1. Introduction

1.1 The problem

Osteoarthritis (OA) is the most common form of arthritis and is regarded as among the top ten conditions contributing to the world’s disease burden (World Health Organisation (WHO) 2003). It is chronic and a leading cause of pain and reduced functional ability due to the involvement of key joints, such as the tibiofemoral joint (TFJt) of the knee (Sharma and Kapoor 2007). The knee is the largest and one of the most complex weight-bearing joints in the human body. It provides structural and dynamic stability and permits mobility of the lower limb (Al-Obaid et al., 2007). Although it consists of two main articulations: the TFJt and the patellofemoral joint (PFJt), it is the medial TFJt that is most commonly affected by OA (Bennell et al., 2011). In OA, ageing may trigger certain physiological and biochemical alterations which can propagate joint dysfunction. Age-related changes such as altered cartilage composition, abnormal subchondral activity of the osteocytes or structural malalignment profiles, such as abnormal foot posture and varus knee alignments, can precipitate the osteoarthritic process (Bellamy 1988; Holliday 1995; Arking 1998; Wang et al. 2009). However, the influence and potential mediating effect of lower limb alignment factors such as foot posture has only recently received research attention (Levinger et al., 2010; 2012).

Foot posture is regarded as influential in early-stage OA patients as alterations to foot posture and function with the use of foot orthoses such as lateral wedge orthoses (LWOs) have been documented (Crenshaw et al., 2001; Kerrigan et al., 2002). Toda and Tsukimura (2004) demonstrated that a lateral wedge works on the premise of laterally tilting the heel of the foot, inducing a valgus angulation of the ankle and reducing the varus alignment of the knee joint. This reduced pain and improved the knee-health related quality of life outcomes. However, the results of other studies have been varied and inconclusive (Pham et al., 2004; Butler et al., 2007 and Raiij et al., 2010). A Cochrane review conducted by Brouwer et al. (2007) reported that there is only ‘silver’ level evidence suggesting LWOs have a small beneficial effect. This could be attributed to only a handful of randomised controlled trials (RCT’s) conducted. There have also been limitations such as small participant numbers, interventions that have not been adequately described and the inclusion of OA patients with varying disease severity (Bennell et al., 2011). Perhaps more important is the fact that many studies fail to consider or document foot posture making it difficult to compare data and establish a link between medial TFJt OA outcomes and foot posture. Foot posture and function is linked with plantar pressure assessments and with tibial rotations due to the kinematic coupling of
the lower limb (Chuckpaiwong et al., 2008; Bellchamber and Bogert 2000; Pohl and Buckley 2006). It therefore follows that it may affect medial TFJt loading and could influence OA patient outcomes suggesting an improvement in existing conservative treatments. It is clear that there is a need to assess and consider a standardised foot position in this pathological group.

Currently, there is no cure and management strategies are focussed on minimising pain, improving physical functioning and increasing the knee-health related quality of life in OA patients (Zhang et al., 2008). Non-pharmacological interventions such as LWOs are considered a front-line management approach although the research is limited when compared with pharmacological and surgical alternatives (Tallon et al., 2000). Well-designed studies which are constructed in accordance with RCT performance guidelines such as the CONSORT (Consolidated Standard for Reporting Trials) statement are warranted. This will provide a standardised manner of reporting trial design, analysis and interpretation of the results and would address the limitations discussed by Bennell et al., (2011) previously. The role of foot posture and the combined effect with LWOs on loading transfer along the lower limb kinetic chain could provide a more refined clinical insight for TFJt OA management.

1.2 Aim of the thesis

The overall aim of the thesis is to establish clinical lower limb alignment profiles in normal (non-pathological) and OA participants and investigate the potential influence of these profiles on medial TFJt OA patient outcomes. The role of LWOs will also be investigated alongside alignment profiles as a conservative treatment intervention in medial TFJt OA participants.

It begins with an overview of the literature relating to the functional anatomy of the TFJt, normal and abnormal lower limb alignment profiles and how these may contribute to the development and progression of medial TFJt OA (Chapter 2). It then provides a detailed description of the methodological processes and data collection protocols (Chapter 3). Chapter four presents the comparative study between the OA and non-OA groups. The clinical effectiveness of LWOs will then be evaluated in Chapter 5 in a non-blinded block randomised RCT in which the primary outcome will be patient-centred outcome scores and the secondary outcomes will be in-shoe plantar pressure measurements. The results will be explored within the context of foot posture and other spatial gait characteristics that may be significant based on findings from the preceding chapters (Chapter 4 and 5). Finally, Chapter 6 summarises the key findings of each preceding chapter, its clinical implications and recommendations for further research.
1.3 Significance of the thesis

There is a worldwide prevalence of medial TFJt OA and its prevalence is increasing due to the longevity of the population, sedentary lifestyles and the obesity pandemic (Murphy et al., 2008). This is accompanied by increasing healthcare costs, global economic stresses and, despite this, a drive to improve the value and quality of care for a patient (Kirkup 2012). Therefore, furthering our understanding of how front-line treatment options such as LWOs work within the context of lower limb alignment factors such as foot posture could result in evidence-based, cost-effective and clinically effective management strategies. This would reduce healthcare and human costs associated with invasive treatment options such as surgery or long-term pharmacological management. These are only appropriate for the small number of OA patients with advanced disease and/or severe symptoms (Juni et al., 2006).

For this thesis, a series of clinical measures were used to establish and compare normative clinical reference values for lower limb alignment in mild-moderate OA and normal participants. This would address a gap in the evidence base on the impact of foot posture and its potential influence on improving patient-centred outcomes such as pain and quality of life. It could be a relevant clinical indicator of knee OA development and help detail a patient subgroup that is most suited or responsive to LWO treatments based on standardised foot position.
2. Literature Review

The aim of this chapter is to appraise the literature on the relevance of lower limb alignment profiles and various methods available within a clinical setting. It will also identify gaps in the evidence base with regards to these profiles in medial knee osteoarthritis. Section 2.1 will provide an overview of osteoarthritis with a background, classification and clinical presentation along with the aetiology and pathophysiology of the disease in the knee. Section 2.2 will discuss normal and abnormal lower limb alignment profiles focussing on foot posture and knee alignment. Section 2.3 will review methods available for assessing foot posture, knee alignment and the choice of kinetic variables (plantar pressure parameters). Section 2.4 discusses OA management strategies and conservative interventions such as foot orthoses. Section 2.5 covers patient centred outcome scores and their relevance in the treatment of medial TFJt OA. It discusses their significance, intra-rater reliability, validity and rationale for inclusion in the studies. Finally, section 2.6 provides a key summary of the literature review.

2.1 Background, Aetiology and Pathophysiology

Background: Epidemiology, Classification and Clinical Presentation

Osteoarthritis (OA) is the most common form of arthritis and is the leading cause of chronic disability and impaired mobility due to the involvement the knee (Hunter and Felson, 2006; Moskowitz et al., 2007). TFJt OA is the most common form of lower extremity OA (Oliveria et al., 1995). Increasing life expectancy and an obesity epidemic is expected to make OA a leading cause of disability by 2020. Its incidence increases from the age of 40, with more women affected than men from the ages of 40-70 (Murphy et al., 2008; Dunlop et al., 2010). In the UK, the total cost of OA on the economy is estimated to be 1% of the gross national product or valued at £3.2 billion in monetary terms but this is thought to be a conservative estimate (NICE 2008). It is the second most common reason for loss of working days and affects 10 million people (Arthritis Care 2012). The budgetary constraints placed on the National Health Service (NHS) in recent years and the increasing costs of healthcare provision and resources will see the gradual increase of OA management costs (Kirkup 2012).

