly relating to rearfoot position and motion (Hinman *et al*., 2008, Butler *et al*., 2009, Chapman *et al*., 2011, Chapman *et al*., 2015). Chapman *et al.*, (2015) highlighted that rearfoot motion in a control shoe could predict biomechanical response to lateral wedge insoles in a group of medial compartment osteoarthritis patients. However, it is unknown whether barefoot motion which is more used in clinical situations can successfully predict biomechanical response to lateral wedge insoles when worn in shoes. Additionally, it is unknown whether static measures of the foot and rearfoot (FPI - a common assessment in clinics), are useful indicators for biomechanical response to lateral wedge insoles.

Previous literature has assessed the change in rearfoot motion when wearing lateral wedge insoles but this has only been examined with intra-cortical bone pins (Jones *et al*., 2012). This approach is invasive and therefore quantification of rearfoot motion when wearing lateral wedge insoles needs to be analysed with a new approach in the shoe condition. This will help to determine the changes that lateral wedge insoles inflict upon the rearfoot rather than incorporating the motion of the shoe and also make further advancements in the literature.

Therefore, whilst previous studies have demonstrated the effects of using LWI and their effects on the knee joint, the precise underlying mechanisms of foot posture and its effects on the EKAM, and the impact of LWI on the foot and ankle remain unclear within the literature.

2.12 Thesis Objectives

The primary objectives of this thesis are:

a) To determine whether clinical static foot posture (quantified using the FPI), can represent the dynamic rearfoot.
b) To determine if any relationship exists between clinical static foot posture (quantified using the FPI) and the magnitude of the EKAM.
c) To determine whether the rearfoot kinematics have any relationship with the magnitude of the external knee adduction moment.
d) To determine whether foot posture impacts on the effectiveness of lateral wedged insoles and the reduction of EKAM in patients with OA of the knee.
e) To examine the accuracy of rearfoot kinematic measurements using novel methods barefoot and inside the shoe.
f) To examine the effect of lateral wedge insoles on rearfoot motion using in-shoe measurement techniques.

Chapter Three

Methodology and Repeatability

3.1 Introduction

In this chapter, the biomechanical methods that define the 3D motion data capture, force measurement and segment modelling and computation are presented, also a test-retest study that was conducted by the investigator to ensure repeatability of the investigators reflective marker placement to determine the error within the future planned studies.

3.2 Data Collection

In order to calculate the biomechanical variables of the lower limbs in the biomechanical model, both motion data and force data need to be captured during the designated locomotion. Both the motion and force data need to be synchronised so to build up the relationship between kinematic variables and forces acting on the foot and at each joint.

3.2.1 Kinematic data capturing using infra-red cameras

Kinematic data were collected by a Qualisys motion capture system with sixteen computerised infra-red Oqus cameras (Qualisys AB, Gothenburg, Sweden) at 100Hz which reflect red light from the markers, back to the cameras to provide the 2-D position (coordinate image) of each marker (the position of the marker is found by a beam of light reflected from the marker, back to the cameras). Each marker must be seen by at least two cameras (two light beams) at any one time during capture time in order for its 3-D location to be determined within the global coordinate system (Cappozzo *et al*., 2005, Kaufman and Sutherland, 2006, Payton and Bartlett, 2008). At least three non-co-linear reflective markers are required on a segment to define its position and orientation accurately in a 3-D space (Cappozzo *et al*., 1996).

When the position and orientation of the body segment is determined in the same way, the angle between the two segments can then be calculated (ROM) (Kaufman and Sutherland, 2006).

3.2.2 Ground reaction force measurements using force plates

The ground reaction force which was used in the calculation of the kinetic output was measured with floor embedded force plates (BP400x600, AMTI Watertown, MA, USA) at 1000Hz. In total, four force plates were used in the study (figure 3.1). The measurement of the ground reaction force was synchronised and collected in Qualisys Track Manager (QTM) software that operated the motion capture system. The force plates were set up and calibrated by the centre engineers using CalTester software, a quality assurance tool for the purpose of validating the laboratory settings of force plates by corroborating the spatial synchronisation of the force plates and forces (C-Motion, 2016). Based on the CalTester test results, the accuracy of the force vector orientation ≤1° and COP location ≤3mm, which was equally true for each force plate (CMAS University of Salford lab standards).

Figure 3.1: The Gait Laboratory at the University of Salford. Floor embedded force plates are depicted in the centre of the image numbered 1-4.

3.2.3 *Calibration of the motion capture system*

In order to collect complete, accurate and reliable data in the measurement volume (the space around the force plates) during walking, the camera system must be adjusted, aligned and calibrated before use. The system is firstly calibrated statically in order to identify the orientation and position of each camera in relation to the global coordinates system of the gait laboratory, and secondly dynamically to ensure all motions within the measurement volume are captured.

The tool used to carry out static calibration of the 3-D motion capture system was an L-shaped rigid metal frame (figure 3.2), with four reflective markers attached in the designated positions. Before calibration, the L-shaped frame was placed on the corner of the first force plate, and the outside surface of the L-Frame was aligned with the side surface of the force place. The fixed markers of the L-frame were used to define the X and Y axis of the laboratory coordinate system (Global system). The positive X axis points forward, the positive Y axis points to the left when facing forward, and the axis defined with X and Y represented the positive Z axis (upwards).

The origin of the force platform is in the centre of the force plate below the top surface, by manufactural design. The origin of each force plate was automatically calculated in the laboratory frame based on its parameters and settings.

Figure 3.2: The position of the L-shaped frame for calibration. *Figure 3.3: The calibration wand.*

A separate tool was used to calibrate the space used during dynamic trials. This tool was a T-shaped metal frame (figure 3.3) with reflective markers positioned in fixed points along the length of the structure at a distance of 750.43mm. A capture time of 60 seconds was used to enable the space to be fully calibrated and the T-shaped wand tool was randomly moved around the testing space ensuring that both the lower floor level and higher level were covered completely. Concurrently, the L-shaped tool was placed on the force platform. This determined the location (position and orientation) of the 16 cameras relative to the gait laboratory coordinate system (Payton and Bartlett, 2008).

In the calibration, the distance between the origin of the coordinate system of the motion capture, i.e. the laboratory coordinate system, and the optical centre of each camera would be determined, which was represented with the three coordinates of X, Y and Z. For wand calibrations, the default origin of the coordinate system is in the centre of the corner marker. After the calibration process was complete and passed, both the calibration residual results for each camera and the standard deviation of the wand length were recorded to be below 1mm, meaning any markers position in the trial will be located to within 1mm of its true position.

The lower the residual result, the more accurate the calibration and the 3-D marker coordinate from the measurement.

Following the completion of calibration, the setting up of the system and force plates followed. The settings of other devices such as the amplifier and analogue board were checked and all force plates were reset to remove the signal offset before the test commenced. An offset removal manoeuvre was performed between each trial and condition in order to minimise the noise level, by resetting the force plates.

3.2.4 The test protocol

As knee OA was the focus of the study, the lower limbs including; the pelvis, left and right thighs, legs and feet were the main body segments for the biomechanical analysis. To define each segment, the predefined anatomical markers were placed on the landmark position of each segment. To track the three dimensional motion of each segment, a minimum of three markers per cluster were firmly attached to each segment for tracking the movement during dynamic tests. The main test for determining the biomechanical variables of each involved segment and joints were walking tests. In order to define the model of each segment, a static test was performed in each test session or condition, during which all markers (both anatomical and tracking markers) were recorded when the subject stood still in the motion capture space. The dynamic walking tests were performed until a minimum of five good walking trials were achieved. Walking trials were conducted along a walkway (15 metres long, 6 metres wide) with force platforms (AMTI: Advanced Medical Technology Incorporation, Watertown, USA) embedded within. A good walking trial meant successful marker capture had taken place, and at least a clean stance phase on one force plate was achieved.

3.2.5 Participants

Healthy participants were recruited from within the staff and student population at the University of Salford, and the patients with medial compartment knee osteoarthritis were recruited from within NHS patient lists. Testing was conducted in the clinical gait laboratory at The University of Salford.

3.2.6 Procedure

On arrival at the clinical laboratory, all test procedures and equipment used within each particular study were briefly explained to each subject and he or she was given the opportunity to ask any questions. Individuals then signed the informed consent form. Participants then donned shorts after changing in a private area, and several anthropometric measurements were taken for later use in data analysis (height and mass).

3.2.6.1 The Foot Posture Index

Firstly, individual participant's foot posture was assessed, and the foot was statically and clinically measured using the Foot Posture Index (FPI) scale (a 6 criteria foot posture assessment) (table 3.1, figure 3.4) in order to determine the degree to which the participants foot was pronated, supinated or in a neutral position, to establish if any relationship existed between dynamic and static foot posture.

The subject stood in a relaxed bipedal position. The six criterion of the FPI include the following assessment items which were carried out on both limbs of each subject within the study: talar head palpation - the head of the talus is palpated on the medial and lateral side of the anterior aspect of the ankle. Supra and infra lateral malleolar curvature – the curves above and below the lateral ankle malleoli are observed and compared. Calcaneal frontal plane position – the inversion/eversion of the calcaneus is observed (angular measurements are not required, only visual appraisal). Bulging in the region of the talo-navicular joint – the area is observed. Bulging in this area is associated with a pronated foot, and a flat appearance of the skin directly over the talo-navicular joint indicates a neutral foot. Height and congruence of the medial longitudinal arch – the area is observed, taking both the arch height and the arch congruence into consideration, as both the height and shape of the arch can indicate foot function. Abduction and adduction of the forefoot on the rearfoot – requires the observation of the foot from the posterior aspect, in line with the long axis of the calcaneus (not the long axis of the whole foot) (table 3.1, figure 3.4).

Each item was scored on a 5-point scale (between -2 and +2), providing a sum of all items between -12 (highly supinated) and +12 (highly pronated), with a score of 2 to 12 indicating a pronated foot, a score of -2 to -12 indicating a supinated foot, and a score of +1 to -1 indicating a neutral foot (Redmond *et al*., 2006, Levinger *et al*., 2010, Barton *et al*., 2012, Lee *et al*., 2015) (table 3.1, figure 3.4). The total FPI score was then used later in the data analysis. The FPI was assessed solely by the same examiner (the investigator), who had previous experience in taking these measurements.

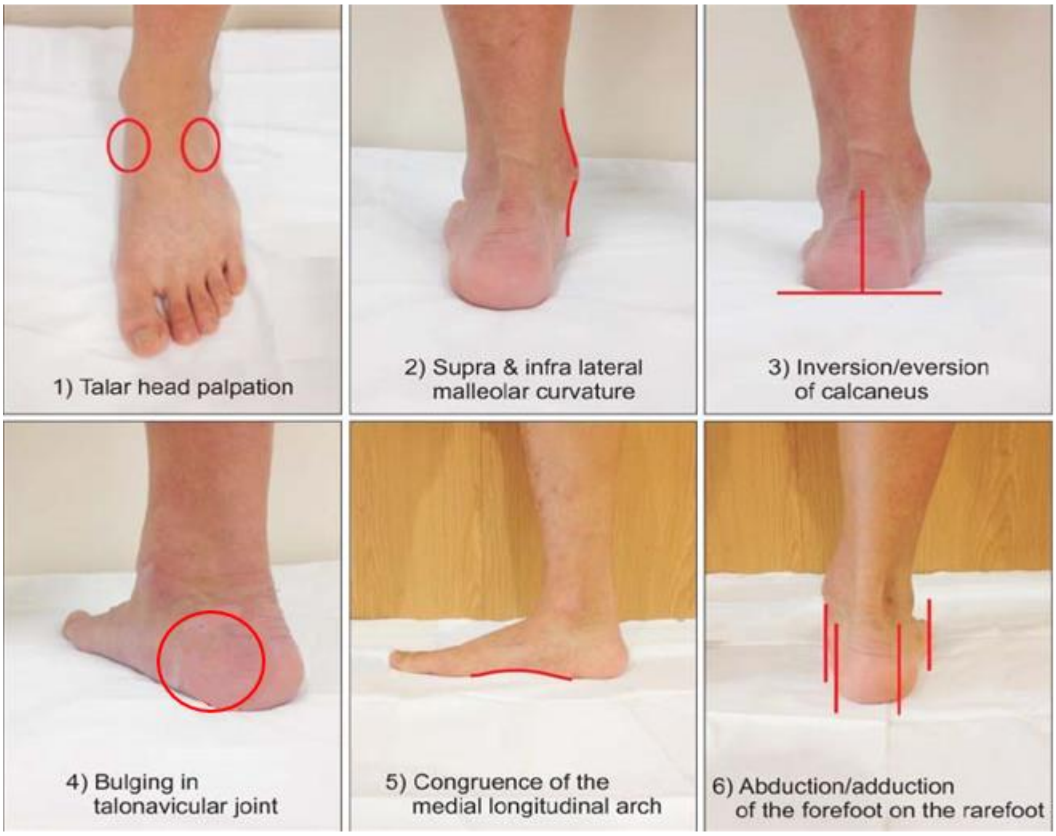

Figure 3.4 – Figure depicting the locations of the six criteria of the Foot Posture Index (Lee et al., 2015).

Table 3.1 – An explanation of the six criteria of the Foot Posture Index (FPI).

FPI Score	-2	-1	0	1	2
Talar Head Palpation.	Talar head palpable on lateral side but not on the medial side	Talar head palpable on lateral side and slightly palpable on the medial side	Talar head equally palpable on lateral and medial side	Talar head slightly palpable on lateral side and palpable on medial side	Talar head not palpable on lateral side but palpable on medial side
Supra and infra lateral malleolar curvature	Curve below the malleolus either straight or convex	Curve below the malleolus concave but flatter or more shallow than the curve above the malleolus	Both infra and supra malleolar curves roughly equal	Curve below malleolus more concave than curve above malleolus	Curve below malleolus markedly more concave than curve above malleolus
Calcaneal frontal plane position	More than an estimated 5̊ inverted (varus)	Between vertical and estimated 5̊ inverted (varus)	Vertical	Between vertical and estimated 5̊ everted (valgus)	More than an estimated 5̊ everted (valgus)
Bulging in the region of the talo-navicular joint (TNJ)	Area of TNJ markedly concave	Area of TNJ slightly, but not definitely concave	Area of TNJ flat	Area of TNJ bulging slightly	Area of TNJ bulging markedly
Height and congruence of the medial and longitudinal arch	Arch high and acutely angled towards the posterior end of the medial arch	Arch moderately high and slightly acute posteriorly	Arch height normal and concentrically curved	Arch lowered with some flattening in the central portion	Arch very low with severe flattening in the central portion-arch making ground contact
Abduction/adduction of the forefoot on the rearfoot	No lateral toes visible. Medial toes clearly visible	Medial toes clearly more visible than lateral	Medial and lateral toes equally visible	Lateral toes clearly more visible than medial	No medial toes visible. Lateral toes clearly visible

3.2.6.2 Gait Analysis

Participants were then prepared to commence the walking trials. Subjects were then given appropriately sized standard footwear (Ecco Zen) and reflective markers were directly placed on to the skin, attached using hypoallergenic double sided adhesive tape, fixed to the base of the reflective markers. Footwear conditions varied for each study, and participants were therefore asked to remain barefoot or were given a pair of lateral wedged insoles (LWI) (Salford Insole Lateral Wedge Technology) (figure 3.5) at specific times.

Figure 3.5: Salford Insole Lateral Wedge Technology

All test procedures within the studies were carried out within two hour time slots over single test sessions. Prior to the commencement of data collection, subjects were given the opportunity to become familiar with all equipment and interventions used within the studies. Participants were asked to walk across the testing area for 5 minutes in order to ensure the footwear and LWI (where used) had an exact fit, were comfortable and were not causing the subject any discomfort or annoyance. Also, to ensure that the wrap bandages and pelvis belt were not wrapped too tightly. Prior to each test condition (barefoot, shod, and shod with 5° LWI) subjects were requested to stand stationary over one of the force platforms so that a static 3-D image could be gained by the sixteen infrared cameras. The investigator then ensured all reflective markers were present and unobstructed and the walking trials commenced in a randomised order.

3.2.6 The placement of reflective markers (anatomical and technical)

Flat based reflective markers measuring 14.5mm in diameter (figure 3.6) were attached to bony landmarks on both limbs and fixed cluster pads were attached to the lateral aspect of each segment at the shank, thigh and pelvis for the trials. The reflective markers were used to calculate 3-D kinematic data allowing the position and orientation of body segments and underlying bones to be represented (Van Sint, 2007). Marker locations varied depending on the study (additional or varying markers used within different studies are detailed in individual chapters).

Fig. 3.6: 14mm Reflective marker

The reflective markers are lightweight to ensure the weight of the marker itself does not cause skin movement artefact, and are composed of a reflective sphere and plastic base. The reflective markers reflect infrared light which is emitted from light emitting diodes (LED's) which are located around the lenses of the 16 cameras within the gait laboratory. The reflective markers were attached to each individual's skin over bony anatomical landmarks on both upper and lower limbs using hypoallergenic adhesive tape.

For each study, the foot segment was different, and reflective marker placement varied. Therefore, the exact placement of the reflective markers will be detailed within the individual study chapters.

The locations of the reflective markers in the barefoot condition in both healthy participant and medial knee OA patient studies were as follows: on the foot ($1^{st,}$ 2^{nd} and 5^{th} metatarsal head and calcaneal tubercle, styloid and navicular), ankle (medial and lateral malleolus), knee (lateral and medial femoral condyle, tibial tuberosity and fibular head), thigh (greater trochanter), pelvis (right and left anterior superior iliac spine, right and left posterior and superior iliac spine, and right and left iliac crest) and the shoulder (left and right acromial). Within the shod footwear condition, the shoes were assumed as a rigid body, as with previous research and the reflective markers were glued on to shoes (on the 1st and 5th metatarsal heads, 5th metatarsal base, superior and inferior calcanei, medial and lateral calcanei, and the toe cap) (figure 3.7).

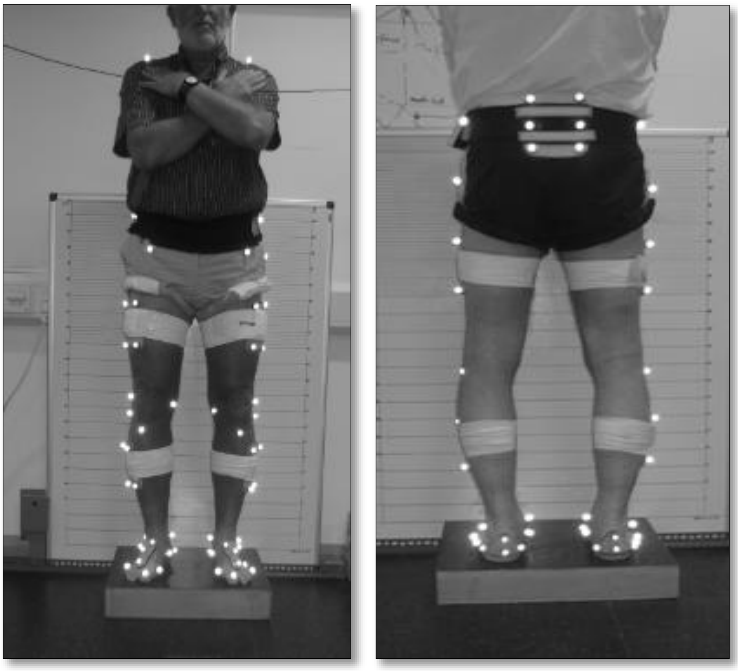

Figure 3.7: Anatomical and technical reflective markers (anterior and posterior).

In addition to individual reflective markers, fixed cluster pads (figure 3.7, figure 3.8), made of rigid plastic plates, with four markers attached to each were utilised for the study and were attached to the shank, thigh and pelvis (also the rearfoot and forefoot during barefoot walking conditions only) using both double sided adhesive tape (figure 3.8) and non-migratory Fabio Foam Super Wrap bandages (figure 3.8). An overwrap technique was utilised in order to attach the clusters pads to the segment to minimise migration of these planes down the limbs when compared to skin mounted clusters as demonstrated by Manal *et al*., (2000) due to the inability of intra-cluster marker movement to occur during the trials.

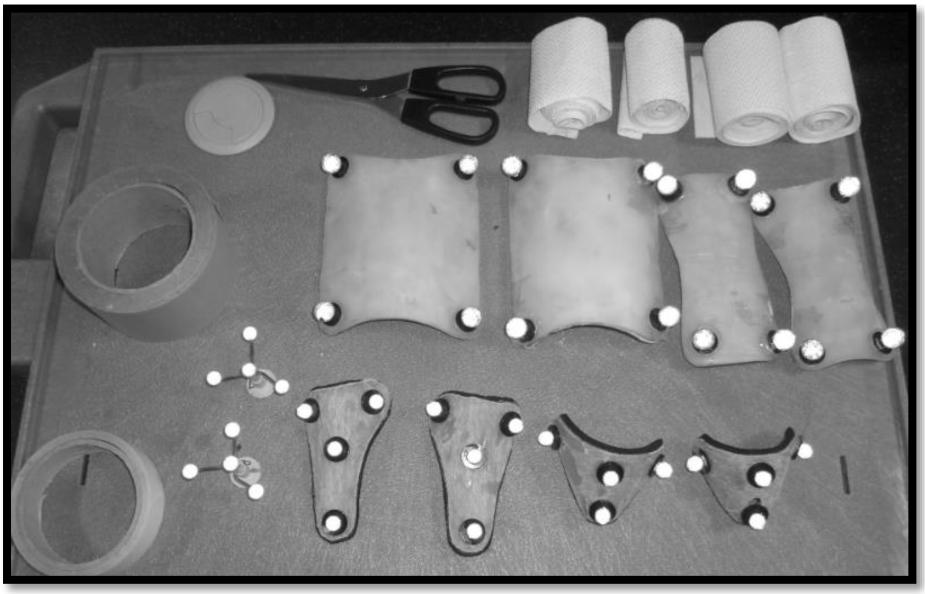

Fig.3.8: Cluster pads, double sided adhesive tape, Fabio Foam Super Wrap.

Movement can take place due to the skin and soft tissues moving over the underlying bone (skin and soft tissue movement artefacts), and could cause significant error within the study (Cappozzo *et al*., 1996). For this reason, the calibration anatomical systems technique (CAST) was utilised in the study which allowed the determination of the movement of individual segments and their anatomical significance during the movement trials, whilst accounting for measurement error (Cappozzo *et al*., 1996, Buczek *et al*., 2010).

Although a variety of marker sets have been suggested, CAST provides superior anatomical relevance when compared with the modified Helen Hayes (HH) marker set (Kadaba *et al*., 1989). HH was a previously adopted model with the primary advantage of being a simple model with a small number of markers, although it has a number of disadvantages, namely because it only utilises three rotational degrees of freedom (DOF) for the hip and knee, and two DOF for the ankle, with the foot represented as a vector omitting important coronal plane ankle motion. A small number of markers are used, with large distances between each marker present meaning the model is less advanced with low resolution imaging systems (Della Croce *et al*., 2005, Collins *et al*., 2009). In the HH model, the anatomical markers are used to track movement, resulting in the shifting of distal segments depending on the movement of proximal segments. This introduces error to the measurements obtained (Schwartz *et al*., 2004, Cereatti *et al*., 2007).

CAST attempts to reduce soft tissue artefact, which are major limitations in kinematic gait analysis along with landmark identification (Collins *et al*., 2009). Skin movement and soft tissue artefact can cause errors as large as the range of motion (ROM) of the joint and more accurate tracking may be achieved with clusters of markers on rigid plates, placed away from bony landmarks in the centre of segments, rather than close to the joints whilst still allowing for segment reconstruction (Collins *et al*., 2009) as demonstrated by Manal *et al*., (2000). Apart from displacement of rotation axes and skin movement artefacts, the position and orientation of joint mounted markers should remain the same. The CAST utilises 6 degrees of freedom (DOF) and the technical markers track the movement of each segment independently, allowing 6 DOF (rotational and translational) at each joint (Cappozzo *et al*., 2005, Cereatti *et al*., 2007) and has been shown in previous research to reduce a number of errors presented by previous models (Cereatti *et al*., 2007). A model using 6 DOF is favoured over the HH as it illustrates comparable performance and improves on HH and overcomes a number of theoretical limitations (Collins *et al*., 2009) whilst allowing for detailed ankle coronal plane motion.

3.2.7 Walking Conditions

The walking conditions (barefoot, standard footwear (shod) and shod with lateral wedge insole) varied from study to study and therefore the footwear conditions specific to individual studies will be detailed within each study methodology.

For all walking conditions the order of testing was randomised to ensure that any possible carry-over effects were minimised and to prevent bias. A trial was considered good only when the foot was placed completely on the force platform during the stance phase of the gait cycle. Walking trials were conducted until a minimum of five good trials were achieved. The five best walking trials for each condition were selected and used for data processing.

3.3 Data Processing

Following data collection, all joint kinematic and kinetic data was processed using Qualysis Track Manager Software where each marker was identified, labelled and digitised (figure 3.9).

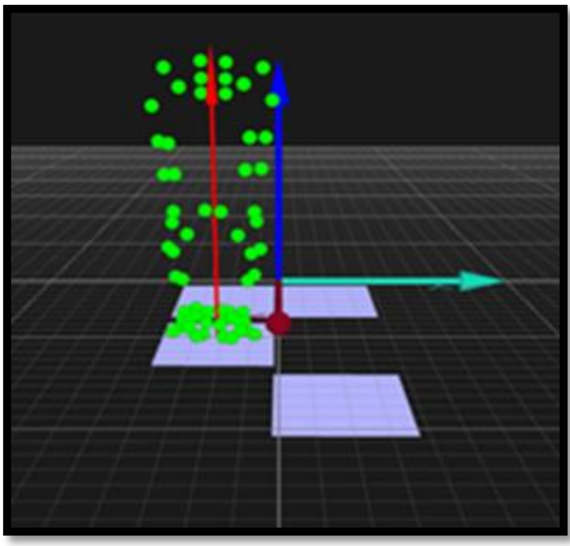

Figure 3.9– Qualysis Track Manager

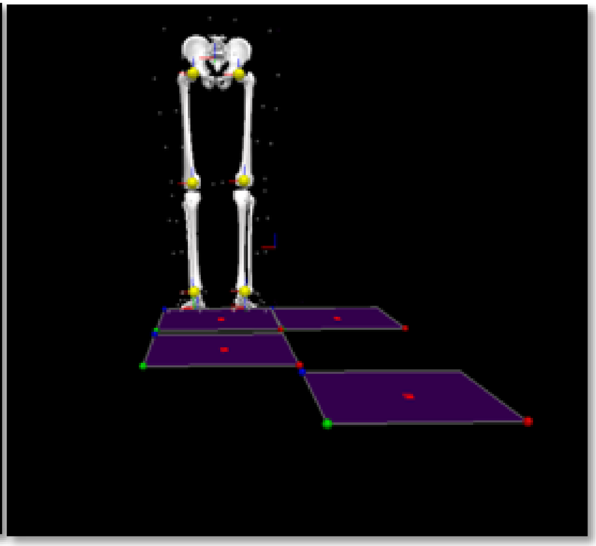

Figure 3.10 Visual 3D Model

All successful trials were then exported to Visual 3D (V3D) (figure 3.10) software (version 4.91, C-Motion Inc, Rockville, MD, USA). Dynamic skeletal graphics created in V3D (figure 3.10) using the marker set depicted in figure 3.7, controlled by subject kinematics were used to assist with the interpretation of results (Buczek *et al*., 2010). A V3D model comprises of a collection of rigid segments, each of which relates to a subjects particular body segment (major bone structures). The position and orientation of a segment with six variables is known as a segment POSE (3 variables describe the position of the origin, 3 variables describe the rotation) in 3-D space, normally 3 variables describe the segment translation in three perpendicular axes (vertical, medial-lateral and anterior-posterior), and 3 variables describe the rotation about each axes of the segment (sagittal, frontal and transverse). The positions of reflective markers are translated into the pose of the corresponding model, identified using motion tracking equipment by V3D (Visual 3D, 2015). The motion-tracking apparatus tracks the reflective markers which are applied to specific locations on or near the subject's body, and not the actual body segments. The body segments which are tracked are defined by proximal and distal endpoints located inside the subject's body (Visual 3D, 2015). As mentioned previously, markers and sensors can be placed inside the subject's body, however for this study, markers were attached over bony (anatomical) landmarks, on each subject's skin.

The model is referred to as a six degree of freedom (DOF) model due to having six variables that describe its position and orientation in 3-D space (3 variables describe segment translation in three orthogonal axes, and 3 variables describe the rotation about each axis). Individual subjects anthropometric measurements (height and body mass) were entered into the software to calculate the length and the centre of mass of the segment for use in kinetic data analysis. Pelvis, thigh, leg and foot segments were then modelled using anatomical landmarks or joint centres and the radius of the proximal and distal end of the segment and the tracking markers, with the interpretation of results (Buczek *et al*., 2010).

The VISUAL3D model segments and tracking markers are detailed in table 3.2.

Table 3.2: Visual 3D building of the biomechanical model segments.

Segment	Proximal radius/joint	Distal radius/joint	Tracking markers
Pelvis	- Right anterior superior iliac spine - Left anterior superior iliac spine	- Right posterior superior iliac spine - Left posterior superior iliac spine	Pelvis cluster pad (4 tracking markers) Left and right anterior posterior iliac spine
Thigh	- Hip joint centre* - Greater trochanter	- Medial femoral condyle - Lateral femoral condyle	Thigh cluster pad (4 tracking markers)
Shank	- Medial femoral condyle - Lateral femoral condyle	- Medial malleolus - Lateral malleolus	Shank cluster pad (4 tracking markers)
Foot	- Medial malleolus - Lateral malleolus	- 1st metatarsal head (in barefoot and shod) - 5th metatarsal head (in barefoot and shod)	Superior/inferior calcaneus, medial/lateral calcaneus (in shod) Heel cup cluster (4 markers) (barefoot) Hallux in barefoot and shod

***** Hip joint centre is automatically calculated by using anterior and posterior superior iliac spine markers using the regression equation by Bell and Brand (1990)

The maximum gaps of marker data was filled with polynomial interpolation algorithms. Motion and force plate data was filtered using a Butterworth 4th order bi-directional low pass filter with cut off frequencies of 6Hz for kinematics as used previously by Winter (2009) and 25Hz for kinetics as used previously by Schneider and Chao (1983) based on a residual analysis (Yu *et al*., 1999). Joints kinematics were calculated using an X-Y-Z Euler rotation sequence, where X represented flexion/extension, Y adduction/adduction or varus/valgus, and Z internal/external rotation. Joint kinetic data were calculated using 3-D inverse dynamics and the joint moment data was normalised to body mass and presented as external moments referenced to proximal segment. Automatic gait event definition was utilised in all trials, which captured data when the vertical GRF exceeded 20 Newtons (N) in value. The gait cycle was defined as the movement and events from heel strike of the foot on the force platform, to the subsequent heel strike of the same foot. Stance phase was defined as heel strike of the foot to the subsequent toe-off of the same foot. Each gait parameter of interest for each of the studies was then exported from V3D to Microsoft Excel 2010 (Microsoft Washington, USA) for further analysis.

The thesis aims to gain a more thorough understanding of loading at the knee joints in both healthy individuals and knee OA patients, considering the effects of wearing lateral wedge insoles (LWI) on the loading at the knee joint. For such a study to be accomplished sufficiently, the reliability of the investigator must be assessed prior to the collection of the study data. A test-retest reliability study was therefore conducted in order to enable the researcher to appreciate the measurement error present in the results, which would entirely arise from the placement of the reflective markers.

3.4 Test-Retest Reliability Study - Kinetics and Kinematics in Barefoot and Shod

Clinical gait analysis is a both a valuable and reliable technique when used for the purpose of establishing the consequences of orthotic interventions on kinematic and kinetic data (Schwartz *et al*., 2004), however the results obtained can be affected by certain factors.

Several factors that are paramount in ensuring measurement errors are reduced, and can be controlled include: accuracy and consistency of marker positioning, walking speed, faulty or inaccurate equipment, and data processing inaccuracies (Schwartz *et al*., 2004). Cappozzo *et al*., (1996) implies that the placement of reflective markers on bony landmarks can lead to variability and greater measurement error, with these locations being more difficult to palpate and identify due to covering by adipose tissue and muscle layers (Baker, 2006). The precise placement of reflective markers is imperative in accurately calculating and determining the positioning of joints, with inaccuracies and mistakes in the location of these joints (due to the incorrect placement of reflective markers) having the potential to cause significant errors in the calculation of joint kinetic and kinematic data (Della Croce *et al*., 1997, Stagni *et al*., 2000, Baker, 2006).

After carrying out test-retest reliability of gait data in previous studies, encouraging results (high repeatability) were achieved in healthy individuals (Kadaba *et al*., 1989, Andrews *et al*., 1996). Birmingham *et al*., (2007) conducted a repeatability study on individuals with knee OA and included the EKAM within assessments. It was concluded that the EKAM was highly repeatable with the ICC measuring 0.86, indicating excellent test-retest reliability. The Birmingham study utilised a modified Helen Hayes marker set however, and therefore results should be treated with caution due to the HH model having a number of disadvantages (Kadaba *et al*., 1990), namely due to it only adopting three rotational DOF for the hip and knee, and two DOF for the ankle. The HH marker set utilises low resolution imaging systems, due to a small number of markers used, with large distances between them (Della Croce *et al*., 2005). Additionally, in the HH model, anatomical markers are used to track movement, resulting in the movement of distal segments, depending on the movement of proximal segments, introducing error to the measurements (Schwartz *et al*., 2004, Cereatti *et al*., 2007).

In this study the CAST reflective marker placement technique will be used in order to target some of these limitations, aiming to reduce measurement error by using a six DOF marker set which utilises technical markers which track the movement of each segment independently, allowing three rotational and three translational degrees of freedom (six DOF in total) at each joint (Cappozzo *et al*., 2005, Cereatti *et al*., 2007), thereby reducing a number of errors presented by previous models, and also showing comparable performance to and overcoming limitations of previously used models (for example the HH method) (Cereatti *et al*., 2007, Collins *et al*., 2009).

The overall aim of the thesis is to gain a more thorough understanding of loading at the knee joints in both healthy individuals and knee OA patients, considering the effects of wearing lateral wedge insoles (LWI) on the loading at the knee joint. Therefore, in order for such a study to be accomplished sufficiently, the reliability of the investigator in placing reflective markers needed to be assessed prior to the collection of the study data. This study was therefore conducted in order to enable the researcher to understand the measurement error present in the results. The placement of these markers should be as identical as possible over subsequent subject gait laboratory visits to ensure that any difference observed after the use of interventions is from the intervention itself and not from the experimenter error in marker placement.

Some errors present in experimental biomechanics can be contributed to test design and control and data processing, however the aim of this study is to focus on the test-retest reliability of reflective marker placement by the investigator. Between day test-retest repeatability of kinetic and kinematic waveform data within the study was quantified using the correlation of multiple coefficient (CMC) and the standard error of the measurement (SEM). The CMC is a measure of the strength of the association between two variables (independent explanatory and dependant prediction) and was used to measure the accuracy and statistical difference in the placement and replacement of the reflective markers within the study between days. Kadaba *et al*., (1989) and Growney *et al*., (1997) used the CMC in previous similar studies. The value of the CMC aims to be greater than 0.70 (which can be considered as indicating acceptable repeatability, with 1 indicating identical results and 0 indicating no association) (Growney *et al*., 1997, Queen *et al*., 2006, Collins *et al*., 2009). The SEM represents a standard deviation of errors of measurement present within the study allowing quantification of error and the extent to which individual trials provide accurate results. Low levels of SEM indicate high levels of accuracy, and therefore high levels of SEM indicate low levels of trial accuracy. The SEM is calculated by carrying out a standard deviation of the trials multiplied by the square root of gait cycle figures (Growney *et al*., 1997).

A systematic review conducted by McGinley *et al*., (2008) concluded that reliability varied widely across studies and gait variables reviewed, however the majority of studies reported error of 5˚ and less for all gait variables, excluding hip and knee rotation. It was stated that error ranging between 2˚ and 5˚ is likely to be regarded as reasonable, and error of less than 2˚ is considered acceptable. McGinley *et al*., (2008) suggested that error in excess of 5˚may be large enough to influence clinical interpretation and therefore, should be carefully considered. Data reviewed within the paper identified the majority of studies and gait variables reported errors that ranged from 2˚ and 5˚. High errors were present within some reviewed studies, however generally low CMC values were reported within the same studies. Therefore, for some gait variables, error magnitudes did not reflect CMC indices (McGinley *et al*., 2008).

3.4.2 Test-Retest Study Aims

The study aimed to determine the inter-trial and intra-trial reliability of walking whilst under two conditions (barefoot and shod), both of these footwear conditions will be utilised within future experiments. The study also aimed to assess the reliability of using a heel cup cluster marker set to establish and verify the ability of the researcher in applying and using cluster markers over subsequent subject visits to the gait laboratory.

It was hypothesised that the marker replacement by the investigator would be reliable, however small error would exist due to skin movement artefact occurring between the skin and underlying bones, and anatomical landmark location.

3.4.3 Methods for repeatability assessment

After approval from the Research Ethics Panel of the academic audit and governance committee at The University of Salford (ethical approval number HSCR13/42), participants for the repeatability assessment were recruited from three different populations. For the kinematic and kinetic data, six healthy subjects were recruited, and for the FPI (Foot Posture Index) data, four healthy subjects were recruited from within the staff and student population at the University of Salford. For the imageJ data, five NHS patients with medial compartment knee OA were recruited.

Prior to the commencement of testing, each participant read and signed a written informed consent statement and individual demographic information (date of birth, height, mass and shoe size) for each participant was recorded. Table 3.3 summarises the demographic characteristics of all participants.

Table 3.3: Mean demographic measurements for all reliability study participants.

Healthy participants (N=6) Kinetics and Kinematics	
Age (years)	*31.5±9.29*
Height (m)	*1.72±0.09*
Mass (kg)	*82.17±15.17*
Healthy participants (N=4) Foot Posture Index (FPI)	
Age (years)	*30.2±5.56*
Height (m)	*1.68±0.07*
Mass (kg)	*78.17±19.64*
OA patients (N=5) ImageJ	
Age (years)	*62±10.03*
Height (m)	*1.73±0.04*
Mass (kg)	*85.90±6.29*

Table 3.4 – Inclusion and exclusion criteria

Inclusion Criteria	Exclusion Criteria
Good general condition of health, aged 18 years or over and able to walk without aids or assistance.	Experience or evidence of lower limb injuries (including bone fracture and ligament injury to the hip, knee, ankle and foot) within the six months prior to testing.
No previous surgeries on the lower limbs (for example total knee arthroplasty or unicompartmental knee arthroplasty).	Has disabilities or lower limb deformities which influence normal gait.
Has no known history of osteoarthritis or other bone diseases (for example osteoporosis).	Does not agree to the study conditions or protocol, and does not give consent.

In order to assess the test-retest reliability (repeatability) of gait data, each participant visited the gait laboratory on two separate occasions, two weeks apart. The shapes of the waveforms demonstrating different gait parameters were explored in detail. Kinetic and kinematic data were collected by the 16 infrared cameras, and force platforms which allow inverse dynamics to be performed in order to calculate the hip, knee, and ankle external moments (Winter *et al*., 1990) (Please refer to the methodology at the beginning of this chapter (3.2.1) for the full methodology, including; system calibration, reflective marker placement and model building).

3.4.4 The repeatability assessment results

Overall, the repeatability results demonstrated high reliability between gait laboratory visits on different days, two weeks apart, in both conditions (barefoot and shod) after five successful walking trials were conducted in each condition.

The following figures present the SEM (for both visits), and the standard deviation (SD) of the CMC results for individual subjects for kinematics and kinetics, which include: joint angle, GRF, and the heel cup cluster, in both left and right limbs in sagittal, frontal, and transverse planes. The SEM was used within this study for individual subjects. Therefore, the possible error that could exist within the study is presented.

3.4.4.1 Repeatability of kinematics during barefoot walking

Results obtained during each session indicate highly reliable repeatability of test-retest marker placement during normal walking, in both limbs under the barefoot condition. The CMC was between 0.88 and 0.99 indicating the repeatability is high with a very low error as the SEM indicates a low degree of error.

Table 3.5 depicts the mean and STD of the CMC of joint ROM for all participants in the barefoot condition.

Table 3.5– The repeatability of the joint angle in barefoot walking.

	Left Limb			Right Limb		
Barefoot	Visit 1-2			Visit 1-2		
Angles	SEM º	CMC	SD º	SEM º	CMC	SD º
Hip Angle X	1.88	0.98	0.03	1.79	0.96	0.04
Hip Angle Y	1.62	0.96	0.02	1.70	0.94	0.02
Hip Angle Z	2.15	0.89	0.04	1.69	0.91	0.04
Knee Angle X	1.28	0.98	0.02	1.73	0.94	0.01
Knee Angle Y	1.87	0.90	0.06	1.34	0.91	0.02
Knee Angle Z	2.47	0.91	0.03	2.10	0.99	0.04
Ankle Angle X	1.69	0.97	0.01	1.15	0.96	0.02
Ankle Angle Y	1.45	0.88	0.07	1.42	0.92	0.03
Ankle Angle Z	1.48	0.92	0.02	1.86	0.91	0.03

X = Flexion/Extension Y = Abduction/Adduction Z = Internal/External Rotation).Max: Maximum, SEM: Standard Error of Measurement, CMC: Coefficient of Multiple Correlation, SD: Standard Deviation.

3.4.4.2 Repeatability of kinematics during shod walking

The results attained under the shod condition again demonstrated high repeatability. Table 3.6 depicts the CMC to be between 0.86 and 0.99. The SEM is low, and therefore the error is minimal, indicating good marker placement repeatability

Table 3.6 – The repeatability of the joint angle in shod walking.

	Left Limb			Right Limb		
Shod	Visit 1-2			Visit 1-2		
Angles	SEM º	CMC	SD º	SEM º	CMC	SD º
Hip Angle X	1.67	0.97	0.02	1.31	0.98	0.02
Hip Angle Y	1.70	0.95	0.02	1.41	0.94	0.02
Hip Angle Z	1.33	0.90	0.03	2.38	0.89	0.01
Knee Angle X	1.76	0.98	0.01	1.78	0.99	0.01
Knee Angle Y	1.69	0.94	0.04	1.85	0.94	0.04
Knee Angle Z	2.68	0.89	0.03	2.21	0.89	0.06
Ankle Angle X	1.12	0.97	0.01	1.05	0.97	0.01
Ankle Angle Y	0.90	0.86	0.08	1.49	0.92	0.04
Ankle Angle Z	2.42	0.91	0.02	1.69	0.90	0.05

Max: Maximum, SEM: Standard Error of Measurement, CMC: Coefficient of Multiple Correlation, SD: Standard Deviation.

3.4.4.3 Knee flexion moment and knee adduction moment (EKAM) repeatability

Table 3.7 demonstrates high repeatability results for both the knee flexion moment and the EKAM. The CMC was between 0.88 and 0.95 which indicates high repeatability.

Table 3.7 - The knee flexion and adduction moment (EKAM).

	Knee Flexion Moment (sagittal Plane) Visit 1-2					
Condition	Left Knee			Right Knee		
	CMC	SD º	SEM Nm/kg	CMC	SD º	SEM Nm/kg
Barefoot	0.94	0.05	0.09	0.93	0.03	0.06
Shod	0.91	0.04	0.07	0.94	0.03	0.04
	Knee Adduction Moment (Coronal Plane) Visit 1-2					
Condition	Left Knee			Right Knee		
	CMC	SD º	SEM Nm/kg	CMC	SD º	SEM Nm/kg
Barefoot	0.88	0.05	0.05	0.94	0.03	0.09
Shod	0.93	0.04	0.06	0.94	0.02	0.09

Max: Maximum, SEM: Standard Error of Measurement, CMC: Coefficient of Multiple Correlation, SD: Standard Deviation, V: Visit.

3.4.4.4 Repeatability of a heel cup during barefoot walking

Results for the heel cup cluster relative to the tibia and relative to the lab (gait laboratory) tests identified the between day testing as reliable. On both test days, the CMC was highly reliable, and measured between 0.78 and 0.99. The SEM demonstrated a low error, which indicates the test-retest as being reliable (table 3.8).

Table 3.8 – Heel Cup Cluster Angular Movement Repeatability (X = Dorsiflexion/Plantarflexion, Y = Eversion/Inversion, Z = Abduction/Adduction)

	Left Limb			Right Limb		
Heel Cup Cluster	Visit 1-2			Visit 1-2		
Angles	SEM º	CMC	SD	SEM º	CMC	SD
Heel Cup Cluster X	1.84	0.93	0.04	1.31	0.96	0.02
Heel Cup Cluster Y	1.37	0.89	0.08	1.64	0.91	0.05
Heel Cup Cluster Z	1.19	0.88	0.04	1.75	0.88	0.08

Max: Maximum, SEM: Standard Error of Measurement, CMC: Coefficient of Multiple Correlation, SD: Standard Deviation, V: Visit, Lab: Gait Laboratory, Heel Cup: Heel Cup Cluster.

3.4.4.5 Repeatability of the Foot Posture Index

Table 3.9 depicts data obtained during a pilot study for assessing the foot posture index (FPI) in healthy subjects. The pilot study was carried out to ensure repeatability of the use of the FPI assessment by the researcher. The FPI assessment was carried out twice, with a two week break in between each assessment. The data was identified as non-parametric, and therefore, the Wilcoxon Signed-Rank test was performed on the data. Results indicate similarities in the results between score 1 and score 2, therefore indicating no significant differences in the left ($p=0.102$) and right feet ($p=0.180$) between days.