OA can be diagnosed in a clinical setting by symptom presentation such as pain and/or functional limitations or by the presence of joint alterations such as radiographic evidence of joint space narrowing, subchondral sclerosis and osteophyte proliferation (Moskowitz et al., 2007). While there is a diagnostic discordance between evidence of radiographic TFJt OA and symptomatic TFJt OA, the National Institute of Health (2008) suggests that the radiographic degenerative process of OA should be conceptually separated from the clinical symptom presentation. Within a clinical context, the most compelling definition of TFJt OA is structural presentation and pain which affects the knee
joint quality and range of movement. As a result, symptomatic arthritis which is disease-based and has a clinical presentation is recommended for studies investigating the causes, progression and management strategies for TFJt OA. Dieppe and Brandt (2003) state that in knee pain patients without serious locking or severe loss of function, radiographic evaluation is not routinely recommended. It is regarded as both expensive and having a limited clinical value within the context of OA. It is also important to differentiate between symptomatic OA and other causes of knee pain such as referred pain or soft tissue conditions. Dieppe and Lohmander (2005) state that despite this, OA is an easily distinguishable clinical condition with key characteristics that permits clinical diagnosis. The American College of Rheumatology (ACR, Altman 1986) presented a set of clinical criteria for the classification of idiopathic TFJt OA and is as follows:

- **Knee pain:** Pain on movement of the joint during activities such as climbing stairs or walking long distances and any three of the following features;
- **Increased age:** Patients are usually over the age of 50
- **Stiffness:** Patients with symptomatic OA experience short spells on inactivity stiffness (less than 30 minutes) which is not maintained on joint movement
- **Crepitus:** Patients experience creakiness on moving the joint
- **Bony Tenderness:** Patients experience sensitivity and feelings of discomfort on joint manipulation.
- **Bony Enlargement:** Patients present with osteophytic lipping or osseous protrusions as a result of the OA degenerative process.
- **No palpable warmth:** This differentiates the OA patients from patients with inflammatory conditions such as rheumatoid arthritis.

The ACR criteria and more recent updates by Zhang et al., (2010) including family and medical history has been used in research studies because of their clinical applicability, and high sensitivity (95%) and specificity (69%) in diagnosing OA compared to rheumatoid arthritis and other painful conditions of the knee (Peat et al., 2006; Thorstensson et al., 2009). This variation in clinical diagnostic methods is perhaps also a result of the limited understanding of the aetiology and pathophysiology of TFJt OA (Hunter and Felson 2006).
Articular cartilage has viscoelastic and compressive properties due to the predominant composition of its extracellular matrix consisting of type II collagen and proteoglycans (proteins which are heavily glycosylated). Under normal ageing conditions, the matrix is subjected to a dynamic remodelling process in which there is a balance between degradative and synthetic enzyme processes which maintains the normal articular cartilage volume (Ling and Bathon 2011). However, in OA the matrix degradative enzymes are over-expressed, resulting in a shift in this dynamic balance. There is an initially metabolically active spurt of chondrocytes leading to ‘brood clusters’ in the cartilage matrix. The chondrocytes produce excessive amounts of proteoglycans and collagen fibres within the matrix that leads to initial thickening and could be a protective mechanism. Whilst initially this mechanism may help to protect the underlying subchondral bone from increased loading on specific joint sites such as the medial knee aspect, OA progresses to cartilage fibrillation, fissuring and eventual disappearance of the articular cartilage thickness altogether (Kumar and Clark 2005). Ultimately, the quality, arrangement and size of collagen fibres decreases and this is matched by a decrease in proteoglycan content. Quite simply, OA is a disruption in the homeostasis of articular cartilage and bone.

OA is an idiopathic disease process as there are several factors that could trigger the homeostatic imbalance and subsequent pathogenesis of the disease (Hunter and Felson 2006). Figure 1 highlights these factors. This illustration can also be discussed in the context of ageing theories and specifically, stochastic and systemic mechanisms (Arking 1998). Stochastic mechanisms are based on the occurrence of single random events such as genetic mutations which predispose to OA (Holliday 1995). Systemic mechanisms are based on a hierarchical cascade of interrelated events such as the incidence of abnormal alignment factors that could eventually contribute to injury, overload and instability of a joint structure. Bellamy (1988) and Holliday (1995) furthered this evolutionary theory of ageing to include the possibility that breakdown of joint structures such as articular cartilage are in fact systemic failures that highlight the ‘fault lines’ in anatomical and physiological structures. This weak link theory could be applied to mechanical factors contributing to abnormal joint biomechanics that initiate OA biochemical pathways as in Figure 2.1.

OA is thought to be caused by abnormal mechanical factors acting within the context of other systemic risk factors which includes an increased age or female sex (Hunter and Felson 2006) or genetic predisposition (Peach et al., 2005). Ultimately, mechanical factors play a central role in OA development and progression. The key environmental risk factors such as joint overloading and
lower limb malalignment which are mechanical by nature, can adversely affect the structure and function of the knee joint resulting in either radiographic features and/or symptom presentation. Teichtahl et al., (2003) state that the focus on biomechanical factors such as lower limb alignment profiles are key to deciphering the relatively unknown causes and pathogenesis of TFJt OA.

Figure 2.1 Schematic representation of the link between environmental and endogenous risk factors for TFJt OA development (Dieppe and Lohmander 2005).

The TFJt is the most complex joint in the lower limb and possibly in the human body. The osseous anatomy of the knee is comprised of the proximal tibia, the distal femur and the patella. The osseous structure provides little stability and the knee is therefore supported, stabilised and cushioned by soft tissue structures such as the menisci, ligaments, muscles and tendons. The main ligaments are the medial and lateral collateral ligaments and the anterior and posterior cruciate ligaments which provide static constraints, while the main muscle groups are the quadriceps (vastus lateralis, vastus medialis, vastus intermedius and the rectus femoris) and the hamstrings (semitendinosus, semimembranosus and biceps femoris) providing dynamic constraints (Drake et al., 2010). The menisci are two crescent-shaped fibrocartilaginous structures that are attached to the tibial plateau on the medial and lateral aspect. They provide an increased surface area for weight bearing and therefore help dissipate peak loading on the articular cartilage. They also increase stability by nature of their crescent shapes and improve an otherwise flat tibial articular cartilage (Netter 2011).
However, the medial meniscus is distinctly different to the lateral meniscus as it is larger; half moon shaped as opposed to circular and, is directly attached to the medial collateral ligament making it more adherent to the knee joint capsule. It is more often injured due to this attachment and because it is less mobile during full knee extension than its lateral counterpart (Vanhoenacker et al., 2007). The medial TFJt is cushioned by this meniscus, but is often affected by joint over-loading due to abnormal lower limb mechanics.

OA of the knee most commonly occurs in this medial TFJt compartment. A loading increase on the medial aspect of the TFJt’s articular cartilage could initiate the homeostasis imbalance that leads to cartilage degradation and, is thought to be an important factor in the pathogenesis of OA (Sharma et al., 1998; Hurwitz et al., 2003; Miyazaki et al., 2002). While it is impossible to measure intrinsic knee loading non-invasively, the external knee adduction moment (KAM) is considered a reliable surrogate and a clinical indicator of knee loading (Hunt et al., 2008). KAM is a combination of the ground reaction force (GRF), which passes medial to the knee joint centre and the perpendicular distance of the force from this centre (Andriacchi 1994). The KAM has been related to an increase in medial tibial bone mineral density (Bennell et al., 2008); a decrease in the medial tibial articular cartilage (Jackson et al., 2004) and an increase in medial knee loading (Mundermann et al., 2008).

Figure 2.2 shows a normal GRF in a varus aligned limb (a) and an adjusted GRF which reduces the moment arm and thus KAM in (b).

This KAM is thought to distribute between 60-80% of knee compressive loads to the medial TFJt during normal walking and is greater in individuals with TFJt OA. This initiates but also further increases adverse medial compartment loading in this population (Sharma et al., 1998). Alignment is known to increase KAM as a varus alignment of the lower limb (bow legged) would hypothetically increase the moment arm from the knee joint centre and therefore increase medial loading. The statically assessed anatomical alignment axis of the lower limb accounts for 50% of the KAM variability. The line of progression and degree of foot rotation are also thought to have an impact (Guo et al., 2007). Within a routine clinical setting, the relationship between KAM and symptom presentation can be linked as researchers have shown a significant relationship between mild-moderate TFJt OA symptoms and an increased KAM (Ueda et al., 2003; Thorp et al., 2007).
Alignment is linked with KAM and could be an important factor in mediating patient outcomes in medial TFJt OA. This is because TFJt alignment can affect how the knee responds to loading forces (Lim et al., 2008). The structural integrity of the knee can also be further compromised as a result of other malalignment factors of the lower limb. This can include abnormal foot pronation and/or excessive internal tibial rotation (Donatelli 1996; Llandorf and Keenan 2000; Bashaw and Tingstad 2005).

The position of the foot and its relative dynamic function is a consideration for a range of lower limb musculoskeletal overuse and exercise-related injuries (Murley et al., 2008). In particular, foot posture in medial TFJt OA populations is also thought to alter lower limb alignment and influence dynamic functioning of the lower limb (Guichet et al., 2003). Related spatial gait parameters such as quasi-static angle and base of gait (AOG (degrees) and BOG (centimetres)) are also insightful as they provide an indication of the dynamic position of the foot in midstance (Bryant 2001; Curran et al., 2006). Rutherford and colleagues (2007) demonstrated that in mild-moderate TFJt OA

**Figure 2.2** In (a) ground reaction force (GRF) vector which is directed towards the body’s centre of mass. This force acts at a distance from the knee joint centre (red arrow) and produces the KAM. In (b), a lateral wedge placed under the foot increases pronatory (Lidtke 2011).
individuals, an increased foot progression angle (toe-out gait) decreased KAM. This suggests that an increased dynamic AOG could be a compensatory mechanism to reduce medial TFJt loading. An increase in the BOG and AOG has also been linked with increase in foot pronation (Curran et al., 2006). Another factor that may influence TFJt loading is lower limb asymmetry where limb dominance has a moderating effect on the magnitude of medial and lateral GRF. A typically dominant right limb demonstrates an increased AOG, is slightly pronated and exhibits greater medially directed plantar pressures than lateral loading (Polk and Rosengren 2010).

In turn, this pronated foot type (characterised by eversion of the heel, dorsiflexion of the talus and abduction of the forefoot) can increase the varus stresses acting on the knee joint (Liang and Fortin 1991). An abnormal foot posture could occur in tandem with an abnormal TFJt alignment resulting in the progression of medial TFJt OA symptoms. However, foot posture characteristics, spatial gait assessments and limb dominance in OA populations have only been established in a limited number of studies (Levinger et al., 2010). Also, OA studies which focus on conservative lower limb interventions rarely consider foot posture and knee alignment (Table 2.1). It has also been postulated that a varus knee alignment could lead to compensatory foot pronation that enables to foot to be mobile and adaptable when weight bearing in medial TFJt OA (Riegger-Krugh 1996). To decrease subsequent medial knee loading, the foot compensates by pronating which could alter the direction of the GRF and reduces the KAM produced during midstance (Lidtke 2011).

However, whether abnormal foot postures and abnormal TFJt alignments occur concurrently or whether they are risk factor for or a consequence of medial TFJt OA has not been conclusively documented. Previously, while abnormal TFJt alignments are thought to occur as a result of OA development; several authors have now shown that such mechanical factors are in fact a precursor to OA initiation and progression (Slemenda et al., 1998; Sharma et al., 2003). Therefore, identifying if and how these factors differ between healthy and OA knee joints would further our understanding of the influence of mechanical factors on TFJt OA and this could be used as a predictor of TFJt OA development and symptom presentation.
<table>
<thead>
<tr>
<th>Authors, Year of Study, Sample Size and Randomisation</th>
<th>Intervention Specifics</th>
<th>Key Research Findings</th>
<th>Conclusions Drawn</th>
<th>Lower Limb Alignment 'LLA' (Foot Posture and Knee Angle)</th>
</tr>
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<tbody>
<tr>
<td>Maillefert et al., 2001 N = 156 Randomisation not described; Patient-blinded study.</td>
<td>Laterally wedged insoles and neutral insoles were made of Ledos material (rubber based). Laterally wedged insoles were customised based on static evaluation.</td>
<td>• 6-month follow up revealed a significant decrease in NSAID intake and higher degree of compliance in wedged insole compared to neutral insole group. • Self-assessed functional scores improved by at least one grade with orthotic therapy.</td>
<td>The use of insole therapy showed reduced WOMAC scores in both groups and a decrease in the use of pharmacological supplements. 2-year follow-up conducted by Pham et al., 2004 with similar results.</td>
<td>The study made no reference to LLA. The degree of varus alignment was not measured nor was TFJt angle. Foot posture and function was not defined or categorised. Orthoses were customised based on static pedometer evaluations not biomechanical evaluation.</td>
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<tr>
<td>Toda et al., 2001 N= 90 Quasi-Randomisation based on birth date; Non-blinded study.</td>
<td>An elastic subtalar strapped insole (urethane based) versus a traditional lateral wedge insole (rubber based) Standard lateral elevation of 6.35mm.</td>
<td>• Participants wearing the elastically strapped insole had significantly decreased TFJt angle and talar tilt angle. • Pain scores improved significantly on Visual Analogue Scale (VAS) compared to baseline assessments. However there was no between-group analysis.</td>
<td>The strapped insole leads to a valgus angulation of the talus, resulting in correction of the TFJt angle in patients with TFJt OA. Number and degree of adverse effects of orthoses treatment are low</td>
<td>The study evaluated the TFJt angle using standing radiographs with and without the respective insoles. Radiographs are considered the gold standard but are expensive, time and resource intensive and expose participants to radiation. No attempt was made to ascertain foot posture.</td>
</tr>
<tr>
<td>Maly et al., 2002 N = 12 Non randomised; non-blinded study</td>
<td>Repeat measures design where participants had to wear normal footwear, a 5° valgus wedge and an orthotic with built-up 5° valgus wedge</td>
<td>• No change to static alignment or knee adduction moments. • A lateral shift in the centre of pressure (COP) resulted in a reduced knee adduction moment due to outward rotation of the foot. Some gait data was not reported due to</td>
<td>The reduction in the COP was linked to the knee adduction moment suggesting that foot positioning was altered due to an adoption of a toe-out position.</td>
<td>The Hip-Knee-Ankle (HKA) was determined using radiographic findings but foot posture was not measured or discussed. Despite results suggesting an alteration in foot posture due to foot orthoses, no attempt was made to quantify and evaluate changes in lower limb alignment.</td>
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<tr>
<td>Study</td>
<td>N</td>
<td>Design</td>
<td>Intervention</td>
<td>Findings</td>
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<tr>
<td>Toda et al., 2002</td>
<td>88</td>
<td>Quasi-randomisation based on birth date; Non blinded study</td>
<td>A subtalar strapped insole and a sock type ankle support, both with elevations of 6.35mm.</td>
<td>The use of subtalar strapped insole showed a lower TFJt angle. Both groups had decreased pain scores after getting up and at rest compared to baseline. However, there were no comparisons made between groups.</td>
</tr>
<tr>
<td>Pham et al., 2004</td>
<td>156</td>
<td>Randomised Study</td>
<td>Laterally wedged insoles and neutrally wedged control insoles</td>
<td>After 2 years, there was no statistically significant different between the 2 groups in terms of functional performance or WOMAC subscales. The intake of NSAID’s was lower in the group with laterally wedged insoles.</td>
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<tr>
<td>Rubin and Menz, 2005</td>
<td>30</td>
<td>Non-randomised study with no control group.</td>
<td>Non-weight bearing plaster casts of both feet were taken and a polypropylene shell with a 5° lateral wedge made of ethyl vinyl acetate addition was incorporated.</td>
<td>Pain levels were recorded on a VAS and were significantly reduced at 3 weeks and 6 weeks after orthoses were prescribed.</td>
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<td>Shimada et al., 2006</td>
<td>46</td>
<td>Treatment and Control group.</td>
<td>Lateral wedged insoles made of silicon and rubber with a 100mm lateral wedge</td>
<td>The peak external adduction moment of the knee was higher in OA knees than in control. This was reduced with the laterally wedged insole.</td>
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<td>Butler et al., 2007</td>
<td></td>
<td>Customised laterally</td>
<td>The orthoses was able to provide a custom laterally</td>
<td>Providing a custom laterally</td>
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<tr>
<td>Study</td>
<td>N</td>
<td>Type of Study</td>
<td>Interventions</td>
<td>Key Findings</td>
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<tr>
<td>Baker et al., 2007</td>
<td>N = 90</td>
<td>Randomised double-blind, crossover study</td>
<td>The control treatment consisted of a flat 1/8 inch-thick show insert and the intervention group was treated with a 5˚ wedge insole made of NickePlast.</td>
<td>The results showed that there was a decrease in pain scores on the WOMAC pain scale, 50-feet walk time, chair-stand time and the use of pharmacological interventions for knee pain.</td>
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<td>Rodrigues et al., 2008</td>
<td>N = 30</td>
<td>Randomised triple-blinded study with a control group</td>
<td>The intervention group received a medial insole (with an 8mm elevation medially on the rearfoot) and a neutral insole without any elevation. Both groups wore an ankle support with standard shoe.</td>
<td>• There was a significant reduction of pain in the medial insole group as well as a reduction in the WOMAC scores compared to the neutral group. • The medial insole also caused an increase in the TFJt angle, which has been theoretically supported as a viable treatment mechanism in lateral TFJt OA patients. • There was a significant reduction of pain in the medial insole group as well as a reduction in the WOMAC scores compared to the neutral group. • The medial insole also caused an increase in the TFJt angle, which has been theoretically supported as a viable treatment mechanism in lateral TFJt OA patients.</td>
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<td>Hinman et al., 2008</td>
<td>N = 40</td>
<td>Randomised study using a computer-generated table of</td>
<td>Laterally wedged insoles (high density ethyl vinyl acetate) were provided with an elevation of 5˚ on the lateral border.</td>
<td>• Changes to the static mechanical axis were documented after provision of insoles. • There was a reduction in the knee adduction moment and pain on walking.</td>
</tr>
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N = 20 Non randomised trial with no control group | Wedged orthoses with an elevation that provided the maximum pain relief during a lateral step-down test. | Reduce the peak adduction moment during early stance. No issues of discomfort or non-compliance were reported by the authors. | Wedged orthotic device may increase compliance and reduce disease progression. | Decrease in peak adduction moments. However, lower limb alignment profiles were not considered by the study. Orthoses were customised based on results of a lateral step down test and foot posture was not ascertained. |
<table>
<thead>
<tr>
<th>Study</th>
<th>N=</th>
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<th>Outcome Measures</th>
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<td>Raaij et al., 2010</td>
<td>91</td>
<td>Randomised study with control group receiving the knee valgus brace.</td>
<td>Mean improvement in WOMAC pain and physical functioning was also reported at 3 months.</td>
<td>The results of the study indicate that a laterally wedged insole may be an alternative to valgus bracing for conservatively treating medial TFJt OA symptoms. It is moderately more effective than a knee brace in terms of pain scores. Also, half the patients who were provided with insoles responded to laterally wedged insoles after 6 months.</td>
<td>The study did measure the HKA angle in participants which they found were not significantly influenced by conservative treatment mechanisms. However, the increase compliance and better tolerance to foot orthoses compared to knee braces recommends their use as a conservative alternative to surgical interventions. Specific foot posture characteristics were not considered.</td>
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<td>Bennell et al., 2011</td>
<td>200</td>
<td>Double blinded randomised controlled trial</td>
<td>At 6 months, the primary outcome score was pain severity using the Visual Analog Scale (VAS) and WOMAC pain subscales. While neither device were able to influence knee alignment, 17% of participants responded to allocated treatment.</td>
<td>The results indicate that when lateral wedge insoles are worn for 12 months, they provide no symptomatic or structural benefits when compared with flat control inserts.</td>
<td>The study did not consider foot posture or knee alignment profiles. Footwear was identified as a major confounding factor however; participant’s own footwear choices were not documented.</td>
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Table 2.1 Medial TFJt OA studies have used laterally wedged orthoses as a conservative intervention. They have rarely evaluated or discussed the role of clinical lower limb alignment profiles particularly foot posture and frontal plane TFJt alignment.
2.2 Lower Limb Alignment Profiles