Table 3.9 –FPI repeatability pilot study results.

Participant ID Number	FPI Final Score 1		FPI Final Score 2		Difference	
	Left	Right	Left	Right	Left	Right
1.	7	6	6	6	1	0
2.	7	8	5	6	2	2
3.	2	2	2	2	0	0
4.	5	6	4	5	1	1

FPI: Foot Posture Index, ID: Identification.

Table 3.10 depicts data obtained for the rearfoot which was analysed using ImageJ software. The analysis was carried out to ensure test-retest repeatability of the investigator when using ImageJ analysis software. The ImageJ analysis was carried out three times in both left and right feet for five knee OA patient's rearfoot photographs. Results indicate similarities between the first, second and third analysis, and no significant differences in both the left (p=0.994) and right rearfoot (p=0.996).

Table 3.10 –Rearfoot ImageJ repeatability results

	ImageJ Repeatability Results (Rearfoot)					
	Right Rearfoot			Left Rearfoot		
Patients	1st Measure (°)	2nd Measure (°)	3rd Measure (°)	1st Measure (°)	2nd Measure (°)	3rd Measure (°)
1	82.18	82.74	82.72	86.18	86.46	86.7
2	90.72	89.16	89.7	94.69	94.25	94.81
3	85.51	85.72	85.56	95.67	95.01	95.35
4	88.12	88.18	88.28	87.68	87.4	87.47
5	95	94.62	95	93.91	93.91	93.99

3.4.5 Discussion of repeatability results

The high repeatability within the study concurs with previous findings by Kadaba *et al*., (1990) and Growney, (1997). The majority of previous studies have investigated test-retest reliability of hip, knee and ankle angles in healthy subjects; however they have utilised a different marker set. The most commonly utilised is the HH marker set which only adopts three rotational DOF for the hip and knee, and two DOF for the ankle, meaning measurement systems were less advanced, with a higher possibility of error and inaccurate results than when using a CAST marker set (which was utilised within this study), which allows 6 DOF (rotational and translational) at each joint (Kadaba *et al*., 1989, Andrews *et al*., 1996, Growney *et al*., 1997, Tsushima *et al*., 2003). Growney *et al*., (1997) conducted gait test-retest reliability on 5 subjects, whereas Tsushima *et al*., (2003) utilised 6 subjects for gait test-retest reliability. Therefore, six subjects were utilised in order to carry out repeatability of marker placement in this study. The small sample size could be considered a limitation of the study, however similar previous studies have used 5 to 6 subjects also (Growney *et al*.. 1997, Tsushima *et al*., 2003).

The primary outcome measures within this thesis would be related to rearfoot motion and knee loading and the results regarding the knee flexion moment and the EKAM can be described as indicating good test-retest reliability of EKAM in healthy subjects. The CMC indicated the knee flexion moment be 0.92-0.94. The EKAM CMC was recorded at 0.88-0.95. These findings indicate high repeatability, and are in agreement with previous similar reliability studies that have evaluated healthy subjects (Kadaba *et al*., 1989, Andrews *et al*., 1996, Tsushima *et al*., 2003, Growney *et al*., 2007), and other studies which have evaluated OA patients (Birmingham, 2007) during walking. The previously mentioned studies imply that the EKAM is acceptable for use in subjects when evaluating varying interventions and carrying out clinical examinations.

Previous studies have identified a high degree of repeatability when subjects are instructed to walk at self-selected (within normal) speeds (Kadaba *et al*., 1990, Growney, 1997), therefore during test-retest reliability, subjects were directed to walk at self-selected speeds (within normal walking speeds) which resulted in measurable time of gait to be highly repeatable.

The results between-day in barefoot CMC were identified as between 0.88 and 0.99 during walking, in shod CMC varied from 0.86 to 0.99. These findings are indicative of good test-retest reliability in joint kinematics and kinetics represented by GRF, and are comparable to findings of similar previous repeatability studies that have evaluated healthy subjects (Kadaba *et al*., 1989, Andrews *et al*., 1996, Growney *et al*., 1997).

Additionally, repeatability of the heel cup cluster during test-retest varied between 0.78 and 1 which indicates good repeatability. Repeatability results of the heel cup cluster are important to obtain and evaluate in order to quantify error present with the use of the device, to ensure accurate assessment of rearfoot can be conducted in healthy subjects and osteoarthritis patients in further investigations. Although the repeatability study was carried out on healthy individuals, one can assume the results would be the same for individuals with knee OA. In previous studies, the variability of between day measures and error has been attributed to marker reapplication (Kadaba *et al*., 1989). Several factors are known to influence both within and between day reliability, such as skin marker movement, referenced static alignment and task difficulty (Ferber *et al*., 2002, Ford *et al*., 2007). During the repeatability study, the investigator worked alone in solely attaching the reflective markers to the participants in all trials in an attempt to create a highly repeatable study, which may have contributed to the high reliability. The maximum SEM for kinematic and kinetic data was reasonably low within the study, indicating low error to be present within the investigation. A systematic review by McGinley *et al*., (2008) investigated the reliability of three-dimensional gait measurements and recommended that error of 2° or less is widely considered as acceptable, as such errors are likely to be of small magnitude and therefore do not require explicit consideration within data interpretation. McGinley *et al*., (2008) also stated that error between 2° and 5° should be regarded as reasonable, and suggested that errors in excess of 5° may be large enough to mislead clinical interpretation. Furthermore, the paper by McGinley *et al*., (2008) stated that the highest error present within reviewed studies was often greater than 2°, and frequently occurred within the transverse plane of motion. It was therefore concluded that error of between 2-5° is acceptable in the transverse plane (McGinley *et al*., 2008). The highest error present within this investigation was found in the transverse plane of motion. The largest error present was 2.47°. According to McGinley *et al*., (2008) this is an acceptable level of error.

The data obtained within the study was used to calculate the maximum error. The maximum error within the study is less than 2° for all kinematic and kinetic data, and therefore can be considered as acceptable when considering the recommendations made by McGinley *et al*., (2009).

It is impossible to remove all error from a study, and therefore there will always be some error present within measurements. However, the investigator can gain an understanding of the effects that the error present has.

Differences between sessions have been identified in previous similar studies, along with a number of researchers demonstrating varying results in reliability. Trends can be identified across particular planes of motion. The sagittal plane has frequently been identified as providing the greatest stability across measurements during gait (Kadaba *et al*., 1989, Ferber *et al*., 2002, Queen *et al*., 2006). This tendency was clearly evident in findings of the repeatability study, and can be seen in the above graphs. Frontal and transverse planes of movement are recurrently documented as being more susceptible to errors in marker placement throughout the literature (Kadaba *et al*., 1989) which may explain the tendency for lower between-session reliability values. This finding was identified within repeatability results in this study, with frontal (Y) plane values indicating the largest occurrence of error in all three conditions (barefoot (0.88) and shod (0.86). In the heel cup cluster results, the transverse (Z) plane was identified as having the largest incidence of error, at 0.78. Although some error was present within the study, with the frontal and transverse planes indicating the largest error, the study still demonstrates high repeatability in marker placement due to all results being close to 1, with 1 signifying identical gait traces.

Small variances were identified within the between visit results of the FPI repeatability investigation. However, the variance within the FPI score was minimal, and the overall FPI classification was still the same (for example pronated), therefore the investigators ability at conducting research using the FPI can be considered consistently good, providing accuracy within results obtained.

Results of the ImageJ investigation identified similar results between all limbs, for both the left and right rearfoot, indicating good repeatability and investigator competence when analysing photographic evidence of the rearfoot using ImageJ software.

3.5 Conclusion and Indications for the Methodology

In conclusion, the study undertaken demonstrates that certain variables indicate high consistency within test and retest sessions in the gait laboratory with a relatively low standard error of measurement identified within the variables. Furthermore, results show that the repeatability of marker placement in all conditions was good and can be used to quantify kinematics and kinetics accurately by the investigator in future studies. Additionally, results obtained after conducting a repeatability pilot test on the researcher's ability to assess the foot posture index and ImageJ analysis indicate that the researcher can accurately assess foot posture and can also accurately analyse the rearfoot using ImageJ.

Chapter Four

The Role of Static and Dynamic Foot Posture and Rearfoot Motion on the Magnitude of the EKAM

Chapter Summary

This chapter consists of two sections, the first section assessed static foot posture using the Foot Posture Index (FPI) in order to identify any association between rearfoot motion and foot posture relative to the magnitude of the EKAM, aiming to provide an understanding of foot posture in barefoot and whether there is a relationship to the EKAM. The second section of this chapter examines and analyses previously collected data from a population of 100 healthy participants in order to establish any relationship between the FPI scores, FPI static eversion and inversion, and dynamic rearfoot motion, related to the magnitude of the EKAM, in order to determine the association between the outcome parameters of clinical examination and the magnitude of the EKAM. It was anticipated that this investigation would give some understanding into whether clinical foot parameters have a role in the magnitude of the EKAM.

4.1 General Introduction

Static foot posture has been discussed in previous research as possibly contributing to the onset and progression of a number of lower limb musculoskeletal conditions (Donatelli, 1987, Tiberio, 1987, Reilly *et al*., 2009, Levinger *et al*., 2010, Gross *et al*., 2011, Levinger *et al*., 2012, Abourazzak *et al*., 2014, Buldt *et al*., 2015) as it may alter the mechanical alignment and dynamic function of the lower limbs (Guichet *et al*., 2003, Levinger *et al*., 2010). Little is known about the consequences of abnormal foot morphology (pes planus and pes cavus) and the risk of knee and lower limb tissue damage and symptoms despite the central role foot posture plays in lower extremity biomechanics (Gross *et al*., 2011, Buldt *et al*., 2015).

A study by Gross *et al*., (2011) investigated the relation between foot posture, knee pain and compartment specific knee cartilage damage in 1903 older adults using the Staheli Arch Index (SAI) and concluded that a pes planus foot posture is associated with knee pain, medial tibiofemoral, and patellofemoral cartilage damage in older adults. Findings indicated a biomechanical link between an excessively pes planus foot posture and mechanical stress on the tibiofemoral and patellofemoral compartments of the knee (Gross *et al*, 2011).

However, there has been little investigation into foot posture and function as an outcome measure for predicting the EKAM. The precise underlying mechanism articulating foot posture and function to the aetiology of knee injury has not been identified within the literature, and therefore it remains unclear (Gross *et al*., 2011, Buldt *et al*., 2015). Reilly *et al*., (2009) advocates that foot posture and function possibly play a role in the pathogenesis of medial knee OA as previous investigations have identified differences in the foot postures of healthy individuals and individuals with medial compartment knee OA. The effectiveness of certain orthotic interventions such as lateral wedge insoles (LWI) when used in the treatment of a number of musculoskeletal conditions may be influenced by foot posture (Reilly *et al*., 2009).

Previous research has recommended an in depth knowledge of foot posture and also investigator competency in the assessment of foot posture in order for a full understanding of the effect of interventions used to treat musculoskeletal conditions and their effects on the knee and lower limb joints to be attained when conducting future research into the lower limbs and orthotic interventions (Levinger *et al*., 2010, Levinger *et al*., 2012). A comprehensive understanding of orthotic interventions would enable investigators of future research projects to identify participants who are most likely to benefit from these types of interventions (Levinger *et al*., 2010, Levinger *et al*., 2012). Accurate and reliable assessment of foot posture can provide an appreciation into how foot postures may influence or be influenced by certain musculoskeletal conditions, for example reducing the loading on the medial compartment of the knee in patients with knee osteoarthritis (OA) and an understanding of the effects of foot posture on the efficacy of certain interventions can be gained (Redmond *et al*., 2006, Reilly *et al*., 2009), for example the biomechanical response and non-response (the increase or decrease in the magnitude of the EKAM) to LWI, which may vary according to specific foot types.

In healthy limbs, foot pronation in the coronal plane of motion (eversion) relates to low arched (planus) feet and a more medial centre of pressure (COP) (Chiu *et al*., 2013) with the level of low arch depending on an individual's subtalar joint/ankle complex motion. If excessive subtalar joint/ankle complex motion is present, the foot is more planus and has more contact with the supporting surface on the medial/plantar aspect of the foot. However, in patients with medial compartment Knee OA, rearfoot pronation (eversion) has been suggested to potentially reduce the adduction moment by shifting the centre of pressure laterally, indicating an adaptation by the foot in the presence of certain musculoskeletal conditions (such as medial compartment knee OA) to reduce the load on the medial compartment of the knee (Levinger *et al*., 2010, Buldt *et al*., 2015).

In medial compartment knee OA patients, evidence of altered foot kinematics have been identified during gait that are symptomatic of a more everted foot type, including a reduction in the rearfoot frontal plane range of motion (Reilly *et al*., 2009, Levinger *et al*., 2010, Gross *et al*., 2011, Abourazzak *et al*., 2014). A proportion of the load is shifted away from the medial compartment of the knee during foot pronation (eversion) by shifting the centre of pressure laterally, providing some symptom relief (Desal *et al*., 2007, Levinger *et al*., 2010, Levinger *et al*., 2012, Levinger *et al*., 2013).

Lateral wedge insoles have been reported to alter foot motion within the literature; leading to an increase in rearfoot pronation (the subtalar joint valgus moment) (Nester *et al*., 2003, Kakihana *et al*., 2005, Levinger *et al*., 2013). Tibial malalignment (valgus and varus) and the extent of rearfoot range of motion (ROM) may affect individual responses to load altering interventions, such as LWI (Levinger *et al*., 2012). Using a LWI to increase rearfoot pronation on an already pronated foot could potentially lead to unfavourable alterations to lower limb kinematics and therefore the development of musculoskeletal disorders in other areas of the body and at proximal joints (Levinger *et al*., 2010, Levinger *et al*., 2012, Resende *et al*., 2015).

Currently, the literature investigating foot posture and its effects on the EKAM and efficacy of LWI in shod concurrently is limited. Understanding the effects of LWI on the subtalar ankle joint complex is paramount in identifying why individuals respond differently to LWI. A study by Chapman *et al*., (2015) investigated the relationship between response to LWI, and evaluated whether dynamic ankle joint complex coronal plane biomechanical measures could identify participants that were classified as biomechanical non-responders (showing an increase in the EKAM), and participants that were classified as biomechanical responders (showing a decrease in the EKAM) with the use of LWI compared to a control shoe, and explain why such results were attained. Chapman *et al*., (2015) concluded that coronal plane ankle joint complex biomechanics play an essential role in reducing the EKAM when using LWI, which may assist in the identification of those individuals who benefit from LWI intervention. However, no clinical data was obtained during the Chapman *et al*., (2015) trial, and therefore further investigation using clinical assessment techniques is required in order to identify if any relationship exists between clinical static foot posture and dynamic foot motion, and their effects on the magnitude of the EKAM.

The Foot Posture Index (FPI) is a valid, efficient and reliable clinical method of assessing static foot posture (Redmond *et al*., 2008, Abourazzak *et al*., 2014) and allows the assessor to quantify the degree to which a foot is pronated, supinated or neutral (Abourazzak *et al*., 2014). Certain musculoskeletal disorders (for example; knee OA) cause an elevated average FPI score when compared to healthy subjects, indicating a more pronated foot posture in the knee OA population, as identified in a study by Reilly *et al*., (2009) which aimed to identify if the FPI can effectively describe the foot posture of individuals with medial compartment knee OA compared to healthy age-matched controls. The study by Reilly *et al*., (2009) only assessed static foot posture however, and did not investigate dynamic rearfoot or the magnitude of the EKAM. The rearfoot was therefore investigated, as rearfoot motion may influence the effectiveness of LWI intervention due to the rearfoot contacting the ground first and the first peak in EKAM relating to this time period.

Therefore, the first section in this chapter will assess static foot posture in subjects using the FPI in order to identify any relationship between rearfoot motion (dynamic) and foot posture (static), relative to the magnitude of the EKAM. This will provide an understanding of foot posture in barefoot and whether there is a relationship between the static and dynamic rearfoot and the magnitude of the EKAM.

4.2 Chapter Aims

The aim of this investigation was to determine whether varying static and dynamic foot posture has any association with the magnitude of the EKAM in healthy subjects. The research question and hypothesis for this chapter is:

> Does a relationship exist between clinical static foot posture, dynamic rearfoot motion, and the magnitude of the external knee adduction moment?

Therefore, the statistical hypotheses for this chapter will be:

- There is no significant relationship between static foot posture (assessed using the FPI), and the magnitude of the EKAM in healthy subjects.
- There is no significant relationship between dynamic rearfoot motion and the magnitude of the EKAM in healthy subjects.

- There is no significant relationship between clinical static foot posture (assessed using the FPI), and dynamic rearfoot posture in heathy subjects.

4.3 Methods

Approval was obtained from the Research Ethics Panel of the academic audit and governance committee at The University of Salford (ethical approval number - HSCR13/42).

A poster that explained the study and contained contact details was placed onto notice boards in buildings around the University of Salford to attract potential subjects, and information sheets and questionnaires were sent to those individuals who were interested in taking part to ensure they fulfilled the inclusion criteria. Participants were required to be 'asymptomatic' defined as, 'free of symptoms or not causing symptoms' (Youngson, 2004), and therefore free from lower limb injury for a period of at least six months prior to testing (injury was defined as any musculoskeletal complaint that prevented the participant from undertaking their normal exercise or daily routine), and to have no history of lower limb surgery (table 4.1). Following this, an appointment was made with the individual to attend the gait laboratory at the University of Salford, after they agreed to take part in the study.

Table 4.1: Inclusion and exclusion criteria

Inclusion Criteria	Exclusion Criteria
Good general condition of health, aged 18 years or over and able to walk without aids or assistance.	Experience or evidence of lower limb injuries (including bone fracture and ligament injury to the hip, knee, ankle and foot) within the six months prior to testing.
No previous surgeries on the lower limbs (for example total knee arthroplasty or unicompartmental knee arthroplasty).	Has disabilities or lower limb deformities which influence normal gait.
Has no known history of osteoarthritis or other bone diseases (for example osteoporosis).	Do not agree to the study conditions or protocol, and does not give consent.

4.3.1 Participants

Fifteen healthy participants (7 males, 8 females) were recruited from within the staff and student population at The University of Salford to take part in the study. Testing was carried out in the clinical gait laboratory at The University of Salford. On arrival at the gait laboratory, individual participants were firstly briefed on the study. The investigations objectives and what was required of the participant were explained in full and the participant was then shown the equipment that would be used for the duration of the investigations. Consent forms were then read and signed, demographical information was recorded (summarised the mean and standard deviation (SD) in table 4.2), and participant's general information and medical history were recorded using a questionnaire.

Table 4.2: Summarised mean and standard deviation (SD) demographic measurements for all 15 study participants.

Gender	*Males (N=7)*	*Females (N=8)*
Age (years) ± (SD)	*34.43 ± (7.16)*	*36.25 ± (13.29)*
Height (m) ± (SD)	*1.75 ± (0.07)*	*1.64 ± (0.05)*
Mass (kg) ± (SD)	*88.57 ± (13.16)*	*69.38 ± (12.55)*

Participants were then directed to a private changing area to change their clothing into fitted shorts and a comfortable t-shirt that they were previously requested to bring with them.

4.3.2 Data Collection Procedures

The following assessments were carried out on each participant in order to assess clinical static foot posture, and also to assess lower limb kinetics and kinematics;

4.3.2.1 The Foot Posture Index

Individual participant's foot posture was assessed using the Foot Posture Index (FPI), a 6 criteria foot posture assessment (Lee *et al*., 2015). The subject stood in a relaxed bipedal position. The six criterion of the FPI include the following assessment items, which were carried out on both limbs of each subject within the study: talar head palpation curves above and below the lateral malleoli, calcaneal angle, talonavicular bulge, medial longitudinal arch, and forefoot to rearfoot alignment. Each item was scored on a 5-point scale (between -2 and +2), providing a sum of all items between -12 (highly supinated) and +12 (highly pronated), with a score of 2 to 12 indicating a pronated foot, a score of -2 to -12 indicating a supinated foot, and a score of +1 to -1 indicating a neutral foot (Redmond *et al*., 2006, Levinger *et al*., 2010, Barton *et al*., 2012, Lee *et al*., 2015).

The total FPI score, and also the rearfoot classification of the FPI score were then used later in the data analysis within this study to determine if the foot and the rearfoot of individual participants were everted, neutral, or inverted. The FPI scores were used to provide inferences to whether a relationship existed between static rearfoot posture, dynamic rearfoot posture and the magnitude of the EKAM in healthy subjects, and also to establish whether the total FPI score represents rearfoot motion, and if the rearfoot FPI classification can represent the rearfoot motion and the magnitude of the EKAM.

A similar study previously conducted by Buldt *et al*., (2015) assessed the total FPI score amongst other measures to statically measure the whole foot, and concluded that the FPI displayed the strongest association with kinematic variables compared with the other foot measurements. Therefore, this study provides novelty by specifically assessing both static rearfoot posture, and rearfoot motion.

The FPI was assessed by the same examiner, who was experienced at taking these measurements.

4.3.2.2 Gait analysis

Qualisys motion analysis systems with sixteen computerised infra-red OQUS cameras (Qualisys, AB, Gothenburg, Sweden) and two AMTI force platforms (AMTI BP400X600, AMTI, USA) were used to collect kinematic and kinetic data as per Chapter 3 (section 3.2). Marker data were captured by sixteen OQUS infrared cameras (Qualysis, Sweden) and Qualysis Track manager (Qualysis, Sweden), in order to capture the 3D positions of the retro reflective markers that were attached to each subject's skin, over bony landmarks in both lower limbs.

Individual retroreflective markers were placed on the lower limbs as described within chapter 3 (section 3.2.6), on the foot (1st, 2nd, and 5th metatarsal head and calcaneal tubercle, styloid and navicular), ankle (medial and lateral malleolus), knee (lateral and medial femoral condyle, tibial tuberosity and fibular head), thigh (greater trochanter), and the pelvis (right and left anterior superior iliac spine, right and left posterior and superior iliac spine, and right and left iliac crest). Fixed cluster pads, each holding four retroreflective markers were attached to the shank, thigh, pelvis, and the forefoot. Rearfoot data was captured using a heel cup cluster tracking marker set with three retroreflective markers attached to it.

The methodology within this chapter utilised biomechanical data collection procedures in order to define the 3D motion data capture, force measurement and segment modelling and computation which are explained in detail within the methodology chapter of this thesis (chapter 3, section 3.2). Any deviation or additional materials or techniques used within this study are detailed below. Individual participants were requested to stand with both feet on a force platform for 10 seconds whilst a static 3-dimensional image was obtained. A successful trial was one when the foot was placed completely on the force platform during stance phase. Each individual completed five walking trials for each foot at a self-selected speed.

4.3.3 Data Processing

All collected joint kinetic and kinematic data for the 30 lower limbs (both left and right lower limbs of all 15 participants) were processed using Qualisys Track Manager software. Individual reflective markers were labelled and digitised, and any anomalies in movements in marker trajectories were corrected. The data were then exported directly from Qualisys Track Manager software to Visual3D software (version 4.91, C-Motion Inc, USA). The raw marker tracking data were filtered using a Butterworth 4^{th} order bi-directional low pass filter with a cut-off frequency of 6Hz. The analogue data were filtered with a cut-off frequency of 25Hz. Dynamic skeletal graphics created in Visual3D, controlled by subject kinematics were used in the interpretation of results (Buczek *et al*., 2010). Kinematic and force plate data were filtered to prevent noise interference in the results, and gaps and breaks in the data were filled using polynomial interpolation algorithms within Visual3D software to prevent error within the results.

The lower limbs were treated as seven segments modelled as rigid bodies, which were; the pelvis, left and right thighs, shanks and feet. A right-handed local coordinate system of each segment was defined by landmarks placed on the anatomical points. The CODA pelvis model was used, which was defined using the anatomical locations of the ASIS (Anterior Superior Iliac Spine) and the PSIS (Posterior Superior Iliac Spine). The motion was tracked by four reflective markers on a rigid plastic plate fixed with an elastic belt to the back of the pelvis. Each segment was treated as a free rigid body with six degrees of freedom. The joint kinematics were calculated using an X–Y–Z Cardan sequence. The external joint moment data were calculated using three-dimensional inverse dynamics and normalised to body mass (Nm/kg).

Automatic gait event definition was utilised in all trials, which captured data when the vertical GRF exceeded 20 Newtons (N) in value. The gait cycle was defined as the movement and events from heel strike of the foot on the force platform, to the subsequent heel strike of the same foot. Stance phase was defined as heel strike of the foot to the subsequent toe-off of the same foot.

The measurement of both the motion of the lower limbs and the forces acting upon them whilst each subject walked was conducted in order to collect kinematic and kinetic data of the lower limbs. Direct measurement of loading on the medial compartment of the knee is difficult, therefore the EKAM provides an indirect measure of the knee joint loading (Wang *et al*., 1990, Maly *et al*., 2002). Resulting alterations in the EKAM signify changes to the load distribution across the knee joint (Maly *et al*., 2002). The EKAM was extracted during the first peak of early stance phase (0-20% of the gait cycle, 0-33% of the stance phase), which has been shown to be the most directly related to medial compartment loading (Sharma *et al*., 1998, Baliunas *et al*., 2002, Miyazaki *et al*., 2002, Birmingham *et al*., 2007, Henriksen *et al*., 2010, Erhart *et al*., 2011).

The positions of reflective markers are translated into the pose (position and orientation) of the corresponding model (a collection of rigid segments, with each segment corresponding to a body segment and major bone structure), identified using motion tracking equipment within V3D. The body segments which are tracked are defined by proximal and distal endpoints located inside the subject's body (Visual 3D, 2015). The model is referred to as a six degree of freedom (DOF) model due to having six variables that describe its position and orientation in 3-D space (3 variables describe segment translation in three orthogonal axes, and 3 variables describe the rotation about each axis). The anthropometric measurements of individual subjects (height and body mass) were entered into the software for usage in kinetic calculations. Pelvis, thigh, leg and foot segments were then modelled using anatomical landmarks or joint centres and the radius of the proximal and distal end of the segment and the tracking markers (Buczek *et al*., 2010). The Visual3D model segments and tracking markers are detailed in chapter three (table 3.2).

Cluster tracking markers (with four retroreflective markers fixed to each rigid cluster pad) between the shank segment and the foot segment were used to define the rearfoot. Peak EKAM and peak flexion/extension moment (sagittal moment) data were exported from Visual3D to Microsoft Excel software, with the peak representing early stance phase of the gait cycle.

Additionally, range of motion (ROM) of the rearfoot (inversion and eversion) data in stance phase were exported for all trial participants, and analysed using SPSS software.

The mean and standard deviation (SD) of each variable that was exported was calculated using Microsoft Excel software. Data was then transferred to SPSS software, to apply normality testing and the correlation coefficient. Normality testing allows the identification of normal or abnormal distribution (parametric or non-parametric) of data. For parametric data, the Pearson test was applied, and for non-parametric data, the Spearman correlation coefficient test was applied. Statistical analysis, specifically normality testing was performed on the variables in order to identify the most suitable correlation coefficient test to apply. The Kolmogorov-Smirnov test and the Shapiro-Wilks test were utilised (section 4.5.3.1).

4.3.3.1 Statistical analysis

Statistical analysis was performed with SPSS (Statistical Package for the Social Sciences) software programs (IBM SPSS Statistics, IBM Corporation), specifically normality testing was performed on each variable in order to identify the most suitable correlation coefficient test to apply. The Kolmogorov-Smirnov test (ideal for use on sample sizes of 50 or more subjects or the Shapiro-Wilks test (ideal for use on sample sizes of less than 50 subjects) were utilised. A $p<0.05$, indicates non-normal distribution. For the 15 healthy subjects, the Shapiro-Wilks test was used.

The normality test allows the researcher to identify whether these data in each of the variables to be tested was different than that of normal distribution (parametric) or abnormally distributed (non-parametric). For parametric data, the Pearson correlation coefficient test is most suited and was applied, and for non-parametric data, the Spearman correlation coefficient test is most suitable, and was applied.

The parametric testing was applied when three assumptions were met, including; normalcy of data or normal distribution, independence of data (one group did not influence another) and homogeneity of data (where variances in each group are similar).

Within table 4.4 correlations will be noted with a ρ or an *r* value, with ρ indicating data to be non-parametric, and *r* indicating data to be parametric. The ‘perfect’ correlation coefficient is always -1 or +1, +1 indicates perfect positive correlation, and -1 indicates perfect negative correlation. A perfect relationship would depict all points on a scatterplot to fall on a straight line. Correlation can be considered ‘strong’ when falling between -0.7 and -0.9 or +0.7 and

+0.9, moderate when between -0.4 and -0.6 or +0.4 and +0.6, weak when between -0.1 and -0.3 or +0.1 and +0.3, and no correlation or association is present when the correlation coefficient is 0 (Dancey and Reidy, 2011). The level of significance of the results data was $p<0.05$, indicating significant association between the variables. If $p>0.05$, non-significant association was present between the variables.

4.4 Results

Fifteen heathy subjects were analysed in this study (7 males and 8 females). The average age for males was 34.43 (±7.16) years, and for females was 36.25 (±13.29) years, the average height for males was 1.75 (±0.07) m, and for females was 1.64 (±0.05) m, the average mass for males was 88.57±13.16 kg, and for females was 69.38 (±12.55) kg.

The average self-selected barefoot walking speed for all 15 healthy participants (30 healthy limbs) was 1.214 (±0.13) m/s. The average EKAM value for all 15 participants was 0.413 (±0.112) Nm/kg. The average rearfoot range of motion was 10.06 (±2.59) º. The average rearfoot eversion was -1.78 (±2.25) º. The average rearfoot inversion was 8.28 (±3.19) º. The average total FPI for all 15 participants was 2 (±5.1). The average rearfoot FPI was 0 (±1.1), and the FPI range was -6-10 (table 4.3). All measurements for all 15 individual participants are depicted in table 4.3.

Table 4.3 – The mean and standard deviation (SD) for all measurements for both left and right limbs of all 15 participants.

	Frontal Plane Motion					
Limbs	EKAM Nm/kg	Rearfoot ROM(°)	Rearfoot Minimum(°)	Rearfoot Maximum(°)	Total FPI	Rearfoot FPI
1	0.474	8.126	-1.179	6.947	7	1
2	0.355	11.978	0.458	12.437	-6	1
3	0.413	9.913	-1.940	7.972	3	1
4	0.623	8.248	-0.403	7.845	-6	2
5	0.434	6.742	-0.399	6.343	2	-1
6	0.413	11.691	-4.274	7.416	6	1
7	0.344	10.764	-2.091	8.673	4	-1
8	0.456	9.400	1.826	11.227	-6	0
9	0.406	13.632	-5.517	8.114	1	0
10	0.194	9.351	-2.594	6.756	-3	-1
11	0.552	12.675	-1.199	11.475	9	1
12	0.391	7.348	0.047	7.395	4	2
13	0.260	13.001	1.311	14.312	8	-1
14	0.484	9.199	0.075	9.274	0	-1
15	0.573	6.937	-2.425	4.512	4	-2
16	0.431	10.471	0.705	11.176	7	1
17	0.257	10.081	1.399	11.481	-6	1
18	0.244	8.961	-1.761	7.199	4	1
19	0.460	7.450	-1.058	6.391	-5	1
20	0.473	4.424	-2.879	1.545	0	-1
21	0.356	12.378	-3.460	8.917	4	1
22	0.407	8.321	-3.562	4.758	3	1
23	0.472	11.578	-5.718	5.859	-6	1
24	0.216	16.647	-3.337	13.309	0	0
25	0.270	10.164	-3.808	6.356	1	-1
26	0.550	12.460	-0.532	11.927	10	2
27	0.411	8.711	-2.082	6.629	4	1
28	0.469	12.878	1.096	13.975	9	-1
29	0.372	11.725	-7.249	4.475	-2	-2
30	0.602	6.76	-2.926	3.833	9	-1
Mean	**0.413**	**10.068**	**-1.783**	**8.285**	**2**	**0**
SD	**0.112**	**2.594**	**2.255**	**3.199**	**5.1**	**1.18**

EKAM: External Knee Adduction Moment, FPI: Foot Posture Index, SD: Standard Deviation.

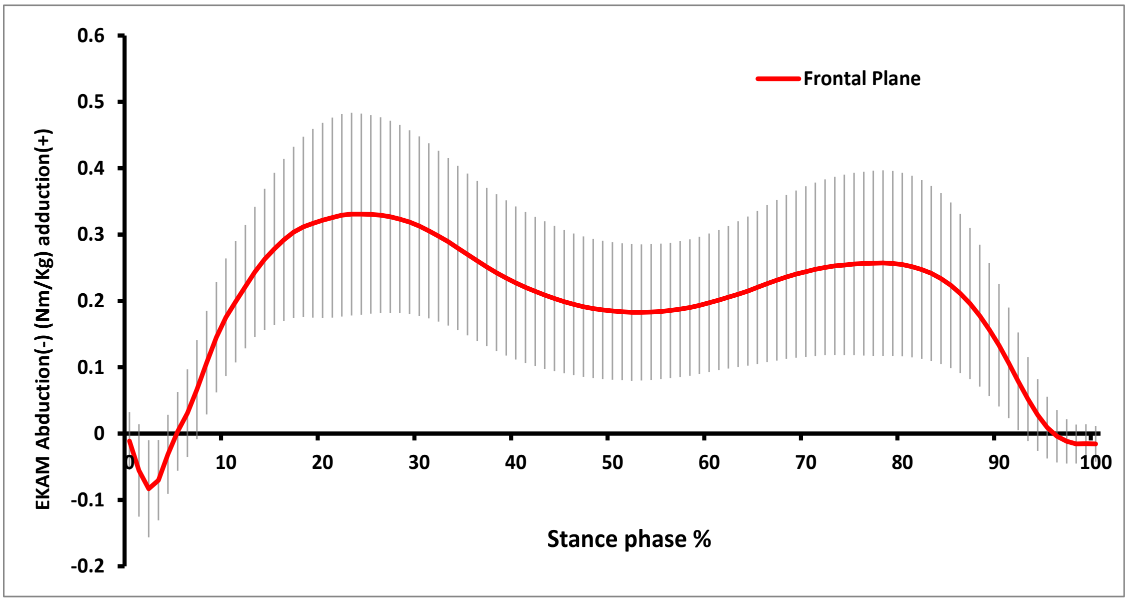

Figure 4.1 – Mean external knee adduction moment (EKAM) in the frontal plane for 30 healthy limbs. Error bars represent ± 1 standard deviation.

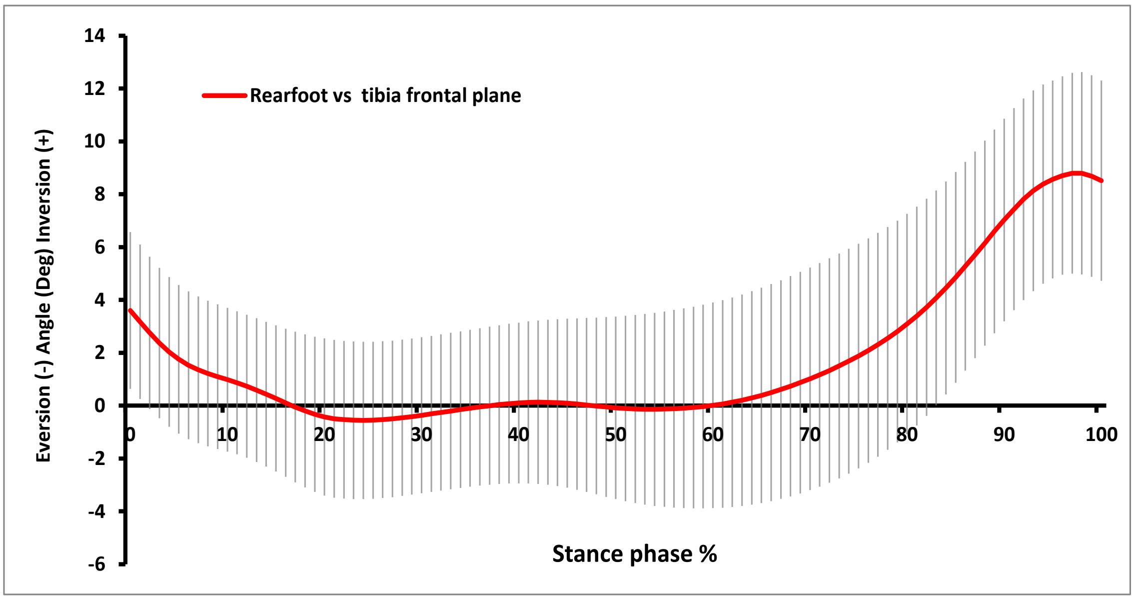

Figure 4.2 – Mean dynamic rearfoot angle motion in the frontal plane for 30 healthy limbs. Error bars represent ± 1 standard deviation.

When used to assess foot posture (statically), the total FPI score and the inversion and eversion rearfoot FPI concluded that no relationship exists between static FPI scores and dynamic foot motion results (when using 3D cameras and reflective markers within the gait laboratory) in both left and right limbs (table 4.4).

Table 4.4 – The relationship between FPI, rearfoot motion and the EKAM.

Rearfoot (Barefoot)	Correlations	P-Value
FPI vs EKAM	ρ= 0.225	P= 0.23
FPI vs inversion	ρ= 0.153	P= 0.42
FPI vs eversion	ρ= 0.047	P=0.80
FPI vs ROM	ρ= 0.138	P= 0.46
Inv/Ev Calc FPI vs EKAM	ρ= 0.094	P= 0.62
Inv/Ev Calc FPI vs ROM	ρ = 0.029	P= 0.87
Inv/Ev Calc FPI vs inversion	ρ= 0.248	P= 0.18
Inv/Ev Calc FPI vs Eversion	ρ= 0.190	P= 0.31
EKAM vs ROM	ρ= -0.358	P= 0.052
EKAM vs Inversion	*r*= -0.241	P= 0.20
EKAM vs Eversion	*r*= 0.072	P= 0.70

FPI: Foot Posture Index, EKAM: External Knee Adduction Moment, ROM: Range of Motion, Max: Maximum. r: Pearson Coefficient Correlation (parametric), ρ: Spearman Coefficient Correlation (non-parametric), Calc: Calcaneus, Inv: Inversion, Ev: Eversion.

No statistically significant relationship was identified between the FPI and the EKAM, p=0.23. Also, no statistically significant relationship was found between the FPI and rearfoot inversion, p=0.42 (table 4.3). In addition, no statistically significant correlation was established between the FPI and rearfoot ROM p=0.46.

Results do show near significant correlation between the EKAM and the rearfoot ROM to be ρ=0.358 (p=0.052), however, the acceptable threshold level of statistical significance was not quite achieved. Additionally, no statistically significant relationship was identified between the EKAM and inversion and eversion rearfoot motion, p=0.20, p=0.70 respectively.

No significant association was found between eversion and inversion rearfoot FPI scores and the EKAM, and the eversion and inversion rearfoot FPI scores and the rearfoot range of motion, p=0.62, p=0.87 respectively. Finally, no relationship was identified between eversion and inversion rearfoot FPI scores and eversion and inversion rearfoot motion, p=0.18, p=0.31, respectively.

4.4.1 Summary and Discussion of Results

This investigation aimed to determine whether a relationship exists between static foot posture, assessed using the FPI, dynamic rearfoot motion, and the magnitude of the EKAM. The hypothesis stated that no significant relationship would exist between static foot posture, dynamic rearfoot motion, and the magnitude of the EKAM.

Results concerning the analysis of the data from the initial 15 subjects (30 healthy limbs) collected by the investigator indicated that overall, no statistically significant relationship was identified between the FPI and EKAM, the FPI and rearfoot motion in the coronal plane, and also rearfoot motion and the EKAM. The one finding which was close to significance was between the EKAM and the ankle/subtalar joint complex ROM ρ=-0.358. The p-value of p=0.052 approached acceptable levels of statistical significance. Therefore, it can be stated that a marginal trend towards significance was present between the EKAM and ankle subtalar joint complex ROM, which indicated some, albeit poor association between the two variables, meaning a decrease in the ROM of the ankle subtalar joint complex led to an increase in the EKAM, or vice versa. A study by Chapman *et al*., (2015) identified that ankle/subtalar joint complex biomechanical parameters play an important role in reducing peak EKAM after investigating dynamic ankle/subtalar joint complex coronal plane biomechanical measures and the EKAM with the use of a LWI compared to a control shoe in 70 individuals with medial compartment knee OA. The Chapman *et al*., (2015) trial concluded that LWI result in the centre of pressure of the foot shifting laterally, a greater degree of eversion at the ankle/subtalar joint complex, and a greater eversion moment compared to control. Also, that coronal plane ankle subtalar joint complex biomechanical measures under the control (shod) condition correlate with the likelihood that participants would experience a reduction in peak EKAM when wearing LWI Chapman *et al*., (2015). However, it was once more concluded that the exact mechanism and relationship between the ankle subtalar joint complex and the EKAM is not fully understood. Furthermore, a study by Jones *et al*., (2014) concluded that coronal plane foot and ankle biomechanical measures are key mechanisms for producing a reduction in the EKAM in patients with medial compartment knee OA when wearing a LWI.

Therefore, the results indicate that simple correlation can be utilised to explain the relationship between the variables, however it does not lead to an explanation of the complexity of biomechanical relationships which may exist between the ankle subtalar joint complex and the EKAM (Buldt *et al*., 2015). A study by Buldt *et al*., (2015) concluded joint rotations of the rearfoot were not related to the magnitude of first peak EKAM in healthy individuals, suggesting that foot posture and the ankle subtalar joint complex do not substantially influence the biomechanics of the knee joint in healthy individuals. Consequently, findings from this study suggest the ankle subtalar joint complex may play a role in the magnitude of the EKAM in healthy subjects, however the exact mechanisms of this relationship are not fully understood, and therefore further investigation is warranted. Increasing the sample size within the study may lead to greater understanding of potential association between the variables. Therefore, further investigation with a larger data set could determine if a relationship exists between clinical static and dynamic rearfoot posture and the magnitude of the EKAM and confirm if the trend to significance of the EKAM association with the range of motion moves to significance.

Within previous investigations in the literature, healthy lower limbs have been assumed to be symmetrical on both right and left sides, in order to simplify data collection and analysis. Lower limb asymmetry is frequently associated with pathology, where significant differences in kinetic and kinematic parameters can be observed between left and right lower limbs (Sadeghi *et al*., 2000, Gouwanda and Senanayake, 2011). Additionally, several studies have identified no significant differences between left and right limbs, or dominant and non-dominant limbs in healthy participants (Hertel *et al*., 2002) which could perhaps suggest that collecting a single limb (either left or right) for all participants would be ideal for this investigation, albeit meaning the data of only 15 limbs would be collected. Conversely, Hertel *et al*., (2002) suggests that different foot postures or foot shapes (different architectural foot types) present between left and right limbs of individuals causing differences in the interface between the foot and the force plate could influence the ground reaction force and also measures in clinical research settings (Hertel *et al*., 2002). Additionally, differences between the right and left limbs of individuals are frequently reported within the literature, and it has previously been stated that the lower limbs are not used equally during ambulation, with Sadeghi *et al*., (2000) concluding that gait is asymmetrical.

Furthermore, the notion of limb dominance, or limb preference, defined as the preferential use of one limb during voluntary motor acts, where the dominant or preferred limb is used in activities, for example kicking, and the non-dominant, or non-preferred limb provides postural and stabilising support, could cause differences in biomechanics and gait measurements

(Sadeghi *et al*., 2000). Therefore, differences may be present between individual's limbs, providing rationale for collecting and analysing both the left and right limbs of all 15 participants (30 limbs in total).

As with any study, there are limitations which could have hampered the findings. It is important to mention that FPI assessment was conducted solely by the investigator who is experienced in carrying out such examinations and who also carried out an FPI repeatability pilot study in order to ensure accurate FPI assessment (chapter 3, section 3.4.4.6), therefore adding credibility to the FPI scores within this investigation. One of the limitations is the relatively small sample of the population represented within the study (15 subjects, 30 healthy limbs), which could be considered too small to accurately determine whether foot posture is related to the EKAM and rearfoot motion. Therefore, in an effort to determine whether any relationship would exist with a much larger sample, a larger data set of 137 healthy limbs was undertaken (Nester *et al*., 2014) in order identify if any association is seen between clinical static foot posture and biomechanical dynamic rearfoot motion and the EKAM.

4.5 Examination of 137 healthy limbs using previously collected data

In order to answer the research question of whether a relationship exists between the clinical static foot posture, dynamic rearfoot motion and the magnitude of the EKAM, the following investigation was conducted on previously collected data to establish if any relationship existed between the FPI scores, FPI eversion and inversion (static) and dynamic rearfoot motion, and the magnitude of the EKAM, in order to determine the association between the outcome parameters of clinical examination and the magnitude of the EKAM.

The analysis aimed to establish if a link was present between foot posture and knee loading, therefore allowing an understanding to be gained into the role of static foot and ankle measurements on the magnitude of the EKAM. Furthermore, the investigation aimed to gain an appreciation into the role of dynamic rearfoot eversion on the magnitude of the EKAM. The value of this work is that it aims to provide some inferences into whether clinical foot parameters have a role in the magnitude of the EKAM.

Clinical foot data; (including the FPI, eversion and inversion in individual participants) dynamic ankle eversion data, and the resulting EKAM were examined using previously collected data (Jarvis PhD thesis, 2013) from a population of 137 healthy limbs.

4.5.1 Methods (these are modified from Jarvis' PhD Thesis, 2013)

One hundred healthy subjects (71 female, 29 male) were originally recruited by a former PhD student at the University of Salford after ethical approval had been gained from the research and ethics panel at the University of Salford (ethical approval code – RGE C08/090) (Jarvis PhD thesis, 2013). Participants (demographics are depicted in table 4.5) were asymptomatic, and were aged between 18-45 years. This was to ensure physiological and skeletal maturity had been reached and to decrease the incidence of health conditions (including osteoarthritis) associated with individuals over the age of 45, which can lead to structural changes in the lower limbs and foot; such as reduced range of motion at the subtalar and ankle joint (Nigg et al., 1992, Jarvis PhD thesis, 2013). Therefore, data obtained by Jarvis can be considered as collected solely from healthy participants.

Screening of participants and data collection including the Foot Posture Index (FPI) was undertaken in the podiatry clinic at the University of Salford by a single experienced podiatrist; ensuring consistent data collection. Symptomatic participants not meeting the inclusion criteria were excluded from the study, and no further data was collected from them. These screening data were recorded on a Microsoft Excel spreadsheet and stored anonymously.

Gait instrumented analysis of the foot and leg was conducted in the gait laboratory at the University of Salford, where 3D foot and leg kinematic data was obtained using a 12 infra-red camera OQUS system (Qualisys system, Qualisys, Gothenburg, Sweden) with retro reflective markers. Walking trials were carried out where participants were requested to walk at a self-selected walking speed. Qualisys Track Manager (QTM) was used for collection and processing (digitisation) of data obtained (Jarvis PhD thesis, 2013).

4.5.1.1 Data Processing

Kinetic and kinematic data re-processing of the original data was carried out by the investigator of this thesis. In brief, data were checked by reviewing individual subject data using Visual3D software, where kinematic and force plate data were filtered to prevent noise interference in the results, and gaps and breaks in the data were filled using polynomial interpolation algorithms within Visual3D software to prevent error within the results. The model was rebuilt using Visual3D to the same specifications as the previous model used within Chapter 3 (section 3.3) in order to identify segments. A new results report pipeline was then applied using

Visual3D. The data previously collected by Jarvis only used kinematic data (Jarvis PhD thesis, 2013), and therefore the results report pipeline enabled the investigator to determine kinetic data (the moment) for each subject. After data checking had been performed, the following data were excluded from processing: data with a low number of walking trials considered inadequate to obtain an accurate result, data which did not depict the moment in results, data which showed an inaccurate moment with noise interference, and data where the foot was not fully placed on at least one force plate, meaning kinetic data could not be achieved.

From the original 100 healthy subjects collected during the Jarvis trial (Jarvis PhD Thesis, 2013), the data concerning 90 subjects (26 males and 64 females) were used for this investigation, and 43 limbs were identified as being unsuitable for further exploration. Therefore, data concerning 137 limbs were identified as being suitable for further exploration by the investigator. Suitable data (with a minimum of 5 successful trials) were exported from Visual 3D to Microsoft Excel and prepared for analysis. The positions of reflective markers are translated into the pose (position and orientation) of the corresponding model (a collection of rigid segments, with each segment corresponding to a body segment and major bone structure), identified using motion tracking equipment by V3D (Visual 3D, 2015). The body segments which are tracked are defined by proximal and distal endpoints located inside the subject's body (Visual 3D, 2015). The model is referred to as a six degree of freedom (DOF) model due to having six variables that describe its position and orientation in 3-D space (3 variables describe segment translation in three orthogonal axes, and 3 variables describe the rotation about each axis). The anthropometric measurements of individual subjects (height and body mass) were entered into the software for usage in kinetic calculations. Pelvis, thigh, leg and foot segments were then modelled using anatomical landmarks or joint centres and the radius of the proximal and distal end of the segment and the tracking markers (Buczek *et al*., 2010). The Visual3D model segments and tracking markers are detailed in chapter three (table 3.2). The model segments were consistent with the model segments used within section 4.5.3 of this chapter.

Kinematic and kinetic data were filtered using a Butterworth 4th order bi-directional low pass filter with cut off frequencies of 6Hz for kinematics (Winter, 2009) and 25Hz for kinetics (Schneider and Chao, 1983) (Yu *et al*., 1999). Joints kinematics were calculated using an X-Y-Z Euler rotation sequence, where X (sagittal plane) represented flexion/extension, Y (coronal plane) adduction/abduction or eversion/inversion, and Z (transverse plane) internal/external rotation. Joint kinetic data were calculated using 3-D inverse dynamics and the joint moment data was normalised to body mass and presented as external moments referenced to proximal segment. Each gait parameter of interest for each of the studies was then exported from V3D to Microsoft Excel 2010 (Microsoft Washington, USA). The rearfoot was defined using cluster tracking markers (with four retroreflective markers fixed to each rigid cluster pad) between the shank segment and the foot segment.

Peak EKAM and peak flexion/extension moment (sagittal moment) data were exported from Visual3D to Microsoft Excel software, with the peak representing early stance phase of the gait cycle. Additionally, range of motion (ROM) of the rearfoot (inversion and eversion) and ankle subtalar joint data during stance phase were exported for all trial participants, and analysed using SPSS software.

Microsoft Excel software was used to collect the mean and standard deviation (SD) of each variable that was exported. Data was then transferred to SPSS software, to apply normality testing and the correlation coefficient. Normality testing allows the identification of normal or abnormal distribution (parametric or non-parametric) of data. For parametric data, the Pearson test was applied, and for non-parametric data, the Spearman correlation coefficient test was applied. Statistical analysis, specifically normality testing was performed on the variables in order to identify the most suitable correlation coefficient test to apply. The Kolmogorov-Smirnov test and the Shapiro-Wilks test were utilised (section 4.5.3.1).

4.5.2 <u>Results</u>

The data analysis was undertaken in order to further explore any possible link between static and dynamic foot posture and the magnitude of the EKAM using a larger data set to identify if any relationship existed between the FPI and rearfoot motion, and FPI and the magnitude of the EKAM, and rearfoot FPI classifications and rearfoot motion, and the magnitude of the EKAM.

Ninety healthy subjects participated in the study. The mean age for all participants was 30.2 (± 9.17) years, age range 18-45 years; mean height 1.67 (±0.08) m; height range 1.54-1.84 m; mean mass 71.7 kg (±14.0); mass range 47-107 kg; mean body mass index (BMI) 25.14 (±5.05) kg/m2 (table 4.5). The average self-selected walking speed of all participants was 1.292 (±0.146) m/s.

Table 4.5: Demographic measurements and standard deviation for all study participants.

Gender	*Males (N=26)*	*Females (N=64)*
Age ± (SD) (years)	*28.2 ± (8.9)*	*29.5 ± (10.4)*
Height ± (SD) (m)	*1.76 ± (0.07)*	*1.64 ± (0.05)*
Mass ± (SD) (kg)	*80.6 ± (12.6)*	*68.1 ± (13.1)*

Results for all participants including; the mean EKAM, mean eversion and inversion dynamic rearfoot, mean ROM (Figure 4.3, 4.4, 4.5), mean subtalar joint eversion and inversion, mean FPI, and the FPI range are depicted in table 4.6.

Table 4.6: The mean and standard deviation (SD) for all measurements for 137 heathy limbs.

Barefoot		
Measurements	Mean	SD (º)
Peak EKAM (Nm/kg)	0.304	0.13
Sagittal Moment (Nm/kg)	0.243	0.23
Rearfoot Inv (º)	9.23	3.76
Rearfoot Ev (º)	-4.18	3.17
ROM (º)	13.42	3.28
Ev STJ (º)	-12	3.03
Inv STJ (º)	11	4.05
Rearfoot FPI	0	0.85
Total FPI	3	3.56

Peak EKAM: First peak maximum external knee adduction moment, Sagittal moment: Maximum first peak. FPI: Foot Posture Index, ROM: Range of Motion, STJ: Subtalar Joint, Ev: Eversion, Inv: Inversion, SD: standard deviation.

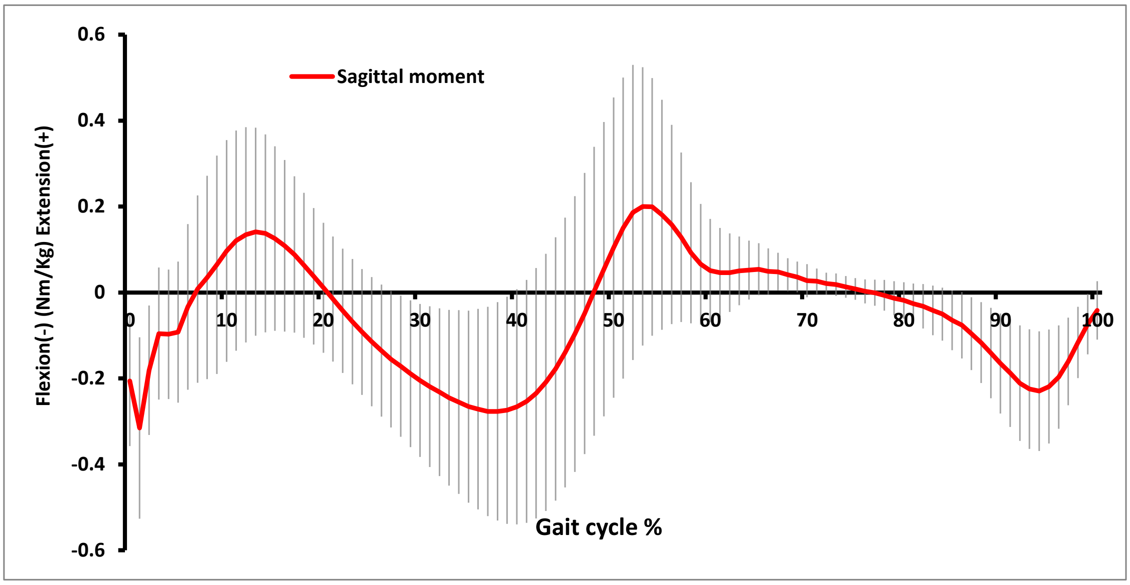

Figure 4.3 – Mean knee flexion/extension moment in the sagittal plane for 137 limbs. Error bars indicate the ± 1 standard deviation.

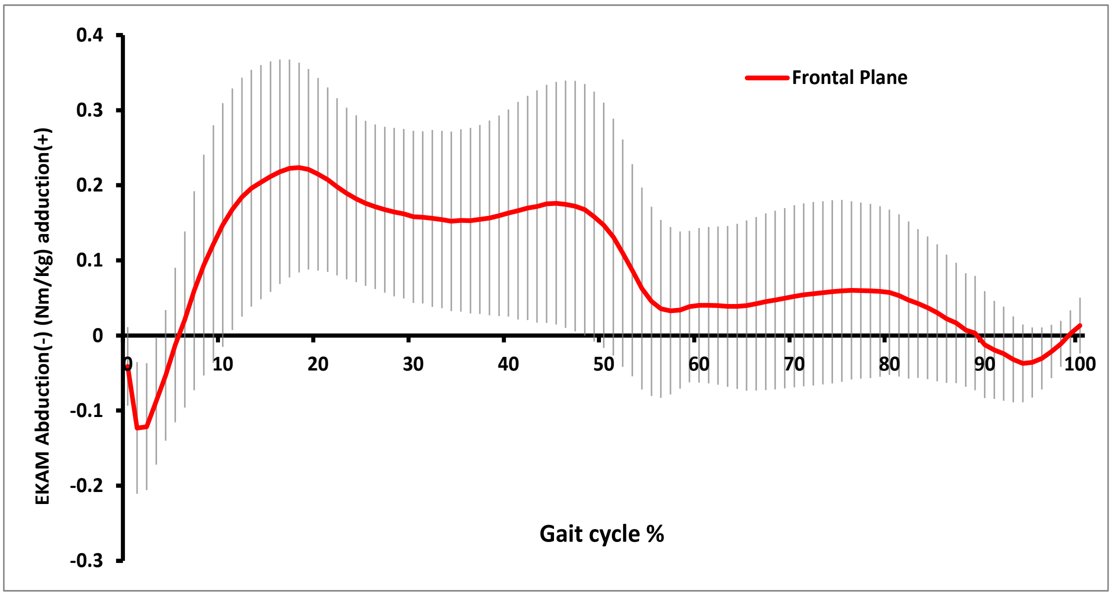

Figure 4.4 – Mean external knee adduction moment (EKAM) in the frontal plane for 137 limbs Error bars indicate the ± 1 standard deviation.

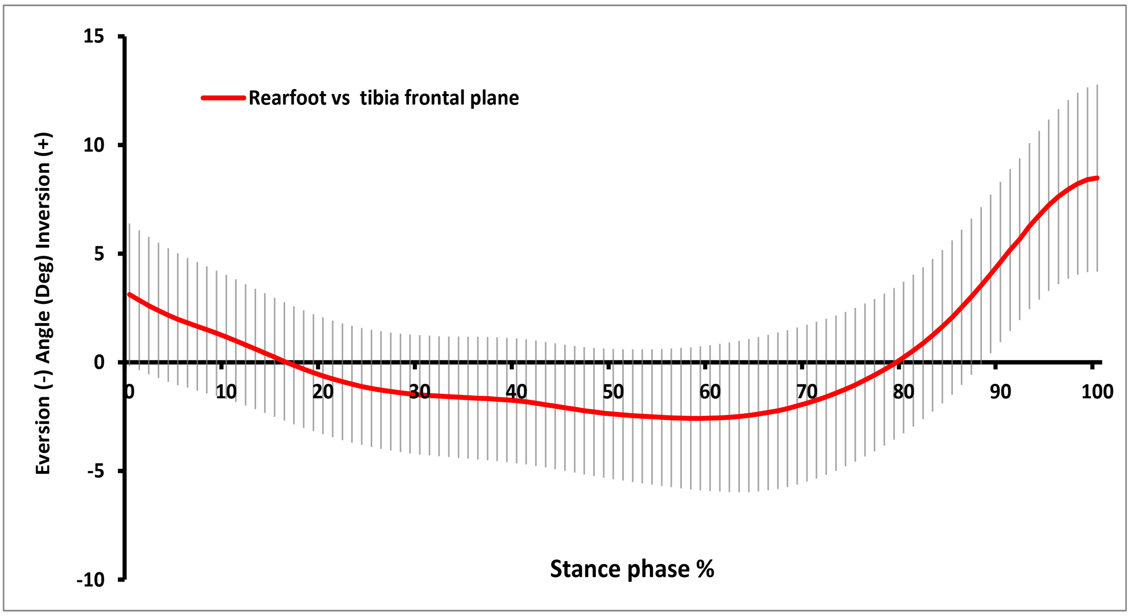

Figure 4.5 – Mean dynamic rearfoot angle motion in the frontal plane for 137 limbs. Error bars indicate the ± 1 standard deviation.

The results indicate that no relationship existed between the FPI and the max EKAM, *r*=-0.118 (p=0.170) (table 4.7). Additionally, no association was identified between the FPI and rearfoot ROM, *r*=0.145 (p=0.095). Results concerning the FPI and dynamic inversion and eversion of the rearfoot indicate no relationship exists, *r*=0.116 (p=0.176) and ρ=0.040 (p=0.642) respectively. No relationship was identified between the FPI and subtalar joint eversion and inversion, r=-0.040 (p=0.643) and r=0.052 (p=0.546) respectively. Also, no association was found between eversion and inversion of the rearfoot in the FPI classification (static) and the EKAM and the ROM (dynamic) r=-0.045 (p=0.601) and ρ =0.089 (p=0.298) respectively.

Conversely, eversion and inversion of the rearfoot in the FPI classification data demonstrates a weak negative relationship to eversion dynamic rearfoot data, ρ=-0.183 (p=0.032) (table 4.7). Also, a weak negative relationship was identified between the EKAM and dynamic inversion and eversion of the rearfoot, r=-0.259 (p=0.002), ρ=-0.201 (p=0.019) respectively (table 4.7). However, the relationship was very weak and therefore, it can be considered that minimal correlation existed between FPI inversion, eversion and dynamic rearfoot, also between the EKAM and dynamic rearfoot eversion and inversion (figure 4.6, 4.7 and 4.8).

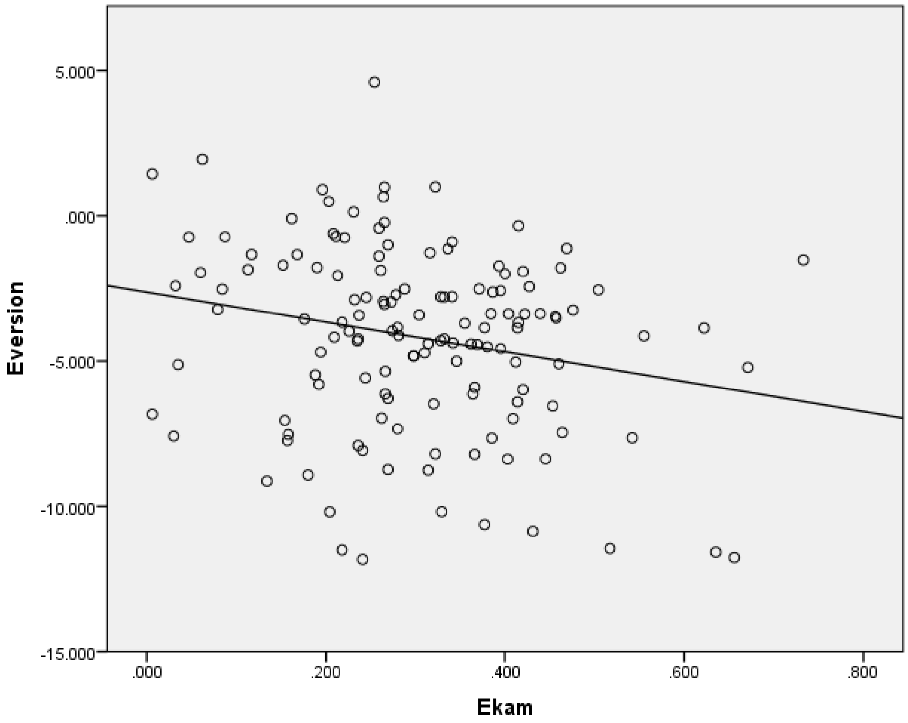

Figure 4.6 – Scatterplot graphs depicting the correlation between eversion and the EKAM.

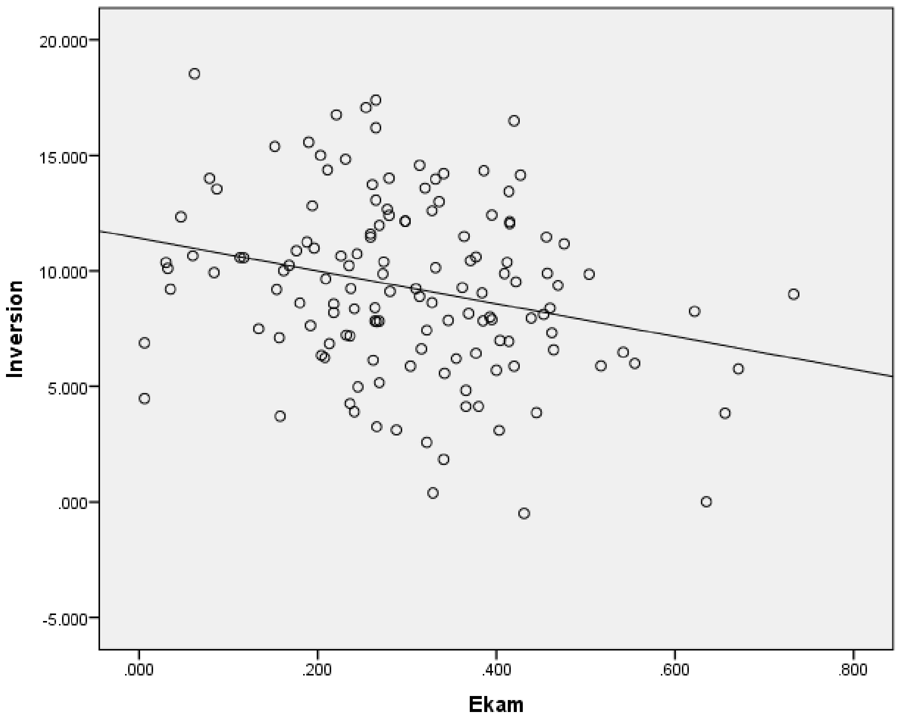

Figure 4.7 – Scatterplot graphs depicting the correlation between inversion and the EKAM.

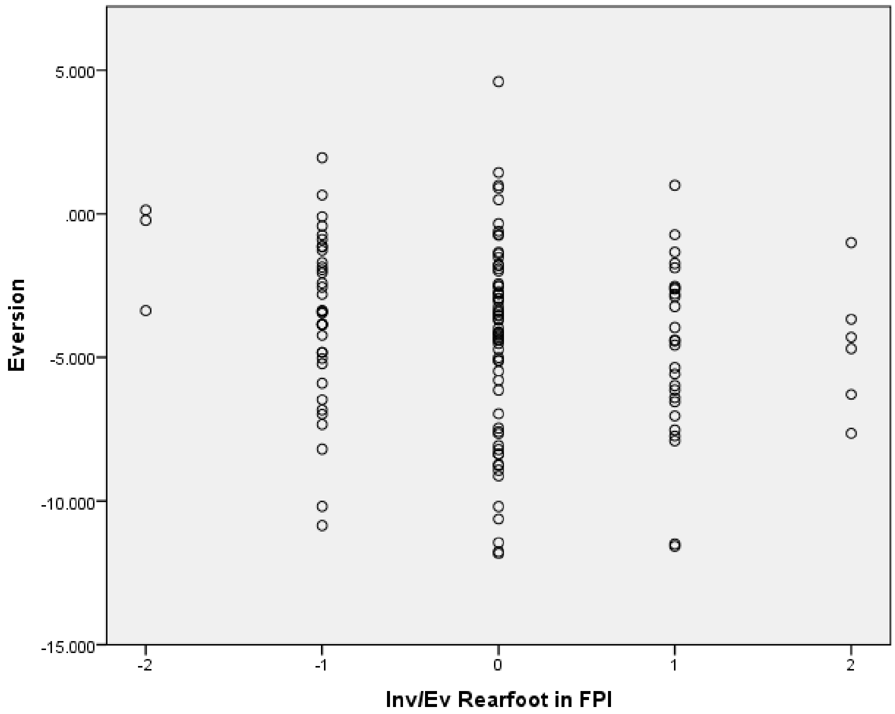

Figure 4.8 – Scatterplot graphs depicting the correlation between inversion/eversion rearfoot FPI vs eversion.

Table 4.7 - The relationship between FPI, rearfoot motion and the EKAM in 137 healthy limbs.

Rearfoot (Barefoot)	Correlations	P-Value
FPI vs EKAM	r= -0.118	P= 0.170
FPI vs ROM	r= 0.145	P= 0.095
FPI vs Inversion	r= 0.116	P= 0.176
FPI vs Eversion	ρ= -0.040	P= 0.642
FPI vs STJ Eversion	r= -0.040	P= 0.643
FPI vs STJ Inversion	r= 0.052	P= 0.546
Inv/Ev Calc FPI vs EKAM	ρ= -0.045	P= 0.601
Inv/Ev Calc FPI vs ROM	ρ= 0.089	P= 0.298
Inv/Ev Calc FPI vs inversion	ρ= -0.075	P= 0.384
Inv/Ev Calc FPI vs Eversion	ρ= -0.183	**P= 0.032**
EKAM vs ROM	r= -0.082	P= 0.341
EKAM vs Inversion	r= -0.259	**P= 0.002**
EKAM vs Eversion	ρ= -0.201	**P= 0.019**
EKAM vs STJ Eversion	r= 0.051	P= 0.552
EKAM vs STJ inversion	r= 0.050	P= 0.562

FPI: Foot Posture Index, EKAM: External Knee Adduction Moment, ROM: Range of Motion, STJ: Subtalar Joint, Calc: Calcaneus, r: Pearson Coefficient Correlation (parametric), ρ*: Spearman Coefficient correlation (non-parametric).*

The results indicated that no association exists between the FPI, EKAM and rearfoot motion when not classifying individuals according to foot type which can be achieved with the FPI. However, some results showed very weak yet still significant association, which indicates that further investigation is required in order to determine if any relationship exists after dividing the limbs into groups related to the rearfoot FPI classification and to answer the research question, that if any relationships exist between static foot posture (assessed using the FPI), dynamic rearfoot motion and the magnitude of the EKAM.

4.5.3 Does classifying the data into foot type groups (inverted, everted and neutral) demonstrate a relationship between static foot posture, dynamic rearfoot motion and the magnitude of the EKAM?

Analysis of the data was conducted by the investigator by dividing the 137 healthy limbs into three groups, classified using the measurements of the rearfoot, according to the FPI. The data were therefore separated into groups; inverted, neutral, and everted. The classification of the rearfoot type was determined using FPI scores (zero – neutral, one-two – everted, minus one – minus two- inverted). Of the 137 healthy limbs, 33 were identified as everted, 65 were identified as neutral, and 39 were identified as inverted, according to rearfoot FPI classification scores. The aim of the grouping of limbs and analysis was to identify if any association existed between the FPI scores for each individual group (inverted, everted or neutral) and dynamic rearfoot motion and magnitude of the EKAM.

Statistical analysis methods (including normality testing and the correlation coefficient) were similar to those used previously within this chapter (section 4.5.3.1). The Shapiro-Wilks test was applied for the everted and inverted FPI groups, and the Kolmogorov–Smirnov test was applied to the neutral FPI group, reflecting the number of limbs in each group.

In addition, one-way ANOVA was conducted to identify if any significant differences existed between the three groups in the sagittal moment EKAM, rearfoot eversion and inversion, and subtalar joint inversion and eversion.

4.5.3.1 Results

After classifying the data of 137 healthy limbs in to three groups (everted (33 limbs), neutral (65 limbs) and inverted (39 limbs) classified using the FPI), the mean and standard deviation of all measurements are presented below (table 4.8). No significant differences were identified between the three groups in all measurements, with the exception of dynamic rearfoot inversion, eversion and range of motion, where significant differences were found (figures 4.9, 4.10 and 4.11).

Table 4.8: The mean and standard deviation (SD) for all measurements within the three groups.

Barefoot	Everted Rearfoot Group		Neutral Rearfoot Group		Inverted Rearfoot Group		ANOVA
Measurement	Mean	SD (°)	Mean	SD (°)	Mean	SD (°)	P value
Peak EKAM Nm/kg	0.29	0.13	0.31	0.13	0.31	0.15	P=0.88
Sagittal Moment Nm/kg	0.25	0.23	0.25	0.25	0.22	0.22	P=0.76
Rearfoot Inversion (°)	4.81	2.86	3.31	2.81	3.01	3.09	P=0.02
Rearfoot Eversion (°)	-1.69	2.86	-2.17	2.75	-2.66	2.70	P=0.33
Range of Motion (°)	6.51	1.98	5.49	1.84	5.67	1.85	P=0.03
Eversion STJ (°)	-12	3.4	-12	3.2	-12	3.1	P=0.96
Inversion STJ (°)	12	3.6	11	3.9	10	4.5	P=0.10
Rearfoot Foot Posture Index	1	0.4	0	0.0	-1	0.3	
Total Foot Posture Index	6	3.02	4	2.87	1	3.24	

Peak EKAM: First peak maximum external knee adduction moment (Nm/kg), Sagittal moment: Maximum first peak (Nm/kg). FPI: Foot Posture Index, STJ: Subtalar Joint, standard deviation (SD).

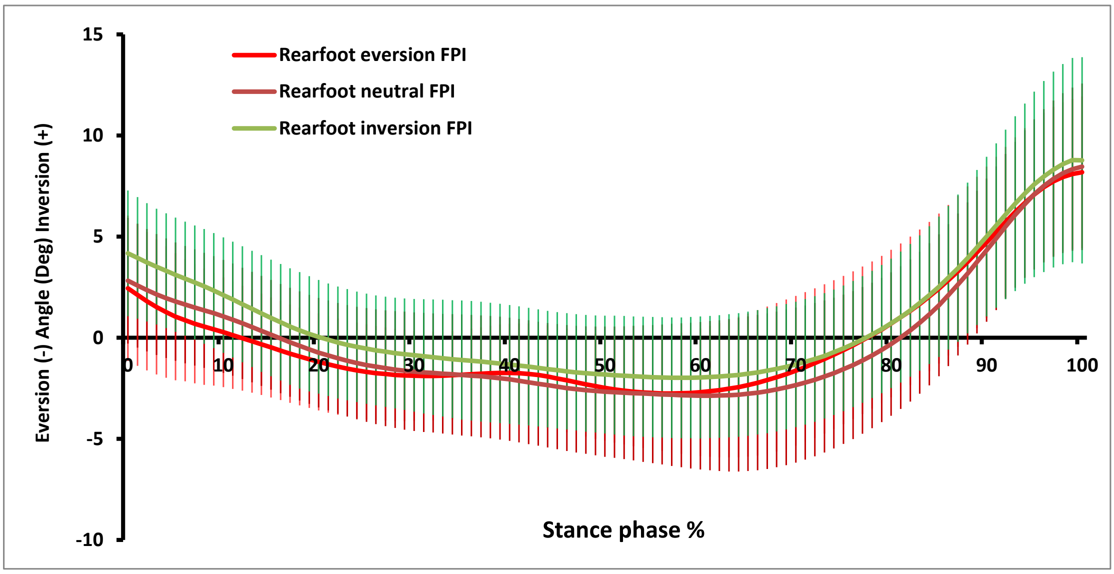

Figure 4.9 – Mean dynamic rearfoot motion (eversion, neutral and inversion) between the groups. Error bars indicate the ± 1 standard deviation for the three groups.

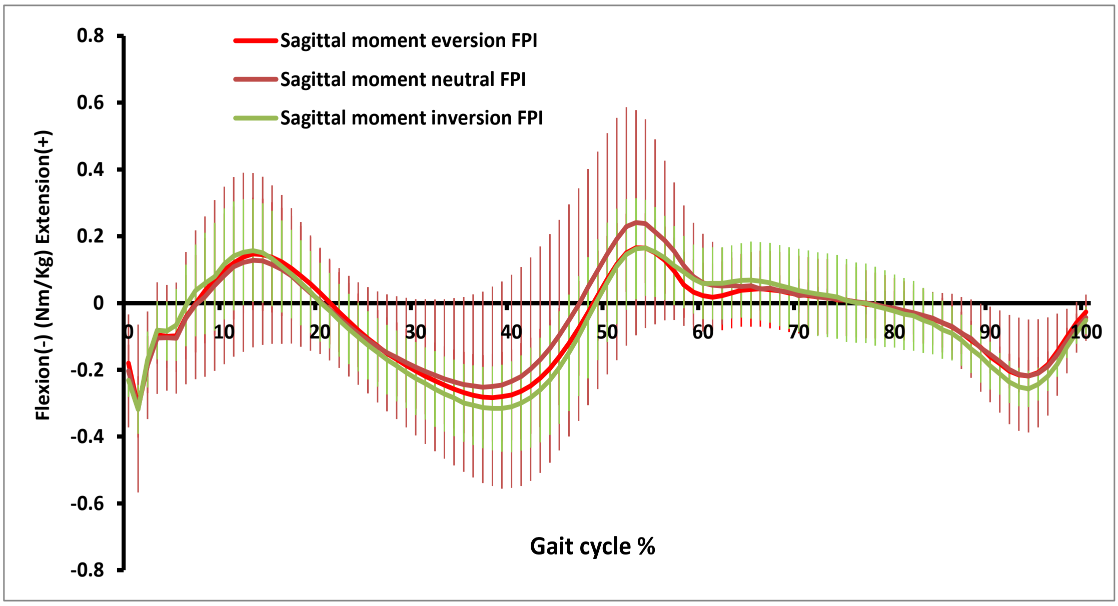

Figure 4.10 – Flexion/extension moment between the three groups (everted, neutral and inverted). Error bars indicate the ± 1 standard deviation for the three groups.

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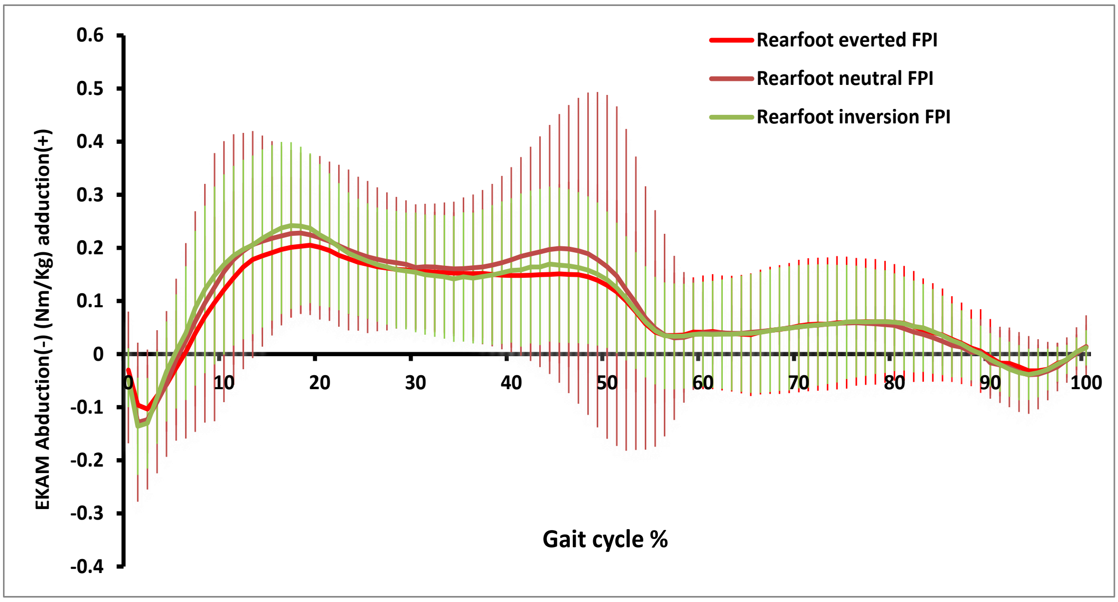


Figure 4.11 – External knee adduction moment (EKAM) between the three groups (everted, neutral and inverted). Error bars indicate the ± 1 standard deviation for the three groups.

The results identified association existed between the different static FPI classifications and dynamic rearfoot motion. However, no association was identified between FPI classifications and the EKAM. Furthermore, no association was indicated between dynamic rearfoot, and the EKAM in all three groups (everted, neutral and inverted FPI classified rearfoot) (table 4.9).

Strong negative association was found between the total FPI score and inversion rearfoot motion in both the neutral rearfoot group and the inversion rearfoot group (neutral r=-0.785 ($p<0.001$), inverted r=-0.668 ($p<0.001$)). Moderate negative association was identified between the total FPI score and inversion rearfoot motion in the everted rearfoot group (r=-0.451(p=0.008).

Strong negative association was also found between the total FPI and eversion rearfoot motion in the three groups classified according to the FPI (inverted r=-0.705, neutral p=-0.993, and everted r=-0.700 ($p<0.001$)) (see table 4.9).

Additionally, a strong negative relationship was found between total FPI eversion and the eversion rearfoot motion group (p=-0.702 $p<0.001$).

Overall, when classifying the rearfoot according to the FPI in the three groups (inverted, neutral and everted rearfoot), the FPI total score and rearfoot inversion and eversion FPI were found to have moderate to strong association with rearfoot motion (inversion and eversion).

Table 4.9 - The relationship between FPI, rearfoot motion and the EKAM in 137 healthy limbs after grouping the limbs depending on their FPI classification (inverted, everted and neutral).

Barefoot (Rearfoot)	**Group 1 Ev RF-FPI**	**Group-2 Neu RF-FPI**	**Group-3 Inv RF-FPI**
	Correlations (P-Value)	**Correlations (P-Value)**	**Correlations (P-Value)**
FPI vs EKAM	ρ= 0.069 (0.704)	ρ= -0.076 (0.546)	*r*= -0.269 (0.098)
FPI vs ROM	*r*= 0.335 (0.041)	*r*= 0.265 (0.033)	*r*= -0.083 (0.617)
FPI vs Max	*r*= -0.451 (0.008)	*r*= -0.785 (0.000)	*r*= -0.668 (0.000)
FPI vs Min	*r*=- 0.700 (0.000)	ρ= -0.993 (0.000)	*r*= -0.705 (0.000)
Inv/EvCalc FPI vs EKAM	ρ= 0.173 (0.335)	N/A	ρ= 0.068 (0.679)
Inv/Ev Calc FPI vs ROM	ρ= 0.182 (0.312)	N/A	ρ= -0.188 (0.252)
Inv/Ev Calc FPI vs Max	ρ= -0.569 (0.001)	N/A	*r*= -0.342 (0.033)
Inv/Ev Calc FPI vs Min	ρ= -0.702 (0.000)	N/A	*r*= -0.462 (0.003)
EKAM vs ROM	ρ= -0.047 (0.796)	*r*= -0.097 (0.449)	*r*= 0.236 (0.148)
EKAM vs Inversion	*r*= -0.035 (0.848)	*r*= 0.031 (0.806)	*r*= 0.238 (0.145)
EKAM vs Eversion	*r*= -0.021 (0.904)	*r*= 0.074 (0.558)	*r*= 0.110 (0.504)

FPI: Foot Posture Index, EKAM: External Knee Adduction Moment, ROM: Range of Motion, Max: Maximum (inversion), Min: Minimum (eversion), STJ: Subtalar Joint, Calc: Calcaneus, r: Pearson Coefficient Correlation (parametric), ρ*: Spearman Coefficient Correlation (non-parametric), N/A: non-applicable (neutral/0 result).*

The hypothesis states that no significant relationship would exist between dynamic rearfoot motion and the magnitude of the EKAM. In order to test this hypothesis further, the dynamic rearfoot data were classified into 3 groups (eversion, neutral and inversion) according to eversion of the rearfoot in the first peak of stance phase of the gait cycle. The eversion group contained 32 limbs, the neutral group contained 70 limbs, and the inversion group contained 31 limbs. The classification of eversion rearfoot motion data into three groups (inverted, everted and neutral) was determined by conducting the mean and standard deviation (1SD). Data was plotted on to a scatterplot where the SD lines were applied above and below the mean line. Positive plots (above the upper SD line) indicate inversion of the rearfoot, negative plots (below the lower 1SD line) indicate eversion of the rearfoot, and plots between the upper and lower SD lines, around the mean line indicate a neutral rearfoot (figure 4.12).

The limbs were divided into three groups (inverted, everted, and neutral) according to eversion rearfoot motion and the EKAM in order to gain further understanding of whether specific rearfoot motion (inverted, neutral or everted) is associated with the EKAM in healthy subjects.

The mean and standard deviation of the peak EKAM and peak rearfoot motion data for the three groups is depicted below in table 4.10. No significant differences were identified in the peak EKAM within the three rearfoot motion groups. Significant differences were identified in dynamic rearfoot motion, between everted, neutral and inverted groups.

Table 4.10: The mean and standard deviation (SD) for Peak EKAM and rearfoot motion for three groups

Barefoot	Everted Rearfoot Motion Group		Neutral Rearfoot Motion Group		Inverted Rearfoot Motion Group		ANOVA
Measurement	Mean	SD (°)	Mean	SD (°)	Mean	SD (°)	P value
Peak EKAM Nm/kg	0.32	0.12	0.30	0.14	0.27	0.13	P=0.069
Rearfoot Motion (°)	-6.13	1.23	-1.93	1.14	1.21	1.11	P=0.000

Peak EKAM: First peak maximum external knee adduction moment (Nm/kg), standard deviation (SD).

Results identified no significant relationship exists between dynamic rearfoot motion (inversion, neutral and eversion) and the magnitude of the EKAM in healthy subjects (table, 4.11).

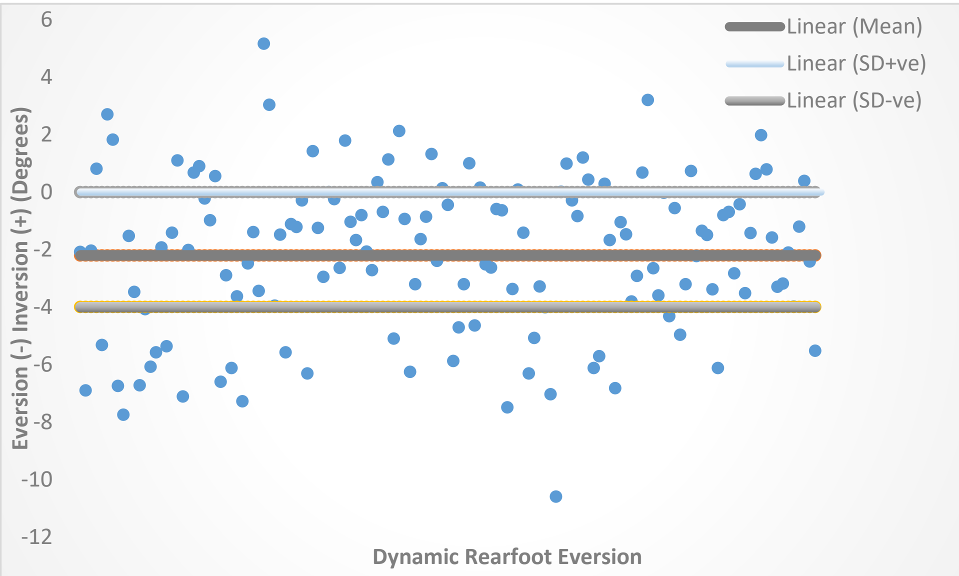


Figure 4.12 – Scatterplot graph depicting the three rearfoot motion classifications - inversion, eversion and neutral. Plots close to the mean line between the two SD indicate a neutral rearfoot motion, plots above the positive SD line indicate inverted rearfoot motion, and plots below the negative SD line indicate an everted rearfoot motion.

Table 4.11 - The relationship between rearfoot motion and the EKAM in 137 healthy limbs after dividing the limbs into three groups - inverted, everted and neutral rearfoot motion.

Barefoot Rearfoot Dynamic 1st Peak	**Correlations (P-Value)**
EKAM vs Eversion	ρ= 0.137 (0.453)
EKAM vs Neutral	*r*= -0.090 (0.445)
EKAM vs Inversion	*r*= 0.060 (0.747)

4.6 Discussion

The investigations within this chapter assessed whether static foot posture and dynamic rearfoot motion could identify if any relationships exist between rearfoot motion and foot posture, relative to the magnitude of the EKAM. Also, whether static foot posture and the dynamic rearfoot contributes to biomechanical alterations which could affect the magnitude of the EKAM. The hypothesis stated that no significant relationship would exist between static foot posture and the magnitude of the EKAM, between the dynamic rearfoot motion and the magnitude of the EKAM, and also between the static foot posture and dynamic rearfoot motion.

After investigating 30 healthy limbs, the results indicated no association was present between the variables. Therefore, 137 limbs were investigated in order to increase the data set, aiming to more accurately determine results and add strength to the investigations.

The results within the chapter found some, although minimal association, with the only association identified between variables present within the 137 limbs between the EKAM and dynamic inversion/eversion, and the rearfoot FPI and dynamic eversion of the rearfoot, where only weak negative association was present, and the relationship identified was minimal. However, significant association was identified between static foot posture and the dynamic rearfoot when limbs were divided into three groups according to their FPI classification. The FPI is a static measurement, and therefore negative association does not provide inferences into whether rearfoot motion increases or decreases and therefore, although association was present within the results, clinical FPI and rearfoot FPI classifications cannot represent biomechanical rearfoot motion. No relationship was identified between static foot posture and the EKAM, and the dynamic rearfoot and the EKAM.

Recent literature has suggested that foot posture can potentially reduce the EKAM (Levinger *et al.*, 2010), and that a pronated foot can reduce the EKAM in medial compartment knee OA patients (Levinger *et al.*, 2010), although the underlying mechanisms connecting foot posture and function remain unclear within the literature (Buldt *et al*., 2015). Results of this investigation, carried out using healthy subjects demonstrate that very limited weak association exists between foot posture and rearfoot motion relative to the EKAM in healthy subjects, and therefore these findings suggest that the EKAM does not vary depending on specific foot postures in heathy subjects. A study by Chuter, (2010) assessed the relationship between dynamic rearfoot motion and FPI scores in the pronated and neutral feet (classified by their FPI score) of 40 healthy subjects. Strong positive correlation was identified between the FPI scores and rearfoot eversion. Chuter (2010) therefore concluded that the FPI is a strong predictor of dynamic rearfoot function. However, the study by Chuter (2010) only included pronated (everted) and normal foot types, and excluded supinated (inverted) foot types from data analysis. Investigations within this chapter however, examined all FPI foot types, and investigated the rearfoot classification of FPI relationship with dynamic motion, with findings indicating no relationship exists between total FPI score and dynamic rearfoot motion. Findings identified some negative association between rearfoot FPI and biomechanical rearfoot motion, however it is not known how rearfoot motion has altered because the FPI is a static measurement, and consequently, the FPI cannot represent rearfoot motion.