The lower limb is one facet of the many segments in the human body’s kinetic chain. This chain is comprised of the foot and ankle; knee; hips and pelvis; spine and the shoulder. It is a complex, inextricable linkage between these segments that makes the human body dynamic, mobile and energy efficient. Functional activities such as walking or climbing stairs are examples of open chain activities as opposed to isolated motions performed in a closed environment such as a squat (closed chain) (Perry and Burnfield 2010). Posture, while often associated with being static, is actually constantly adapting to meet the demands placed on the kinetic chain. It maintains the structural efficiency of the body and this is defined as the alignment of the musculoskeletal system which allows our centre of gravity (COG) to be maintained over a base of support (McLester and Pierre 2007). Optimal posture and alignment ensures that the muscles of the body are optimally aligned to allow proper joint mechanics, in other words, the effective absorption and distribution of forces (Liebenson 2006). An alteration in the alignment or structural efficiency, for example as a result of altered lower limb alignment, could result in excessive stresses placed on certain aspects of the foot and ankle and subsequently the knee and hip joints.

Effective posture confers a neuromuscular efficiency to the body to perform functional activities and classic example of a functional kinetic chain involving open and closed chain motions is human gait (Clark and Lucett 2007). During gait, the foot and ankle provide an interface between the body and the ground below. They dynamically adapt to be rigid at heel strike, mobile for accommodating different ground surfaces at midstance and act as a propulsive lever during toe-off. The knee joint, is the ‘chain-reaction link’ that is the primary shock absorber of forces created by the GRF and impact as the foot contacts the ground. At heel strike, it is only slightly flexed to counteract loading forces, at midstance it extends to assimilate these forces further and enables them to be further dissipated up the kinetic chain. The knee also acts to minimise the displacement of the COG (maintains alignment) and decreases energy expenditure (Perry and Burnfield 2010). Within the context of transfer of forces, proper core stability is also essential to the optimal transfer of forces generated by the lower body to the upper body (Roetert and Ellenbecker 2007). However, if function is determined by structural efficiency and this is essential to performing optimal and efficient human body movements, then proper posture or alignment needs to be clearly defined. This
would allow the identification of improper or abnormal postural alignment specifically in the lower limb that may be specific to knee joint pathologies such as TFJt OA.

In the literature, the definitions of normal and abnormal alignments are unclear due to the various approaches to the assessment and interpretations of knee alignment. This has made it difficult to compare and contrast independent studies of TFJt OA and there have been calls for a standardised approach to measuring and reporting alignment profiles (Kraus et al., 2005; Cooke et al., 2007). Since animal studies, surgical studies and human studies have demonstrated that knee alignment is a predictor of functional and symptomatic knee outcome scores in TFJt OA, this topic warrants further discussion.

2.2.1 Normal Alignment

- **Normal TFJt alignment**

Normal anatomical and mechanical alignments are considered to be important factors in maintaining good posture and determining effective loading mechanisms for the lower limb. There are two recognised ways to assess the knee-alignment angle or TFJt angle: the mechanical axis and the anatomical axis. The mechanical axis is the angle formed between the intersecting lines from the central point of femoral head and the central point of the talus and tibia. The anatomic axis is the angle formed by two lines bisecting the femur and tibia respectively and meeting at the centre of the tibial spine. The axes are assessed differently; the anatomic axis determines the TFJt angle using a radiograph or a goniometer while the mechanical axis is assessed on full-length radiograph. While the mechanical axis can more accurately predict transmission of forces across the TFJt, the use of a full-limb radiograph has restricted use in a clinical research setting with large patient numbers. This is because it is expensive, requires specialist resources such as skilled radiographers and equipment and exposes patients to pelvic irradiation (Mirzayan 2006). Irradiation introduces unnecessary risks particularly as the anatomical axis alternative, a goniometer, is safe, cost-effective and easy to implement in a clinical setting. It has also demonstrated excellent correlations with the mechanical axis of the knee joint ($r = 0.70$, $p < 0.0001$) and could therefore be regarded as a clinically applicable surrogate (Kraus et al., 2005). The reference values used for the interpretation of a normal anatomical axis is from Berg (2000). Figure 2.3 is an illustration of the measurement of the TFJt angle in a normal TFJt alignment profile and abnormal (varus or valgus TFJt alignment profile).
Figure 2.3 An illustration of a varus, normal and valgus foot posture using Berg’s (2000) interpretation of the anatomical axis and a superimposed goniometer (Normal = 170°, Varus (bow-legged) = > 170° and Valgus (knock-knees) = < 170°) (Adapted from McHone 2011).

A neutral knee alignment was first postulated by Moreland et al., (1987) where neutral was defined when alignment was 180°; varus when alignment was towards a varus orientation (> 180°) and valgus when alignment was towards a valgus orientation (< 180°). Recently, Reeves and Bowling (2011) described that a neutral alignment is associated with a centrally aligned ground reaction force and the absence of a knee adduction moment applied to the TFJt. Clinically, this neutral alignment has been associated with a range of anatomical axis values from 170° - 180° (Callaghan et al., 2003). It is important to differentiate between a hypothesised state of perfect lower limb alignment (180°) and a normal lower limb alignment range that presents a true representation of lower limb orientation (170° - 180°) and takes into account the variability that is characteristic of biological organisms.

For instance, some researcher’s state that mild varus values tend to be the norm in an asymptomatic population (Hsu et al., 1990; Chao et al., 1994 and Cooke et al., 1997) while Berg (2000) and Kamath et al., (2010) suggest that a valgus position of 170° - 175° is a normal TFJt alignment. In Kraus’ paper (2005), the following reference frame was based on the gold standard mechanical –axis angle from a full-limb radiograph and was adopted: varus
<178.5°; normal 178.5 ° - 180 ° and valgus >180 °. It should also be noted that these variations in the’ normal’ front plane alignment of the knee are prone to bias from gender or age. Young adult males tend to display greater varus angles than women and in an elderly asymptomatic population, the mean TFJt angle is closer to neutral or 180° (Callaghan et al., 2003). Therefore, for a particular demographic where factors such as age, gender and pathology are considered, a normal TFJt alignment needs to be established.

- Normal Foot Posture and Function

The foot and ankle are a multidimensional and dynamic complex (Perry and Burnfield 2010). The foot is the terminal link in the lower kinetic chain. It is robust enough to support the weight of the body during gait and malleable enough to absorb shock and adapt to changes in the ground terrain due to pronation and supination (Perry 2010). Pronation of the subtalar joint (STJ) is comprised of adduction and plantarflexion of the talus resulting in the eversion of the calcaneus, dorsiflexion of the ankle and abduction of the forefoot. Supination of the STJ is an opposing motion sequence to pronation and consists of abduction and dorsiflexion of the talus resulting in an inversion of the calcaneus, plantarflexion of the ankle and adduction of the forefoot. Supination occurs to increase the stability of the foot to provide adequate leverage for propulsion and maintenance of the forward movement of the limb (Root et al., 1977; Scarleto 1971). The STJ also interacts with the midtarsal joint (MTJ) as STJ pronation causes the MTJ axes to become more parallel, thereby allowing the entire foot to become mobile. When the STJ supinates, the MTJ axes become non-parallel and the foot becomes more rigid (McPoil and Knecht 1985). During normal gait, pronation occurs as the forefoot loads through to midstance (30% of the gait cycle) and re-supination occurs as the body weight passes over the foot (50% of the gait cycle) and the contralateral limb moves ahead (Whittle 2007). These key motions are paramount to dissipating compressive, tensile, shearing and rotatory forces effectively during the stance phase of gait (Root et al., 1977; Donatelli 1987).

Normal pronation and supination occurs in sequence through the stance phase and is accompanied by the external and internal rotation of the tibia along the kinetic chain as part of a coupling linkage. There are distinct coupling mechanisms involved in the gait cycle: dorsiflexion of the ankle joint is coupled with the eversion of the calcaneus and plantar flexion of the joint is coupled with inversion (Wiesel 2010). A coupled relationship also
exists between the STJ of the foot and the tibia, where, with every degree of STJ pronation, the tibia internally rotates by one degree simultaneously (Swedan 2001). This is the contemporary understanding of the lower limb coupling mechanism, but it was in 1935, that Elfman and Manter originally discussed the concept of an oblique axis about which movement occurred between the talus and calcaneus. Subsequently, Manter (1941) reported the STJ axis as being 42° in the sagittal plane and deviated both anteriorly and medially by 16°. Inman (1969) concurred with these findings but reported significant inter-participant variation. The movement of the STJ is rotationary about an oblique axis, similar to a screw where the STJ behaved like a right-handed screw in the left foot and a left-handed screw in the right foot. This action is referred to by Inman as a hinge connection between the leg and the foot; ultimately the STJ movements like pronation translate as internal rotation of the tibia and supination translates as external rotation of the tibia (Mann 1982). The STJ complex therefore acts as a universal joint or as a necessary directional torque converter during gait (Hunter et al., 1995). Figure 2.4 illustrates this concept of torque-converter effect within the lower limb. Between the initial contact to midstance phase of the gait cycle, there is an external rotation of the pelvis which causes the femur to externally rotate alongside. The calcaneal and pelvic segments are therefore moving in opposition, and when combined with an over-pronation of the foot and eversion moment of the calcaneus, this can result in overloading forces through the TFJt (Nigg and Hintermann 2002). The coupling mechanism is therefore an important factor influencing the transmission of forces along the lower limb and how medial TFJt could be affected by abnormal STJ motions (e.g. over-pronation). The normal movement and timing of the STJ are also important because it influences MTJ alignment and foot’s relative flexibility or rigidity.
The foot has a dynamic ability to adapt its structure to enable function. If this ability is impeded due to abnormal foot posture, optimal function may be diminished resulting in instability, overloading and injury to the lower limb. During gait, both neutral foot types and a pronated foot types exhibit a lateral heel strike pattern. During midstance however, while a normal foot type will then pronate to absorb shock and subsequently re-supinate ready for toe-off, a pronated foot type will over-pronated during midstance and while loading the midfoot, the weight is transferred more medially along the foot therefore inhibiting efficient shock absorption. The pronated individual is also less efficiently able to re-supinate to produce a stable foot for propulsion and toe-off. Therefore, while in normal foot type, weight is evening distributed throughout the foot, this is not the case for a foot that over-pronates (Hintermann et al., 1998). As discussed previously, the coupling mechanism would then translate this motion into internal tibial rotation which has been shown to increase medial knee loading thus propagating uneven weight distribution across the knee joint.

It is important to categorise what is normal and abnormal foot posture with the use of clinical assessment tools as this can predict the ability of the STJ to function effectively and affect the entire kinetic chain through the gait cycle. The concept of normal foot posture in a healthy individual is the subject of debate due to its variations in the demographic findings based on age or BMI (Redmond et al., 2008; Aurichio et al., 2010). Increasing age has been correlated...
with a more pronated foot posture and individuals with higher BMI’s have been associated with lower medial longitudinal arches, a broader midfoot and flatter feet (Riddiford-Harland et al., 2000). However, while Menz and Munteanu (2005) reported a borderline neutral foot posture as being normal in an older population, other authors have found that a mildly pronated foot type is more ‘normal’ than a neutral foot type (Burns et al., 2005; Cain et al., 2006). Therefore, while normative foot postures have been established in specific populations such as naval recruits, footballers and an elderly population (Yates and White 2004; Redmond et al., 2008; Jain et al., 2011), it is evident that there is not a universal foot posture norm. Thus, normative foot posture characteristics for specific populations needs to be established taking into account factors such as BMI or TFJt alignment. The various methods of assessing foot postures will be discussed in section 2.3 (Tools for assessing lower limb alignment).
2.2.2 Malalignment

- **Abnormal TFJt alignment**

As previously discussed, when the TFJt has an abnormal anatomical axis (deviating from the norm of $170^\circ$-$180^\circ$), the direction of the GRF is affected. The KAM is determined by the direction of the GRF where an increased distance from the knee joint centre increases the moment lever arm. Therefore, it is thought that a varus knee alignment alters the direction of the GRF thereby increasing the KAM which can increase the compressive stresses to the medial compartment of the TFJt (Hinman et al., 2007). This may initiate the OA process and also contribute to its progression in the medial TFJt (Sharma et al., 2003).

It has been noted that a knee alignment change of $5^\circ$ in any direction (varus or valgus) is associated with significantly greater functional deterioration (Sharma et al., 2001) and that knee alignment and KAM are also correlated (Hurwitz et al., 2002; Barrios et al., 2009). Hurwitz and colleagues (2002) found that it was the single best predictor of knee joint loading in a TFJt OA population ($R=0.74$, $p<0.001$). The study also reported that TFJt loading is more closely correlated with static alignment than radiographic disease severity. This indicates the importance of establishing static and dynamic knee alignment profiles in a TFJt OA population.

Figure 2.5 illustrates the three common frontal plane lower limb alignment profiles. The load bearing axis (LBA) is a line drawn from the mid-femoral head to the mid-ankle. The hip-knee-angle angle (HKA) is a line drawn from the central part of the femur to the centre of the knee (femoral mechanical axis) and then extended to the centre of the ankle (tibial mechanical axis). The diagram shows that in theory, any variation to the neutral alignment of the hip, knee and ankle affects the HKA and LBA. For example, in sequence A, the HKA has a negative or varus frontal plane alignment and thus the LBA has moved medial to the knee joint centre which alters normal load distribution and increases medial joint loading (Takahashi et al., 2004; Cooke et al., 2007).
A valgus knee is a knock-knee and is derived from the Latin for ‘bent or twisted’ and a varus knee is one that is bow-legged and derived from the Latin for ‘crooked’ (Kamath et al., 2010). From the figure above, it is evident that in a valgus knee, there is an increased loading on the lateral compartment of the TFJt. Valgus alignments at baseline are associated with a nearly 5-fold increase in lateral TFJt compartment progression of the disease (Sharma et al., 2010).
2001) while others have noted only a borderline significant increase in lateral TFJt OA development (Brouwer et al., 2007). However, there have been more significant associations of TFJt OA development and progression in varus knee alignment profiles. Recently, Sharma et al., (2010) stated that varus alignments, not valgus profiles, increased the risk of developing TFJt OA. This disproportionate loading of the medial aspect of the tibial plateau results in TFJt OA affecting this compartment more than the lateral aspect (Russell and Hamill 2010).