Buldt *et al*., (2015) conducted an investigation similar to this research question, which also used a large data set, into the association between static foot posture, the dynamic foot, and foot kinematics during barefoot walking in 97 healthy individuals. Some statistically significant associations were identified between measures of static foot posture, the dynamic foot and kinematic variables, concluding that the use of clinical measures of foot posture (including the FPI) or dynamic foot motion can only explain a minimal amount of variation in foot kinematics when walking in healthy participants with a range of foot postures. Therefore, the findings by Buldt *et al*., (2015) suggest that foot kinematics cannot be accurately determined using only observations of foot posture.

Differences between the Buldt *et al*., (2015) investigation and this research question include the use of the FPI and the arch index, normalised navicular height, and normalised dorsal arch height to measure the whole foot statically within the Buldt *et al*., (2015) trial, whereas this investigation used only the FPI and focused specifically on the rearfoot, which has not been investigated previously, adding novelty to this investigation. Furthermore, within the Buldt *et al*., (2015) study, motion of the rearfoot, midfoot, medial forefoot, lateral forefoot, and hallux was measured, whereas this study again only focused on the motion of the rearfoot. Buldt *et* *al*., (2015) concluded that the FPI displayed the strongest association with kinematic variables compared with the other foot posture measurements and foot mobility measurements, and for this reason, this study focused solely on collecting FPI data to assess static foot posture.

Results pertaining to dynamic subtalar joint eversion and the EKAM indicate no association exists between the two variables, and similarly no association was identified between the subtalar joint inversion and the magnitude of the EKAM, and subtalar joint inversion and eversion, and the FPI. Likewise, a study by Buldt *et al*., (2015) states that no association existed between rearfoot joint rotation and the EKAM after investigating the relationship between the rearfoot and mid foot joint rotation and the magnitude of the EKAM in 97 healthy adults.

However, investigations using individuals with medial compartment knee OA have provided converse findings. A recent study by Chapman *et al*., (2015) using 70 participants with medial compartment knee OA states that the subtalar joint complex plays a vital role in the reduction of the EKAM with the use of LWI. Also, that the subtalar joint complex biomechanical measures correlate with a reduction of the EKAM with the use of LWI, after conducting gait analysis to evaluate if dynamic ankle joint complex coronal plane biomechanical measures could identify and explain individuals who experienced a change in the EKAM when wearing LWI. Additionally, Levinger *et al*., (2010) identified that alterations in the kinetics and kinematics of the foot during gait can be achieved by increasing the subtalar joint pronation moment in the frontal plane, potentially leading to a reduction in the EKAM, initiated by shifting the centre of pressure laterally in individuals with medial compartment knee OA. Furthermore, the investigation by Levinger *et al*., (2010) identified a more pronated foot type in individuals with medial compartment knee OA classified using the FPI.

These research findings indicate that further investigation into foot posture and the EKAM using medial compartment knee OA patients and LWI may be beneficial in achieving a further understanding of foot posture and the magnitude of the EKAM. However, it can be stated that no relationship exists between the foot posture, rearfoot motion and the magnitude of the EKAM in the overall healthy subject population within the study.

Dividing the 137 limbs into three groups according to individual limb foot posture (classified using the FPI) prior to commencing further investigations allowed any existing further association to be identified. A number of findings indicate very weak yet still statistically significant association; suggesting that further investigation is required in order to determine if any relationship can be identified between static foot posture (assessed using the FPI), dynamic rearfoot motion and the magnitude of the EKAM.

After grouping the 137 healthy limbs according to their FPI classification (inverted, neutral and everted) significant association was identified between the FPI and rearfoot motion, and the rearfoot FPI classification and rearfoot motion. However, no association was present between rearfoot motion and the magnitude of the EKAM, and the total FPI and FPI rearfoot classifications and the EKAM. Correspondingly, Buldt *et al*., (2015) carried out an investigation into foot posture and the EKAM, and similarly grouped the subjects according to their total FPI score classifications. Instead of investigating rearfoot motion, navicular arch was analysed within the Buldt *et al* trial. It was concluded that foot posture does not substantially influence the EKAM during walking (Buldt *et al*., 2015), and therefore findings of this investigation are consistent with previous research outcomes.

Overall, the investigation into healthy subjects identified no association between the FPI and the EKAM. Furthermore, no relationship was identified between rearfoot motion and the magnitude of the EKAM.

Previous investigations conducted using participants with medial compartment knee OA have identified a relationship between the magnitude of the EKAM and foot posture in both shod (in shoe) and shod with the use of orthotic interventions, specifically LWI (Reilly *et al*., 2009, Levinger *et al*., 2010, Levinger *et al*., 2012, Chapman *et al*., 2015). Levinger *et al*., (2010) states that knee OA patient's present altered foot kinematics during gait, including a more pronated (everted) foot type when compared with healthy controls, and therefore a change in normal foot posture. The study by Levinger *et al*., (2010) used the FPI to classify foot posture, as did this investigation. Similarly, a further investigation by Levinger *et al*., (2012) further confirmed the findings of more pronated foot types in populations with medial compartment knee OA. The findings of the Levinger *et al*., investigations therefore indicate that foot posture may play an important role in knee OA. However, the relationship between knee OA and foot posture is not clear, and a more pronated foot posture could be either a risk factor or a consequence of medial compartment knee OA and further investigation is therefore necessary.

Additionally, foot posture may affect the efficacy of orthotic devices when used for the treatment of medial compartment knee OA. Previous investigations by Chapman *et al*., (2015) identified incidences of non-response to LWI intervention in subjects with medial compartment knee OA, and therefore further investigation into the foot posture of subjects who did not respond to LWI is needed. By quantifying rearfoot kinetics and kinematics in LWI it may be established whether foot posture is related to response and non-response in LWI, and additionally, which specific foot posture or postures caused the incidences of response and non-response within the Chapman study.

As with any trial, there are limitations that have to be discussed. It is important to consider that in all investigations within this chapter, kinetic and kinematic dynamic data was collected using solely automated measurement tools, and therefore assessor bias and error was low. Additionally, FPI data was collected by a podiatrist, experienced in carrying out FPI assessments, ensuring credibility and accuracy in the FPI scores.

Data was collected from both the left and right limbs of most participants for the investigation. Previous research has identified no significant differences between left and right limbs, or dominant and non-dominant limbs in healthy participants which could perhaps suggest that collecting a single limb (either left or right) for all participants may have been ideal for this investigation. However, differing architectural foot types present between left and right limbs could influence the ground reaction force and measures in clinical research settings (Hertel *et al*., 2002). Variation and limb dominance present between the right and left limbs of individuals could indicate the lower limbs are not used equally during ambulation, indicating gait to be asymmetrical. Therefore, differences may be present between individual's limbs, meaning collecting and analysing both the left and right limbs of all 15 participants (30 limbs in total) may be advantageous.

The recruited cohort of healthy participants may mean findings are not generalisable to a symptomatic population with knee OA or other lower limb pathologies and therefore further investigation is needed using subjects with medial compartment knee OA.

4.7 Conclusion

In conclusion, the investigation into healthy subjects using the initial 15 subjects (30 healthy limbs) identified no association between the FPI and rearfoot motion, between the FPI and the EKAM, and also between rearfoot motion and the EKAM. A close to significant association was identified between the EKAM and rearfoot range of motion within the 15 subjects, however this was not carried forward to the larger sample of 137 limbs.

The investigation into the 137 healthy limbs did identify a weak relationship to exist between the EKAM and dynamic inversion and eversion of the rearfoot, and also between the rearfoot

FPI and dynamic eversion of the rearfoot when the population was examined as a whole. Furthermore, when classifying the 137 healthy limbs to rearfoot type according to the FPI, significant association between the rearfoot FPI scores and dynamic eversion and inversion, and rearfoot range of motion was identified. However, no relationship was identified between rearfoot motion and the EKAM, and the total FPI, the rearfoot FPI, and the EKAM. Therefore, in healthy subjects, the FPI cannot be used to represent dynamic rearfoot motion by clinicians. However, rearfoot posture classified using the FPI does have some association with dynamic rearfoot motion. Therefore, further clinical assessment methods are needed, as clinical measurements could represent dynamic rearfoot and subtalar ankle joint motion, which could lead to further understanding of the effectiveness of interventions designed for the conservative management of knee OA, such as LWI.

Overall, it can be stated that the clinical total FPI scores do not entirely explain biomechanics of rearfoot motion in healthy subjects.

Current literature states that individuals with medial compartment knee osteoarthritis (OA) exhibit altered foot kinematics during gait, including a more pronated foot type than healthy individuals (Levinger *et al*., 2010, Levinger *et al*., 2012). Therefore, further investigation is needed in individuals with knee osteoarthritis, as research indicates that foot posture may play an important role in both the onset and progression of knee OA (Levinger *et al*., 2010). Additionally, foot kinematics during gait including the rearfoot range of motion may influence individual responses to load-altering interventions such as LWI. Considering altered foot kinematics during gait are present in medial compartment knee OA populations, the findings of the Levinger *et al*., (2012) trial suggest altered foot kinematic patterns could have important clinical implications regarding the effectiveness of LWI, and could also aid in the identification of those individuals who would experience a reduction in their EKAM with LWI, and therefore benefit from the use of LWI (Chapman *et al*., 2015). Therefore, further investigation is required.

However, the relationship between knee OA and foot posture remains unclear. Gross *et al*., (2011) investigated the relationship between foot postures, knee pain and knee cartilage damage, and concluded that a pes planus (pronated) foot posture is associated with knee pain, medial tibiofemoral and patellofemoral cartilage damage in older adults. Findings of the Gross *et al*., (2011) trial suggest a biomechanical link exists between a pes planus foot posture and increased load on the tibiofemoral and patellofemoral compartments of the knee. Foot posture may affect the efficacy of orthotic devices when used for the treatment of medial compartment knee OA (Chapman *et al*., 2015), and incidences of non-response to LWI in subjects with medial compartment knee OA have been reported in previous investigations by Levinger *et al*., (2010), Chapman *et al*., (2011), Levinger *et al*., (2012) Jones *et al*., (2014) and Chapman *et al*., (2015).

Further investigation into foot posture, the magnitude of the EKAM and response and non-response to LWI in individuals with medial compartment knee OA is therefore crucial to establish if foot posture is related to the biomechanical response and non-response to LWI. This thesis consequently aims to conduct future investigations into knee OA patients with the use of LWI in shod to determine the causes of biomechanical non-response to LWI.

Chapter Five

The role of clinical and biomechanical foot and ankle motion on the EKAM and response to lateral wedge insoles in patients with knee osteoarthritis

Chapter summary

The previous chapter focused on healthy individuals, and previous literature has identified differences in foot posture between individuals with medial compartment osteoarthritis and healthy individuals. Therefore this population needs to be examined both in terms of foot and ankle posture/motion associations with EKAM but also their role in the response to a common intervention. Therefore, in the chapter the role of clinical foot posture and barefoot rearfoot motion on the efficacy of lateral wedge insoles and the impact on the magnitude of the EKAM in patients with medial compartment knee osteoarthritis is examined. The chapter aimed to fill the current literature gap surrounding the concurrent collection of lateral wedge insole data and the assessment of clinical foot posture and barefoot rearfoot motion. This will help to determine if barefoot clinical and dynamic foot posture/motion influence the efficacy of lateral wedge insoles when used in the management of medial compartment knee osteoarthritis. The chapter also aimed to understand if any clinical or biomechanical measures related to the biomechanical response and non-response to lateral wedge insoles seen in the literature.

5.1 Introduction

Medial compartment knee osteoarthritis (OA) is a progressive musculoskeletal disorder, common in older individuals, mostly affecting populations over 70 years of age, and rarely before 40 years of age (Petersson, 1996, Woolf and Pfleger, 2003, Levinger *et al.*, 2010, Jones *et al.*, 2015, Chapman *et al.*, 2015). Recent studies have focused on the role of biomechanical factors in the onset and progression of medial compartment knee OA (Lynn *et al.*, 2007, Levinger *et al.*, 2012), and foot posture has been proposed in the literature as a possible factor in the development of lower limb musculoskeletal conditions (Levinger *et al.*, 2012, Arnold *et al.*, 2014, Buldt *et al.*, 2015, Resende *et al.*, 2015) due to its possible influence on the mechanical alignment and dynamic function of the lower limbs (Guichet *et al*., 2003, Resende *et al*., 2015).

Differing foot characteristics between healthy individuals and knee OA patients have been acknowledged in recent literature, with OA patients displaying a more pronated foot posture, when compared with healthy individuals (Reilly *et al*., 2006, Reilly *et al*., 2009, Levinger *et al*., 2010, Levinger *et al*., 2012). The aforementioned studies fail to provide insight into the dynamic function of the foot during gait however, and only provide information regarding foot structure in knee OA patients (Levinger *et al.*, 2012, Arnold *et al*., 2014). Foot motion has the potential to compensate for proximal malalignments, for example varus and valgus, due to triplantar axes of motion (Riegger-Krugh and Keysor, 1996, Levinger *et al*., 2012), and therefore, load modifying interventions have increasingly been investigated for populations with knee OA, with the most common interventions being footwear and orthotic devices, such as lateral wedge insoles (LWI) (Levinger *et al*., 2012).

Biomechanical responses to LWI have been somewhat inconsistent across individuals within the literature to date (Yamaguchi *et al*., 2015) with as much as 30% of individuals with medial compartment knee OA displaying an increase in their EKAM during walking (Chapman *et al*., 2015). Few studies have examined foot kinematics and their consequences on knee loading in medial compartment knee OA patients during gait (Kakihana *et al*., 2005, Butler *et al*., 2009). Chapman *et al*., (2015) investigated whether dynamic ankle joint complex coronal plane biomechanical measures could provide insight into why medial compartment knee OA patients experienced an increase or decrease in their EKAM whilst wearing LWI compared to control shoes. Findings indicated 33% of participants increased their EKAM and 67% decreased their EKAM whilst wearing LWI, compared to a control shoe, and therefore it can be stated that coronal plane ankle and subtalar joint complex biomechanics may influence the EKAM with the use of LWI. Similarly, an earlier study by Kakihana *et al*., (2007) identified 17.6% (9 of 51) of patients with medial compartment knee osteoarthritis experienced an increase in their knee-joint varus moment with the use of a 6º LWI, and were therefore classified as biomechanical non-responders to LWI intervention. The incidence of biomechanical non-response was postulated to be caused by a medially shifted location of the centre of pressure in the foot. Kakihana *et al*., (2007) concluded that further investigation is required.

Chapman *et al*., (2015) concluded that coronal plane foot and ankle biomechanical measures are key mechanisms causing a reduction or increase in the EKAM when wearing LWI. Knee

OA patients who demonstrate a higher peak ankle eversion angle or a higher eversion angle at peak EKAM during a control (shod) condition than a LWI condition are more likely to be classified as biomechanical responders to LWI intervention. Of the 70 participants studied, 20% increased their EKAM, indicating an incidence of biomechanical non-response within the trial. Further research into the incidence of biomechanical non-response in terms of the EKAM within the literature surrounding LWI is therefore necessary. However, the Chapman *et al*., (2015) investigations were only conducted in shod, and therefore, future investigations which assess the rearfoot in barefoot walking conditions may be more ideal to gain further understanding into biomechanical responders and non-responders to LWI intervention.

Although a vast amount of research concerning LWI has reported reductions in the peak EKAM in both healthy individuals and individuals with medial compartment knee OA, LWI have proven ineffective at improving symptoms or slowing disease progression in some clinical trials, and reductions in the peak EKAM are occasionally not consistent across all study findings, with some trials reporting that LWI had no effect on the EKAM (Pham *et al*., 2004, Baker *et al*., 2007, Hinman *et al*., 2008, Barrios *et al*., 2009, Bennell *et al*., 2011, Chapman *et al*., 2015). Therefore, in order to gain a comprehensive understanding of the effect of knee OA interventions on the knee and surrounding lower limb joints, and to also accurately identify suitable patients who are most likely to benefit from these interventions, a complete understanding of foot posture and structure is vital (Levinger *et al*., 2010, Arnold *et al*., 2014). Furthermore, further investigation into LWI is needed to establish the effectiveness on biomechanical and clinical parameters in patients with symptoms of medial knee OA (Fang *et al*., 2006).

Reilly *et al*., (2009) identified foot posture as a possible influence on the effectiveness of orthotic interventions in patients with medial knee OA. The study by Reilly *et al*., (2009) established that the use of LWI to treat osteoarthritis of the knee may further increase the pronation of an already pronated foot, therefore causing further deviation from normal gait. Further investigation is needed therefore, in order to determine whether foot posture may have influenced this incidence of biomechanical non-response within the Chapman *et al*., (2015) trial.

Without in depth comprehension of foot function in individuals with knee OA, it is challenging to design interventions that act between the foot and the supporting surface, and also to measure their efficacy (Arnold *et al*., 2015). The literature fails to investigate the use of LWI for the treatment of medial knee osteoarthritis in relation to foot posture (Arnold *et al*., 2015). However, a number of articles infer that foot posture would be studied in future research in their discussion (Hinman *et al*., 2008, Butler *et al*., 2009). Improving the understanding of foot posture in individuals with medial compartment knee OA is necessary and may allow the prevention or reduction of adverse symptoms associated with the disease. Additionally, it may help to tailor interventions to further suit and provide maximum benefit for individuals. Furthermore, refining existing knowledge of foot posture could also allow an improvement in the efficacy and comfort, and the lessening of negative side effects of interventions that exist for the treatment of medial compartment knee OA, including LWI. Moreover, investigating foot posture could potentially further the understanding of the incidence of biomechanical response and non-response to LWI intervention which exists within the literature. Currently, the exact mechanisms which may link foot posture and function to medial compartment knee loading have not been identified within the literature, and therefore remain unclear (Gross *et al*., 2011), warranting further investigation.

The rearfoot is the first part of the foot to make contact with the ground during heel strike of the gait cycle, and the first peak in EKAM is related to this time period of the gait cycle. Therefore, this investigation assessed the role of clinical static foot posture and dynamic barefoot rearfoot motion in response to the wearing of LWI and the effects and impact on the EKAM in individuals with knee OA.

Investigations within this chapter therefore aimed to understand how foot posture may influence loading on the knee joint, how foot postures may affect the efficacy of LWI, and if there is any relationship between clinical static foot posture, barefoot dynamic rearfoot motion, and the magnitude of the EKAM. Previous studies have investigated the effects of LWI as an intervention to reduce the loading on the medial compartment of the knee, which may be influenced by foot posture. There is however, a lack of research assessing clinical static foot posture and barefoot rearfoot motion and LWI efficacy, therefore this study is an important addition to the current literature.

5.2 Aims

The aims of this investigation were to determine if a relationship exists between clinical static foot posture, barefoot rearfoot dynamic motion, and the magnitude of the EKAM. Additionally, the chapter aimed to establish whether clinical static foot posture and barefoot rearfoot dynamic motion influences the effectiveness of lateral wedged insoles and the change in the external knee adduction moment in patients with osteoarthritis of the knee.

5.3 The statistical hypotheses are:

- There is no significant relationship between static foot posture (assessed using the FPI), and the magnitude of the EKAM in patients with medial compartment knee OA.
- There is no significant relationship between clinical static foot posture (assessed using the FPI), and barefoot rearfoot dynamic motion in patients with medial compartment knee OA.
- There is no significant relationship exists between barefoot dynamic rearfoot motion and the magnitude of the EKAM in patients with medial compartment knee OA.
- Clinical static foot posture and the barefoot rearfoot motion cannot predict biomechanical response when wearing LWI intervention.

5.4 Methods

5.4.1 Patients

Twenty four patients with medial compartment knee OA (table 5.1) were assessed in the gait laboratory at the University of Salford. All patients had received a clinical and radiological diagnosis of medial compartment tibio-femoral knee osteoarthritis (MTFOA) prior to the commencement of trials, and the study included patients who were on the waiting list for knee surgery, however excluded those with grade 4 (bone on bone) MTFOA diagnosed using the Kellgren and Lawrence (KL) scale. Confirmation of radiological diagnosis of MTFOA was performed by a consultant radiologist to ensure consistency in X-ray classification of the patient's knees, and to ensure they were under grade 4 of the KL scale.

Table 5.1: Summarised mean and standard deviation (SD) demographic measurements for all 24 patients.

Gender	*Males (N=14)*	*Females (N=10)*
Age (years) ± (SD)	*64.41 ± (10.22)*	*63.25 ± (8.32)*
Height (m) ± (SD)	*1.73 ± (0.04)*	*1.64 ± (0.05)*
Mass (kg) ± (SD)	*84.2 ± (12.97)*	*81.5 ± (15.30)*

These individuals were part of a larger randomised trial of which the total number of individuals to be seen would be 50, which is still ongoing. Twenty four individual patient's data was collected during the trial. All participants were aged 40-85 years old (the upper age limit was decided on due to the amount of walking involved in the trial).

5.4.2 Recruitment

Recruitment was managed by a research team with extensive experience with this patient population in the same geographical location, and previous success in study recruitment. Patients were recruited from a number of sources, whereby referring practitioners used data access forms, and participants were also recruited through advertising and mailing methods with telephone screening questionnaires. Recruitment incorporated referrals from the Salford Royal NHS Foundation Trust at Salford Royal Hospital, and also from local providers of clinical assessment and treatment services at Salford Royal Hospital, the Walkden Centre, and Trafford Healthcare NHS Trust. Patient identification centres at Central Manchester Foundation Trust, Manchester Primary Care Trust, Pennine Acute Trust, Stockport NHS Foundation Trust, Stockport Primary Care Trust, Bury Primary Care Trust, University Hospitals South Manchester, and Trafford Primary Care Trust were also used to identify suitable participants for the trial.

After individuals had been clinically diagnosed as having MTFOA by clinicians, they were approached by the clinician and informed of the nature of the study, and were asked if they consented to having their details passed on to the recruitment team to take part in the trial. If the individual consented to having their details passed on to the recruitment team, they were requested to provide their details and to also to sign a data access form (DAF) which allowed the contact details to be passed on to the recruitment team. The practitioner forwarded the DAF to the recruitment team, and provided the participant with a patient information sheet, detailing the trial, and what was required of the patient during the trial. On receiving the completed DAF, the recruitment team contacted individual patients via telephone, in order to assess eligibility of individuals using the inclusion and exclusion criteria, and to book an appointment for the patient to attend the gait laboratory at the University of Salford.

Alternatively, if a patient answered an advert, poster or a mailing by contacting the recruitment team using the provided contact details, the recruitment team completed a telephone screening questionnaire with individual patients to assess eligibility for the trial. A patient information sheet was then be sent to the patient via post or email, and the need for an X-ray was assessed.

Once the patient had read the participant information sheet, and eligibility via X-ray and the screening questionnaire had been assessed and confirmed, a gait laboratory appointment was booked.

Table 5.2: Inclusion and Exclusion criteria

Inclusion Criteria	Exclusion Criteria
Has had an X-ray (weight bearing, if possible) within the two years prior to recruitment which indicates definite medial narrowing (KL grade 2 or 3) with no lateral narrowing, and evidence of OA (including the presence of osteophytes and or definite sclerosis). Also has confirmed absence of patellofemoral osteoarthritis (must be less severe OA than medial disease, and cannot be KL grade 3 or higher in the patella-femoral joint).	Has history of high tibial osteotomy or other realignment surgeries, or total knee replacement in the OA afflicted knee, or has had knee arthroscopy procedures within the past 6 months, or has had intra-articular injection into the afflicted knee in the past 3 months.
Aged between 40-85	Shows evidence of tri-compartmental knee OA or KL grade 4 medial tibio-femoral OA, or has inflammatory arthritis including rheumatoid arthritis in the afflicted knee.
Has KL grade 2 or 3 in the tibio-femoral joint (TFJ) diagnosed via X-ray.	Has any foot and ankle pathologies that may contraindicate the use of footwear load modifying interventions (particularly LWI).
The KL grade in the TFJ is higher than the patella-femoral joint (PFJ) and cannot be equal, diagnosed via X-ray.	A general poor condition of health, including mental health, and the inability to understand trial procedures, or the presence of severe co-existing medical morbidities.
The medial joint space narrowing score must be higher than the patella-femoral joint (PFJ) and cannot be equal.	Uses or has previously used orthoses of any description prescribed by a podiatrist or orthoptist within the past two months.
Is able to walk 100 metres without stopping.	Patients with a BMI of over 35, which could affect the accuracy of gait laboratory equipment measurements.
Has a good overall condition of health.	Patients who are unable to walk unaided and require the use of assistive devices such as walking sticks, crutches or walking frames.

5.4.3 Data Collection

Testing was carried out in the clinical gait laboratory at the University of Salford, and data collection and analysis was similar to the methods used within chapter 3 (3.2), with any additional materials or methods used detailed below.

Upon arrival at the gait laboratory at the University of Salford, the individuals were briefed through the investigations and the objectives of the trials were explained in full, along with any equipment and materials that were used. Informed consent was taken, and demographic details (date of birth, height, mass, and shoe size) of individual participants was recorded. Photographic evidence of the medial, anterior, and posterior leg and foot was obtained, and patients were then directed to a private area and requested to change into fitted shorts and a comfortable t-shirt. Baseline pain scores were collected on a 10mm visual analogue scale noting how their knee pain was where 0 was no pain and 10 was the most pain imaginable.

The participant was then prepared for the walking trials which utilised gait analysis methods. Therefore, retro-reflective markers and fixed cluster pads were attached to bony landmarks on the participant's skin (chapter 3 section 3.2.6).

Walking trials were then conducted in three conditions, and the interventions tested were; barefoot, shod (using the subjects own everyday shoe) and shod (using the subjects own everyday shoe) with a LWI (Salford Insole) inserted. Five successful self-selected speed walks (with full foot contact made with the force plates) in each one of the three conditions was performed, and patients were asked to walk over a flat surface with force plates embedded into the floor. To reduce the chance of a carry-over effect, individuals were given time (a few minutes) to adapt to each intervention before testing started. The use of a randomisation procedure also aids in the reduction of any carry-over effects, and therefore a randomisation procedure for the different walking conditions was adhered to using a randomisation plan, run by the trial statistician. The order of the trials was placed in sealed envelopes with participant numbers clearly written on. The trial was considered as single blind, as it was impossible for the principal investigator to be blinded to the walking conditions within the trial.

5.4.3.1 Equipment

Data was recorded using a motion capture system in the gait laboratory at the University of Salford. Sixteen infrared cameras (OQUS, Qualisys AB Sweden), Qualisys Track Manager (Qualisys AB Sweden) 3D reflective markers and four 400x600 floor integrated AMTI force plates (Advanced Mechanical Technology, Ins. USA) were utilised to capture the 3D positions of the retro reflective markers that were attached to both lower limbs of each patient's skin during walking trials (a full explanation of equipment utilised within the trial can be found in chapter 3, section, 3.2 and 3.3).

5.4.3.2 Foot Posture Assessment

The foot was statically and clinically measured using the FPI scale prior to commencing walking. The FPI score was recorded during the trial in order to assess the changes between different walking conditions, and static video picture evidence of the foot was taken to ensure foot posture assessments were accurate to determine any relationship between foot posture, ankle motion and the magnitude of the EKAM.

The magnitude of change in the EKAM in the LWI walking condition was then assessed to determine whether each individual patient was a biomechanical responder or biomechanical non-responder to LWI intervention.

5.4.4 Data Analysis

Kinematic and kinetic data was obtained for 24 patients with MTFOA. The methodology within this chapter utilised biomechanical data collection procedures in order to define the 3D motion data capture, force measurement and segment modelling and computation which are explained in detail within the methodology chapter of this thesis (chapter 3, section 3.2). Any deviation or additional materials or techniques used within this study are detailed below.

The EKAM and sagittal moment were assessed in the LWI walking condition to determine whether individual patients were biomechanical responders or non-responders to LWI. Responders were defined as those individual patients who displayed a reduction of at least 3% in their EKAM when wearing LWI (in comparison to baseline in shod) and no increase in their sagittal moment.

ImageJ image processing software, which can be used to display, edit, analyse and process images including measuring angles and distance, was utilised to verify rearfoot (calcaneus) inversion and eversion using the photographs taken by the investigator of posterior coronal plane individual limbs, whilst participants stood immobile on both legs. The angles of deviation of inversion or eversion from neutral (90º) were determined using the ImageJ angle tool, with measurements of less than 90º classified as everted, and angles of above 90º classified as inverted.

Peak EKAM and peak flexion/extension moment (sagittal moment) data, where the peak represented early stance phase of the gait cycle, were exported from Visual3D to Microsoft Excel software. Range of motion (ROM) of the rearfoot (inversion and eversion) and ankle angle data in stance phase for the three walking conditions were exported from Visual3D for all trial patients, and analysed using SPSS software.

The mean and standard deviation (SD) of each variable that was exported was calculated using Microsoft Excel software. Data was then transferred to SPSS software, where normality testing and the correlation coefficient was applied. Patients were categorised into two groups; 'responders' and 'non-responders'. A patient was defined as a biomechanical responder if they displayed at least a 3% reduction in their peak EKAM with the use of LWI intervention in comparison to their own shoe 'only' condition. Those patients who did not display at least a 3% reduction in their peak EKAM, or exhibited an increase in their peak EKAM were defined as biomechanical non-responders.

Statistical analysis, specifically normality testing was performed on the variables in order to identify the most suitable correlation coefficient test to apply. Normality testing allows the identification of normal or abnormal distribution (parametric or non-parametric) of data. For parametric data, the Pearson test was applied, and for non-parametric data, the Spearman correlation coefficient test was applied. The Shapiro-Wilks test was also applied to the data. For the differences were applied the t-test, paired T-test for all the population together was applied and unpaired t-test for the groups responder and non-responder to LWI were applied. Logistic regression was applied in the coronal plane in barefoot and shod (ankle subtalar joint) and in the clinical static measures to determine if rearfoot barefoot and ankle subtalar joint in shod and clinical foot posture can predict the response to EKAM.

5.5 Results

Twenty four patients with medial compartment knee OA participated in this study (14 males, 10 females), mean age males 64.4 (±10.2) years, mean age females 63.2 (±8.3) years, mean height males 1.73 (±0.04) metres, females 1.64 (±0.05) metres, mean male mass 84.2 (±12.9) kg, mean female mass 81.5 (±15.3) kg, mean BMI males 27.8 (±4.08) kg/m², mean BMI females 29.4 (±4.9) kg/m², mean BMI of all patients 28.5 (±4.43) kg/m².

The average walking speed for barefoot the walking condition was 1.087 (±0.172) m/s. For the shod walking condition, the average speed was 1.141 (±0.191) m/s. The average walking speed for the LWI walking condition was 1.157 (±0.171) m/s. Results indicated walking speed increased in the shod walking condition compared to barefoot by 4.73% ($p=0.006$) (mean difference 0.05 m/s). Walking speed increased in the LWI walking condition compared barefoot by 6.49% ($p<0.001$) (mean difference 0.007 m/s). Results show that walking speed increased in the LWI walking condition compared to shod by 1.44% ($p=0.203$) (mean difference 0.01 m/s).

The mean EKAM, mean rearfoot inversion and eversion and mean ROM are depicted below in table (5.3) (figures 5.1, 5.2). The mean total FPI, the rearfoot FPI, and the rearfoot ImageJ results are also depicted table (5.3).

Table 5.3 – The mean and standard deviation (SD) for all measurements for all 24 patients with medial compartment knee OA.

Measurements	**Mean**	**SD (°)**
Barefoot EKAM Nm/kg	0.451	0.183
Shod EKAM Nm/kg	0.471	0.169
LWI EKAM Nm/kg	0.461	0.186
Barefoot rearfoot eversion (°)	-4.469	3.049
Barefoot rearfoot inversion (°)	3.615	3.813
Barefoot Rearfoot ROM (°)	8.084	3.296
Shod ankle angle eversion (°)	-4.516	6.549
Shod ankle angle inversion (°)	4.079	5.559
Shod ankle angle ROM (°)	8.596	3.717
LWI ankle angle eversion (°)	-5.132	6.437
LWI ankle angle inversion (°)	4.257	6.022
LWI ankle angle ROM (°)	9.390	3.598
FPI Total	-1.041	4.786
FPI Calc In/Ev	-0.208	1.250
Rearfoot ImageJ In/Ev (°)	89.338	4.544

Mom: Moment, LWI: Lateral Ledge Insoles, ROM: Range of Motion, FPI: Foot Posture Index, SD: Standard Deviation, Calc: Calcaneus (rearfoot), In: Inversion, Ev: Eversion.

The total FPI score and rearfoot inversion and eversion results indicate that in medial compartment knee OA patients, no relationship exists between static FPI scores and the dynamic rearfoot in all 24 patients during barefoot walking. Significant negative association was identified between the EKAM and dynamic rearfoot inversion in barefoot walking *r*=-

0.559 (p=0.005). Similarly, significant negative association was found between the EKAM and ankle subtalar joint ROM *r*=0.462 (p=0.020). Therefore, an increase or decrease in ankle subtalar joint ROM may increase or reduce the EKAM. No association was identified between the EKAM and dynamic rearfoot eversion (p=0.302), (table 5.4).

Table 5.4 - The relationship between FPI, rearfoot motion and the EKAM in barefoot walking in patients with medial compartment knee OA.

Rearfoot (Barefoot)	**Correlations**	**P-Value**
FPI vs Eversion	ρ= -0.071	P= 0.741
FPI vs RF Inversion	*r*= 0.033	P= 0.901
FPI vs RF ROM	ρ= -0.027	P= 0.642
Inv/Ev Calc FPI vs Eversion	ρ= -0.141	P= 0.512
Inv/Ev Calc FPI vs Inversion	ρ= -0.136	P= 0.525
Inv/Ev Calc FPI vs ROM	ρ= -0.156	P= 0.468
Sagittal M vs ROM	ρ= -0.338	P= 0.106
EKAM vs RF Eversion	ρ= -0.220	P= 0.302
EKAM vs RF Inversion	*r*= -0.559	**P= 0.005**
EKAM vs RF ROM	*r*= -0.462	**P= 0.023**

FPI: Foot Posture Index, EKAM: External Knee Adduction Moment, ROM: Range of Motion, RF: rearfoot, Calc: Calcaneus, r: Pearson Coefficient Correlation (parametric), ρ*: Spearman Coefficient correlation (non-parametric).*

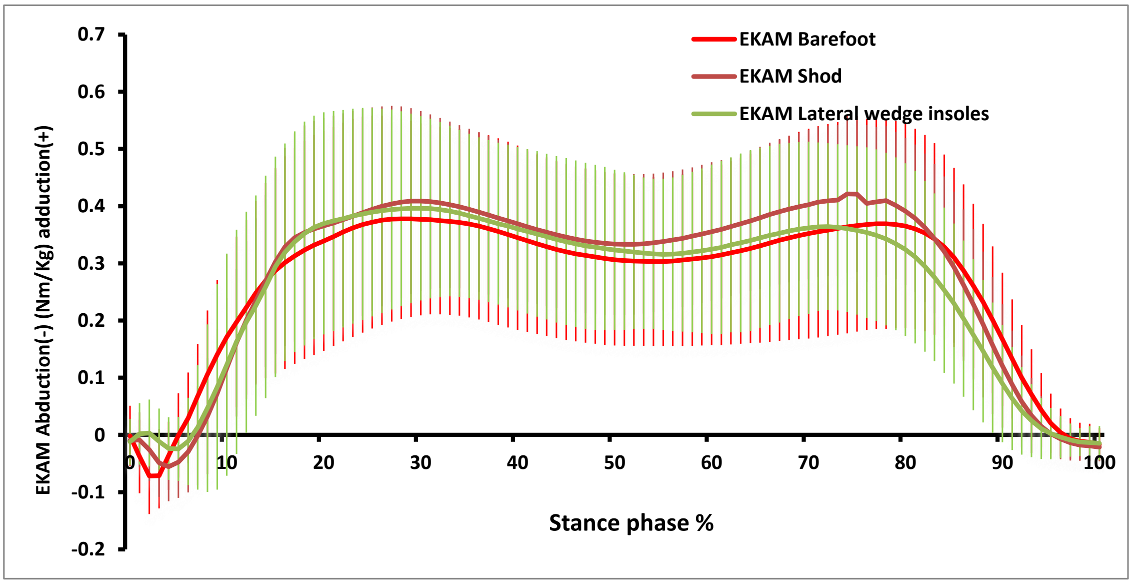


Figure 5.1 – Mean external knee adduction moment (EKAM) during walking in the frontal plane between barefoot, shod and lateral wedge insoles for 24 medial Knee OA patient limbs. Error bars represent ± 1 standard deviation for all three walking conditions.

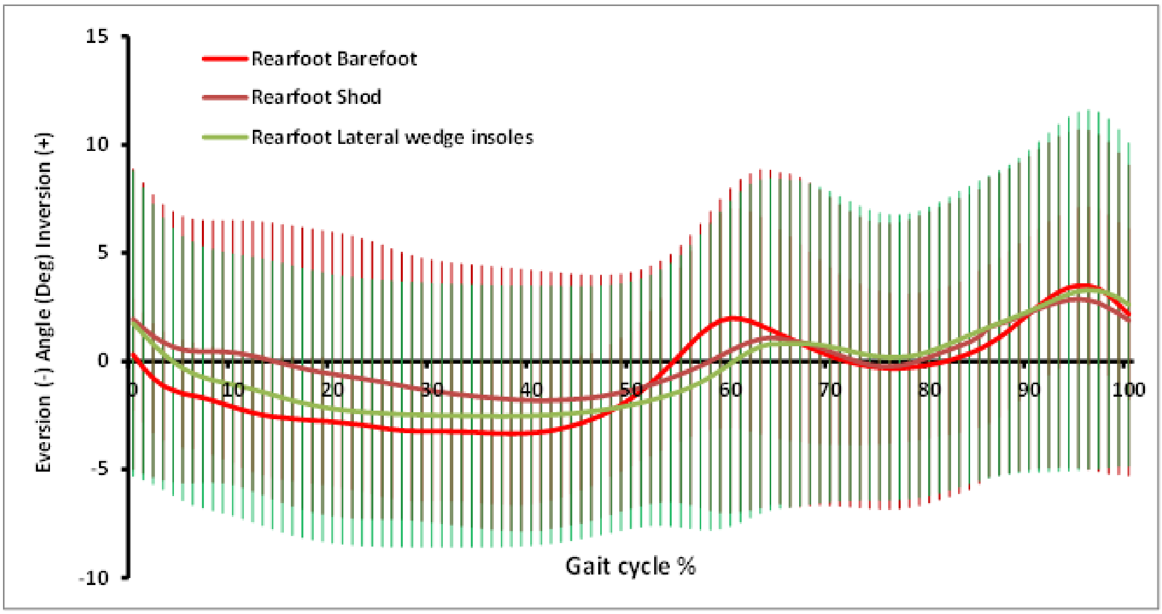


Figure 5.2 – Mean rearfoot angle motion during walking in the frontal plane in barefoot, shod and lateral wedge insoles for 24 medial knee OA patient limbs. Error bars represent ± 1 standard deviation for all three walking conditions.

When looking at the reductions in the EKAM to determine biomechanical response, results indicate that the 12 subjects would be classified as a biomechanical responder to LWI intervention had a mean age of 62.1 (±9.2) years, a mean height of 1.68 (±0.06) metres, a mean mass of 84.7 (±13.69), and a mean Body Mass Index (BMI) of 29.6 (±3.13) kg/m². The 12 subjects classified as biomechanical non-responders had a mean age of 66.2 (±10.3) years, a mean height of 1.71 (±0.06) metres, a mean mass of 80 (±14.3) kg, and a mean BMI of 27.3 (±5.3) kg/m². Mean differences between the average BMI of biomechanical responders and non-responders to LWI intervention was 2.3 kg/m², which is statistically insignificant (p=0.21). There was no difference in pain scores between the two groups. The mean VAS pain scale results for walking pain in the biomechanical responders to LWI intervention group was 5.5 (±1.6), and 5.4 (±1.7) in the biomechanical non-responders to LWI group. Pain was therefore not different between the two groups.

The average walking speed of responders and non-responders is depicted in table 5.5.

Results indicate that in the barefoot walking condition, biomechanical responders walked at a similar, albeit slightly slower speed than biomechanical non-responders (1.4% slower). In the shod walking condition, biomechanical non-responders walked at an increased speed compared to responders by 4.19%. In the LWI walking condition, biomechanical non-responders to LWI intervention increased their walking speed compared to responders by 2.67%. However, no significant differences were present within the results between biomechanical responders and biomechanical non-responders to LWI intervention.

Table 5.5 – Walking speed between biomechanical responders and non-responders to LWI intervention.

Walking Speed	Response to LWI		Non-Response		Mean Differences		
	Mean m/s^{-1}	SD (°)	Mean m/s^{-1}	SD (°)	m/s^{-1}	%	P-Value
Barefoot	1.095	0.134	1.079	0.211	-0.016	-1.444	0.839
Shod	1.117	0.148	1.166	0.231	0.049	4.196	0.544
LWI	1.142	0.100	1.174	0.225	0.031	2.670	0.664

SD: Standard Deviation, LWI: Lateral Wedge Insoles.

Mean measurements including EKAM, rearfoot inversion and eversion and rearfoot range of motion, ankle angle, eversion, inversion and range of motion for barefoot, shod and LWI walking conditions for both biomechanical responders and non-responders to LWI intervention are depicted in table 5.6.

The mean barefoot EKAM, rearfoot ImageJ inversion and eversion, the total FPI, and rearfoot FPI results are depicted in table 5.6.

No significant differences were present between biomechanical responders and non-responders within the variables, with the exception of rearfoot range of motion. More rearfoot range of motion (4.08º) 95% CI 1.88 to 6.30 was observed in biomechanical responders than in non-responders in the barefoot walking condition. Additionally, in the shod walking condition, biomechanical responders to LWI showed an increased ankle angle ROM compared to non-responders of 2.97º 95% CI 0.04 to 5.91. As expected, significant increases were identified in the peak EKAM of biomechanical non-responders compared to responders in all walking conditions (mean difference in barefoot 0.18 Nm/kg (p=0.01), mean difference in shod 0.15 Nm/kg (p=0.03), mean difference in LWI 0.21 Nm/kg (p=0.004))

Table 5.6 – The mean and standard deviation (SD) for biomechanical responders and non-responders to LWI in all 24 patients with medial compartment knee osteoarthritis.

Measurements	**Mean Response to LWI**	**SD (°)**	**Mean Non-Response To LWI**	**SD (°)**	**P-Value**
Barefoot EKAM Nm/kg	0.364	0.109	0.539	0.204	0.015
Shod EKAM Nm/kg	0.397	0.087	0.546	0.200	0.026
LWI EKAM Nm/kg	0.358	0.093	0.564	0.203	0.004
Barefoot rearfoot eversion (°)	-4.651	4.126	-4.287	1.533	0.776
Barefoot rearfoot inversion (°)	5.477	4.350	1.755	1.982	0.013
Barefoot rearfoot ROM (°)	10.128	2.793	6.042	2.413	0.000
Shod ankle angle eversion (°)	-4.227	9.141	-4.805	2.440	0.834
Shod ankle angle inversion (°)	5.856	7.068	2.304	2.789	0.119
Shod ankle angle ROM (°)	10.083	4.229	7.109	2.487	0.047
LWI ankle angle eversion (°)	-4.499	9.052	-5.766	1.960	0.640
LWI ankle angle inversion (°)	6.211	7.469	2.305	3.426	0.113
LWI ankle angle ROM (°)	10.709	3.793	8.071	2.983	0.071
Rearfoot Image J In/EV (°)	90.127	4.381	88.551	4.759	0.407
Foot posture index in total	-1.167	4.345	-0.917	5.384	
Foot Posture index Calc In/Ev	-0.417	1.165	0.000	1.348	

Mom: Moment, LWI: Lateral Ledge Insoles, ROM: Range of Motion,, SD: Standard Deviation, Calc: Calcaneus (rearfoot), In: Inversion, Ev: Eversion.

When using logistic regression to identify whether the rearfoot range of motion during barefoot walking could predict the biomechanical response or non-response to LWI intervention, the results indicated that the rearfoot range of motion can predict response to LWI intervention by 1.786. Therefore, a patient was 1.78 times more likely to respond to LWI intervention when rearfoot motion increased by 1 unit (degree). The 95% CI was between 1.148 and 2.776 ($p=0.01$). Additional measurements including the ankle angle range of motion in shod, the total FPI score, the rearfoot FPI score, Image J inversion/eversion, age, gender, and BMI indicated non-significant results, and therefore, when viewed in this limited sample, cannot be used to predict the biomechanical response and non-response of the EKAM to LWI (table 5.7).

Table 5.6 – Logistic regression (odds ratio) for biomechanical responders to LWI.

Variables	**Odds Ratio (odds of responding)**	**95% CI Lower**	**95% CI Upper**	**P-Value**
Rearfoot ROM barefoot	1.786	1.148	2.776	0.010
Ankle angle ROM shod	1.439	0.977	2.120	0.065
Total FPI	0.989	0.833	1.173	0.896
FPI rearfoot-In/Ev	0.753	0.385	1.474	0.409
ImageJ-In/Ev	1.084	0.901	1.305	0.390
Age	0.955	0.871	1.047	0.325
Gender	0.500	0.096	2.602	0.410
BMI	1.127	0.911	1.393	0.270

ROM: Range of Motion, BMI: Body Mass Index, Inv: Inversion, Ev: Eversion, FPI: Foot Posture Index, CI: Confidence Interval.