The increased incidence of medial TFJt compared to lateral TFJt could be multifactorial and echoes our earlier discussion of TFJt OA as having causal key mechanical factors such as TFJt alignment acting within the context of systemic vulnerability. Anatomically, the medial TFJt has a uniquely structured meniscus that has a reduced mobility and is less able to adapt to adverse load bearing when the knee is in extension during mid-stance. From a functional perspective, in a neutral TFJt alignment, the medial TFJt normally experiences 60-80% of load distribution during gait however, even a slight increase towards a varus alignment (4-6%) can further increase medial TFJt loading by 20% (Tetsworth and Paley 2004). This difference between medial and lateral TFJt loading may explain the increased frequency of medial TFJt OA (Sharma 2004). This shift towards a varus alignment profile could be a naturally occurring anatomical variation. It could also be a result of imbalanced medial loading resulting in joint laxity. Joint laxity is the abnormal displacement of tibia relative to the femur and can alter contact sites of the AC resulting in localised compressive forces. This laxity can increase with age and is more pronounced in women. It is also a predictor for TFJt OA development following a ligament injury (Sharma 2004).

Other factors such as gender differences could also have an influence at a cellular and molecular level. The theories currently being researched include the potential discrepancies between pain sensitivity, hormone levels and vitamin D receptors between men and women (Punsky 2011). In addition to this, Brouwer et al., (2007) found that varus alignments were associated with a 200% increased risk of developing TFJt OA compared to a normal alignment profiles, particularly in overweight and obese individuals. This could be attributed to a higher BMI producing an increased GRF magnitude that increases the KAM and produces abnormal medial TFJt loading (Russell and Hamill 2010). Anderson and Felson (1988) showed that the risk for TFJt OA development increased by 15% for each unit of BMI increase in people with a BMI of > 27kg/m² (normal BMI values are 19 – 24.99 kg/m²).
Individuals with an increased BMI also demonstrate altered dynamic balance and functional performance and there is an association between such knees and greater pain scores in such individuals (Jadelis et al., 2001). Although interactions between BMI and metabolic and cellular activity leading to TFJt OA development have been suggested, there is no clear link between obesity and OA (Teichtahl et al., 2008).

The multi-factorial nature of TFJt OA needs to be considered in order to understand the OA disease process. Even though radiographically established varus alignments have been associated with the magnitude of peak adduction moments in both healthy and OA knees (Sharma et al., 2003; Teichtahl et al., 2003), findings such as these reiterates the concept that although the KAM generated at the knee interface might be the similar, the systemic context which predisposes patients to developing OA differs. Figure 2.6 illustrates the proposed evolution from development of OA to tissue impairment, functional limitations and subsequent disability and how these relations are bidirectional and cyclical.

**Figure 2.6.** The cyclical evolution of OA involving disease pathology, functional impairments and associated limitations (Adapted from Sharma 2004).
Therefore, abnormal alignment of the TFJt has long been assumed to correlate with OA development and progression but the chicken and egg scenario of which came first, malalignment or TFJt OA has been discussed in the literature and a bidirectional relationship has been suggested (Sharma 2004). Therefore, it is important to identify alignment profiles in different pathological groups so that eventually, the clinically applicable measures that prove optimal and reliable can be standardised used as a clinical indicator of TFJt alignment and predictor of any TFJt changes.

- Abnormal Foot Posture and Function

Abnormal pronation and abnormal supination can affect the kinematics of the foot and ankle and consequently the entire lower limb kinetic chain (Donatelli 1996). In abnormal pronation, the foot is hypermobile and has the ability to overplantarflex resulting in a mechanically weak and dynamically unstable foot (Howse and McCormack 2000). Specifically, it affects the distal segments of the lower extremity. In abnormal pronation, the mobile cuboid cannot function efficiently as a pulley for the peroneus longus tendon which stabilises the first ray resulting in first ray hypermobility. It also has an effect on the tibia due to the previously discussed coupling mechanism in which foot pronation is synchronous with the internal rotation, medial deviation and forward inclination of the tibia (Hunter et al., 1995). In abnormal pronation, external rotation of the lower limb which occurs because of foot supination is limited. This is essential to knee extension and is known as the ‘screw home’ mechanism (Massie and Spiker 1990). To permit knee extension therefore, the internal rotation of the femur is the likely substitute to the external tibial rotation. This theory was first hypothesised by Copland (1989) where in abnormal pronation, there is an internal rotation of the tibia is matched by the external rotation of the femur: these opposing forces stress the lateral compartment of the TFJt particularly the lateral AC. Conversely, authors report that a supinated foot type increases the varus moments on in the medial knee aspect particularly affecting the medial AC and medial meniscus (Hunter et al., 1995). In a supinated foot, where there is a lack of external rotation of femur, there is also an increased varus TFJt stress. This can be explained through Nester’s (2000) ‘lag concept’ in which the rotation of the lower limb is assimilated by soft tissues structures (muscles, ligaments and tendons) of the TFJt.
While a normative neutral foot posture (with a neutral STJ) may have originally been predicted in healthy individuals, our definition of normal foot posture needs further consideration. This is because foot posture among healthy individuals is highly variable, ranging from highly pronated to highly supinated, due to changes in lower limb motion (Hunt and Smith 2004) and an increased risk of lower limb injury and abnormal muscle activity in specific populations (Burns et al., 2005). This was a reflection also noted by Murley et al., (2009) as studies with asymptomatic and healthy participants have both demonstrated that the most common static foot type is a slightly pronated foot posture when assessed using the Foot Posture Index version 6 (FPI-6) (Redmond et al., 2008).

In medial TFJt OA participants, Levinger et al., (2010) reported a more pronated foot type compared to healthy controls when assessed using the FPI-6. The differences may be related to the dynamic functioning of the foot during the midstance phase of gait where an OA participant may be less likely to adapt to different ground surfaces. Foot pronation could also be a compensatory offloading mechanism of the medial TFJt as it is known to increase internal tibial rotation and consequently increase external rotation of the femur. This would increase lateral TFJt loading and decrease excessive medial TFJt loading. It has also been suggested that frontal plane deviations of the TFJt, i.e. varus or valgus alignments, could influence foot postural characteristics during the contact phase and might influence foot kinetics (Gheluwe et al., 2005). Due to the interconnectivity of the kinetic chain, abnormal foot posture could also occur alongside abnormal varus or valgus knee alignment profiles. Foot posture is therefore paramount, as it could alter the alignment and consequent dynamic function of the lower limb (Guichet et al., 2003).

Despite the potential implications of foot posture and its effect on the TFJt, only a limited number of studies have been conducted (Table 2.1). Reilly et al., (2006) found no differences in OA and control groups when assessing navicular height in sitting and standing positions. The study sample included 60 people with either hip OA or TFJt OA and 60 controls. The study did report a significantly more everted rearfoot position in the OA group which is a component of foot pronation. Guo et al., (2007) evaluated the foot progression angle (FPA) the degree of toe-out or toe-in gait which is similar to abduction or adduction of the foot) in 10 TFJt OA participants and found that an increased FPA decreased KAM suggesting a more abducted foot type was capable of reducing medial TFJt loading.
Reilly et al., (2009) then used the FPI-6 to compare 20 people with and without TFJt OA and found a more pronated foot type in the OA group compared to a normal foot type in the normal group. There are various methods of assessing foot posture with varying reliability, validity and clinical applicability and these will be presented in the next section (2.3). These findings suggest that changes in foot posture and function during gait have the ability to affect loading of the TFJt and this may have implications on identifying treatment interventions that help unload the medial AC.
2.3 Assessing Lower Limb Alignment Profiles

Two important characteristics of any assessment procedure are reliability and validity. Reliability is defined as the extent to which an assessment produces the same results on repeated trials with one rater (intra-rater reliability) or two or more raters (inter-rater reliability) (Cohen Lawrence 2007). It represents the stability or consistency of measures over time or across different raters. Validity is defined as the extent to which an assessment tool measures what it reports to measure (Kirk and Miller 1986). An assessment tool which is both reliable and valid would therefore provide high-quality data with which to address a proposed hypothesis. Furthermore, within a clinical context, the standardisation and applicability of the assessment methods are also fundamental. Standardisation is the process of evaluating a test in a group of people to obtain a mean and standard deviation that is relative and specific to a certain group. It is critical to establishing normative values, for example, of foot posture or TFJt alignment, within specific pathological and non-pathological populations. The clinical applicability considers the reliability, validity and standardisation but also refers to the ease with which the assessment can be administered in terms of cost, resources, timing and healthy and safety considerations.

There are a range of assessment techniques with varying reliability, validity, standardisation and clinical applicability issues that have been adopted in TFJt OA studies to define and categorise foot posture and knee alignment (Sharma et al., 2001; Cicuttini et al., 2004; Cerejo et al., 2002; Bach et al., 2001 and Takahashi et al., 2004). The gold standard assessment of TFJt alignment involves radiographic measurements of the mechanical axes of the femur and tibia. There are however, noted drawbacks to the clinical application of full limb radiography. These include the risk of exposure to unnecessary radiation, requiring specialist rooms and a human resources and cost implication (Issa et al., 2007). This method has also been described as cumbersome and financially unviable for larger clinical participants groups (Kraus et al., 2005). Large, cross-sectional participant studies where conservative treatments (such as braces and foot orthoses) are being evaluated in a clinical context require a simpler, practical and reliable alternative to assessing alignment profiles.

In OA population studies, few studies adopt a clinical approach to assessing knee alignment and foot posture characteristics. For example, there are a range of clinical techniques used to define static foot posture. These vary from footprint methods, measurement of the navicular
height and rearfoot angle measurements to multidimensional foot posture categorisation methods such as the FPI-6. Static foot postures are important because they can offer an insight into dynamic foot function as previously discussed.

The different assessment methods warrant discussion if they are to be used in assessing lower limb alignment profiles within a clinical setting as they have had limited mention in the evidence base.

2.3.1 Foot Posture Assessment

As highlighted in the introduction, Table 2.1 contains research studies that have been conducted in the last 10 years which have focussed on using foot orthoses to conservatively manage TFJt OA. None of the studies considered foot posture assessments important enough to include within the study design, despite previous researchers suggesting that foot posture may explain differences in knee outcome scores in treatment groups (Reilly et al., 2009). Perhaps, a contributor to its limited use is the considerable disagreement regarding the most appropriate method for categorising foot posture and the varying reliability, validity and clinical applicability of existing measures (Razeghi and Batt 2002).

A major consideration in the evaluation of foot posture is a method of classification that is valid, reliable and clinically applicable. There are a range of methods that have been used to classify foot posture and test its corresponding validity with varying results. The methods were: visual observation (Walker and Fan 1998); footprint analysis (Rosenbaum et al., 1994), measurement of frontal plane heel position (Root et al., 1977; Sobel et al., 1999), assessment of the navicular tuberosity (Mueller et al., 1993) and radiographic techniques (Cavanagh et al., 1997 and Metaxiotis et al., 2000). Many of these methods are associated with poor reliability and validity while radiographic exposure is hazardous, time-consuming and expensive. For example, the poor reliability and validity of the navicular tuberosity has been attributed to large measurement errors associated with anatomical variation of the navicular and the inability to locate the neutral reference foot posture. A more recent measure is the foot posture index, (FPI-6) which was developed in response to a need for a clinical measure of assessing foot posture that is quick, easy and reliable (Redmond et al., 2006).
The FPI-6 is composed of six validated, criterion based observations of the rearfoot, midfoot and forefoot. The criterion are: talar head palpation, curves above and below the lateral malleoli, inversion/eversion of the calcaneus, bulge of the talonavicular joint, congruence of the medial longitudinal arch and adduction/abduction of the forefoot on the rearfoot. The FPI-6 is an observational assessment tool based on a 5-point Likert scale where each criterion can score between a -2 to +2. The resulting composite score can range from -12 and +12 with negative values representing a supinated posture and positive values generally categorising a more pronated foot type. Figure 2.7 shows the postulated reference values used to interpret FPI categories.

<table>
<thead>
<tr>
<th>Foot Posture</th>
<th>FPI Score Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Highly Pronated</td>
<td>+10 - +12</td>
</tr>
<tr>
<td>Pronated</td>
<td>+6 - +9</td>
</tr>
<tr>
<td>Normal</td>
<td>0 - +5</td>
</tr>
<tr>
<td>Supinated</td>
<td>-1 - -4</td>
</tr>
<tr>
<td>Highly Supinated</td>
<td>-5 - -12</td>
</tr>
</tbody>
</table>

Figure 2.7 FPI reference scores that are used to categorise foot posture for the left and right foot respectively (Redmond et al., 2001).

Redmond et al., (2008) conducted a study to identify normative foot posture profiles in healthy individuals. The main analysis on 619 participants revealed that a slightly pronated foot posture (FPI = +4) is normal when in a comfortable stance position. This has been verified by other researchers who report normal FPI scores of +5 in the population (Yates and White 2004; Menz et al., 2005). Scott and colleagues (2007) also suggest an age-related variation in foot posture scores where a more pronated foot posture (FPI = +4) was prevalent in an older population (with a mean age 80.2 years, SD ±5.7) than a group of young adults (FPI = +2.54, mean age 20.9 ± 2.6).
There are some studies for and against the use of FPI with regards to its reliability (Evans et al., 2003 and Cornwall et al. 2008). Cornwall et al., (2008) looked at the reliability of the original eight-version FPI versus the modified, six-criterion based index and reported moderate levels of interrater reliability (0.53 – 0.66) for FPI-8. They also reported a significant learning or experience effect in administering the FPI assessment tool which meant that in order to improve reliability, the FPI should be administered on 20 feet as practice. The FPI-8 was then made even more reliable with the removal of specific criteria: Helbing’s sign (curve of the Achilles tendon) and the congruence of the lateral foot leading to the refined FPI-6 (Keenan et al., 2007). In other studies however, it has been deemed only adequately reliable in different clinical situations with intra-class correlation coefficients between 0.62 – 0.91 suggesting that interrater reliability needs to be established (Evans et al., 2003, Yates and White 2004 in Redmond 2005). The FPI-6 has also undergone validity testing using Rasch analysis (Rasch is the current standard for the development of scales that deliver health care outcomes) and demonstrated good metric properties, good individual item accommodation and good overall accommodation of the six criteria to the Rasch model (Keenan et al., 2006). In addition to its reliability and validity status, the FPI is practical as it requires little palpation of the foot, marking of lines or the use of instruments. Thus addressing concerns raised by McPoil and Cornwall (1994) and Menz (1994) over the use of goniometers and the validity of subtalar joint neutral positions are addressed.

Scharfbillig et al., (2004) compared 4 criteria of the FPI-6 with radiographic measures and reported that the FPI-6 did demonstrate moderate- good reliability, but the composite score did not compare to the current gold standard of radiographic assessment. However, unlike radiographic measures, the FPI-6 does include soft-tissue factors (supramalleolar and inframalleolar curves) in the evaluation of foot posture while radiographic assessment relies only on bony structures. It is also comparatively safer and cost effective to administer in a clinical setting.

The FPI-6 is the only foot posture measure that captures information about the static foot in multiple segments without complex measurement procedures such as radiographic imaging of the foot. Furthermore, classification of foot posture based on the FPI-6 has shown an association with the development of TFJt OA (Reilly et al., 2009) and this may be because foot posture is indicative of dynamic function despite having previously demonstrated a weak relationship with dynamic foot function (Redmond et al., 2006; Nielson et al., 2008).
recent study by Cornwall and McPoil (2011) showed that subjects with more pronated foot postures demonstrated greater foot mobility (vertical and medial-lateral) compared with supinated foot postures when using the FPI-6. The results support the use of the FPI-6 as a useful clinical tool that because it conveys not only foot posture characteristics but infers dynamic foot function and mobility.