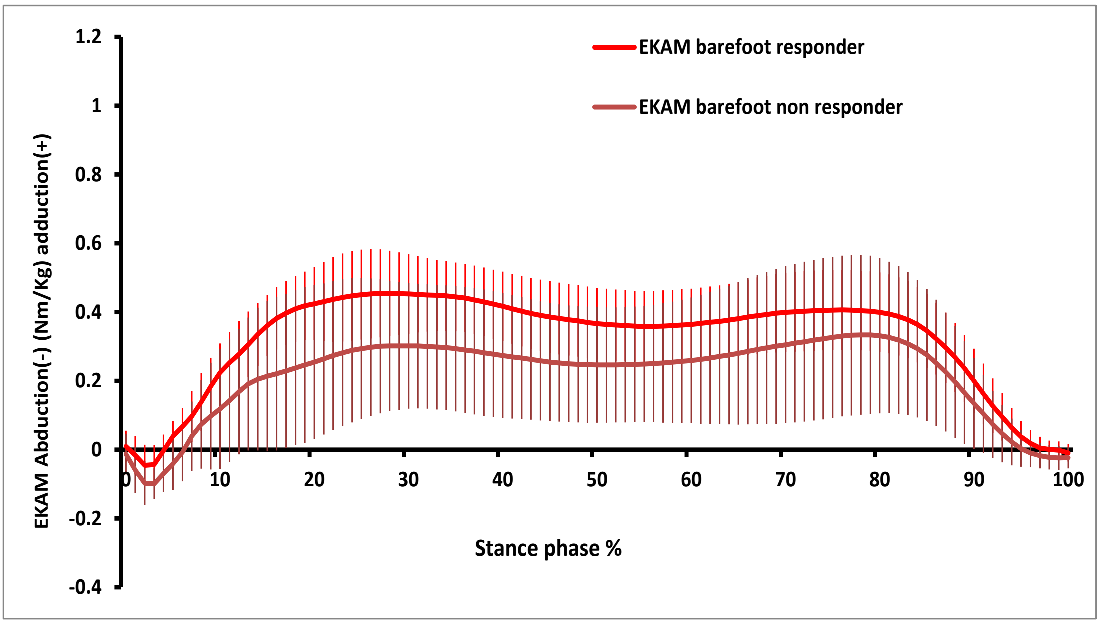


Figure 5.3 – Mean external knee adduction moment (EKAM) during barefoot walking in the frontal plane between biomechanical responders and non-responders to lateral wedge insoles in patients with medial knee OA. Error bars indicate the ±1 standard deviation.

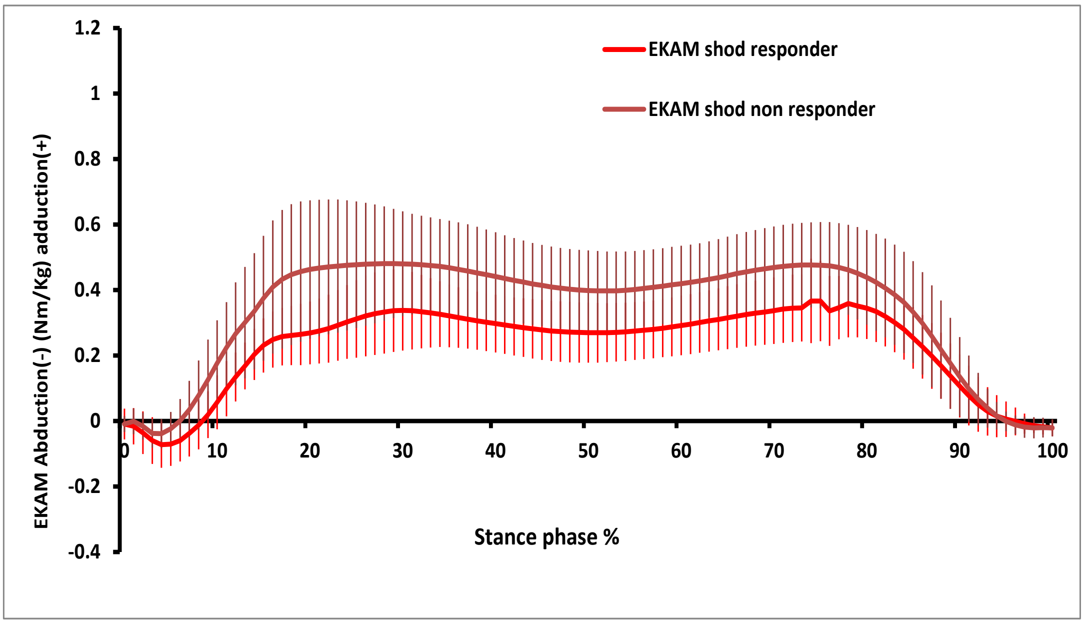


Figure 5.4 – Mean external knee adduction moment (EKAM) during shod walking in the frontal plane between biomechanical responders and non-responders to lateral wedge insoles in patients with medial knee OA. Error bars indicate the ±1 standard deviation.

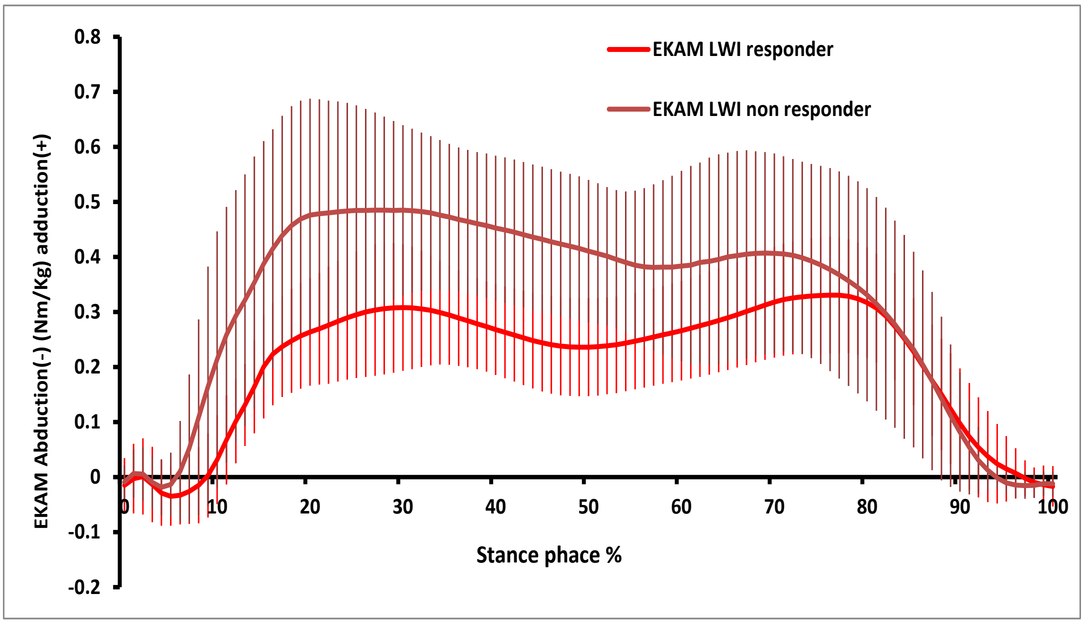


Figure 5.5 – Mean external knee adduction moment (EKAM) during lateral wedge insoles walking in the frontal plane between biomechanical responders and non-responders to lateral wedge insoles in patients with medial knee OA. Error bars indicate the ±1 standard deviation.

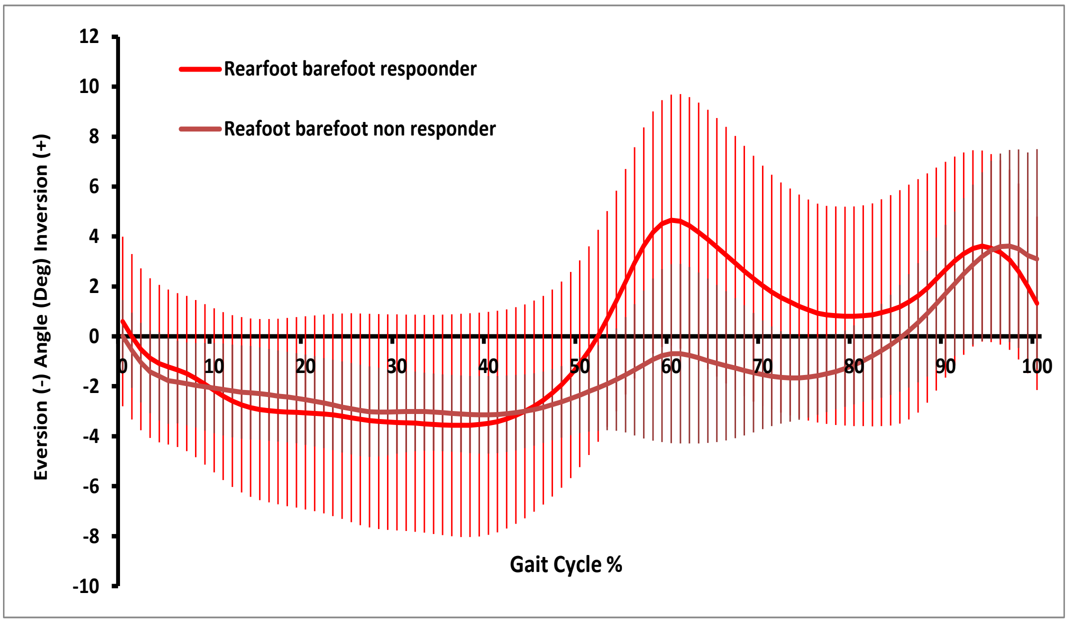


Figure 5.6 – Mean rearfoot angle motion during barefoot walking in the frontal plane between biomechanical responders and non-responders to lateral wedge insoles in patients with medial knee OA. Error bars indicate the ±1 standard deviation.

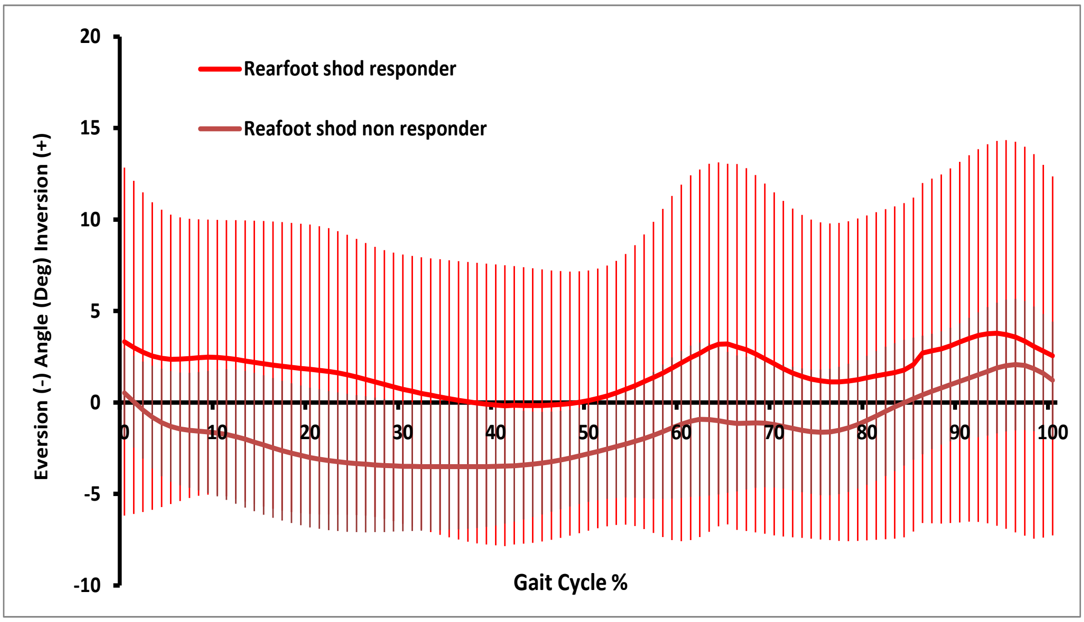


Figure 5.7 – Mean rearfoot angle motion during shod walking in the frontal plane between biomechanical responders and non-responders to lateral wedge insoles in patients with medial knee OA. Error bars indicate the ±1 standard deviation.

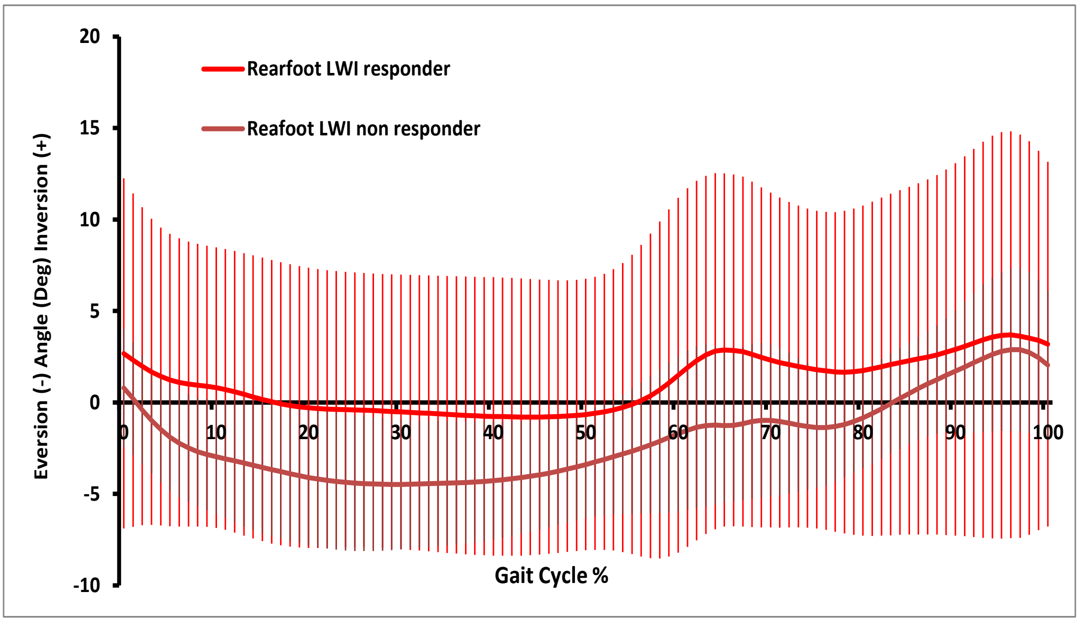


Figure 5.8 – Mean rearfoot angle motion during lateral wedge insoles walking in the frontal plane between biomechanical responders and non-responders to lateral wedge insoles in patients with medial knee OA. Error bars indicate the ±1 standard deviation.

5.6 Discussion

The aim of this investigation was to determine if a relationship exists between clinical static foot posture, barefoot rearfoot motion, and the magnitude of the EKAM. Also, whether these measures influence the effectiveness of LWI and changes in the magnitude of the EKAM in patients with medial compartment knee osteoarthritis.

After investigating 24 medial compartment knee OA patients, no significant association was identified between static foot posture and dynamic foot posture, and similarly, no association was identified between static foot posture and the magnitude of the EKAM.

The results of this investigation indicate that the FPI cannot predict the potential relationship between the FPI and the magnitude of the EKAM in patients with medial compartment knee OA, or the possible relationship between the FPI and rearfoot motion in patients with medial compartment knee OA. In agreement with the findings of this research question, Buldt *et al*., (2015) conducted an investigation into the EKAM and knee joint rotations in varying foot posture groups (classified using the Foot Posture Index) to determine the relationship between rearfoot joint rotations and the magnitude of the EKAM in 97 healthy individuals. The study reported that foot posture and foot joint rotations do not substantially influence knee joint rotations and the EKAM when healthy individuals walked at a comfortable pace. An additional comparable study, also by Buldt *et al*., (2015) investigated the associations of clinical static foot posture (quantified using the Foot Posture Index) and foot mobility with foot kinematics during barefoot walking in healthy individuals. Findings indicated that kinematics of the foot cannot be accurately determined from observations of clinical foot posture (using the Foot Posture Index) alone in healthy subjects (Buldt *et al*., 2015). The Buldt *et al*., (2015) investigations used healthy subjects however, and therefore it can be stated that in both healthy subjects and patients with medial compartment knee OA, the FPI does not represent rearfoot motion. This study demonstrates that the FPI and rearfoot FPI scores cannot be used to predict those individuals with medial compartment knee OA who will respond and will not respond to LWI intervention. This finding has not previously been reported within the literature, and therefore this study is a novel addition to the literature.

Some moderate association was found between the magnitude of the EKAM and dynamic rearfoot inversion in the barefoot walking condition within this study. Furthermore, moderate negative association was identified between EKAM and rearfoot range of motion in the barefoot walking condition. Therefore, the motion of the rearfoot may impact on the magnitude of the EKAM. Lateral wedge insoles were found to increase the eversion of the ankle subtalar joint complex and also the eversion moment, compared to the no wedge control condition. Additionally, Levinger *et al*., (2010) identified that increasing the ankle subtalar joint complex pronation moment in the frontal plane led to alterations in the kinetics and kinematics of the foot during gait, potentially leading to a decrease in the EKAM and shifting of the centre of pressure in the foot in individuals with medial compartment knee OA. This study demonstrates that LWI resulted in a lateral shift in the centre of pressure in the foot, a more everted ankle subtalar joint complex, and greater eversion moment compared to shod. Findings of this study are consistent with those reported previously within the literature (Kakihana *et al*., 2005, Kakihana *et al*., 2007, Butler *et al*., 2009, Hinman *et al*., 2012, Chapman *et al*., 2015).

Correspondingly, similar previous studies have identified association between ankle motion and the magnitude of the EKAM, presenting alike findings to this investigation. Chapman *et al*., (2015), investigated 70 patients with medial compartment knee OA, concluding that coronal plane ankle subtalar joint complex biomechanical measures influence the magnitude of the EKAM with the use of a LWI. Similar to the findings of Levinger *et al*., (2010) and Chapman *et al*., (2015), this study identified that association exists between the dynamic rearfoot and the magnitude of the EKAM in patients with medial compartment knee OA. However, the study by Chapman *et al*., (2015) only investigated the foot in shod, whereas this research question also assessed the barefoot. Findings of this investigation may therefore lead to further understanding of rearfoot and ankle subtalar joint complex motion, and their possible role in the magnitude of the EKAM and the response or non-response to LWI in patients with medial compartment knee OA.

After grouping participants into biomechanical responders and biomechanical non-responders to LWI intervention, logistic regression results indicated that the probability of being a biomechanical responder to LWI intervention increases by 1.79 times when rearfoot motion increases by 1º. Therefore, patients with a larger range of rearfoot motion are more likely to experience a reduction in their EKAM when wearing LWI, and therefore be classified as biomechanical responders to LWI.

This study investigated patients with medial compartment knee OA when walking in barefoot and shod, in order to identify patients who were most likely to respond to LWI intervention. After applying logistic regression, a significant relationship was found between barefoot range of motion, and the magnitude of the EKAM. Therefore, increase in the rearfoot range of motion can predict the changes in the magnitude of the EKAM, and consequently, biomechanical response and biomechanical non-response to LWI intervention. This finding has not previously been reported within the literature.

Findings indicate that biomechanical responders to LWI display higher amounts of rearfoot motion than biomechanical non-responders to LWI.

Butler *et al*., (2009) established that peak eversion, eversion excursion, and peak eversion moment increased, while peak EKAM decreased when participants walked with a LWI in shod compared to no wedge in shod. Butler *et al*., (2009) therefore stated that LWI lead to increased rearfoot eversion, and inversion moments. Similarly, Kakihana *et al*., (2005) stated that walking with a LWI attached to a barefoot significantly reduced the EKAM and increased the subtalar joint valgus moment when compared to the no wedge barefoot walking condition. This finding indicates that an increase in the subtalar joint ankle complex range of motion could lead to a reduction in the magnitude of the EKAM. Both the Kakihana *et al*., (2005) and the Butler *et al*., (2009) studies contained major differences compared to this investigation. Firstly, although Butler *et al*., (2009) assessed rearfoot motion, the study only quantified rearfoot motion in shod, and not in a barefoot walking condition, whereas this investigation assessed rearfoot motion in barefoot, shod and LWI walking conditions. Secondly, Kakihana *et al*., (2005) did not assess the LWI in shod, only in a barefoot walking condition, whereas this investigation assessed LWI in shod, which seems sensible, since LWI are intended for use in shod walking. Finally, this investigation divided the results into two groups; biomechanical responders and non-responders to LWI, aiming to understand the causes of the incidence of biomechanical non-response identified within the results, while both Kakihana *et al*., (2005) and Butler *et al*., (2009) studies did not.

LWI aim to reduce the EKAM, with the lateral wedge causing eversion of the rearfoot, and shifting the centre of pressure in the foot laterally (Jones *et al*., 2012, Chapman *et al*., 2015). The extent to which LWI can influence rearfoot motion may depend on the amount of range of motion available at the rearfoot. Patients with knee OA often experience reductions in frontal plane motion of the foot compared with healthy controls, and therefore a limited range of motion may impact on the effectiveness of a LWI, and thereby possibly creating an incidence of biomechanical non-response (Levinger *et al*., 2012). The available range of motion at the rearfoot may also affect patient acceptance of LWI, as a recent study by Bennell *et al*., (2011) reported that 47% of study participants rated LWI as less comfortable than the flat control insoles also used within the investigation. However, the perceived discomfort associated with the LWI may have been due to the fact that the 5º lateral wedge insole was manufactured using a high density ethyl vinyl acetate material, whereas the flat control insole was made of easily compressible, low density ethyl vinyl acetate (Bennell *et al*., (2011). Further examination of patient acceptance of LWI is therefore required, as comfort perception of interventions is important to ensure adherence to and possibly response or non-response to LWI intervention.

Findings of this study therefore indicate that patients with a less everted subtalar ankle joint complex and less rearfoot motion may display restricted frontal plane ankle range of motion. Therefore, when wearing LWI, the restricted ankle joint range of motion may prevent sufficient eversion (pronation) of the foot, and therefore the load at the knee joint remains unaltered, potentially causing the incidence of biomechanical non-response to LWI (Chapman *et al*., 2015).

Findings of this investigation have implications for the clinical evaluation of individuals with medial compartment knee OA, and also for the prescription of LWI for the conservative treatment of medial knee OA. Patients who display an increased rearfoot ROM are more likely to respond to LWI, and therefore further investigation is required. Future investigation should consider the use of clinical assessment to quantify and evaluate rearfoot motion in barefoot walking, and link clinical assessment with biomechanical analysis in order to further understand LWI and biomechanical response and non-response to LWI intervention, to ensure LWI are only prescribed to individuals who are likely to achieve a reduction in their EKAM with their use.

This study identified that compared to barefoot and shod walking conditions, walking speed increased with the use of a LWI in patients with medial compartment knee OA. Likewise, a comparable study by Jones *et al*., (2012) using medial compartment knee OA patients, also identified a significant increase in walking speed with the use of a LWI. In this study, biomechanical non-responders to LWI intervention walked at faster speeds than biomechanical responders when walking in the LWI condition by 2.67%. An increase in walking speed causes the stance phase of the gait cycle to shorten which may prevent the centre of pressure in the foot from shifting laterally, despite the presence of a LWI. Therefore, the magnitude of the EKAM is only minimally reduced. The effectiveness of LWI could therefore be increased by adopting a slower walking speed, which requires reduced levels of knee flexion and thus lower levels of shock absorption to aid the reduction of load on the medial compartment of the knee joint (Mundermann *et al*., 2004, Foroughi *et al*., 2010). Therefore, walking speed may influence the efficacy of LWI, and may have contributed to the incidence of biomechanical non-response within this study. However, no study has assessed the role of increasing walking speed and changes in the reduction of EKAM with lateral wedge insoles so this is unknown.

Body mass index scores were calculated from demographic data for individual patients within the study. The mean BMI score of the 24 medial compartment knee OA patients within this study was 28.5 kg/m^2, and therefore indicates that the study sample is in the 'overweight' category. Although similar to the mean participant BMI of previous investigations by Levinger *et al*., (2010) and Levinger *et al*., (2012) (29.9 kg/m^2 and 29.9 kg/m^2 respectively), a number of pertinent studies within the literature have considerably higher subject mean BMI scores, the highest being 33.8 kg/m^2 (Butler *et al*., 2009) which are categorised as 'obese' (Butler *et al*., 2009, Jones *et al*., 2014, Chapman *et al*., 2015, Jones *et al*., 2015). Therefore, this study demonstrates that the sample utilised is indicative of typical medial compartment knee OA individuals. Considering the incidence of biomechanical non-response present within the results, twelve participants within this study were identified as biomechanical non-responders to LWI, and 12 participants were identified as biomechanical responders to LWI. The mean BMI of the biomechanical non-responders and biomechanical responders were 27.3 kg/m^2 and 29.6 kg/m^2, respectively. The mean BMI score for non-responders to LWI intervention was therefore noticeably lower than both the mean BMI score for biomechanical responders within the study, and also the mean BMI scores of participants within similar previous studies (Butler *et al*., 2009, Jones *et al*., 2014, Chapman *et al*., 2015, Jones *et al*., 2015).

The additional analysis was conducted to identify if any further measures existed which could possibly be used to predict biomechanical response to LWI intervention. However, no differences in findings were identified between BMI, age and gender. Therefore, BMI, gender and age cannot predict response and non-response to LWI intervention.

As is the case with the majority of research, limitations existed within this study. It is important to consider that patients used their own shoes for both the shod and the LWI walking condition. Therefore, footwear may play a role on foot motion, and also peak EKAM response to walking conditions and LWI intervention. Recent literature by Lewinson *et al*., (2016) does infer that the control condition should be subjects own shoe so this does mitigate this limitation somewhat. However, further investigations are required to determine how differing footwear types (including rigid supportive and soft) may influence biomechanical response to LWI.

The sample size for the two groups was relatively small and thus increasing the sample size within this study may lead to further understanding of response and non-response to LWI intervention and help to give definitive information.

This investigation assessed the immediate effect of LWI on the magnitude of the EKAM, and did not take into account the possible alteration in the reduction of the EKAM when wearing LWI over a longer period of time. Previous investigations by Haim *et al*., (2012) and Shakoor *et al*., (2013) have evaluated the effect of long term wearing of specialist footwear, concluding that participants exhibited reduced peak EKAM even when they were not wearing the devices after using individually prescribed specialist footwear for six months. Patients with medial compartment knee OA therefore may experience neuromuscular adaptations to knee OA treatment strategies (Chapman *et al*., 2015). Further research into the long term effects of LWI is therefore essential.

Whilst foot and ankle motion were not analysed within this aspect of the study, it must be acknowledged that the foot together with the shoe were viewed as a rigid body within this study and also in the study by Chapman *et al*., (2015). Therefore, foot motion which may take place within the shoe could have possibly been underestimated or estimated. Future investigations with the use of a multi-segment foot model are warranted, which would allow the separate investigation of areas of the foot, for example the rearfoot which will ensure that the construct of the shoe remains intact but the information on the actual rearfoot can be examined. Therefore future research questions which follow will aim to gain further understanding into rearfoot motion in shod and with LWI intervention using a novel marker set.

5.7 Conclusion

In conclusion, this investigation demonstrated that a relationship exists between the dynamic rearfoot and the external knee adduction moment in patients with medial compartment knee osteoarthritis, and also that the rearfoot range of motion in the coronal plane plays an important role in the biomechanical response and non-response to lateral wedge insoles. An increase in the range of motion at the rearfoot may predict the response to lateral wedge insole intervention. These findings have important clinical implications, and allow the prediction of an individuals' biomechanical response (an increase or decrease in the external knee adduction moment) to the wearing of lateral wedge insoles. Therefore, allowing the targeting of lateral wedge insoles to medial compartment knee OA patients that will benefit from their use. Future investigations should aim to establish a clinical assessment which allows the evaluation of the range of motion of the foot and ankle subtalar joint complex in barefoot walking, as expensive, time consuming, and complex 3D motion analysis systems which are currently required to identify changes in foot kinematics are not available in all organisations.

This investigation viewed the foot in shod walking conditions as rigid bodies. However, within this investigation, it was not possible to quantify rearfoot motion in shod. Further investigation is therefore needed and will be conducted in the following chapter, utilising a heel pin cluster marker, to quantify rearfoot motion in shod, and in shod with a LWI inserted. Furthermore, this chapter has indentified the differences in walking speed between biomechanical responders and biomechanical non-responders to LWI intervention. In this investigation, biomechanical non-responders walked at higher speeds than biomechanical responders to LWI intervention. Therefore, further investigations into walking speed will be conducted on healthy subjects to identify whether walking speed can influence the efficacy of LWI.

Therefore, the following chapter will consist of investigations using a heel pin cluster marker to quantify rearfoot motion in barefoot and shod walking conditions, an investigation to identify whether differences are present between rearfoot motion in shod, and in shod with a LWI to gain further understanding of the effects of a LWI on the rearfoot, and finally an investigation to establish if increased walking speed influences the biomechanical response to LWI.

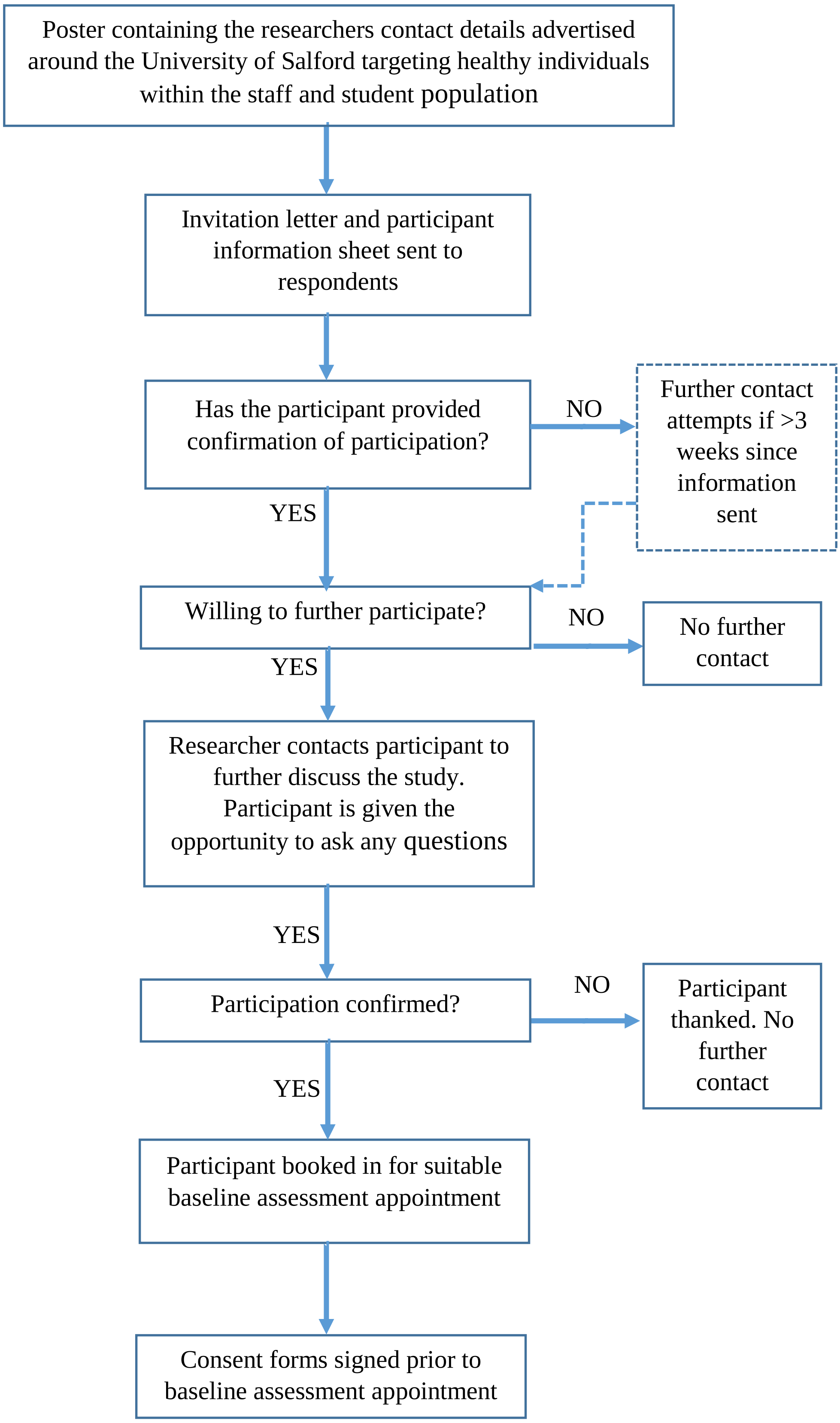
Chapter Six

In the preceding chapter, rearfoot motion was acknowledged as a possible influence on the biomechanical response and non-response to LWI. It was concluded therefore, that further investigation into motion of the rearfoot is required to increase the understanding of this motion, and provide some insight into why some individuals do not experience a reduction in their EKAM with the use of LWI. However, the collection of rearfoot motion in-shoe is challenging, and therefore methods to understand this are needed in order to examine the influence of lateral wedge insoles during gait.

This chapter aims to investigate and examine three primary research questions; 1) what are the kinematic differences between two different approaches to capturing rearfoot motion (a heel cup cluster and heel pin cluster marker set) to evaluate rearfoot motion in 3 orthogonal planes (sagittal, coronal, and transverse) during both barefoot and shod walking. The heel pin cluster was assessed between barefoot and shod (in shoe) to determine the effect of shoes on rearfoot motion, and whether barefoot walking represented shod walking in healthy subjects. Secondly, this approach was then used to examine the second research question 2) what is the effect of lateral wedge insoles on rearfoot motion and EKAM. Thirdly, it is common in studies assessing lateral wedge insoles with medial compartment OA participants that speed is increased, but it is unknown what happens to the biomechanical response when individuals have a change in speed. Therefore, the third research question 3) what is the effect of a change of speed on the biomechanical response with lateral wedge insoles.

These three research questions are all novel in nature and offer an insight into rearfoot motion and orthotic management.

Participant Recruitment Process for the 15 Healthy Participants in Investigations within Thesis Chapter 6



6.1 Research Question 1: Does the heel pin cluster represent the heel cup cluster when used to quantify rearfoot motion, and do differences exist between barefoot rearfoot motion in barefoot and shod.

6.1.1 Introduction

Rearfoot motion can be described as, 'the natural sequential pattern of pronation and supination during the stance phase of gait' (McGinnis, 1999, McGinnis, 2013) at the calcaneus and subtalar/ankle joint, and is an important component of the gait cycle (Winkelmeyer *et al*., 2006). Rearfoot motion is commonly quantified in the frontal (coronal) plane of motion for clinical and research purposes, and is 'the angle between the foot segment and the lower leg (shank) segment' (Winkelmeyer *et al*., 2006). Foot mobility is vital in absorbing the GRF of the body (Cavanagh, 1990, Wernick and Volpe, 1996), and therefore subtalar pronation during the gait cycle aids in shock absorption during initial heel contact, and the adaptation of the foot and lower limbs to varying surfaces. Additionally, pronation allows rotation and the absorption of this rotation in the lower limbs (Cavanagh, 1990, Wernick and Volpe, 1996). Subtalar pronation leads to eccentric control of the supinators, and aids in the weight bearing capacity of the foot, allowing it to perform as a stable lever to propel the body forwards during the gait cycle (Cavanagh, 1990, Wernick and Volpe, 1996).

Motions of the foot associated with pronation include; dorsiflexion (of the talocrucal joint), eversion (of the calcaneus), and abduction (of the forefoot) (Winkelmeyer *et al*., 2006). The rearfoot plays an important role in the reduction of the EKAM during the early stance phase of gait due to the role of the ankle subtalar joint complex in the mechanical mechanisms of medial knee loading (Chapman *et al*., 2015). Hinman *et al*., (2012) identified that a lateral shift in the centre of foot pressure caused the ground reaction force (GRF) to move towards the centre of the knee, reducing the ground reaction force (GRF) distance and the EKAM. Furthermore, the use of a LWI intervention causes a lateral shift in the centre of force pressure, which causes an increase in the ankle eversion moment, and shortening of the knee GRF lever arm, therefore reducing the EKAM (Kakihana *et al*., 2005, Kakihana *et al*. 2007, Barrios *et al*., 2009, Butler *et al*., 2009, Jones *et al*., 2013, Chapman *et al*., 2015). The EKAM has been found to be linked to both the progression and severity of medial compartment knee osteoarthritis (Jones *et al*., 2012, Chapman *et al*., 2015).

Foot motion has the potential to compensate for proximal malalignments for example varus and valgus due to triplantar axes of motion of the subtalar and midtarsal joints (Michaud, 1993, Riegger-Krugh and Keysor, 1996, Levinger *et al*., 2012). It is therefore fundamental that a complete and accurate understanding of foot motion both in shod and barefoot is gained in order to address any effects foot posture may have on the lower limbs (Levinger *et al*., 2012).

Various methods of measuring rearfoot motion have been utilised within the literature for both barefoot and in shod footwear conditions, such as the use of intra-cortical bone pins fixed into the bones of the foot, which have been reported as the most accurate method available in order to determine rearfoot motion (Westblad *et al*., 2002, Shultz and Jenkyn, 2012, Jones *et al*., 2012). The use of the bone anchored markers accurately quantifies skeletal motion, and aims to overcome inaccuracies identified within experiments reported within the literature, such as movement of the foot within the shoe with the use of other techniques such as shoe mounted markers, and skin motion occurring between markers and underlying bone when using markers attached to the skin of the foot (Reinschmidt *et al*., 1992, Reinschmidt *et al*., 1997, Sinclair *et al*., 2013). However, the use of bone anchored markers has been considered too invasive and therefore application of this technique is limited (Sinclair *et al*., 2013), consequently improved non-invasive methods of quantifying rearfoot motion are still required and this warrants further investigation.

The most commonly adopted non-invasive technique of determining rearfoot motion makes use of reflective markers fixed directly on to the skin of the foot and lower limbs (in barefoot conditions) and fixed on to the skin through windows cut out into the footwear (in shod conditions) (Sinclair, 2014, Bishop *et al*., 2015).

Previous research has also investigated the placement of reflective markers upon the surface of the shoe, directly over the site of bony landmarks assuming the shoe to be a rigid body (Sinclair *et al*., 2013). A study conducted by Sinclair *et al*., (2014) investigated whether 3D reflective markers attached to the skin in order to represent the movement of the foot using a three segment foot model (midfoot-calcaneus, forefoot-midfoot and forefoot-calcaneus articulations) provide differing foot kinematics when compared with reflective 3D markers attached to the surface of the shoe. Results indicated that shoe mounted markers do not accurately represent foot motion within the shoe due to the limited space and high possibility that interaction between the heel and the shoe takes place during gait. Various parameters of rearfoot motion (eversion ROM, peak eversion, peak transverse plane ROM, velocity of external rotation and peak eversion velocity) in shod were concluded as being significantly underestimated with the use of shoe mounted markers, compared to results using holes (windows) cut into the shoe with markers attached to the skin. Therefore, it can be stated that kinematics of the foot derived from the use of shoe mounted markers do not accurately capture, and therefore consequently do not represent the true motion of the underlying skeletal frame (Stacoff *et al*., 1991, Stacoff *et al*., 2000, Bishop *et al*., 2012, Bishop *et al*., 2013, Sinclair *et al*., 2014). However, within the investigations by Sinclair *et al*., (2013) and Sinclair *et al*., (2014), rearfoot kinematics were captured using markers placed externally on the shoe and on the skin through windows cut in the shoe simultaneously, whilst participants walked in shod. Therefore, rearfoot motion in shod walking compared to barefoot walking and the effect of the shoe on rearfoot motion remains unclear

Skin movement artefact could easily affect these inaccuracies further (Sinclair *et al*., 2014). A similar study by Stacoff *et al*., (2001) used shoe mounted markers to represent heel motion and concluded that heel motion was not accurately represented by shoe mounted markers. The study also recommended attaching markers directly to the skin in order to obtain more accurate representations of rearfoot kinematics (Stacoff *et al*., 1991). Recent research has therefore increasingly criticised the efficacy of shoe mounted reflective markers for the use of obtaining rearfoot motion data (Stacoff *et al*., 1991, Stacoff *et al*., 2000, Shultz and Jenkyn, 2012, Sinclair *et al*., 2013, Bishop *et al*., 2013, Sinclair *et al*., 2014) and research has led to the foot in the shoe no longer being viewed as a rigid body (Sinclair *et al*., 2013). There is a need therefore, to discover whether the method of attaching reflective markers to the skin through windows in the shoes in order to obtain rearfoot motion data in shod is accurate when compared to barefoot conditions, which has not been previously addressed within the literature. Concern has been highlighted in recent research about the possible impacts of the type of shoe used when assessing rearfoot motion in shod, as foot kinematics may vary depending on varying shoe types (Shultz and Jenkyn, 2012).

A study by Morio *et al*., (2009) concluded that wearing of footwear (specifically open sandals) constrains natural barefoot motion during walking and running, and can even impose a specific foot motion pattern on the feet, therefore affecting rearfoot motion and potentially leading to lower limb pathologies. The study also discovered, similar to previous research that the stiffer the shoe structure, the more the natural motion of the foot was modified (Stacoff *et al*., 1991, Freychat *et al*., 1996, Morio *et al*., 2009). Therefore, data collected during barefoot walking does not represent shod walking, and the use of a heel pin cluster marker may allow an insight into rearfoot motion in shod, and also the effect of differing shoe types on rearfoot motion.

Concerns have also been highlighted regarding the effects that cutting holes in the footwear may have on the integrity of the shoe structure. Therefore, rearfoot motion within the shoe (Shultz and Jenkyn, 2012, Bishop *et al*., 2015) becomes more difficult to measure whether or not the shoe is functioning as it would in its pre-modification state (Bishop *et al*., 2015). A study by Shultz and Jenkyn, (2012) investigated the maximum diameter of a window that could be cut into three different shoe uppers without significantly compromising the shoes structural integrity or altering the kinematics of the foot within the shoe during walking. Holes made in footwear when investigating rearfoot motion must be large enough to avoid interfering with markers during gait, but small enough to retain the shoes structural integrity (Shultz and Jenkyn, 2012). Previous investigations by Johanson *et al*., (1994) and Butler *et al*., (2007) similarly concluded that applying markers to the skin of the foot, rather than the shoe could be more accurate than markers attached to the external surface of shoes. However, Johanson *et al*., (1994) completely removed the back of the shoe in order to measure rearfoot motion, which could potentially affect rearfoot motion by altering the structure of the shoe, and Butler *et al*., (2007) found a 10% reduction in the shoes stability after cutting two holes into the heel counter, and therefore take should be taken when modifying footwear for the purposes of quantifying rearfoot motion in shod.

Several additional studies have also used holes made in shoes, however little or no validation of the shoes structural integrity was conducted after making the holes in order to place markers on the skin (Clarke *et al*., 1983, Stacoff *et al*., 1991, Stacoff *et al*., 1992, Reinschmidt *et al*., 1992, Nawoczenski *et al*., 1995, Butler *et al*., 2007, Eslami *et al*., 2007 Shultz and Jenkyn, 2012). No method to systematically assess changes in structural integrity as a result of shoe modification currently exists within the literature (Bishop *et al*., 2015).

After using heel pin cluster and heel cup cluster marker sets to assess rearfoot motion, it was concluded that the shoe hole size should not affect shoes structural integrity in a study by Shultz and Jenkyn (2012). Therefore, a maximum shoe hole size of 2.7 cm x 2.3 cm should be used in future studies utilising cluster markers in order to determine representative rearfoot motion in shod (Shultz and Jenkyn, 2012). It is worth noting however that the study by Shultz and Jenkyn (2012) which investigated the maximum diameter for holes in shoes without compromising shoe integrity and consequently possibly influencing rearfoot motion, used a multi segment foot model, and five holes were made in each shoe utilised within the trials to allow the insertion of pin cluster markers. Therefore, the number of holes made within the shoe, in addition to the size of the holes on the shoe may have affected the structure of the shoe, and led to changes in rearfoot motion. Perhaps therefore, a slightly larger diameter of a single hole made in a shoe on the lateral aspect of the calcaneus in order to quantify rearfoot motion using a heel pin cluster would lead to a lesser effect on rearfoot motion and shoe integrity.

Furthermore, Shultz and Jenkyn (2012) speculated that the shoe aperture size limit may depend on both the design and brand of the shoe. Since the study by Shultz and Jenkyn (2012) utilised three differing training type shoes with soft material mesh uppers (Saucony Grid), perhaps a shoe type constructed using a stiffer upper material, such as leather would allow a slightly larger aperture diameter to be made in the shoe, without compromising shoe integrity.

A number of trials have used heel cups with clusters of reflective markers attached to them in order to determine barefoot rearfoot motion, with the heel cup usually attached directly to the skin (Findlow *et al*., 2011, Nester *et al*., 2014). Utilising a heel cup cluster marker to obtain rearfoot motion data has been used as a reliable method in previous research (Findlow *et al*., 2011, Nester *et al*., 2014), however a heel cup cluster marker is not possible within shod, and therefore a heel pin cluster marker may be more ideal. Therefore, heel pin cluster markers (three rigid steel pins with a reflective marker glued to each pin, attached to a plastic screw bolt with a fourth marker fixed to the top of the plastic bolt) (figure 6.1) are ideal for this task. Heel pin cluster markers only require a small aperture in the shoe in order to be attached to the heel skin, independent of the shoe, and can be used for both barefoot and shod trials.

Theoretically, the pin cluster marker can be attached to the medial, posterior, or the lateral side of the heel. The medial side attached pin cluster marker often has an interference with the contralateral foot, and the posterior attached pin marker cluster involving an aperture on the seam of the medial and lateral heel quarter may damage the integrity of the shoe body, also the vertical position can be a problem. When the pin cluster is attached too high, it is the top skin surface of the achilles tendon and not stable. When the pin cluster is attached to the lower part of the heel, the long pin strut and cluster can hit the floor during heel strike due to the landing angle of the foot and make the individual aware of this so their gait may alter. Therefore, the lateral pin marker cluster placement becomes an obvious good option to track the heel movement within the shoe. It is not known however, whether the heel pin cluster, which only attaches to the lateral aspect of the calcaneus can accurately represent rearfoot motion as adequately as the heel cup cluster, which surrounds the heel from the medial to lateral aspect does, needs to be investigated to determine its usefulness in future studies.

The differences between heel cup cluster markers and heel pin cluster markers when determining rearfoot motion in barefoot walking have not been previously addressed within the literature. Therefore, the first aim of the study was to examine the differences between the kinematic results from heel cup cluster and heel pin cluster markers during barefoot walking.

Furthermore, the heel pin cluster was assessed between barefoot and shod walking to determine the effect of shoes on rearfoot motion, and whether the barefoot heel pin cluster rearfoot motion represented shod heel pin cluster rearfoot motion in healthy subjects.

6.1.2 The statistical hypotheses for this study

- There is no significant difference present between the heel cup cluster marker and the heel pin cluster marker when used to evaluate rearfoot motion in healthy subjects in barefoot and shod walking conditions.
- There is no significant difference between the heel pin cluster marker in barefoot and the heel pin cluster marker in shod.

6.1.3 Methods

6.1.3.1 Participants

After approval from the Research, Innovation and Academic Engagement Ethical Approval Panel at The University of Salford (ethical approval number – HSCR13/42), fifteen healthy participants (7 males, 8 females) were recruited from within the staff and student population at The University of Salford to take part in the experiment. Mean and standard deviation participant demographics are depicted in table 6.1. Participants for all research questions contained within this chapter are the same, and therefore they will only be presented here. Participants were required to be free from lower limb injuries for a period of at least six months prior to testing (injury was defined as any musculoskeletal complaint that prevented the participant from undertaking their normal exercise or daily routine), with no history of lower limb surgeries or deformities. Prior to the commencement of testing, the study was explained in full to each participant. Each participant was then required to read and sign a written informed consent statement and individual demographic information (date of birth, height, mass and shoe size) for each participant was recorded. Table 6.1 summarises the mean and standard deviation (STD) demographic characteristics of all fifteen participants.

Table 6.1: Demographic measurements and standard deviation (SD) for all participants for all studies in this chapter.

Gender	*Males (N=7)*	*Females (N=8)*
Age (years) ± (SD)	*34.43 ± (7.16)*	*36.25 ± (13.29)*
Height (m) ± (SD)	*1.75 ± (0.07)*	*1.64 ± (0.05)*
Mass (kg) ± (SD)	*88.57 ± (13.16)*	*69.38 ± (12.55)*

Table 6.2: Inclusion and exclusion criteria

Inclusion Criteria	Exclusion Criteria
Good general condition of health, aged 18 years or over and able to walk without aids or assistance.	Experience or evidence of lower limb injuries (including bone fracture and ligament injury to the hip, knee, ankle and foot) within the six months prior to testing.
No previous surgeries on the lower limbs (for example total knee arthroplasty or unicompartmental knee arthroplasty).	Has disabilities or lower limb deformities which influence normal gait.
Has no known history of osteoarthritis or other bone diseases (for example osteoporosis).	Does not agree to the study conditions or protocol, and does not give consent.

6.1.4 Data Collection

6.1.4.1 Equipment Set up

Testing was carried out in the clinical gait laboratory at The University of Salford. The kinematic and kinetic data were collected using a Qualisys system (16 OQUS infrared cameras at 100Hz, Qualysis AB, Sweden) and the four integrated 4 BP400600 AMTI force plates (Advanced Mechanical Technology, Ins. USA) at 1000Hz. A seven-segment lower limb model was chosen for the study, where all segments, including the pelvis were tracked with a rigid marker cluster with 4 retro reflective markers attached to reduce the skin movement artefact. Four anatomical markers, which are Anterior Superior Iliac Spine (ASIS) and Posterior Anterior Superior Iliac Spine (PSIS) of both sides, were used to define the pelvis model, the markers placed on the medial/lateral femur epicondyle, malleolus were used to establish the thigh and shank model, markers on the malleolus and on the head of the 1st and 5th metatarsal were used to define the segment foot model. The rearfoot was tracked using a heel cup cluster marker (figure 6.2, 6.3) (consisting of three reflective markers) and the heel pin cluster (figure 6.1) marker set in barefoot, and in shod, rearfoot motion was tracked using three markers attached to a heel pin cluster marker. The heel pin cluster has a total of four markers attached to it, however only three reflective markers were analysed so that the same number of markers were evaluated for both the heel cup cluster and the heel pin cluster. Both the movement trajectory of the retro reflective markers attached to each selected segment and the synchronised ground reaction force were captured simultaneously.

6.1.4.2 Trial Procedure for Barefoot and for Shod

Based on the gait test protocol, each subject, wearing all reflective markers was requested to walk in the gait lab at his own natural walking speed back and forth along a marked out passage until five good trials were achieved. Walking trials were firstly carried out barefoot with the heel pin cluster and heel cup cluster marker to quantify the differences between both devices. Secondly, walking trials were conducted in the shod condition using the heel pin cluster to compare rearfoot motion in barefoot and shod.

The standard, size appropriate footwear (Ecco, Zen) used in the shod condition was provided for each participant. Walking trials were considered to be successful (good) if no tracking markers dropped, and the foot was placed completely on the force platform during stance phase.

6.1.4.3 Heel Pin Cluster Markers – Barefoot Examination

The four-marker heel pin cluster used within this study to track and quantify the calcaneus segment was mounted on to the lateral side of the calcaneus (figure 6.1). As explained previously, three markers of the four were utilised. Due to the limited space, the heel cup cluster and the pin cluster shared a small area on the lateral side of the calcaneus bone. In order to avoid any interference between the two clusters, a small aperture (measuring 1cm in diameter) large enough to allow the pin and base to go through and move with the heel bone independently was made on the lateral aspect of the heel cup. Three of the four markers of the heel pin cluster were fixed on three rigid steel pins that were inserted and glued in a plastic screw bolt and the fourth marker was fixed to the head of the top of the plastic bolt (figure 6.1) (figure 6.2) (figure 6.3). Each cluster was attached to the heel skin with the double sided tape (figure 6.2) (figure 6.3) representing the calcaneus (rearfoot segment) independently with the local coordinate system aligned with the local coordinate system of the foot.

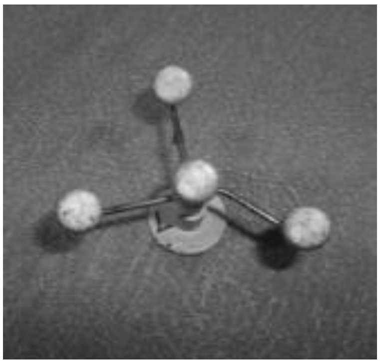


Fig 6.1: Heel Pin Cluster

Fig 6.2: Heel Cup Cluster (lateral)

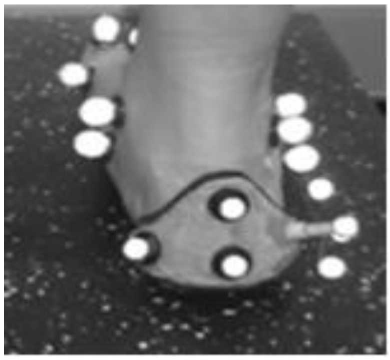


Fig 6.3: Heel Cup Cluster (Posterior)

6.1.4.4 Heel Pin Cluster Markers – Shod Examination

The heel pin cluster marker used within this study represented the calcaneus segment using a four marker cluster attached to the lateral aspect of the calcaneus with a 2.5 cm x 2.5 cm aperture made in the lateral aspect of the shoes (Ecco. Zen) allowing attachment to the skin using double sided tape (figure 6.4). The size of the aperture allowed for the heel pin cluster to easily pass through, whilst remaining as close as possible to the maximum dimensions of 2.7 cm x 2.3 cm which had no effect on rearfoot motion and training shoe function as stated in an investigation by Shultz and Jenkyn (2012).

The skin attachment base as suggested by Schultz and Jenkyn (2012), Majumdar *et al*., (2013), Sinclair *et al*., (2014) and Bishop *et al*., (2015) allowed ease when wearing shoes for study subjects and is therefore easily transferable to a shod walking condition.

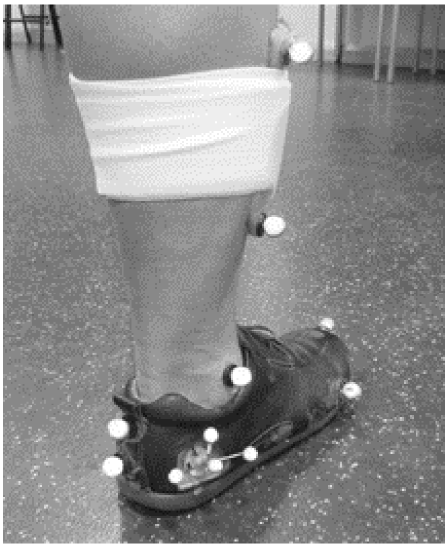


Fig. 6.4 - The heel pin cluster marker in the shod walking condition.

The heel pin cluster was removed from the rearfoot after barefoot data collection was carried out by unscrewing the heel pin cluster marker from the skin attachment base, to ensure participants could easily place shoes on their feet. The skin attachment base was left on the skin to ensure minimal error was present in the results, which could affect the reliability of the heel pin cluster marker, as removal of the skin attachment base would mean replacing it in an identical position and location would be difficult. Care was therefore taken to ensure the skin attachment base remained attached, and consequently the investigator placed taped over the base to add increased stability whilst the participant was putting on the shoes. Participants placed their feet in shoes, with the aid of the investigator to ensure the position of heel pin cluster marker skin attachment based was not altered. The heel pin cluster was then screwed back into the skin attachment base through the aperture made in the lateral aspect of the shoe (figure 6.4). Markings made on the skin attachment base and the heel pin cluster marker allowed the investigator to ensure the heel pin cluster marker was screwed into the same position in shod as it was in barefoot, to ensure minimal error was present in the results.

6.1.5 Data Analysis

Kinematic data was obtained for all 15 participants. Following data collection, all joint kinetic data was processed using Qualysis Track Manager software where each marker was labelled and digitised, and any anomalies in movements in marker trajectories were corrected. The kinematic data collected and digitised with Qualisys were exported directly to Visual3D software (version 4.91, C-Motion Inc, USA). The raw marker tracking data were filtered with a Butterworth 4th order bi-directional low pass filter; the cut-off frequency was 6Hz. Using the similar method, the analogue data were filtered with a cut-off frequency of 25Hz. Dynamic skeletal graphics created in V3D controlled by subject kinematics were used to assist with the interpretation of results (Buczek *et al*., 2010).

The lower limbs were treated as seven segments modelled as rigid bodies, which were; the pelvis, left and right thighs, shanks and feet. A right-handed local coordinate system of each segment was defined by landmarks placed on the anatomical points. The CODA pelvis model was used, which was defined using the anatomical locations of the ASIS (Anterior Superior Iliac Spine) and the PSIS (Posterior Superior Iliac Spine). The motion was tracked by the four markers on a rigid plastic plate fixed with an elastic belt to the back of the pelvis. Each segment was treated as a free rigid body with six degrees of freedom. The joint kinematics were calculated using an X–Y–Z Cardan sequence. The external joint moment data were calculated using three-dimensional inverse dynamics and normalised to body mass (Nm/kg).

The model is referred to as a six degree of freedom (DOF) model due to having six variables that describe its position and orientation in 3-D space (3 variables describe segment translation in three perpendicular axes, and 3 variables describe the rotation about each axis of the segment). Individual subjects anthropometric measurements (height and body mass) were entered into the software in order to calculate kinetics. Pelvis, thigh, shank and foot segments were then modelled by determining the proximal and distal joint radius and the tracking markers.

In terms of the modelling, the heel was defined using the tibia as a virtual segment for proximal and distal markers and was tracked using both the heel pin cluster marker and the heel cup cluster marker. The angular movement of the heel relative to the tibia segment in a gait cycle were calculated when it was tracked with two different marker clusters set in Visual 3D.

Automatic gait event definition was utilised in all trials, which captured data when the vertical GRF exceeded 20 Newtons (N) in value. The gait cycle was defined as the movement and events from heel strike of the foot on the force platform, to the subsequent heel strike of the same foot. Stance phase was defined as heel strike of the foot to the subsequent toe-off of the same foot. Each gait parameter of interest was then exported from V3D to Microsoft Excel 2010 (Microsoft Washington, USA).

Maximum and minimum angles were calculated in three planes, which were sagittal (dorsiflexion and plantarflexion), coronal (inversion/eversion), and transverse (abduction/adduction) was analysed relative to the tibia, and were exported for further statistical analysis.

Data for all variables in the chapter were reviewed before analysis to determine if distribution was normally (parametric) or non-normally distributed (non-parametric) in order to perform statistical analysis. The majority of the data were normally distributed. The Shapiro-Wilks test was used for the 15 healthy subjects. Parametric tests were conducted within this chapter and included the mean, standard deviation and paired t-tests. Non-parametric tests utilised within the study included the median, range and the Wilcoxon Signed-Rank test, carried out using SPSS software.

Statistical analysis was carried out on the data obtained during the stance phase of the gait cycle, after the rearfoot was tracked by both the heel cup cluster marker and the heel pin cluster marker, and the differences between the kinematic results of the two clusters were statistically assessed in barefoot and shod. The differences between the heel pin cluster in barefoot and in shod waking conditions was also statistically assessed. A 95% confidence interval (CI) was applied to the data and is depicted within graphs representing the gait cycle within the results.

For the barefoot walking condition only, the differences during stance phase were analysed to determine the error between the heel segment, tracked using the heel cup cluster and the heel pin cluster markers during barefoot walking. Root mean squared deviation (RMSD) was calculated to determine the error magnitude between the two motion tracking methods. The RMSD is a frequently used quantitative measurement of the mean difference between two values or variables (the heel cup cluster and the heel pin cluster markers), and represents the standard deviation of the differences between predicted and observed values. The RMSD allows the collective of the magnitude of the errors in predictions between two variables into a single measure, and in this instance was used to compare the differences between two values that vary, however neither is accepted as standard. The RMSD is a good measure of accuracy, however only serves to compare forecasting errors of different measures of variable, and not the error present between the variables. The RMSD is the square root of the mean square error, or the square root of variance, known as the standard deviation. The RMSD was calculated using the following equation:

$$\mathrm{RMSD} = \sqrt{\frac{\sum_{t=1}^{n}(x_{1,t} - x_{2,t})^2}{n}}.$$

In order to understand the agreement between the two different cluster markers, the Bland-Altman method was applied to the data obtained during the barefoot walking condition within this investigation to analyse the agreement between the heel pin cluster and the heel cup cluster markers. The Bland-Altman method measures the mean differences between two sets of measurements (the heel pin cluster and the heel cup cluster markers) where there is potential for error to be present. The Bland-Altman method also measures the standard deviation (SD) of any differences to measure random fluctuations around the mean differences, and show that if two measurements do not agree well, they do not measure the same agreement consistently. A good correlation may indicate similar variance in measurements, but does not necessarily imply good agreement between the two measurements, and therefore Bland-Altman plots are advantageous to determine this level of confidence.

6.1.6 Results

The average self-selected walking speed for the participants in the barefoot walking condition was 1.214 m/s, and for the shod walking condition was 1.223 m/s.

The angular movement of the rearfoot about the tibia in three planes are presented in figure 6.5, figure 6.6 and figure 6.7 which was represented by the heel cup cluster and heel pin cluster during barefoot walking. The curves represent the mean value and the 95% confident interval of each component in a gait cycle. The results demonstrated that the two different clusters followed the same pattern of angular movement in the three planes when they were used to track the heel motion. The relative errors between the two cluster marker devices could be found to be higher in the movement of frontal and transverse plane due to their smaller range of motion.

The RMSD absolute error of the heel angle (table 6.3) indicated that the maximum error was 0.88° degrees in the sagittal plane, 1.37° in the coronal plane, and 1.21° in the transverse plane. These results also indicated fairly small and acceptable overall error. The differences in same directional angular movement between the heel pin cluster and the heel cup cluster were very small, with 0.8°/0.01° of plantar-/dorsiflexion in the sagittal plane, 0.08°/0.95° of eversion/inversion in the frontal plane and 0.36°/0.67° of abduction/adduction in the transverse plane. All p values of the T-test indicated the differences were statistically insignificant. Agreement was identified using Bland-Altman plots between the heel pin cluster and the heel cup cluster markers in dorsiflexion and also in plantarflexion (figure 6.8, figure 6.9), in inversion and eversion (figure 6.10, figure 6.11), and likewise in adduction and abduction (figure 6.12, figure 6.13) respectively, relative to the tibia (table 6.3).

Table 6.3 indicates minimal differences between the heel cup cluster and the heel pin cluster with regards to inversion and eversion rearfoot motion. The small differences present were recorded the during stance phase of the gait cycle. Table 6.3 represents the differences between the heel cup cluster and the heel pin cluster within the transverse plane of motion (adduction and abduction).

Table: 6.3 – Differences between the heel pin cluster and the heel cup cluster and the RMSD between the heel pin cluster marker and the heel cup cluster marker in the three planes of motion. Full stance phase, and therefore both minimum and maximum rearfoot motion are reflected.

Relative_Tibia	Mean (°)					Relative_Tibia	Mean (°)					
Barefoot	Heel Cup	Pin Cluster	SD Cup	SD Pin(°)	P value	Barefoot	Heel Cup	Pin Cluster	SD Cup (°)	SD Pin(°)	P value	RMSD
Plantar Flex (X)	-1.21	-2.01	2.29	2.86	0.133	Dorsi Flex (X)	15.31	15.30	3.45	3.41	0.984	0.88
Eversion (Y)	-2.35	-2.43	2.43	2.13	0.897	Inversion (Y)	7.86	8.81	3.75	4.32	0.068	1.37
Abduction (Z)	-0.75	-1.11	5.26	4.44	0.662	Adduction (Z)	8.27	8.94	4.87	4.63	0.470	1.21

SD = Standard Deviation) (Heel Cup = Heel cup cluster marker) (Relative_Tibia = Relative to the tibia) (Pin Cluster = Heel pin cluster marker) (Cup = Heel cup cluster marker) (Mean min = mean minimum) (Dorsi Flex = Dorsi flexion) (RMSD =Route mean square deviation) (Plantar Flex = Plantar flexion).

The angular movement of the rearfoot in three planes are presented in figure 6.5, figure 6.6, and figure 6.7 represented by the heel cup cluster and the heel pin cluster during barefoot walking. The curves represent the mean value and the 95% confident interval of each component in a gait cycle. The results demonstrated that the two different cluster markers followed the same pattern of angular movement in the three planes when they were used to track the heel motion.

Figure 6.5 depicts small differences were identified between the heel cup cluster and the heel pin cluster in relation to rearfoot motion (dorsiflexion/plantar flexion) in the sagittal (X) plane. These findings represent low error between the heel cup cluster and the heel pin cluster.

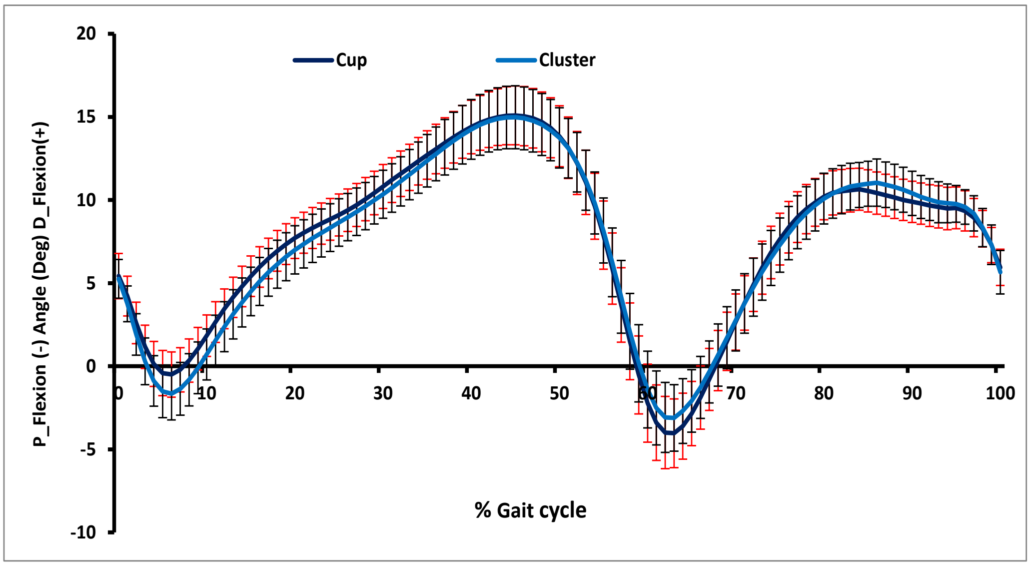


Figure: 6.5 – Sagittal plane rearfoot motion in barefoot represented by the heel cup cluster and the heel pin cluster reflective markers. Error bar represent the ±95% CI.

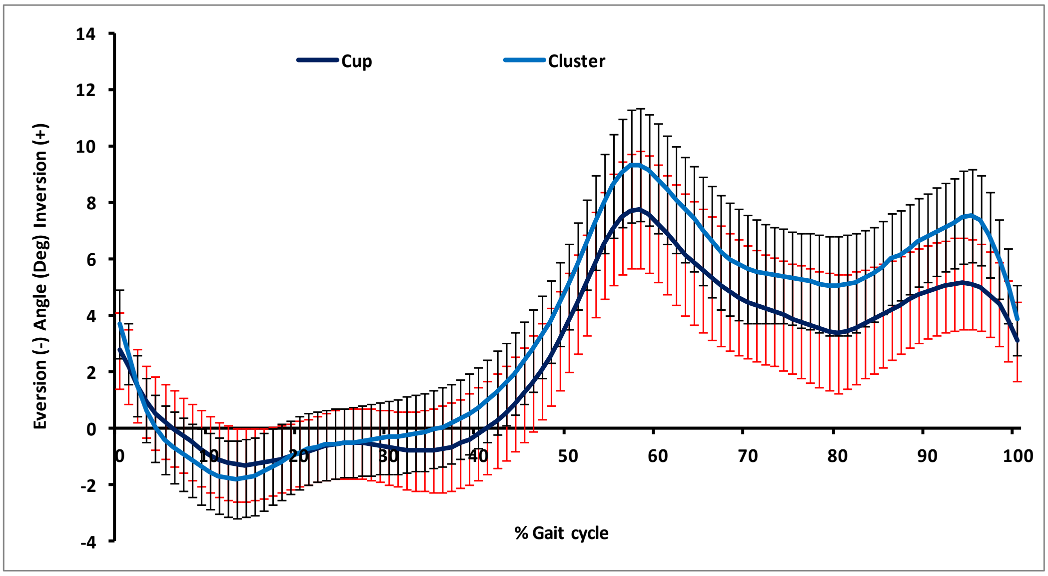


Figure: 6.6 - Coronal plane rearfoot motion in barefoot represented by the heel cup cluster and the heel pin cluster reflective markers. Error bar represent the ±95% CI.

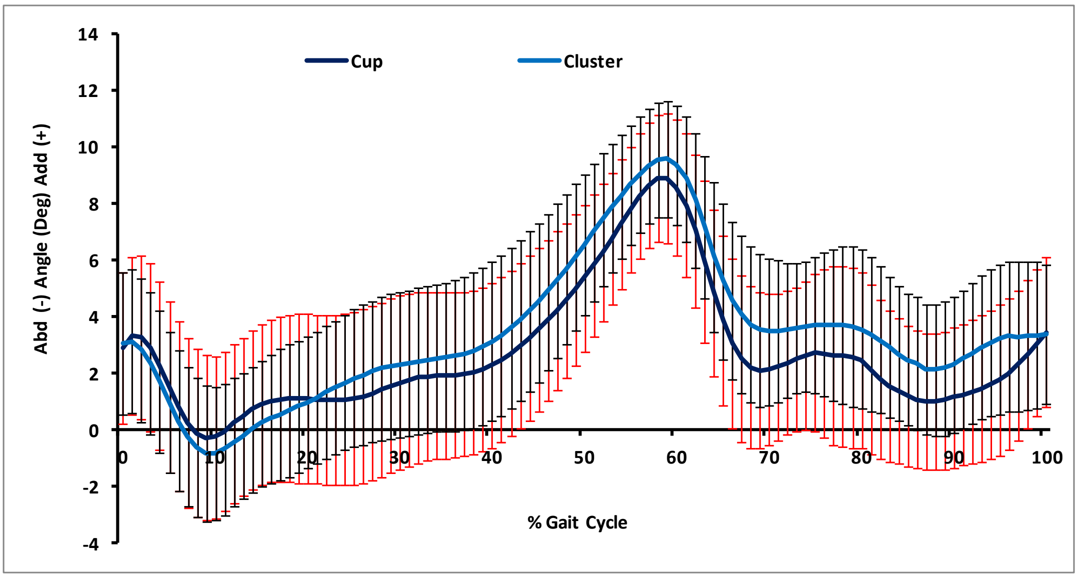


Figure: 6.7 - Transverse plane rearfoot motion in respect of the tibia in barefoot represented by the heel cup cluster and the heel pin cluster reflective markers. Error bar represent the ±95% CI.

The Bland-Altman method was conducted in order to quantify the agreement between the heel cup cluster marker and the heel pin cluster marker. A number of variables indicated no significant differences were present between the two marker methods, and therefore the Bland-Altman method allowed an understanding of the correlation between the heel pin cluster and the heel cup cluster markers to be achieved.

The below figures and table 6.4 depict the Bland-Altman plots. Results indicate no significant differences were present between the heel cup cluster marker and the heel pin cluster marker, and therefore agreement was present between the two marker devices in the coronal, sagittal, and transverse planes.

Linear regression indicated no significant differences to be present, therefore showing agreement to be present between the heel cup cluster marker and the heel pin cluster marker (table 6.4).

Table 6.4 – Bland-Altman agreement results for the heel pin cluster and the heel cup cluster markers in 3 planes of motion.

Bland Altman Plot Agreement Results for the Pin & Cup Clusters in Barefoot											
Relative_Tibia	Mean differences		95% CI		Regression	Relative_Tibia	Mean differences		95% CI		Regression
Barefoot	Mean	SD (°)	Upper	Lower	P value	Barefoot	Mean	SD (°)	Upper	Lower	P value
Plantar Flex (X)	0.80	1.94	3.00	-3.00	0.247	Dorsi Flex (X)	0.01	1.02	1.99	-1.99	0.887
Eversion (Y)	0.58	1.43	2.22	-2.22	0.904	Inversion (Y)	-1.25	1.16	3.52	-3.52	0.896
Abduction (Z)	0.37	3.19	5.89	-5.89	0.329	Adduction (Z)	-0.68	3.53	5.59	-5.59	0.802

CI: Confidence Interval, SD: Standard Deviation, Plantar Flex: Plantarflexion, Dorsi Flex: Dorsiflexion.

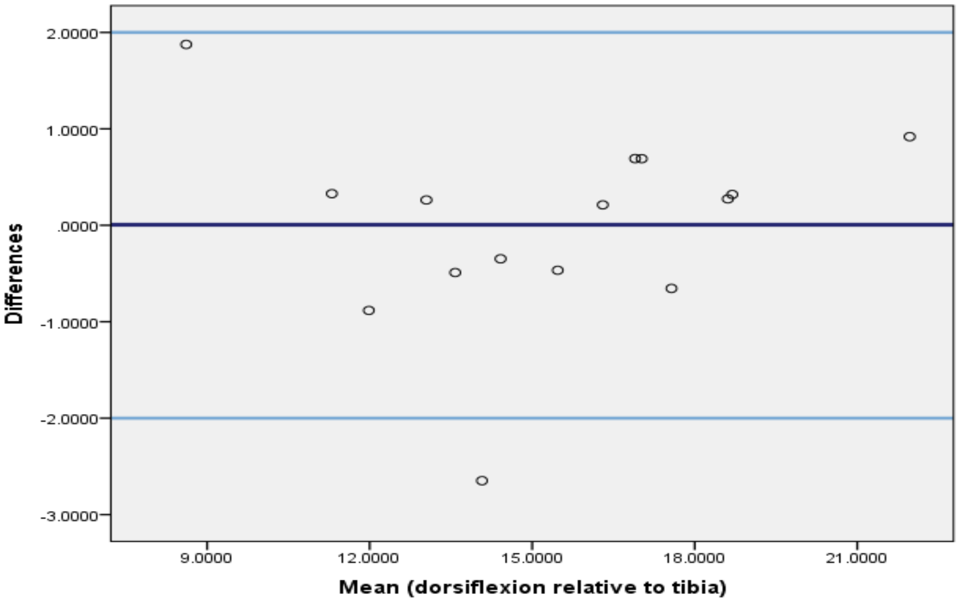


Figure 6.8 – Rearfoot dorsiflexion relative to the tibia. Upper and lower lines (light blue lines) indicate the 95% confidence interval. The middle line (dark blue) indicates the mean differences between the heel pin cluster and the heel cup cluster markers.

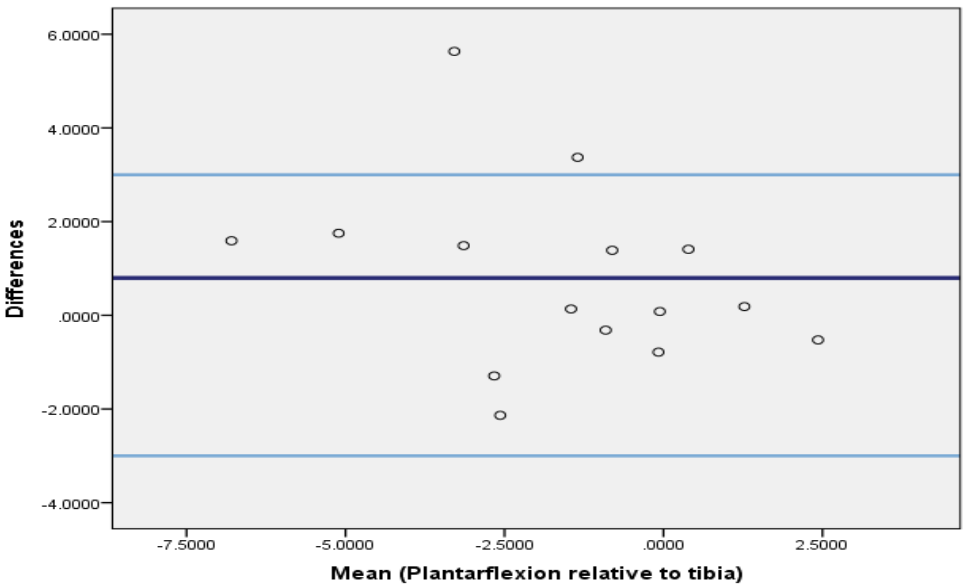


Figure 6.9 – Rearfoot plantarflexion relative to the tibia. Upper and lower lines (light blue lines) indicate the 95% confidence interval. The middle line (dark blue) indicates the mean differences between the heel pin cluster and the heel cup cluster markers.

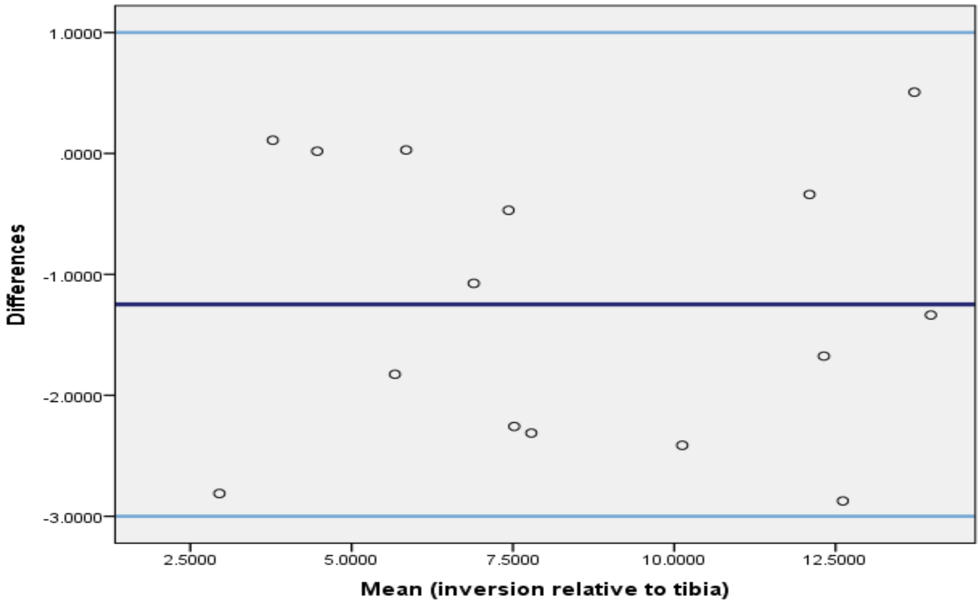


Figure 6.10 – Rearfoot inversion relative to the tibia. Upper and lower lines (dark blue lines) indicate the 95% confidence interval. The middle line (dark blue) indicates the mean differences between the heel pin cluster and the heel cup cluster markers.

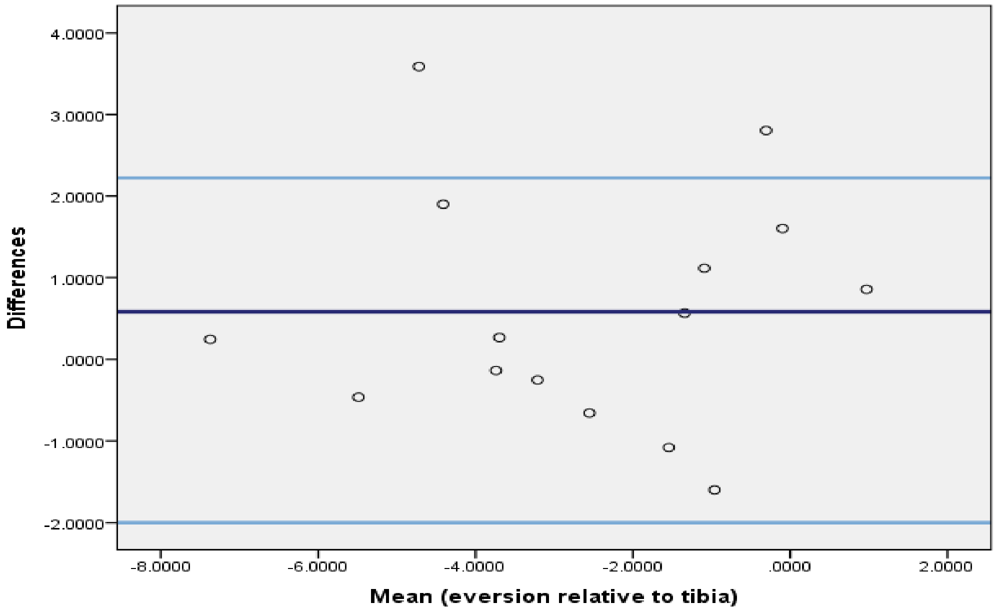


Figure 6.11– Rearfoot eversion relative to the tibia. Upper and lower lines (light blue line) indicate the 95% confidence interval. The middle line (dark blue) indicates the mean differences between the heel pin cluster and the heel cup cluster markers.

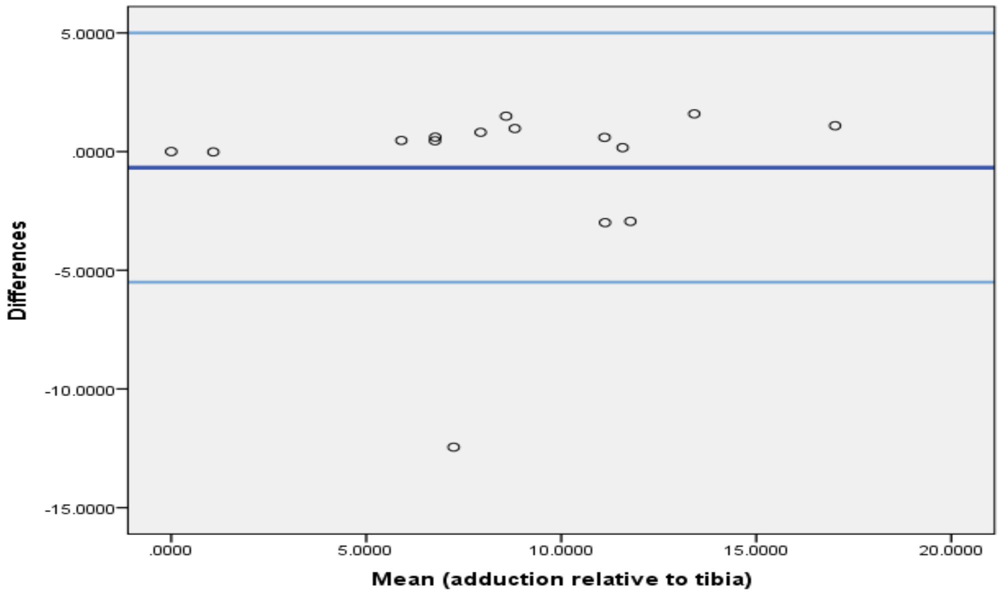


Figure 6.12– Rearfoot adduction relative to the tibia. Upper and lower lines (light blue lines) indicate the 95% confidence interval. The middle line (dark blue) indicates the mean differences between the heel pin cluster and the heel cup cluster markers.

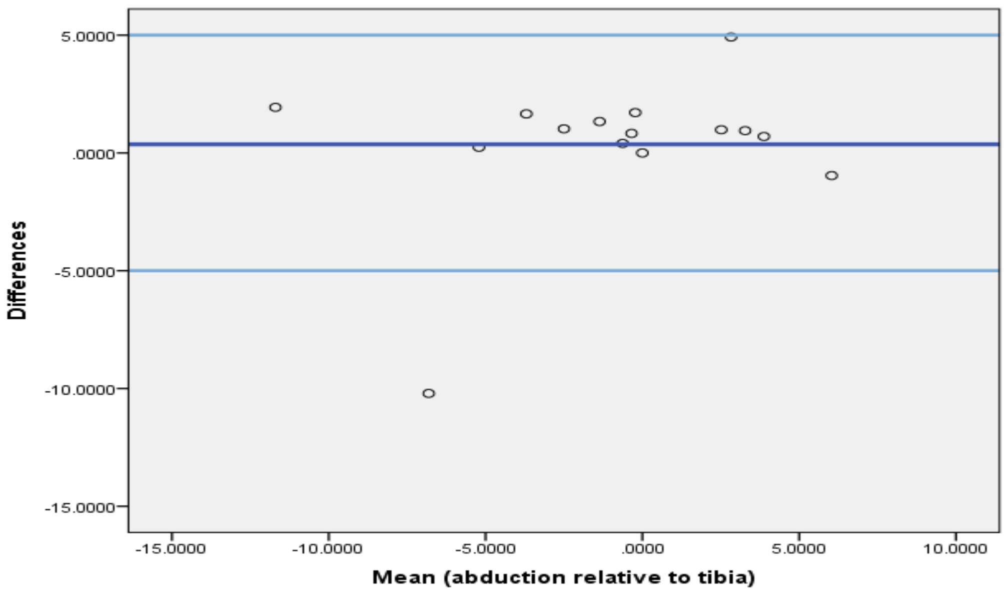


Figure 6.13– Rearfoot abduction relative to the tibia. Upper and lower lines (light blue lines) indicate the 95% confidence interval. The middle line (dark blue) indicates the mean differences between the heel pin cluster and the heel cup cluster markers.

6.1.7 Summary of findings

The results indicate agreement between the heel pin cluster and the heel cup cluster, suggesting that the heel pin cluster marker can be used to represent rearfoot motion in three planes with acceptable accuracy. The results show no statistically significant differences with very low error (less than 1.5 degrees), and therefore the heel pin cluster marker is as effective as the previously utilised heel cup cluster marker set used in chapter 3 and 4. Small and insignificant differences present may have been caused by skin movement artefact. The null hypothesis has therefore been accepted.

Based on the results achieved from the study it can be assumed that the heel pin cluster marker arrangement may be an effective and accurate method to track the heel movement within shoes. However, it not known whether the barefoot movement captured using the heel pin cluster marker represents the same movement when wearing a shod condition.

6.1.8 Comparison of barefoot shod and walking

The second part of the section aimed to understand whether barefoot rearfoot motion was reflected when individuals wore a shod condition. During both examinations (barefoot and shod), there was no difference in speed between the different conditions (P = 0.311). The average self-selected walking speed for the participants was 1.214 ±0.132m/s in barefoot, 1.223 ±0.135m/s in shod.

The results of this section indicate a difference between the heel pin cluster in shod compared to barefoot. Table 6.5 depicts the findings in the sagittal plane (plantarflexion and dorsiflexion), the coronal plane (inversion and eversion) and the transverse plane (adduction and abduction). The results demonstrate that in the sagittal plane (dorsiflexion and plantarflexion) rearfoot motion in shod relative to the tibia both increased by approximately 4 to 5° compared to the barefoot condition. The P Value indicated differences between the barefoot and shod footwear conditions (P<0.01) (P<0.01). Regarding rearfoot motion, in the coronal plane (inversion and eversion), relative to the tibia in shod, an increase was observed for both inversion and eversion compared with the barefoot condition by approximately 5 to 10° (P=0.004). In the transverse plane (abduction and adduction) relative to the tibia in shod, results proved inconsistent. A decrease in abduction was observed, as well as a decrease in adduction in shod, compared to barefoot. However, rearfoot adduction in the right limb increased relative to tibia.

A similar finding was also identified when examining the range of motion (ROM) when comparing between the heel pin cluster marker in barefoot and shod condition relative to the tibia in the coronal plane indicated significant differences p=0.006 (4.4º). However, in the sagittal and transverse plane of motion, no significant differences were identified (table 6.6).

Table: 6.5 - Differences between the heel pin cluster in shod and barefoot conditions.

Relative_Tibia	Mean min (°)					Relative_Tibia	Mean max (°)				
Shod	Shod	Barefoot	SD Shod(°)	SD BF (°)	P value	Shod	Shod	Barefoot	SD Shod(°)	SD BF(°)	P value
Plantar Flex (X)	1.37	-2.01	3.28	2.91	0.002	Dorsi Flex (X)	20.58	15.30	3.54	5.21	0.000
Eversion (Y)	2.08	-2.43	2.68	2.87	0.004	Inversion (Y)	18.47	8.81	4.62	4.74	0.000
Abduction (Z)	-3.25	-1.11	6.21	7.91	0.090	Adduction (Z)	7.98	8.94	4.93	5.48	0.248

SD: Standard Deviation, Relative_Tibia: Relative to the tibia, Mean min: mean minimum, Mean max: Mean maximum, Dorsi Flex: Dorsi flexion, Plantar Flex: Plantar flexion.

Table: 6.6 - Differences between the heel pin cluster in shod and barefoot conditions for the range of motion.

ROM	Rearfoot relative to tibia (°)				
Planes	Barefoot	Shod	SD BF	SD Shod	P value
Sagittal (X)	17.740	19.213	4.402	3.815	0.077
Coronal (Y)	11.946	16.393	3.177	5.070	0.006
Transverse (Z)	11.750	11.234	3.662	4.111	0.331

SD: Standard Deviation, ROM: Range of motion, BF: Barefoot.

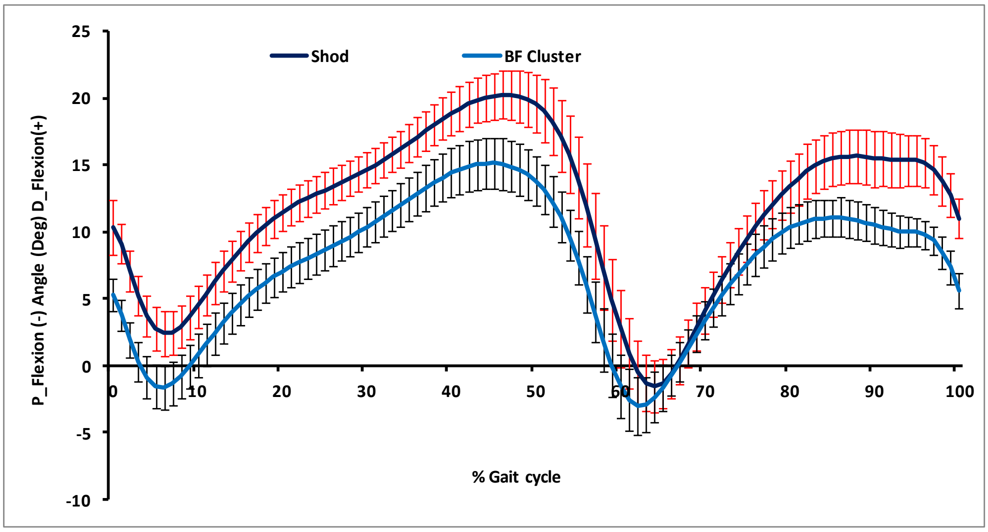


Figure: 6.14 - Rearfoot motion Sagittal plane (dorsiflexion/plantarflexion) in shod represented by a heel cup cluster and a heel pin cluster reflective marker. Error bars represent the 95%CI.

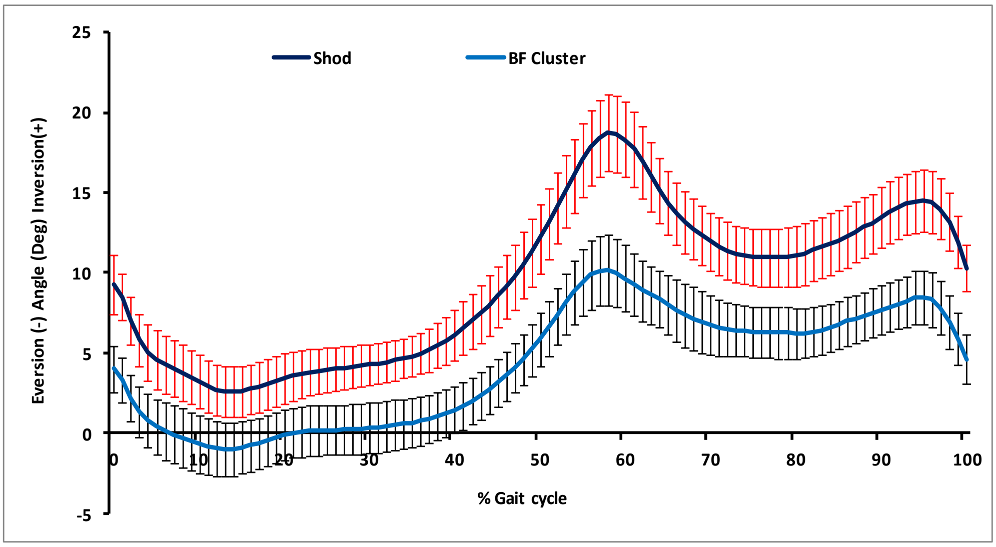


Figure: 6.15 - Rearfoot motion coronal plane (eversion/inversion), in shod represented by a heel cup cluster and a heel pin cluster reflective marker. Error bars represent the 95%CI.

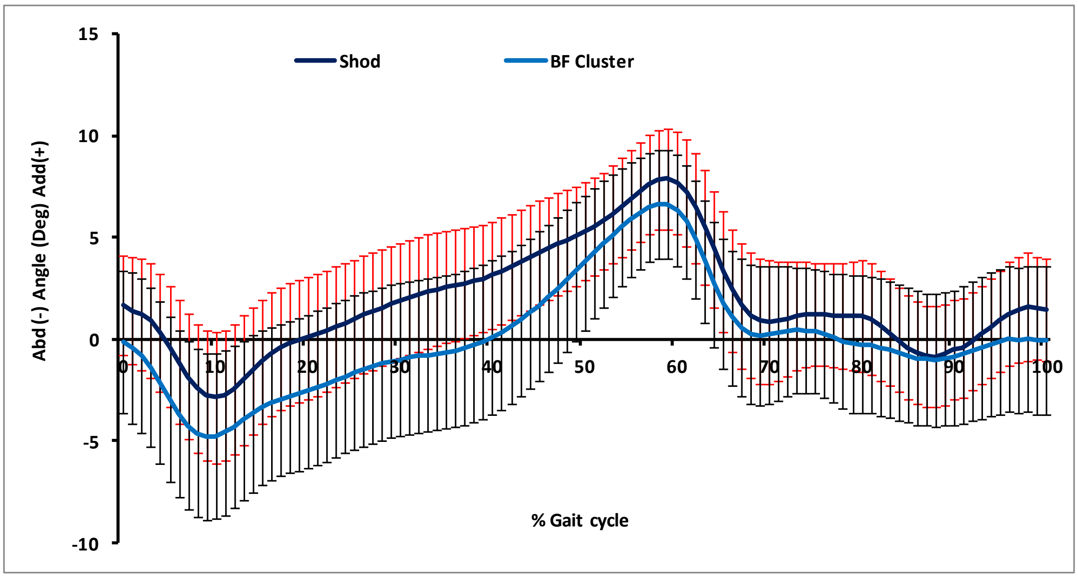


Figure: 6.16 - Rearfoot motion transverse plane (adduction/abduction) in shod represented by a heel cup cluster a heel pin cluster reflective marker. Error bars represent the 95%CI.

6.1.9 Discussion

This research question aimed to investigate the differences between heel cup cluster markers and heel pin cluster markers when used to evaluate rearfoot motion in three planes of motion (sagittal, coronal and transverse), in barefoot walking. The second research question was to assess the efficacy of the heel pin cluster in both barefoot and shod to determine the effect of shoes on rearfoot motion to conclude if barefoot rearfoot motion represents shod barefoot motion during walking in healthy subjects.

Results concerning the use of a skin mounted heel cup cluster when compared with a skin mounted heel pin cluster during barefoot walking suggest no significant differences in rearfoot motion were present between the heel pin cluster and the heel cup cluster in three planes of motion. The very low RMSD indicates that the heel pin cluster is an acceptable method when used to quantify rearfoot motion.

Small and insignificant differences present between the heel cup cluster and the heel pin cluster do not affect the overall efficacy of the heel pin cluster. The low error present within the results (less than 1.5 degrees) is most likely due to skin movement artefact taking place between the skin attachment and the underlying bones. This study finding agrees with previous research by Sinclair *et al*., (2013) who stated that error may be present in data obtained using skin mounted markers due to skin motion taking place between the reflective markers attached to the skin, and the underlying bones. Skin movement artefact may vary between the heel pin cluster marker and the heel cup cluster marker. The heel cup cluster marker is attached to the entire surface of the calcaneus, whereas the heel pin cluster marker is only attached to a small area on the lateral aspect of the calcaneus. Therefore, it is possible that more skin movement artefact is present with the use of the heel pin cluster marker.

An effective way of removing the skin movement artefact occurrence from the results would be to use intra-cortical bone pins to assess rearfoot motion (Jones *et al*., 2012) as previously utilised by Westblad *et al*., 2002, who conducted a study to identify differences between intra-cortical bone pin reflective markers and skin mounted reflective markers attached to the lower limbs and calcaneus when used to quantify rearfoot motion in three healthy participants. The skin mounted markers provided good results, which were comparable to the intra-cortical bone pin marker results, and root mean squared (RMS) differences to describe discrepancies between the intra-cortical pin and skin mounted reflective markers of tibio-calcaneal rotations, inversion/eversion, plantar/dorsiflexion, and abduction/adduction were 2.5º, 1.7º, and 2.8º respectively. Additionally, inversion/eversion about the talocalcaneal joint showed an RMS difference of 2.1º (Westblad *et al*., 2002). The discrepancies identified between the intra-cortical bone pin reflective markers and the skin mounted reflective markers may have been caused by skin movement artefact between the skin and underlying bones. However, the study by Westblad *et al*., (2002) indicates that skin mounted reflective markers are an acceptable method of quantifying rearfoot motion, and since the RMS error was considered to be low within the Westblad *et al*., (2002) trial, the results of this section of the study using heel cup cluster and heel pin cluster reflective markers can be considered very good as the RMSD was less than 1.5 º in three planes of motion. The RMSD result therefore indicates that the differences present within the results of the heel cup cluster and heel pin cluster markers were likely due to skin movement artefact occurrence. However, the use of intra-cortical bone pins to quantify rearfoot motion is considered too invasive. Therefore, it is difficult to remove the incidence of skin movement artefact when quantifying rearfoot motion and results should be interpreted with this in mind.

When assessing the difference between barefoot and shod walking, the data obtained indicated significant differences between the heel pin cluster in barefoot and the heel pin cluster within the shod condition. Utilising a heel pin cluster marker attached to the skin in shod to quantify rearfoot motion can be considered more accurate than the use of reflective markers fixed to the outside of the shoe surface during shod. Motion of the rearfoot may take place within the shoe, and previous research has indicated that various parameters of rearfoot motion are significantly underestimated with the use of shoe mounted markers compared to heel pin cluster results attached to the skin through apertures in the shoes, meaning the shoe cannot be viewed as a rigid body (Stacoff *et al*., 1991, Stacoff *et al*., 2000, Bishop *et al*., 2012, Bishop *et al*., 2013). Similarly, Sinclair *et al*., (2013) concluded that shoe mounted markers do not fully represent true foot movement in shod, and that the foot in shod cannot be viewed as a rigid body, after comparing 3-dimensional tibiocalcaneal kinematics between reflective markers fixed externally on shoes and also on to the skin, attached through apertures made in the shoe (Sinclair *et al*., 2013). The heel cup cluster marker has been proven as an accurate method of quantifying rearfoot motion previously within the literature. However, no validation of the heel pin cluster has yet been conducted. Therefore, this research question compared the differences between the heel pin cluster and the heel cup cluster markers concurrently whilst participants walked in barefoot.

Data from this research question suggests that eversion and inversion both increased in shod, demonstrating an increase in inversion and eversion compared to barefoot. This result represents a higher ROM of the rearfoot in shod than in barefoot. This finding may be due to the footwear used in the shod condition. Footwear was standard for all subjects involved in the study; however the sole of the shoe provides a larger amount of cushioning than when walking barefoot. The cushioning, footwear type and footwear material all influence rearfoot motion, and therefore this finding could possibly change depending on the type of footwear used, as implied in previous research by Stacoff *et al*., (1991), Morio *et al*., (2009), Tsai and Powers, (2009), Blanchette *et al*., (2011) who concluded that the type, structure and stiffness of footwear used within trials can affect rearfoot motion. Furthermore, the walking condition itself could have affected individual’s gait, and consequently rearfoot motion. Barefoot walking has previously been associated with decreased walking speed, decreased stride length, and decreased hip and knee joint moments, furthermore, increased cadence, and knee flexion and ankle plantarflexion angles, compared to walking in shod (Lythgo *et al*., 2009, Sacco *et al*., 2010, Tsai and Lin, 2013). Changes in gait patterns in barefoot walking compared to shod walking coincide with cautious gait, suggesting that walking barefoot affects the confidence of individuals, and that footwear can affect gait stability (Menant *et al*., 2008, Tsai and Powers, 2009, Blanchette *et al*., 2011) and barefoot walking is likely to be associated with increased balance in individuals (Tsai and Lin, 2013). Therefore, confidence of walking between barefoot and shod could influence rearfoot motion.

Additionally, individual participants may have been more aware of the cluster marker set when walking in barefoot, but less so in the shod walking condition, which may have influenced rearfoot motion. Results obtained for rearfoot abduction motion within the shod condition were variable, implying significant differences were present between the rearfoot motion in shod compared to barefoot when using a heel pin cluster marker. However, adduction and abduction in shod indicated no significant differences compared to barefoot data. Overall, the majority of the rearfoot abduction results indicated no significant differences between shod and barefoot. However, with regards to rearfoot motion, abduction decreased in shod compared to the barefoot condition. These findings indicate the foot is somewhat constricted by the shoe in the shod condition, as abduction decreased in shod, which further confirms findings by Stacoff *et al*., (1991) and Morio *et al*., (2009).

The use of a heel pin cluster marker allows rearfoot motion to be represented and obtained in both shod and barefoot conditions, and also allows the differences between footwear conditions to be identified. Using a heel pin cluster marker therefore overcomes some difficulties experienced in previous research, such as allowing rearfoot motion to be accurately quantified in both barefoot and shod using the same device. The heel pin cluster marker provides an acceptable alternative to invasive intra-cortical bone markers and is more acceptable than shoe mounted reflective markers. Additionally, the heel pin cluster marker aims to ensure (as much as possible) the integrity of footwear used in shod conditions due to the small circumference of the heel pin marker device, requiring only a minimal alteration to the shoes, as opposed to requiring the removal of the entire heel counter. Furthermore, the heel pin cluster marker allows the foot to be quantified in segments, where the rearfoot can be quantified separately by attaching the heel pin cluster marker to the skin of the rearfoot through windows made in the shoes. Previous investigations within the literature used reflective markers fixed to the external surface of the shoes, where the foot and shoe were viewed as one rigid body, and possible foot motion inside the shoe was not entirely explored. However, the heel pin cluster marker does not allow the comparison between barefoot and shod walking, and therefore further research is needed.

6.10 Conclusion

These findings have important clinical implications regarding the efficacy of heel pin cluster markers, as results have indicated it was an accurate and acceptable method when compared with heel cup cluster markers for determining the 3D motion of the rearfoot in three planes of motion (sagittal, frontal and transverse) in healthy subjects.

With regards to the shod footwear condition, results identified differences between rearfoot motion in shod when compared to barefoot in three planes of motion (sagittal, frontal and transverse) in healthy subjects. Barefoot walking therefore cannot be viewed to be the same as shod, due to the effects of footwear on rearfoot motion and further research to understand these factors is required. These findings have important clinical implications for future research. Specifically in the understanding of rearfoot motion and its effects on the efficacy of interventions designed to reduce the loading on the medial compartment of the knee for the treatment of medial compartment knee osteoarthritis, such as lateral wedge insoles.

However, the heel pin cluster is an acceptable method of quantifying both barefoot and shod rearfoot motion data. The footwear used within this study was a flat shoe, meaning there is little for the foot to be changed by a midsole. Therefore, the heel pin cluster marker can be considered an appropriate method to confidently determine rearfoot motion within variations of the shod footwear conditions in clinical research, to assess rearfoot motion in shod versus different orthotics in shod walking. Therefore, allowing challenges within previous literature concerning interventions in shod which used reflective markers on the outside of the shoe surface to be overcome.

The findings of this section of the study will allow an advance in the understanding of investigations into orthotic interventions (particularly lateral wedge insoles) specifically designed for the conservative treatment of lower limb musculoskeletal conditions, such as medial compartment knee osteoarthritis on rearfoot motion, and their effects on the lower limbs in shod walking. Previous studies have investigated either barefoot walking, LWI attached to a barefoot with subtalar strapping (Kuroyanagi *et al*., 2007), or LWI in shod. With the exception of a study by Jones *et al*., (2012) no in-shoe data collection using a heel pin cluster marker examining the effect of a LWI on rearfoot motion in shod has been conducted. Quantifying rearfoot motion in shod with lateral wedge insole intervention using the heel pin cluster marker may provide inferences into the response and non-response to lateral wedge insoles on the external knee adduction moment in individuals with medial compartment knee osteoarthritis.

6.2 Research Question 2: What are the effects of a lateral wedge insole on rearfoot motion and the EKAM

6.2.1 Introduction

Measuring rearfoot kinematics in shod can be considered an effective tool to identify alterations in foot posture, allowing comparison between shod, varying insoles, and footwear conditions (Arnold and Bishop, 2013, Chapman *et al*., 2015). However, limited studies within the literature to date have investigated in-shoe rearfoot motion when wearing LWI.

Hatfield *et al*., (2016) conducted an investigation which assessed the immediate alterations in ankle subtalar joint biomechanics with the use of two types of LWI (standard LWI and LWI with arch support) inserted into sandals, compared to a control sandal (no LWI) in 26 participants with medial compartment knee OA, quantified using reflective markers attached to the skin of the foot around the sandal straps. Both the standard LWI and the LWI with arch support led to a significant reduction in the EKAM. The wearing of the standard LWI also resulted in small increases in eversion angles and moments at the ankle subtalar joint, however the LWI with added arch support did not (Hatfield *et al*., 2016). The use of sandals within the study may have led to different findings than with the use of a fully structured shoe. Furthermore, the foot was modelled as a rigid body within the study meaning only ankle subtalar joint biomechanics were assessed. Assessing the rearfoot as a separate segment may provide further understanding into rearfoot motion in shod and shod with a LWI. Therefore, further investigation using a fully structured shoe, with a heel pin cluster marker attached to the skin of the foot through apertures made in the shoe, meaning the foot would no longer be viewed as a rigid body is required in order to examine possible differences in rearfoot motion between shod and shod with LWI.

Similarly, Chapman *et al*., (2015) conducted a study using reflective markers fixed onto the exterior of shoes to quantify rearfoot motion in a control shoe and in shod with LWI in 70 patients with medial compartment knee OA, and viewed the foot as a rigid, single segment inside the shoe. Chapman *et al*., (2015) concluded that coronal plane ankle subtalar joint complex biomechanical measures play a key role in reducing the EKAM when wearing LWI after identifying that LWI shifted the centre of foot pressure laterally and caused an increase in eversion at the ankle subtalar joint complex and also the eversion moment compared to the control walking condition. The peak eversion ankle subtalar joint complex angle and the ankle peak EKAM angle in the control condition led to a prediction of individual EKAM reduction in the LWI walking condition. However, it was stated that the use of a more sophisticated foot model allowing the differentiation between the rear and the forefoot would be more ideal to accurately quantify rearfoot motion in shod.

Kakihana *et al*., (2005) assessed the biomechanical effects of LWI on the knee and subtalar joint moments of 13 elderly healthy individuals and 13 elderly knee OA patients during gait using a neutral insole and a LWI. Results demonstrated a significant decrease in knee joint varus moments and an increase in subtalar joint valgus moments in both healthy individuals and knee OA patients with the use of the LWI when compared to a neutral insole. The LWI caused a lateral shift in the centre of pressure during stance phase of the gait cycle, which may explain the decrease in the knee joint varus moment, indicating that the knee joint varus moment in OA patients is associated with the angle and moment of the subtalar joint during gait with the use of LWI (Kakihana *et al*., 2005). However, the study by Kakihana *et al*., (2005) used LWI attached directly to the barefoot of participants, and did not quantify the rearfoot motion of individuals in shod with LWI, therefore results must be interpreted with caution, as it is difficult to compare findings to those studies that quantified rearfoot motion with the use of a LWI in shod due to the possible effects of shoe structure, soles, and stiffness on rearfoot motion.

Recent investigations by Butler *et al*., (2009) examined the effects of LWI when used for the conservative treatment of medial compartment knee OA on the frontal plane mechanics of the rearfoot and hip during walking in 30 patients with medial compartment knee osteoarthritis. Rearfoot motion was quantified using 3D reflective markers attached to the skin over the calcaneus, through windows made in the heel counter of training shoes (Butler *et al*., 2009), as opposed to markers fixed to the external surface of the shoes, which can lead to underestimations of rearfoot motion (Stacoff *et al*., 2001). Results showed that peak eversion, eversion excursion, and the peak eversion moment increased in LWI compared to no wedge, and also that the peak knee adduction moment decreased in the LWI walking condition compared to the no wedge walking condition. The study concluded that LWI result in increased rearfoot eversion and inversion moments, increased movement and joint moments at the rearfoot, and reducing joint moments at the knee. However, LWI used within the Butler *et al*., (2009) investigations were not standard 'off the shelf' insoles, but were semi-customised to individual participants, and the level of lateral wedging added to shoes varied from 5-15º between participants. Therefore, findings are not clear, due to the variation within the interventions used within the study. An investigation into rearfoot motion, quantified using a heel pin cluster marker in shod utilising standard, ‘off the shelf’ identical LWI in varying shoe sizes has not been carried out previously within the literature, and is therefore needed. The study by Butler *et al*., (2009) states that findings were in agreement with those of Kakihana *et al*., (2005), however the variation in walking conditions within the two studies mean the findings are difficult to compare.

In terms of accuracy and gold-standard marker collection, Jones *et al*., (2012) utilised intra-cortical bone pins to determine the alterations in frontal plane foot and ankle motion and moments, eradicating the possible incidence of skin movement artefact, and observed an increase in subtalar joint eversion with LWI in shod. However, the kinematic response of some individuals was found to vary, potentially providing an insight into why an incidence of biomechanical non-response (no reduction in the EKAM) to LWI intervention exists.

This study will therefore expand on research conducted by Kakihana *et al*., (2005), Butler *et al*., 2009, and Jones *et al.*, (2012) and will quantify rearfoot motion in shod compared with LWI in shod using a heel pin cluster reflective marker device fixed to the skin of the foot on the lateral aspect of the calcaneus through small windows made in the shoe. Therefore, the aim of this investigation is to determine if a LWI alters rearfoot motion, and also, if a relationship exists between rearfoot motion and the EKAM when quantified using a heel pin cluster marker.

6.2.2 The statistical hypotheses for this study:

- There is no significant difference in rearfoot motion (quantified using a heel pin cluster) in LWI walking conditions compared to shod walking conditions in healthy subjects.
- There is no relationship between rearfoot motion (quantified using a heel pin cluster) in shod and the EKAM in healthy subjects.
- There is no relationship between rearfoot motion (quantified using a heel pin cluster) in LWI and the EKAM in healthy subjects.

The methods used within this research question are identical to those used in section 6.1.3. Therefore, the heel pin cluster marker appraised above will be utilised in further investigations within this chapter.

6.2.3 Data Collection

Testing was carried out in the clinical gait laboratory at The University of Salford using 16 OQUS infrared cameras (Qualisys AB Sweden), Qualisys Track manager (Qualisys AB

Sweden), and four integrated AMTI force plates (Advanced Mechanical Technology, Ins. USA) in order to capture the 3D positions of the retro reflective markers that were attached to each subject's skin, over bony landmarks in both lower limbs.

The methodology applied to this section was identical to the methodology described earlier within the chapter (section 6.1.3).

Five successful walking trials were conducted on each participant at a self-selected speed. Walking trials were firstly carried out in the shod condition and secondly in shod with a 5° lateral wedge insole (LWI) (SalfordInsole) inserted into the shoe. Standardised, size appropriate footwear (Ecco, Zen) was provided for each participant for use within the study. Walking trials were only considered to be successful when the foot was placed completely on the force platform during stance phase.

The heel pin cluster marker used within this study which represented the calcaneus segment using a four marker cluster attached to the lateral side of the calcaneus with a window made in the lateral aspect of the shoe measuring 2.5 x 2.5 cm (figure 6.4), allowing attachment to the skin using double sided tape.

After the shod condition walking trials were completed, the heel pin cluster markers were removed in order to conduct further walking trials in the shod with LWI condition. The heel pin clusters were therefore removed (from both limbs) in order for the participant to be able to remove and replace the shoes on their feet. The skin attachment was left on the skin and was not removed, to ensure minimal error was present in the results, which would have affected the reliability of the cluster marker. If the skin attachment base of the cluster pin was removed, replacing it in the exact same position would be difficult. The investigator therefore took care to ensure it remained attached and placed tape over the skin attachment base to provide increased stability. The pin cluster markers are unscrewed from the skin attachment base, and the foot was carefully inserted into the shoe with the LWI inside by the participant with the aid of the investigator, to minimise the risk of the skin attachment base moving. Once the participant was in the shod with LWI condition, the pin cluster was screwed back into the skin attachment base through an opening made in the shoe. The walking trials in shod with LWI were then continued.

6.2.4 Data Analysis

Kinematic and kinetic data was obtained for 15 healthy participants. A full explanation of building of the model and data analysis steps can be found earlier within the chapter (section 6.1.7). The identical static model was used for both sets of walking, as no markers changed their location with the insertion of the LWI. Maxima and minima of the rearfoot motion were analysed in three planes; sagittal (dorsiflexion/plantarflexion), coronal (inversion/eversion) and (abduction/adduction)) and the two were compared using statistic test. The difference over the stance phase of the gait cycle mean value was then analysed in order to determine the differences between rearfoot motion represented by heel pin clusters in the shod and the shod with LWI footwear conditions. The rearfoot was defined as between the shank segment and the foot segment, and was tracked using the heel pin cluster marker. Data were calculated using the heel pin cluster in shod and shod with LWI in three planes of motion in order to determine if there were any differences between the two conditions. Statistical analysis including paired T-tests were conducted on the data obtained within the study after checking the data for normality. Also the normality testing was performed on each variable in order to identify the most suitable correlation coefficient test to apply. The Shapiro-Wilks test was applied for the 15 healthy subjects Error bars depicted on the graphs within the results section represent the 95% confidence interval (CI).

6.2.5 Results

This research question aimed to investigate rearfoot motion in healthy subjects in shod compared to shod with a LWI using a heel pin cluster device to determine if a LWI alters rearfoot motion. After conducting walking trials under both footwear conditions (shod and shod with a LWI inserted), no significant differences in speed between the two footwear conditions were observed ($P = 0.311$), (shod 1.22 ±0.14 m/s, shod with LWI 1.23 ±0.14 m/s).

Results indicate significant differences in rearfoot motion were present during stance phase between the shod and LWI walking conditions in the three planes of motion (sagittal, coronal and transverse), with the exception of rearfoot abduction, which indicated significant differences.

Results indicated significant differences in rearfoot motion were present between shod and LWI within the three planes of motion. Significant differences were also present in rearfoot plantarflexion and dorsiflexion in the sagittal plane of motion ($p=0.04$) ($p=0.03$), respectively. LWI led to an increase in plantarflexion by 2.95º and a decrease in dorsiflexion by 2.93º during the stance phase of the gait cycle. In the coronal plane of motion, significant differences were also identified in rearfoot motion between shod and LWI. Eversion significantly increased by 1.95º with the use of a LWI compared to shod ($p=0.005$), and inversion significantly decreased by 3.8 º in LWI compared to shod ($p=0.01$).

Rearfoot abduction in LWI increased when compared to shod by 1.33 º ($p = 0.04$). However, rearfoot adduction indicated no significant differences between shod and LWI ($p=0.45$).

The mean peak frontal plane minimum and maximum rearfoot motion and the EKAM in both shod and LWI walking conditions for individual subjects are depicted in table 6.7.

Significant differences were identified in the first peak of stance phase (early stance) frontal plane minimum rearfoot motion between the shod and LWI walking conditions. LWI increased rearfoot eversion by 1.38 º ($p=0.02$). Conversely, no significant differences were found in first peak frontal plane maximum rearfoot inversion motion ($p=0.36$) (table 6.7).

Table 6.7 – The mean and standard deviation (SD) for all measurements for 15 participants in first peak.

First Peak Frontal Plane (Inversion(+) Eversion (-)						
Subject	Minimum Shod **(°)**	Maximum Shod **(°)**	Minimum LWI **(°)**	Maximum LWI **(°)**	EKAM Shod (Nm/kg)	EKAM LWI (Nm/kg)
1	1.879	8.143	-2.311	7.810	0.362	0.384
2	-1.226	3.717	-1.954	3.893	0.376	0.182
3	12.889	16.171	12.920	14.147	0.448	0.206
4	-0.125	6.983	-3.021	6.915	0.621	0.603
5	1.933	8.974	1.665	10.340	0.437	0.412
6	0.012	7.447	-2.064	8.540	0.500	0.472
7	2.065	8.526	1.302	6.641	0.377	0.362
8	0.241	8.393	-3.829	7.226	0.342	0.379
9	-2.875	6.300	-5.973	5.144	0.436	0.382
10	-1.888	12.784	-2.237	10.614	0.300	0.242
11	1.075	11.551	1.919	10.165	0.417	0.379
12	-0.412	7.412	-1.535	8.350	0.387	0.277
13	-3.757	8.877	-8.227	5.038	0.409	0.339
14	5.735	11.925	5.457	11.431	0.453	0.457
15	3.214	6.615	5.993	10.675	0.582	0.578
Mean	1.251	8.921	-0.126	8.462	0.430	0.377
SD **(°)**	3.884	2.966	5.089	2.688	0.086	0.121

LWI: Lateral Wedge Insoles, EKAM: External Knee Adduction Moment, SD: Standard Deviation. Results in bold indicate biomechanical non-response (no reduction in the EKAM) to LWI intervention. – (negative): eversion, positive: inversion.

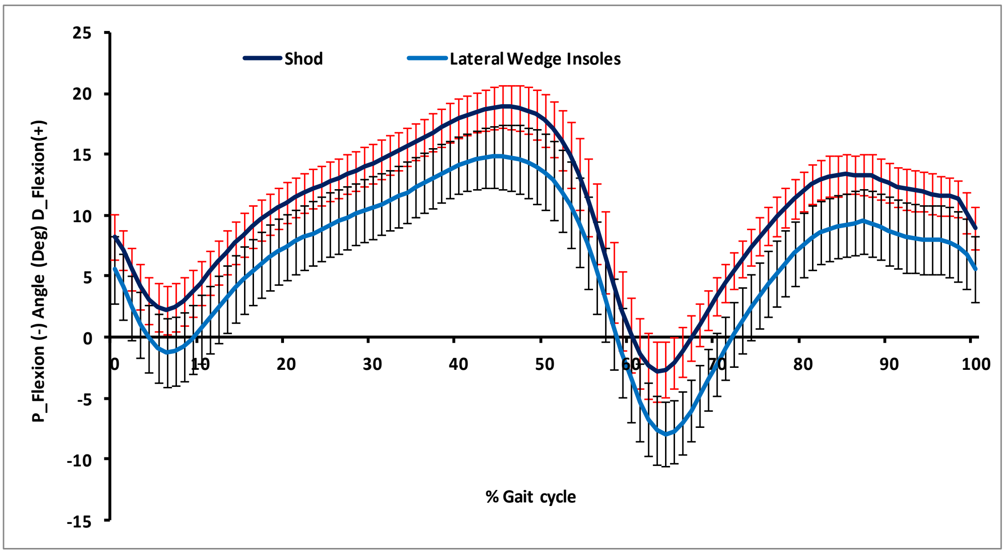


Figure 6.17: Rearfoot motion in shod and wedge in the sagittal plane, represented by a heel pin cluster. Error bars represent the mean 95%CI.

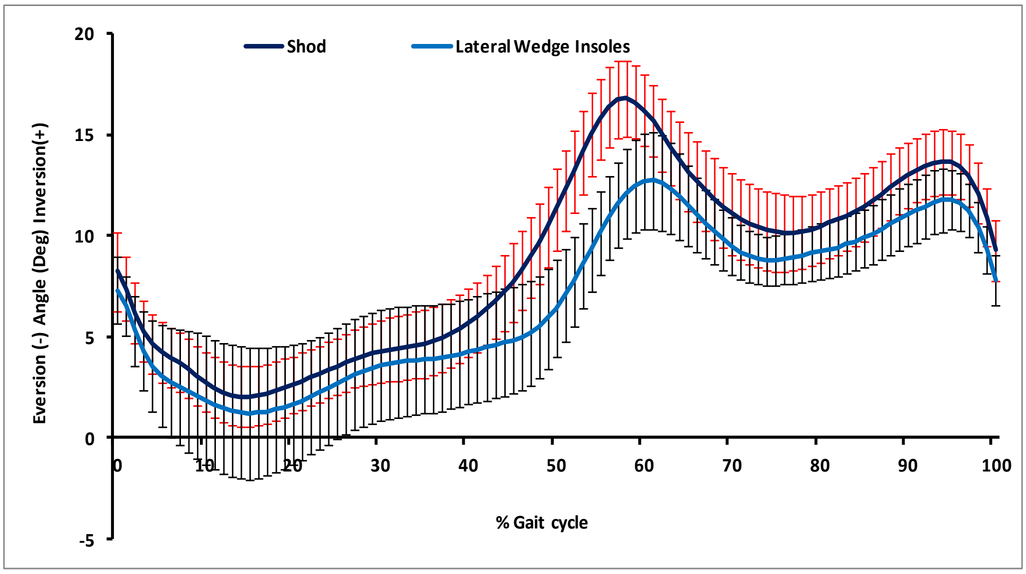


Figure 6.18: Rearfoot motion in shod and wedge in the coronal plane, represented by a heel pin cluster. Error bars represent the mean 95%CI.

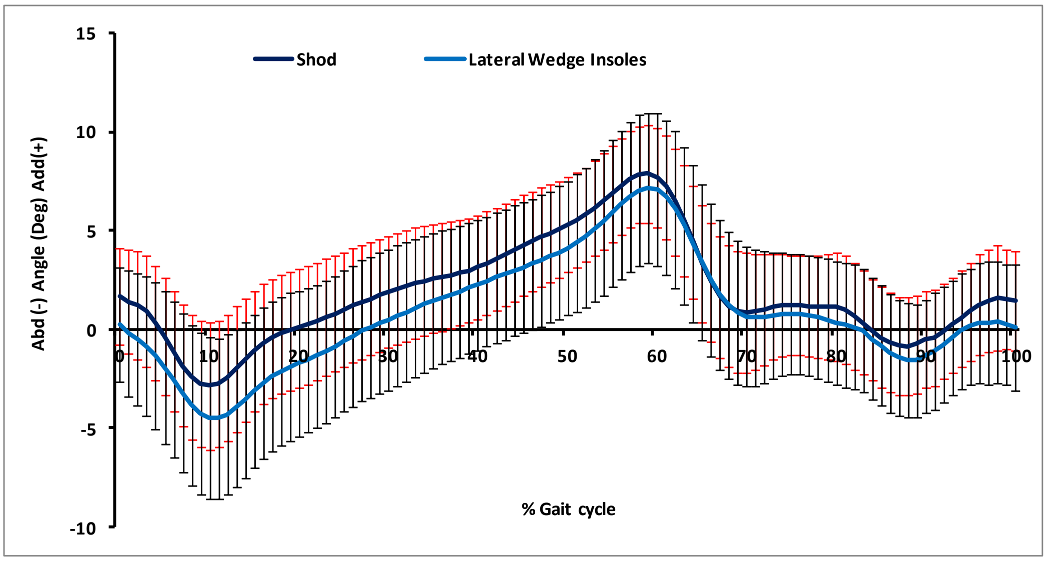


Figure 6.19: Rearfoot motion in shod and wedge in the transverse plane, represented by a heel pin cluster. Error bars represent the mean 95%CI.

External knee adduction moment (EKAM) was calculated during the walking trials, and a reduction in the EKAM was identified in the LWI condition compared to in shod (p=0.018) (shod EKAM 0.430 (±0.086) Nm/kg, LWI EKAM 0.377 (±0.121) Nm/kg) (figure 6.20) (table 6.6).

Of the 15 subjects, 12 subjects were biomechanical responders to the LWI walking condition, and 3 (subject numbers 1, 8, and 14) were biomechanical non-responders to LWI, and therefore did not show a reduction in the EKAM (table 6.6).

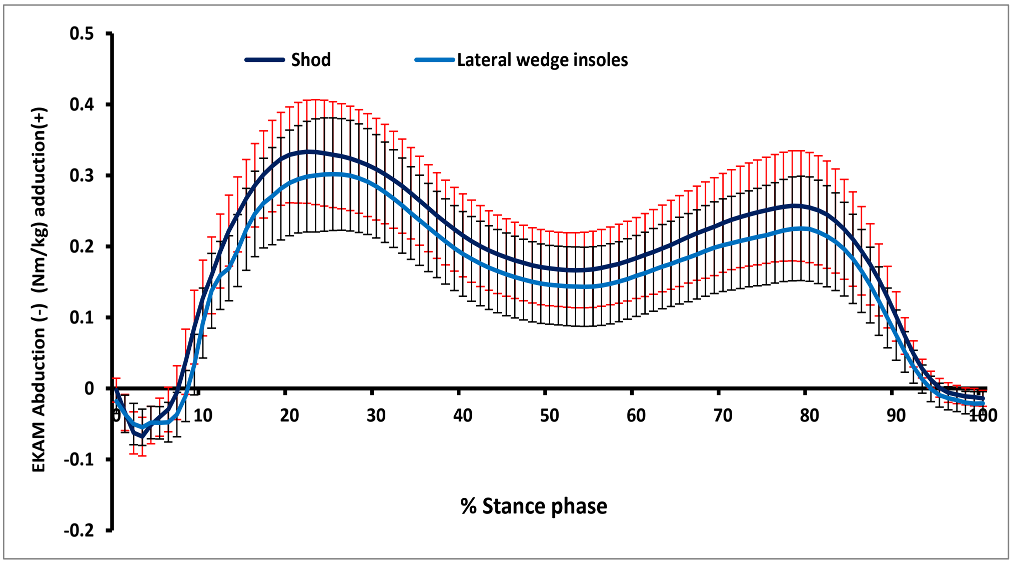


Figure 6.20 – Graph depicting the EKAM in both shod and lateral wedge insoles walking conditions. Error bars represent the 95%CI for the shod and LWI walking conditions.

Table 6.8: Differences between rearfoot motion in shod and LWI relative to the laboratory frame and the tibia.

	Mean min (°)						Mean max (°)				
Wedge	Shod	Wedge	SD Shod (°)	SD W (°)	P value	Wedge	Shod	Wedge	SD Shod (°)	SD W (°)	P value
Plantar Flex (X)	1.69	-1.26	3.87	5.32	0.048	Dorsi Flex (X)	19.43	16.50	3.73	6.50	0.035
Eversion (Y)	1.25	-0.70	4.02	4.88	0.005	Inversion (Y)	16.03	12.23	2.52	4.63	0.015
Abduction (Z)	-4.06	-5.39	3.49	4.00	0.045	Adduction (Z)	7.03	7.58	3.71	5.33	0.458
Rearfoot angle at first peak EKAM											
Wedge	Shod	Wedge	SD Shod (°)	SD W (°)	P value	Wedge	Shod	Wedge	SD Shod (°)	SD W (°)	P value
Eversion (Y)	1.25	-0.13	3.88	5.09	0.02	Inversion (Y)	8.92	8.46	2.97	2.69	0.360

SD: Standard Deviation, Relative_Tibia: Relative to the tibia, Mean min: mean minimum, Mean max: Mean maximum, (Wedge, W: Lateral wedge insoles, Dorsi Flex: Dorsi flexion, Plantar Flex: Plantar flexion.

Results indicated no association was present between the EKAM and rearfoot eversion, and the EKAM and inversion of the rearfoot in shod (p=0.903) (p=0.891) respectively (table 6.9).

Furthermore, no association existed between the EKAM and rearfoot eversion and the EKAM and rearfoot inversion when wearing LWI (p=0.475) (p=0.492) respectively (table 6.9).

Table.6.9 The relationship between EKAM and the rearfoot motion in shod and lateral wedge insoles in healthy subjects

Measurements in First Peak	**Correlations (P-Value)**
EKAM vs Eversion Shod	*r*= -0.035 (0.903)
EKAM vs Inversion Shod	*r*= 0.039 (0.891)
EKAM vs Eversion LWI	*r*= 0.200 (0.475)
EKAM vs Inversion LWI	*r*= -0.192 (0.492)

EKAM: External Knee Adduction Moment, LWI: Lateral Wedge Insoles, r: Pearson Coefficient Correlation (parametric)

6.2.6 Discussion

This research question aimed to investigate differences in rearfoot kinematics between shod and shod with LWI, represented by a heel pin cluster marker. The heel pin cluster marker has been verified as a reliable method of quantifying rearfoot motion in shod in previous investigations by the researcher (section 6.1) and thus, was utilised within this research question.

Results of in-shod versus LWI in-shod identified significant differences between the two conditions to be present in all three planes of motion in stance phase. Additionally, during the first peak of minimum frontal plane rearfoot motion, significant differences were present between shod and LWI, this may have been caused by the influence of the LWI on the rearfoot during the stance phase and the first peak of heel strike. The rearfoot makes contact with the ground during heel strike of the gait cycle, and the first peak in EKAM is related to this time period of the gait cycle. The LWI causes the centre of pressure in the foot to shift laterally, causing eversion of the foot, and a reduction in EKAM (Kakihana *et al*., 2005). In agreement with Kakihana *et al*., (2005), Butler *et al*., (2009) similarly stated that walking with a LWI increases the eversion moment, peak eversion, and eversion excursion at the rearfoot.

The rearfoot motion in shod compared with LWI in shod during stance phase indicated statistically significant differences of approximately 1 to 3°. In the sagittal, frontal and transverse planes, minimum plantarflexion, eversion and abduction increased in the shod with LWI condition compared to the shod condition. In addition, dorsiflexion and inversion decreased in the shod with LWI condition compared to shod. Plantarflexion and eversion may have increased due to the LWI being higher on the lateral side, causing lifting of the lateral side of the foot. Dorsiflexion and inversion perhaps decreased due to the medial side of the foot being lower within the shoe than the lateral side when the LWI was inserted, which may have led to the decrease in the EKAM.

The EKAM results indicate that the LWI had an effect on joint loading, and the use of a LWI led to small differences in the kinematics of the rearfoot. Therefore, a slight change in kinematics of the rearfoot appears to cause a change in the EKAM. Similarly, Chapman *et al*., (2015) suggested that coronal plane ankle-subtalar joint complex biomechanical parameters contribute to the reduction of the EKAM when wearing LWI. Alterations in rearfoot kinematics with the use of a LWI in this study were minimal, and therefore some differences may have been caused by skin movement artefact occurring around the LWI due to differences in the sole of the shoe caused by the LWI itself.

Rearfoot motion during stance phase in the sagittal and coronal planes indicated significant differences between the shod and shod with LWI conditions. In the transverse plane of motion, abduction and adduction provided inconsistent results, perhaps due to the footwear used within the study and possible skin movement artefact occurrence. It can be concluded that the LWI causes a better fit of the shoe to the foot, therefore constricting the rearfoot motion of the foot within the shoe. Abduction and adduction in shod compared to the barefoot condition provided inconsistent results. However, the findings indicate the foot is somewhat constricted by the shoe with LWI, which further confirms findings by Stacoff *et al*., (1991) and Morio *et al*., (2009).

The increased amount of eversion identified within the trial was correspondingly reported by Butler *et al*., (2009). The Butler *et al*., (2009) study examined the effects of LWI when used for the conservative treatment of medial compartment knee OA on the frontal plane mechanics of the rearfoot and hip during walking in 30 patients with medial compartment knee osteoarthritis. Three-dimensional reflective markers attached to the skin over the calcaneus, through windows made in the heel counter of training shoes were utilised. Findings of the Butler *et al*., (2009) study suggested that the increased amount of rearfoot motion identified with the use of a LWI requires greater muscle torques in order to control the increased rearfoot motion with the use of LWI. Furthermore, variation in results regarding eversion when wearing a LWI in shod was stated in previous studies by Kakihana *et al*., (2005) and Kakihana *et al*., (2007), who observed an increase in eversion and also an increase in the frontal plane moment with the use of a 6º LWI attached directly to the barefoot of participants, implied as being related to the centre of pressure of the foot and the subtalar joint. The study by Butler *et al*., (2009) states that findings were in agreement with those of Kakihana *et al*., (2005), however the variation in walking conditions between the studies mean the findings are difficult to compare.

Chapman *et al*., (2015) conducted a trial using 70 patients with medial compartment knee OA who underwent gait analysis whilst walking in a control shoe and a LWI. An increase in eversion at the ankle/subtalar joint complex, and greater eversion moments were identified in the LWI condition compared to the control condition. These biomechanical responses to LWI could be key in reducing medial compartment knee joint loading, especially when considering that Hinman *et al*., (2012) identified that a shift in the centre pressure in the foot caused a shift in the GRF towards the centre of the knee, therefore reducing the EKAM (Chapman *et al*., 2015).

However, in healthy subjects, when using a heel pin cluster marker to quantify rearfoot motion in shod and shod with LWI walking conditions, the rearfoot did not show any statistically significant relationship to rearfoot inversion and eversion and the magnitude of the EKAM in shod. Additionally, no statistically significant association existed between rearfoot inversion and eversion and the magnitude of the EKAM in shod with LWI.

Inconsistent findings were identified in results concerning inversion and eversion rearfoot motion in shod and in shod with LWI in both biomechanical non-responders and biomechanical responders in individuals. Therefore, no specific differences were detected in rearfoot motion between responders and non-responders. This could be because the subjects within the study were healthy, and presented no lower limb pathologies.

Considering these findings, it can be stated that rearfoot motion cannot predict the magnitude of the EKAM in healthy subjects. Therefore, further investigation is required to understand biomechanical response and non-response to LWI intervention.

Foot motion, specifically pronation is commonly accepted as influencing the kinematic pattern of the lower extremities, including the tibia (Reischi *et al*., 1999). Therefore, further investigation concerning the tibia may provide an insight into biomechanical response and non-response to LWI intervention. However, a study by Reischi *et al*., (1999) concluded that the magnitude and timing of peak foot pronation was not predictive of the magnitude and timing of tibial rotation, indicating that the tibia may move independently of the rearfoot, and that the motion of the tibia varies when compared to the motion of the rearfoot. For example, if the centre of foot pressure shifts laterally, and the GRF moves closer to the centre of the knee joint a reduction in the EKAM occurs and an individual is classified as a biomechanical responder to LWI. However, in a number individuals the tibia may move differently, away from the moment arm for example, which would cause an increase in the EKAM, causing an individual to be classed as a biomechanical non-responder to LWI intervention. The motion of the tibia may therefore affect the efficacy of LWI in individuals, and therefore further investigation using both healthy subjects and patients with medial compartment knee OA is required.

6.2.7 Conclusion

In conclusion, significant differences existed between shod and LWI walking conditions with regards to rearfoot motion when represented using a heel pin cluster marker during stance phase of the gait cycle. Moreover, significant differences were present between shod and LWI in minimum frontal plane rearfoot motion in the first peak of stance phase. The changes in rearfoot motion with the use of a LWI compared to shod identified within the walking trials may allow a change in kinetics, leading to a reduction in the EKAM, and therefore reducing the load at the medial compartment of the knee joint. Findings imply that rearfoot motion may be considerably influenced by LWI. However, no relationship exists between rearfoot motion and the EKAM, and the minimum and maximum frontal plane rearfoot motion of individuals was inconsistent with magnitude the EKAM. Therefore rearfoot motion cannot independently predict the magnitude of the EKAM (biomechanical response and non-response to LWI) in healthy subjects.

Rearfoot motion may therefore be important in initiating alteration in the EKAM. Further research is therefore required using a heel pin cluster marker in patients with medial compartment knee osteoarthritis, which may lead to increased understanding of rearfoot motion and biomechanical response and non-response to LWI.

6.3 Does walking speed affect the biomechanical response when wearing lateral wedge insoles?

6.3.1 Introduction

Certain musculoskeletal conditions, specifically osteoarthritis (OA) of the knee, cause a reduction in walking speed compared to healthy participants (Kaufman *et al*., 2001, Al-Zahrani and Bakheit, 2002, Mundermann *et al*., 2003, Zeni *et al*., 2010, Mills *et al.*, 2013, Henderson *et al.*, 2015) associated with a decreased stride length and an increase in stance time during the gait cycle (Al-Zahrani and Bakheit, 2002, Landry *et al*., 2007).

Previous research has concluded that the clinical state of a patient is reflected in his or her walking speed, with slower walking speeds related to the further disease progression of medial compartment knee OA (Andriacchi *et al*., 1977, Brinkmann *et al*., 1985, Mills *et al.*, 2013). A number of musculoskeletal conditions cause deviations from a normal gait cycle (Mundermann *et al*., 2003). In patients with knee OA, an altered gait style is adapted, which differs from the walking style of healthy controls. Mundermann *et al*., (2003) observed medial compartment knee OA patients to adopt a walking style that reduced the EKAM when walking at slower speeds, which is likely to reduce the load on the knee joint, therefore providing some symptom (pain) relief (Robon *et al*., 2000, Mundermann *et al*., 2003, Mundermann *et al*., 2004).

The consequences of varying walking speed are a fundamental concern in gait studies when measurements are based on the level of GRF and acceleration, due to the effects of walking speed on the EKAM and the subsequent impact on knee joint loading (Zeni and Higginson, 2009, Wilson, 2012). An increase in walking speed often causes an increase in the load at the knee joint, caused by an increase in the dynamic ground reaction forces that are proportional to the walking speed (Wilson, 2008, Zeni and Higginson, 2009, Zeni and Higginson, 2010, Foroughi et al., 2010). In addition, a study by Zeni and Higginson, (2009) identified alterations in gait parameters to be caused by slower walking speeds, when walking speeds were freely chosen by participants, rather than a result of knee OA disease progression.

It is well known that LWI cause a reduction in the EKAM compared to flat, or neutral (non-wedged) insoles, and they have been suggested as an effective intervention method to achieve a reduction in the EKAM therefore shifting a proportion of the load away from the medial compartment of the knee joint to the lateral compartment and providing some OA symptom relief (Hinman *et al*., 2008, Hinman *et al*., 2009, Bennell *et al*., 2011, Zhang *et al*., 2012, Jones *et al*., 2012, Skou *et al*., 2013). It is not known whether an increase in walking speed (which would increase the vertical ground reaction force) would reduce the effectiveness of a LWI. A number of studies have identified an increase in walking speed with LWI intervention, however, it is unknown if the increase in walking speed would reduce the effectiveness of the LWI. Chapman *et al*., (2015) conducted a trial involving 70 patients with medial compartment knee OA using a control shoe (shod) and a LWI inserted into the shoe. A small and insignificant difference was identified between conditions (mean shod – 1.163m/s, mean wedge – 1.166m/s).

Similarly, Hsu *et al*., (2015) investigated the effects of a 6 week LWI intervention on 10 female medial compartment bilateral knee OA patients. Patients were required to wear the LWI for at least 6.5 hours a day for the 6 week period. Results presented not statistically significant differences in walking speed between the barefoot and shod with LWI conditions at both baseline and follow up (mean walking speed for all participants at baseline barefoot – 0.77m/s, baseline LWI – 0.78m/s, mean walking speed for all participants at follow-up barefoot – 0.90m/s, follow-up LWI – 0.85m/s).

Moreover, Hinman *et al*., (2009) identified an immediate increase in walking speed of 0.6% using a LWI inserted into the shoes (personal shoes) of 20 patients with medial compartment knee OA, compared to shod. After 1 month however, the increase in walking speed between shod and shod with LWI was only 0.1%. Findings were therefore insignificant.

However, Jones *et al*., (2012) identified significant increases in walking speed after the two week use of a LWI for four or more hours per day in patient's own shoes in 28 patients with medial compartment knee OA. Walking speed was significantly increased with the use of a LWI (1.18m/s) compared to baseline. Reductions in pain were also reported with the use of the LWI (WOMAC pain score post LWI – 38.6 against baseline).

In addition to the reductions in pain identified within the Jones *et al*., (2012) trial, Hinman *et al*., (2008) reported an immediate reduction of 24% in pain during walking with the use of a LWI in shod versus shod in 40 knee OA patients. However, walking speed was similar across conditions (0.14m/s in shod and 0.15m/s in shod with a LWI). In contrast, a long term trial by Bennell *et al*., (2011) using 200 medial compartment knee OA patients found no reduction in pain with the use of a LWI compared to a neutral insole in shod. Similar findings were reported by Baker *et al*., (2007) who identified no significant or clinically important pain reductions in 90 knee OA patients after using a LWI for six weeks, compared to a neutral insole.

LWI reduce the EKAM (Jones *et al*., 2012) but an increased walking speed increases the EKAM (Zeni and Higginson, 2009, Zeni and Higginson, 2010, Foroughi *et* al., 2010). No study exists within the literature which investigates the role that increased walking speed has on the magnitude of the EKAM when wearing LWI compared to the role that increasing the walking speed has on the magnitude of the EKAM in shod.

Therefore, the aim of this research question was to investigate the possible effects and impact of varying walking speeds on the magnitude of the EKAM when wearing LWI in healthy subjects. Given that interventions such as LWI reduced the EKAM in previous studies, it is unknown if an increase in walking speed could influence the efficacy and therefore biomechanical response to LWI, meaning that the possible reduction in the EKAM caused by the LWI in the initial baseline assessment may be diminished, or negated.

In the previous chapter with medial compartment osteoarthritis individuals (Chapter 5) it was seen that there was a difference albeit small in walking speed between the responders and non-responders. Furthermore, previous research has also identified a change in walking speed once an intervention is worn. However, it is unknown how walking speed affects the reduction of the EKAM and whether the reductions are consistent with speed changes. Individuals with medial compartment knee osteoarthritis walk at different speeds and therefore it is unknown if the ones who walk faster have a smaller reduction in their EKAM on treatment and may mask the overall % reduction in the sample. Unfortunately, the data is not available to be able to examine this question and therefore examining these speed changes is needed.

Due to the amount of walking and the dynamic impact at higher walking speeds, most patients would find it extremely challenging to complete the required walking trials. It is also unwise to ask individuals to walk at greater speeds in an intervention that they are not accustomed to, and therefore, the research question was performed on the healthy subjects. However, given that the majority of studies on lateral wedge insoles do cross over the healthy-OA paradigm, the outcome from the analysis will be equally as effective in gaining an understanding of the joint effect of walking speed and LWI on the magnitude of the EKAM.

6.3.2 The statistical hypotheses for this research question

- There is no significant difference in reduction of the EKAM between self-selected and increased walking speeds with the use of lateral wedge insole intervention compared to shod in healthy subjects.

6.3.3 Methodology

Fifteen healthy participants (7 males, 8 females) were recruited to take part in the study. Participants were required to be free from lower limb injury for a period of at least six months prior to testing (injury was defined as any musculoskeletal complaint that prevented the participant from undertaking their normal exercise or daily routine), and to have no history of lower limb surgery. The protocol of the study was reviewed and approved by the ethic committee at the University of Salford. All subjects provided informed consent before participation. The mean and standard deviation (SD) demographic characteristics of all fifteen participants are depicted in table 6.1.

For each subject, five successful walking trials were captured for each walking condition (shod and shod with a LWI), firstly at a self-selected speed, and then at 20% faster than the self-selected speed. The 20% increased walking speed was chosen as this was deemed large enough an increase to examine the response of the lateral wedge insoles to this change in speed. Whilst this maybe higher than differences in speeds in patients, it was felt that in individuals who walk with a higher speed may mask some of the differences due to a lower reduction in the EKAM. Walking speed was controlled with timing gates, with the 20% greater speed calculated from individual subjects self-selected speeds (using the maximum increased by 0.5% for error, and the minimum, reduced by 0.5% for error, calculated by finding the average of three walking trials). All walks that did not fall into the cut off points calculated using the minimum and maximum (too fast or too slow) were excluded from the data analysis. Participants were advised to adjust the walking speed to make it within the controlled range.

A walking trial was only considered successful after participants full feet made contact with both force plates (embedded into the floor in the gait laboratory) during the stance phase of the gait cycle. Walking trials were firstly conducted in the shod condition and secondly, in shod with a 5° LWI (SalfordInsole) inserted into the shoe. Standardised, size appropriate footwear (Ecco, Zen) was provided for each participant for use within the study. Five successful walking trials were recorded for each trial condition. Overall, six different conditions were undertaken within the study (shod at a self-selected speed and shod at a 20% greater than self-selected speed, shod with LWI at a self-selected speed and shod with a LWI at a 20% greater speed). All walking trials were carried out during a single visit to the gait lab.

Data collection, equipment used and the trial procedures were the same as those utilised previously within this chapter (sections 6.1.3 and 6.1.4).

6.3.4 Data Analysis

Kinetic data was obtained for 15 lower limbs. Following data collection, all joint kinetic data was processed using Qualysis Track Manager software where each marker was labelled and digitised, and any anomalies in movements in marker trajectories were corrected. A full explanation of the data analysis steps employed within this section are presented within (section 6.1.7).

Statistical Analysis

The first peak EKAM during stance phase was analysed for both shod and shod with LWI walking conditions. Normality testing was applied to determine the distribution of the data. The Shapiro-Wilks test was applied for the 15 healthy subjects (both left and right limbs). The majority of the data were normally distributed (parametric), and therefore paired T-tests were performed in order to identify any statistically significant differences between the shod and shod with LWI interventions, carried out using SPSS software.

6.3.5 Results

The average self-selected walking speed for the participants was 1.22 m/s (±0.135) in shod, and 1.23 m/s (±0.139) in the LWI condition (p=0.159) indicating no significant differences between the two walking conditions at self-selected walking speeds. The average 20% increased walking speed for participants was 1.50 m/s (±0.164) in shod, and 1.51 m/s (±0.171) in the LWI condition (p=0.195), indicating no significant differences between the two walking conditions at 20% increased walking speeds. Unsurprisingly, when comparing between the self-selected walking speed and increase 20% walking speed in shod and LWI indicated significant differences between the two different walking speed (p=<0.001) (p=<0.001) respectively.

The results also indicated, that unsurprisingly, a reduction in the EKAM was observed when wearing a LWI compared to shod. Expectedly, the results showed that in both footwear conditions (shod and shod with LWI), a 20% increase in walking speed from self-selected speed led to an increase in the vertical ground reaction force and the first peak of EKAM in stance. The GRF and EKAM normalised to body mass are presented in table 6.11 and table 6.12.

Table 6.10 – Mean EKAM in shod and LWI walking conditions in limbs of all 15 subjects

.

	Knee EKAM (Nm/kg)			
Subject	**Shod**	**Shod Fast**	**Wedge**	**Wedge Fast**
1	0.362	0.456	0.384	0.434
2	0.376	0.291	0.182	0.196
3	0.448	0.396	0.206	0.362
4	0.621	0.708	0.603	0.641
5	0.437	0.564	0.412	0.552
6	0.500	0.511	0.472	0.496
7	0.377	0.404	0.362	0.391
8	0.342	0.430	0.379	0.533
9	0.436	0.522	0.382	0.473
10	0.300	0.341	0.242	0.349
11	0.417	0.461	0.379	0.469
12	0.387	0.457	0.277	0.432
13	0.409	0.423	0.339	0.379
14	0.453	0.530	0.457	0.533
15	0.582	0.686	0.578	0.618
Mean	0.430	0.479	0.377	0.457
SD	0.086	0.114	0.121	0.114

EKAM: External Knee Adduction Moment, Wedge: Lateral Wedge Insole, Fast: Faster walking speed, SD: Standard Deviation.

Table: 6.11 - The EKAM (Nm/Kg) of all walking conditions.

	Knee EKAM	
Conditions	EKAM (Nm/Kg)	SD (°)
Shod	0.43	0.086
Shod Fast	0.479	0.114
Wedge	0.377	0.121
Wedge Fast	0.457	0.114

(SD = Standard deviation, EKAM = External knee adduction moment).

Table: 6.12 -Vertical GRF of all walking conditions.

Conditions	GRF	SD (°)
Shod	1.11	0.07
Shod F	1.22	0.09
Wedge	1.12	0.07
Wedge F	1.22	0.09

(F = Fast, SD = Standard deviation, GRF = Ground Reaction Force).

The results indicate that at self-selected walking speed, the walking condition (shod, and shod with LWI) did not alter the GRF, which allows comparison between the two conditions. When walking speed increased, the dynamic force between foot and ground would increase accordingly. The vertical GRF results for the 15 limbs indicated an increase of 8.1-10.1% in the first peak, i.e. from 1.1 times of body weight to 1.2 times which were the same amount of increase in the two conditions.

When walking speed was increased by 20% from self-selected walking speed, significant differences were identified in both shod and LWI. When walking at a 20% increased speed with LWI compared to a self-selected speed with LWI, the EKAM increased by 21.3% ($p=<0.001$) (mean difference 0.08 Nm/kg). The 20% increase in walking speed led to an increase in the EKAM in the shod condition ($P<0.001$).

When walking at self-selected speeds, the use of a LWI led to a significant decrease of 12.3% (p=0.018) in the EKAM compared to shod in (mean difference 0.05 Nm/kg).

The results indicate that when walking at the 20% increased speed, the reduction in the EKAM in LWI compared to shod was 4.46% (p=0.09) (mean difference 0.02 Nm/kg). However, the reductions in the EKAM were not statistically significant (figure 6.21) (table 6.11).

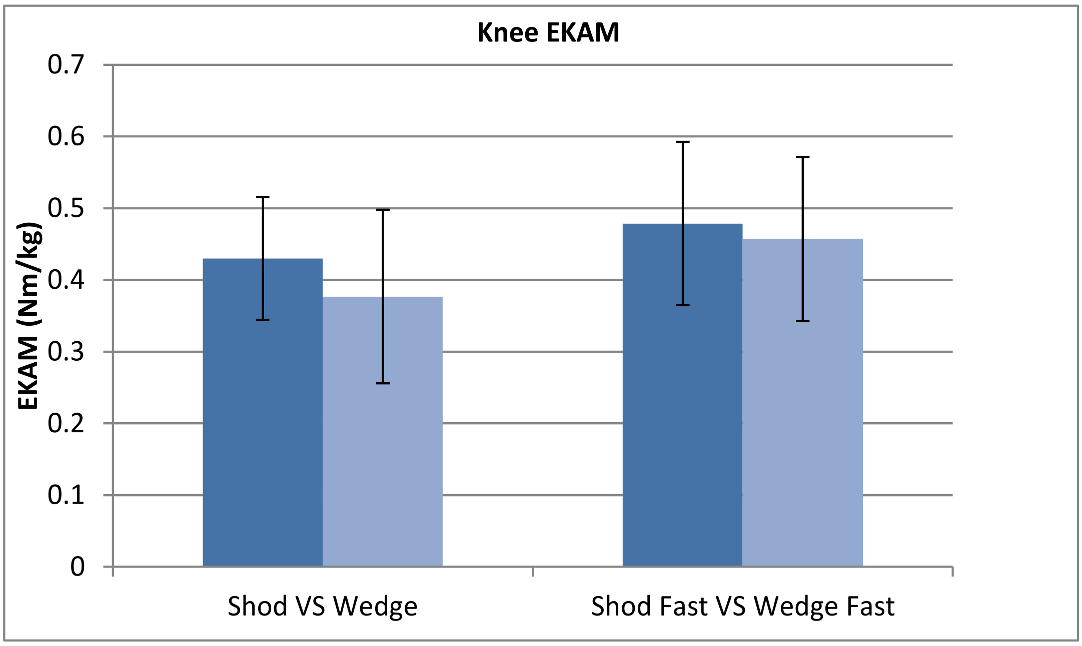


Figure: 6.21 - The EKAM in shod versus wedge at self-selected speeds and shod fast versus shod with LWI 20% increased walking speed in the left knee.

When looking at the individual subject response to the lateral wedge insoles at the two different speeds, it was seen that 12 individuals had a reduction in EKAM at the self-selected speed, and three individuals did not have a reduction in EKAM. At the faster walking speed, 10 individuals had a reduction in EKAM, and 5 individuals did not have a reduction in EKAM.

Therefore, in alignment with chapter 5 on biomechanical response and non-response, it can be seen that 12 individuals would have been classed as biomechanical responders at the self-selected walking speed.

6.3.6 Discussion

The research question aimed to gain an understanding of the effect of walking speeds and LWI on the magnitude of the EKAM. Results indicate that LWI are an effective intervention for initiating a reduction in the EKAM when walking at both a self-selected walking speed, and a walking speed 20% faster than self-selected walking speed. The use of LWI can result in a reduction of the EKAM as the results demonstrated. Previous investigations by Butler *et al*., (2007), Hinman *et al*., (2008) and Jones *et al*., (2012) also identified a reduction in the EKAM with the use of LWI, suggesting that LWI could be an effective intervention in reducing the EKAM by alleviating a proportion of the force transmitted through the medial compartment of the knee joint (Shelburne *et al*., 2008). The reduction in EKAM is theorised to be achieved by moving the centre of pressure laterally up to 5mm, which would result in the reduction of the resultant valgus moment arm (Kerrigan *et al*., 2002, Shelburne *et al*., 2008, Hinman and Bennell, 2009). However, in the previous chapter, it was identified that there are inconsistent reductions in EKAM when wearing lateral wedge insoles, linking in the biomechanical responders and non-responders. One of the factors for these individuals may have been their overall walking speed, and this is demonstrated here where the overall reduction decreases once a change in speed (albeit quite a reasonable increase) is seen.

Findings show that the use of a LWI when walking at self-selected speeds compared to shod leads to a reduction in the EKAM. Results identified that when increasing walking speed by 20%, a reduction in the EKAM was achieved in the LWI walking condition compared to shod. However, the reduction in the EKAM was not statistically significant.

The minimal reduction in the EKAM identified in the LWI walking condition when walking speed was increased by 20% from self-selected speed may suggest that faster walking speeds reduce the efficacy of LWI. When subjects walked at a 20% increased speed in shod with LWI, compared to a self-selected speed in shod with LWI, the EKAM increased by 21.3% ($p=<0.001$) in the left limb. Therefore, an increase in walking speed may affect the response to LWI in patients with medial compartment knee OA.

An increased walking speed results in a shortening of the stance phase of the gait cycle, perhaps not providing enough time for the centre of foot pressure to shift laterally, even with the use of a LWI, therefore only affecting the magnitude of the EKAM minimally, subsequently leading to a small reduction in the EKAM.

Adopting a slower walking speed could therefore increase the effectiveness of LWI, as a slower walking speed requires reduced levels of knee flexion, and consequently lower levels of shock absorption to help reduce the load on the knee joint (Mundermann *et al*., 2004, Foroughi *et al*., 2010). However, a slower speed of walking was not assessed in this chapter as the majority of the literature with interventions demonstrates increases rather than decreases in speed. Hinman *et al.*, (2009) identified insignificant increases in walking speed after one month of using a LWI in shod, compared to shod only. Additionally, Jones *et al.*, (2012) identified a reduction in pain and a significant increase in walking speed after comparing walking with a LWI to shod only in 28 patients with medial compartment knee OA after a two week intervention period.

However, LWI have proven ineffective at improving symptoms or slowing disease progression in some clinical trials, and reductions in the peak EKAM are occasionally not consistent across all study findings, with some trials reporting that LWI had no effect on the EKAM (Pham *et al*., 2004, Baker *et al*., 2007, Hinman *et al*., 2008, Barrios *et al*., 2009, Bennell *et al*., 2011, Chapman *et al*., 2015).

The above results note that 3 individuals would have been classified as biomechanical non-responders and 12 individuals as biomechanical responders to LWI when walking at the self-selected speed. When at the faster speed, 10 individuals were biomechanical responders and 5 were biomechanical non-responders. This raises questions in terms of the LWI construction. The inconsistencies in LWI effectiveness could be due to the varying types of LWI available, and the differences in design and materials used, including; thickness, length, wedge gradient, and presence of arch support. A higher density, firmer manufacturing material (providing a varying sole stiffness and varying firmness when compressed during weight bearing) could potentially affect the EKAM reduction percentage (Hinman *et al*., 2008, Nakajima *et al*., 2009, Hinman *et al*., 2009, Jones *et al*., 2015).

Whilst a full length LWI extends along the length of the entire foot, and the whole foot makes contact with the ground during the gait cycle, not just the rearfoot. Full length LWI, rather than heel only LWI should therefore be used for the treatment of individuals with medial compartment knee OA, and within this research question, a standard full length tapered LWI (SalfordInsole) was used. The most common angulation of LWI used for the treatment of medial compartment knee OA within the existing literature is 5º (Jones *et al*., 2015, Yilmaz *et al*., 2015). Tipnis *et al*., (2014) investigated the effect of incrementally increasing LWI wedge degrees on the EKAM and individuals subjective comfort. The Tipnis *et al*., (2014) study concluded that wedge amounts greater than 6º generated little additional mechanical changes or benefits, and wedge amounts greater than 8º negatively affected individual’s subjective comfort. Lateral wedging between 4-6º was considered optimal to produce desirable biomechanical changes and higher comfort perception in individuals (Tipnis *et al*., 2014). Although shown to be effective in reducing medial knee loads, an inclination exceeding 10º has been found to cause foot discomfort for subjects within trials, and therefore the majority of trials use the optimal comfort wedge inclination of 5º (Kerrigan *et al*., 2002, Hinman *et al*., 2009, Hinman *et al*., 2012, Chapman *et al*., 2015, Yilmaz *et al*., 2015). This research question therefore utilised a 5º LWI for all LWI footwear conditions within walking trials, however further investigation surrounding differing LWI gradients is required as it might be that different amounts throughout the length of the lateral wedge (e.g., 10 degrees more distally from the heel) would allow a reduction in first peak EKAM as the foot became plantigrade but would still allow comfortable fitting inside the shoe.

When walking at a 20% increase of self-selected walking speed in shod, compared to a 20% increase of self-selected walking speed in shod with a 5º LWI inserted, a reduction of 3.15% in the EKAM was identified when individuals walked at the faster speed in shod with LWI. The reduction in the EKAM was not statistically significant however. In addition to the combination wedge idea, a further reduction in the EKAM could potentially be achieved by using LWI of varying wedge gradients or material density in future study.

6.3.7 Conclusion

The use of LWI in the study provided a reduction in the EKAM compared to the shod condition at self-selected walking speeds. This finding indicates LWI to be a beneficial intervention when used in healthy subjects to reduce the EKAM at normal walking speed. Minimal insignificant reductions in the EKAM when walking speed was increased by 20% when wearing LWI, compared to the shod condition were identified. Therefore, walking at increased speeds impacted the efficacy of LWI within this study. These findings have not previously been reported within the literature and have significant clinical implications for future research surrounding conservative treatment methods for knee OA and increased walking speeds when pain is reduced in individuals. Walking speed therefore requires further research, and future investigations should utilise varying gradients and designs of LWI at varying walking speeds in patients with medial compartment knee OA as these may be a factor affecting the biomechanical response of individuals to LWI intervention.

6.4 Chapter Summary

Investigations conducted within chapter six firstly identified the heel pin cluster marker to be an accurate and acceptable method for determining the 3D motion of the rearfoot in three planes of motion (sagittal, frontal and transverse) in healthy subjects when compared with a heel cup cluster marker. Findings have important clinical implications regarding the efficacy of heel pin cluster markers. Since the heel pin cluster marker was recognised as an acceptable method of quantifying rearfoot motion in barefoot, the heel pin cluster marker was utilised to assess rearfoot motion in shod. Differences were identified between rearfoot motion in shod when compared to barefoot in three planes of motion (sagittal, frontal and transverse) in healthy subjects. Barefoot walking therefore cannot be viewed to be the same as shod, due to the effects of footwear on rearfoot motion. These findings have important clinical implications for future research, specifically in the understanding of rearfoot motion and its effects on the efficacy of interventions designed to reduce the loading on the medial compartment of the knee for the treatment of medial compartment knee OA, such as LWI. The use of a heel pin cluster will enable future investigations to assess varying shoe designs and structure on the efficacy of and biomechanical response to LWI.

Quantifying rearfoot motion in shod with lateral wedge insole intervention using the heel pin cluster marker may provide inferences into the biomechanical response and non-response to LWI on the EKAM in individuals with medial compartment knee OA. Therefore, the heel pin cluster was assessed in shod and in shod with LWI to determine if any differences in rearfoot motion were present between the two conditions.

Significant differences existed between shod and LWI walking conditions with regards to rearfoot motion. Furthermore, significant differences were present between shod and LWI in minimum frontal plane rearfoot motion in the first peak of stance phase of the gait cycle. The small changes in rearfoot motion with the use of a LWI compared to shod identified within the walking trials may allow a change in kinetics, potentially leading to a reduction in the EKAM. Rearfoot motion cannot independently predict the magnitude of the EKAM, and therefore biomechanical responders and non-responders to LWI in healthy subjects. Further investigations into the motion of the foot and the tibia, and their effects on the magnitude of the EKAM in both healthy subjects and patients with medial compartment knee OA are required. Furthermore, investigation into factors during gait which may play a role in the efficacy of LWI intervention, such as walking speed, have not been previously addressed within the literature. Therefore, increasing walking speed in healthy subjects was assessed to determine if walking speed affected the biomechanical response to LWI. It was concluded that LWI provided a reduction in the EKAM compared to the shod condition at self-selected walking speeds. Minimal insignificant reductions in the EKAM were identified when walking speed was increased by 20% when wearing LWI, compared to when walking speed was increased by 20% in the shod condition. This finding has not previously been reported within the literature and has significant clinical implications for future research surrounding the design of conservative treatment methods for medial compartment knee OA, including LWI.

Chapter Seven

Overall conclusions and future investigations

7.1 Summary and conclusion

The overall aim of this thesis was to determine the role of the foot and ankle on the magnitude of the external knee adduction moment, and the impact on the effectiveness of lateral wedge insoles in both healthy subjects and patients with medial compartment knee osteoarthritis.

The initial focus of this thesis was a review of the existing literature surrounding knee osteoarthritis (OA), the external knee adduction moment (EKAM), lateral wedge insoles (LWI) and foot posture, presented in chapter two. The literature review identified that the following gaps were evident; a lack of investigation into the role of static and dynamic foot and ankle posture and motion on EKAM existed. Additionally, a lack of investigations into the biomechanical non-response to LWI intervention in knee OA patients was identified, which could possibly be related to rearfoot posture and motion. Furthermore, the literature failed to investigate whether barefoot rearfoot motion could successfully predict the biomechanical response to LWI when medial compartment knee OA patients walk in shod. Within the literature, it was not known if static measures of rearfoot and ankle motion, such as the Foot Posture Index are useful at indicating individual biomechanical response to LWI. Furthermore, only limited in shod and shod with LWI rearfoot motion data was found to exist within the literature. Finally, foot posture and its effects on EKAM, and the impact of LWI on the foot and ankle remain unclear within the literature.

The literature review allowed the researcher to gain a more profound understanding of the current state of research pertaining to the topic, and additionally, enabled the researcher to identify existing gaps within the literature from previous studies. A theoretical base justifying the need for further investigation concerning knee OA and foot posture was discussed.

Clinical guidelines recommend LWI, amongst other treatments as effective conservative management techniques for the treatment of medial compartment knee OA, however results from previous trials using LWI intervention have provided inconsistent results concerning reductions in the EKAM and therefore knee joint loading, and incidences of biomechanical non-response have been reported within the literature. Further investigation was therefore warranted.

Therefore, the aim of chapter four was to assess static foot posture in order to identify if a relationship existed between rearfoot motion and foot posture relative to the magnitude of the EKAM (a predictor of knee load), allowing future investigations to assess responders and non-responders to LWI intervention after an appreciation of foot posture in barefoot in healthy subjects was attained. The investigation aimed to determine whether the rearfoot (static and dynamic) is related to the magnitude of the EKAM in healthy subjects. Overall, no relationship was identified between the FPI and the EKAM, and also between the FPI and rearfoot motion. However, results indicated the relationship between rearfoot ROM and the EKAM was close to significant. Previous investigations within the literature have also identified a relationship between rearfoot motion and the EKAM. The investigation population was considered too small however, and therefore further investigation was undertaken in the form of exploration of a previously collected larger data set. FPI scores, dynamic ankle eversion data, and EKAM data from 137 healthy limbs was analysed to determine association between outcome parameters of clinical examination and the magnitude of the EKAM in order to identify a link between foot posture and knee loading, and to understand the role of static foot and ankle measurements and the magnitude of the EKAM. The investigation allowed an understanding to be gained into the role of dynamic rearfoot eversion on the magnitude of the EKAM. The value of this investigation was that it allowed inferences into whether clinical foot parameters have a role in the magnitude of the EKAM to be gained. No relationship was identified between variables, with the exception of the EKAM and dynamic rearfoot inversion and eversion, where a weak relationship was identified. Findings therefore imply that in healthy subjects, rearfoot motion may play a role in the magnitude of the EKAM.

Data from the 137 healthy limbs was then grouped into foot posture classifications (inverted, everted and neutral) in order to identify if any association existed between the FPI classification and dynamic rearfoot motion and the magnitude of the EKAM. No significant differences were identified in all groups between all variables. Strong negative association was identified between the FPI and rearfoot motion, and between the rearfoot FPI and rearfoot motion when limbs were divided into three groups (inverted, everted, and neutral) which added novelty to the literature. However, negative association does not provide inferences into whether rearfoot motion increases or decreases, as the FPI is a static measurement. Although association was present within the results, the association was negative and therefore clinical FPI and rearfoot

FPI classifications cannot represent biomechanical rearfoot motion. Results from this investigation suggested that the FPI may not be an ideal assessment to represent rearfoot motion in healthy subjects. Therefore, alternative assessment methods of the ankle subtalar joint complex are required, and future research should reflect this.

Furthermore, dividing the dynamic rearfoot data into three groups (inversion, eversion, and neutral) led to the conclusion that no relationship existed between rearfoot motion and the EKAM in healthy subjects. However, previous literature has stated that the dynamic rearfoot and static foot posture may play an important role in both the onset and progression of medial compartment knee OA, and may affect the efficacy of and the biomechanical response and non-response to LWI. Consequently, further investigation was required.

Chapter five therefore assessed the role of foot posture in response to the wearing of LWI, and the effects and impact on the EKAM in individuals with knee OA aiming to increase the understanding of how clinical static foot postures and biomechanical dynamic rearfoot motion may affect loading on the knee joint, the efficacy of LWI, and if a relationship exists between LWI and the magnitude of the EKAM. Despite previous studies investigating the effects of LWI as an intervention to reduce the loading on the medial compartment of the knee (which may be influenced by foot posture), a lack of research assessing clinical static foot posture, dynamic biomechanical rearfoot motion, and the magnitude of the EKAM with the use of a LWI was identified. Therefore, this study is an important addition to the literature.

The results found no relationship existed between static foot posture and dynamic rearfoot motion, moreover, no relationship was identified between static foot posture and the magnitude of the EKAM in patients with medial knee OA. Therefore, clinical static foot posture (FPI) cannot predict rearfoot motion and the magnitude of the EKAM in both healthy subjects and patients with medial compartment knee OA, and should not be used as a predictor of biomechanical response or non-response to lateral wedge insole intervention. Additionally, Body Mass Index, age, and gender cannot predict medial compartment knee osteoarthritis patients that will respond to LWI. These findings add novelty to the investigations and may aid the further understanding and improvement of interventions for the treatment of medial compartment knee OA, such as LWI.

Some association was identified between the dynamic rearfoot and the EKAM in patients with medial compartment knee OA. Results indicated that patients with a larger rearfoot range of motion are more likely to respond to LWI, which has been reported in previous research in shod walking. This investigation was the first to identify that barefoot rearfoot motion is a significant predictor of biomechanical response to LWI in patients with medial compartment knee OA. This finding has important clinical implications that may lead to further understanding of individual biomechanical response or non-response to LWI. Future studies should investigate the range of motion at the rearfoot, which could be assessed in a clinical setting, both statically and dynamically to identify possible relationships to biomechanical rearfoot range of motion. The collection of rearfoot motion in shod is challenging however, and therefore methods to understand this are required in order to investigate the influence of LWI on gait. Furthermore, the results indicated that walking speed varied between biomechanical responders and non-responders to LWI, with the non-responders walking faster than responders. It was concluded that further investigation is required into walking speed and LWI.

Chapter six involved an investigation which aimed to identify and examine possible differences between heel cup clusters and heel pin clusters when used to evaluate kinematic rearfoot motion during barefoot walking in three planes of motion, which had not previously been addressed within the literature. A heel pin cluster marker can be considered an acceptable method when used to quantify rearfoot motion in barefoot walking, and therefore may increase the understanding of rearfoot motion and its possible effects on knee loading. The heel pin cluster was then assessed between barefoot and shod walking conditions to determine the effect of shoes on rearfoot motion, and whether barefoot rearfoot motion, quantified using a heel pin cluster marker, represented rearfoot motion in shod when quantified using a heel pin cluster marker in healthy subjects. Within the shod footwear condition, results identified differences between rearfoot motion when compared to barefoot in three planes of motion (sagittal, frontal and transverse) in healthy subjects. Barefoot walking therefore cannot be viewed to be the same as shod, which has not previously been identified within the literature and may lead to further understanding of rearfoot motion in shod. Additionally, these findings may lead to future investigations into the impact of footwear (such as the density and thickness of the shoes sole, shoe structure and manufacturing materials) on rearfoot motion and gait.

Investigations aiming to identify the differences between shod and LWI walking conditions in three planes of motion were then conducted, and findings indicated significant differences were present between walking conditions (shod and LWI) during stance phase of the gait cycle. Additionally, the results achieved from heel strike to the period of time when the first peak of EKAM occurred in minimum and maximum frontal plane rearfoot motion indicated that significant differences in minimum frontal plane rearfoot motion were present between shod and LWI intervention. These findings indicate significant differences were present in minimum frontal plane rearfoot motion between shod and LWI, and therefore increases in frontal plane rearfoot motion are towards eversion with the use of a LWI compared to shod, which may be caused by the lateral gradient of the LWI, which reduces the EKAM by shifting the centre of pressure in the foot laterally. The significant changes in rearfoot motion quantified using a heel pin cluster marker during stance phase and the first peak of stance phase of the gait cycle, identified during walking with a LWI compared to shod may allow a change in kinetics, possibly leading to a reduction in the EKAM, and therefore a reduction in the load on the medial compartment of the knee joint.

These findings are consistent with the literature, and may allow further understanding of rearfoot motion in shod and the effects of LWI on the rearfoot with the use of a heel pin cluster in future studies using patients with medial compartment knee OA.

The efficacy of LWI when used at increased walking speeds compared to shod was investigated, which had not previously been conducted within the literature, and aimed to determine whether an increase in walking speed led to a reduction in the magnitude of EKAM with the use of LWI compared to shod. The gait of participants was firstly examined at self-selected walking speed, and secondly at a 20% increased walking speed.

A reduction in the EKAM was identified with the use of a LWI compared to the shod condition when participants walked at self-selected speeds. LWI are therefore a beneficial intervention when used in healthy subjects to reduce the EKAM at normal walking speeds. Findings indicated minimal and insignificant reductions in the EKAM were present when walking speed was increased by 20% with the use of LWI compared to the shod condition. Moreover, a 20% increase in walking speed from self-selected speeds with the use of a LWI led to an increase in the EKAM compared to self-selected walking speeds. It can therefore be stated that walking at increased speeds led to a reduction in the efficacy of LWI. These findings have not previously been reported within the literature and therefore, future research surrounding conservative treatment methods for knee OA should consider the efficacy of the treatment when worn at increased walking speeds. Considering the results from a clinical perspective, these findings may contribute to clinician’s recommendations to individual patients concerning walking at slower speeds when wearing LWI in order to achieve an optimal reduction in EKAM and therefore the maximal benefits of LWI use.

Additionally, walking speed could possibly be a factor affecting the biomechanical response of individuals to LWI intervention, and consequently walking speed requires further exploration within future research. Furthermore, future studies should focus on varying LWI designs (shape, length, wedge gradient and manufacturing material) and their possible influences on the magnitude of the EKAM in patients with medial compartment knee OA when walking at increased speeds.

7.2 Thesis Novelty

Aspects included within this thesis had not been previously conducted, and therefore can be considered novel, adding to the literature, and also the knowledge of both experimenters and clinicians within the field of medial compartment knee OA.

The primary novelty in this thesis was the examination of rearfoot motion in barefoot, to determine if rearfoot motion can predict biomechanical response and non-response to LWI intervention in patients with medial compartment knee OA. This thesis was therefore the first to conclude that rearfoot motion in barefoot can predict which patients with medial compartment knee OA may respond or not respond to LWI intervention.

This study was the first to examine clinical measurements including the FPI, BMI, gender and age of participants in order to assess whether they could predict if an individual was likely to be a biomechanical responder or non-responder to LWI. The study was therefore the first to conclude that clinical measurements cannot predict biomechanical response to LWI intervention.

The thesis also investigated individual participant's limb data into three groups according to Foot Posture Index classifications, which included; inverted, neutral and everted in order to determine if a relationship existed between static foot posture, rearfoot motion and the magnitude of the EKAM in healthy subjects. Additionally, this study divided individual participant's limb data into three groups; inversion, neutral, and eversion, according to rearfoot motion in order to identify if a relationship existed between rearfoot motion and the magnitude of the EKAM. Dividing the limbs of participants in such a way had not been conducted previously within the literature.

This thesis contains the first study to assess the differences between a heel pin cluster marker and a heel cup cluster marker when used to quantify rearfoot motion in barefoot and shod. Additionally, the investigation which used a heel pin cluster to quantify rearfoot motion in shod compared to in shod with LWI had not been carried out previously. The relationship between rearfoot motion and the magnitude of the EKAM quantified using a heel pin cluster marker was investigated within this thesis using healthy subjects, and had not been conducted previously.

This thesis investigated the differences between walking speed in biomechanical responders and non-responders to LWI intervention in a population of medial compartment knee OA patients. Such an investigation had not been conducted previously. Walking speed was found to be faster in biomechanical non-responders to LWI intervention, which has not been reported before within the literature. Investigations performed within this thesis included the exploration of the effects of LWI and walking speed on the EKAM, to determine if an increase in walking speed influences the biomechanical response to LWI in healthy subjects, which had not been carried out previously.

7.3 Future Studies

This thesis has highlighted some potential future studies that would allow further investigation of the role of the rearfoot in patients with medial compartment knee osteoarthritis. In health care clinics, it is quite rare to see 3-D data capture facilities being available. Therefore, in order for the results to be confirmed from this thesis, a clinical generalisability study would be the next step. This would involve simple measurements of the rearfoot range of motion (using 2-D analysis which is common in podiatric and physiotherapy clinics) to determine whether there is a cut-off angle where biomechanical response is true. The most complete design would be a blinded design whereby the clinician determines whether the individual would respond from their clinical data collection, confirmed by 3-D analysis. This would need a larger sample size of individuals but would be a large step to stratify patients.

It is not known from the literature whether biomechanical response affects clinical and structural outcomes. Therefore, an assessment of the importance of biomechanical changes would be a future option to determine the impact of lateral wedge insoles on these measures. This would be a costly study to undertake but would be worthwhile to bring these different methodological aspects together in one study, which has not been performed before. Within this thesis, the incidence of biomechanical non-response to LWI intervention was identified and assessed immediately after the wearing of the LWI. No previous study has investigated the long term biomechanical non-response to LWI, and therefore it is unknown whether biomechanical response may take place in a previous biomechanical non-responder, after the long term use of LWI. Therefore, further investigation is needed to determine whether response changes over time.

Additionally, the biological response to LWI intervention is not investigated within the literature, and therefore assessment of the importance of biological changes should be considered within future investigations to determine the impact of LWI on biological measures. Methods of assessment could include X-rays, biomarker assessment, and MRI and should be conducted as part of a longitudinal investigation, so that the effects of LWI on the biology of the knee can be assessed over a long period of time.

Further investigation using the heel pin cluster marker in shod is required in patients with medial compartment knee OA, however time constraints of this PhD meant that further investigation was not possible within this thesis. Therefore, future studies should investigate the differences and the relationship between rearfoot motion and the EKAM in patients with medial compartment knee OA and response and non-response to LWI intervention. Further investigation into the effects of varying gradients and designs of LWI, and varying footwear, together with increased walking speed is required, as the degree, thickness, shape, length and density of LWI, the design of shoes, and walking speed can impact the biomechanical response and non-response to LWI in patients with medial compartment knee OA.

Previous investigations have concluded that walking with LWI can lead to an increase in walking speed in patients with medial compartment knee OA. Further investigation is therefore necessary, and should focus on whether walking speed affects individual biomechanical response to LWI. Investigations should also aim to determine whether walking speed contributes to the incidence of biomechanical non-response of individuals to LWI intervention in both healthy participants and patients with medial compartment knee OA present within both this study and reported within the literature.

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Appendices

Appendix One

University of Salford
MANCHESTER

Research, Innovation and Academic Engagement Ethical Approval Panel

College of Health & Social Care
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r.shuttleworth@salford.ac.uk

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20 August 2013

Dear Yousef,

RE: ETHICS APPLICATION HSCR13/42 – The effects on in-shoe ankle motion and varying speed on knee loading whilst wearing lateral wedged insoles

Based on the information you provided, I am pleased to inform you that application HSCR13/42 has now been approved.

If there are any changes to the project and/ or its methodology, please inform the Panel as soon as possible.

Yours sincerely,

Rachel Shuttleworth

Rachel Shuttleworth
College Support Officer (R&I)

Appendix Two

NHS
Health Research Authority
National Research Ethics Service

NRES Committee North West - Greater Manchester East
3rd Floor, Barlow House
4 Minshull Street
Manchester
M1 3DZ

Telephone: 0161 625 7820

22 May 2013

Dr Richard Jones, Senior Lecturer in Clinical Biomechanics
University of Salford
PO18 Brian Blatchford Building
Frederick Road
Salford
M66 PU

Dear Dr Jones

Study title:	**Effect of Lateral WEDGE insoles on Osteoarthritis knee pain and joint loading. The WEDGE study.**
REC reference:	**13/NW/0362**
IRAS project ID:	**129483**

The Research Ethics Committee reviewed the above application at the meeting held on 21 May 2013. Thank you for offering to attend the meeting to discuss your study; as you are aware, this was not considered necessary since the application was found to be most satisfactory..

We plan to publish your research summary wording for the above study on the NRES website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to withhold permission to publish, please contact the Co-ordinator, Elaine Hutchings, nrescommittee.northwest-gmsouth@nhs.net.

Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Ethical review of research sites

NHS Sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Other: 13 Patient letter week 6, 10 and 16 gait visits	V2	01 February 2013
Other: 08 Patient thank you letter	V2	01 January 2013
Other: 09 GP letter completed study	V2	01 February 2013
Other: UMAL Professional Indemnity		09 July 2012
Participant Consent Form: 03 WEDGE Informed consent	V1.3	01 February 2013
Participant Information Sheet: 02 WEDGE PIS	V2	12 February 2013
Protocol	01 WEDGE protocol	12 February 2013
Questionnaire: WEDGE questionnaires	V2	23 April 2013
Questionnaire: 07 WEDGE follow up questionnaires	V2	23 April 2013
Questionnaire: 12 WEDGE Pain Comfort Scores	V2	23 April 2013
REC application	129483/442702/1/161	23 April 2013

Membership of the Committee

The members of the Ethics Committee present at the meeting are listed on the attached sheet.

Chris Houston declared an interest in this study. It was agreed that he could remain in the room during the review of the application but would not participate in the deliberations.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

Further information is available at National Research Ethics Service website > After Review

13/NW/0362	Please quote this number on all correspondence

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

With the Committee's best wishes for the success of this project.

Yours sincerely

Mr Francis Chan
Chair

Email: nrescommittee.northwest-gmeast@nhs.net

Enclosures:	*List of names and professions of members present at the meeting*
	"After ethical review – guidance for researchers"
Copy to:	*Mrs Sue Braid, University of Salfor*
	Mrs Rachel Georgiou, R&D, Salford Royal NHS Foundation Trust

NRES Committee North West - Greater Manchester East

Attendance at Committee meeting on 21 May 2013

Committee Members:

Name	*Profession*	*Present*	*Notes*
Mr David Asher	Retired Community Locum Pharmacist	Yes	
Mr James Burns	Retired	Yes	
Mr Francis Chan	Consultant Orthopaedic Surgeon	Yes	Chair
Dr Jacqueline Crowther	Research Assistant	No	
Dr Mary Dolan	Nurse Lecturer	No	
Dr Michael Hollingsworth	Retired Senior Lecturer in Pharmacology	Yes	
Mr Christopher Houston	Lay Member	Yes	
Mr Simon Jones	Specialist Podiatrist - Paediatrics	Yes	
Dr Priyadarshan Joshi	Consultant Psychiatrist	Yes	
Dr Philip Lewis	Consultant Cardiologist	Yes	
Professor Janet Marsden	Professor of Ophthalmology and Emergency Care	Yes	
Mrs Mary Speake	Clinical Research Practice Educator	No	

Also in attendance:

Name	*Position (or reason for attending)*
Sian Goodwin	Acting Assistant Co-ordinator
Elaine Hutchings	Committee Co-ordinator