Previously, assessment of foot mobility was conducted using the navicular drop or navicular height test. Navicular drop is a specific measure of sagittal plane mobility of the midfoot using the vertical change of the navicular tuberosity. Although there is a relationship between navicular height and ACL injuries and TFJt OA, it has demonstrated poor inter-rater reliability (Picciano et al., 1993). Navicular height is a measure of the height of the navicular tuberosity from the floor. As a single clinical measure of foot posture, navicular height demonstrates good reliability in an adult population (Evans et al., 2003), but has its limitations as the foot is a multiplanar complex and unlike FPI-6, normative values of navicular height have received little attention in the literature (Curran 2008). Also, the FPI-6 has demonstrated significant differences in foot posture in OA populations compared to controls; other studies have found no such significant difference when using navicular height (Reilly et al., 2009; Levinger et al., 2010) suggesting that navicular height may have limitations. Therefore, a combination approach of using both FPI-6 and navicular height might be the optimal measures for clinical use and as such warrant further investigation on: the intra-rater reliability and, establishing normative values in a healthy population so that comparisons can be drawn with an OA population.

2.3.2 Tibiofemoral Joint (TFJt) Alignment Assessment

- **Static Assessment of TFJt**
  There has been interest in front plane alignment assessment by Sharma et al., (2001) however the diversity of measurement approaches has made it difficult to contrast and correlate findings in medial TFJt OA. As with all assessment tools, in addition to being interpreted differently, each have their respective advantages and drawbacks that warrant discussion (Vanwanseele et al., 2002).

A full-limb radiograph when weight bearing is reported as the gold standard method for establishing the mechanical and anatomic axes of the lower limb (Cooke et al., 2007). It is an
expensive procedure, requires specialist resources and involves exposure to ionizing radiation (Vanwanseele et al., 2002). The variability of radiographic evaluation was also performed by Illahi and colleagues (2001) with four physicians independently measuring the anatomic TFJt angle in a blinded and random study design. The measurements were within 3- 4˚ of the first reading 95 – 98% of the time while with a goniometer, the results were within 5˚ for 95% of the time (standard error of measurement). The maximal difference noted was 6˚ whereas with a goniometer, it was 7˚. Therefore, the variability can be described as being almost comparable and when amalgamated with the additional cost, time and resources needed, clinical alternatives are more appealing.

Clinical measures such as inclinometer, plumb line or goniometer have been suggested as cost-effective and reliable alternatives to radiographic methods (Hinman et al., 2009). Also, the reliability and validity of a measurement tool, especially in comparison with the gold standard for TFJt alignment results have been studied (Kraus et al., 2005). The authors reported that the goniometer was the most reliable physical examination method out of 42 techniques evaluated and although the authors reported a high intraclass correlation coefficient of 0.94. The authors also found that it correlated well with the full-limb radiograph technique. This reliability pattern was also reported by Cibere et al., (2004) who found excellent inter rater reliability (kappa 0.88) when a goniometer was used in patients with TFJt OA. A limitation that has been associated with the goniometer is the assumptions that the tibia is perfectly straight when it might have a slight bowing or curvature that is not accounted for (Tang et al., 2000). This could lead to tangible differences between the mechanical axis and the anatomical axis however, Kraus et al., (2005) found a strong correlation between the two axes ($r = 0.75$ and $r = 0.88$). Indeed other authors have even aligned the lower goniometer arm with the patella tendon as opposed to along the estimated bisection of the tibial shaft (Hinman et al., 2006). The reason for using this method has been due to the high reliability associated with this measure in OA participants. The method described by McDaniels et al., (2003) where the goniometer was aligned with the tibia showed better correlation with the mechanical axis on radiograph ($r = 0.72$). The method by Kraus et al., (2005) using the centre of the patella as the central point of the goniometer with the arms extending along the centre of the thigh and the lower legs demonstrated excellent correlations with radiographic counterparts ($r = 0.70, p < 0.0001$). When using this technique therefore, the goniometer could be a suitable clinical assessment tool for use in an OA
population as it is more reliable and cost-effective than alternatives such as radiographic measures.

Figure 2.8 An illustration of the use of seven retroreflective markers placed along the visually assessed TFJt with a superimposed goniometer whose central axis coincides with the centre of the patella as described by Kraus et al., (2005).

- Dynamic Assessment of TFJt
  Following on from static evaluation of the TFJt alignment, dynamic methods are also important as Hilding et al., (1995) found that static radiographic alignments are reflective of dynamic loading conditions during gait. This was echoed by Barrios et al., (2010) when a combination of both static and dynamic evaluations of TFJt alignment were found to be the best predictors of KAM and subsequent TFJt loading. This is because osseous changes as well as changes to soft tissue structures can affect the ‘normal’ knee alignment. Muscle imbalances could also affect the dynamic TFJt alignment as has been demonstrated (Lynn and Costigan 2007; Amin et al., 2008). The authors found that changes in foot posture during gait can alter hamstring muscle activation which may assist in unloading the TFJt’s AC, while later, Amin and colleagues reported that there was no association between quadriceps
strength and AC deterioration of the TFJt. This is despite previous research findings of decreased quadriceps function being associated with greater knee pain and impaired physical functioning (Slemenda et al., 1997; Hurley et al., 1997). Rice et al., (2011) discussed that OA knees have strength deficits of 20-45% compared with healthy knees. Quadriceps weakness in OA is associated with reduced dynamic stability and physical functioning (Hassan et al., 2001; Felson et al., 2007). It also results in a reduced protective function of the TFJt especially during the early contact and midstance phase of gait when the quadriceps contracts eccentrically to cushion the knee and decelerate the limb consequently reducing loading (Brandt et al., 2008).

Assessment of the TFJt can be done in three conditions: weightless, standing and during gait. A weightless evaluation allows the evaluation of soft tissue structures such as ligaments and their respective ranges of motions along with patellar tracking. However, standing and dynamic assessments are key as they demonstrate any overall alterations to the TFJt alignment (Brown et al., 2009). When compared with observational techniques, computed gait analysis has the ability to identify motions during gait that may occur too quickly for the naked eye (Curran and Dananburg 2005). Dynamic assessment of the TFJt can be assessed using 3 dimensional (3D) approaches with 2 or more camera which affords greater accuracy at the expense of elaborate set up times and cost of resources. The Vicon Motion Capture System (VICON, Oxford UK) is an example of a 3D system that consists of 6 cameras and is designed to track motion in a 3D space. A marker on an individual appears as highly illuminated pixels compared to a background. This information is stored in a data station and the Vicon system then links the correct positioning of each marker to form a continuous trajectory, or pathway depicting how far each marker has moved over time. A disadvantage of this method is that at least three cameras must view a marker for the data point to be recorded (Benning et al., 2005). While 3D systems may have a smaller associated measurement error, they can also be complex to understand requiring skilled interpretation (Louw 2011). Therefore, 3D optoelectronic motion analysis systems such as the Vicon are also seldom used in clinical practice (Nielsen and Daugaard 2008). This is opposed to a single camera assessment for a 2 dimensional (2D) video gait analysis which is cost-effective and simple, however, in order for greatest accuracy, the plane of interest, for example, the frontal plane of the TFJt, must be tangential to the cameras optical axis. While Curran and Dananburg (2005) outlined the advantages and disadvantages of these systems, 2D systems
remain of most interest due to the ease of application in a clinical setting and relative cost-effectiveness compared with 3D systems.

The Quintic Biomechanics software (Quintic Consultancy Limited) is a biomechanics and performance analysis programme that allows detailed analysis of 2D digital video recordings. One of the features of the Quintic software is the ability to digitise recordings and track frontal plane TFJt angles particularly at the midstance phase of the gait cycle. The TFJt angles would be generated using marker locations on a frame-by-frame basis. One of the disadvantages of the Quintic compared to 3D systems such as the Vicon is that in order for enhanced recording accuracy, the plane of motion must remain parallel to the camera’s focal plane. This could be addressed through the detailed spatial placement of the video camera (location on the walkway, height of the camera from the ground and orientation/axis of the video camera on the tripod). Another factor to consider is that unlike some other systems such as the APAS gait (Ariel Dynamics LTD), the Quintic requires manual digitisation of marker locations. This can be time-consuming but ensures that there is a reduction of the effect of random manual errors through data smoothing processes. Other factors to consider are the visibility of the reference markers during gait (adequate lighting available) and also that the gait pattern is natural and not subject to sudden stops, directional changes or loss of balance of the individual. Therefore, in order to obtain optimal and accurate TFJt alignment data within a clinical setting, retroreflective markers that reflect even minimal lighting and of a known dimension should be used to enhance accuracy (McNamara et al., 2008). With due considerations for the drawbacks, the Quintic software is an optimal clinical gait analysis software that is simple to use, cost-effective and can accurately determine frontal plane TFJt making it attractive from a clinical research perspective.
2.3.3 Plantar Pressure Assessment

The plantar aspect of the foot is responsible for the transmission of ground reaction forces from the ground through the lower limb and this is a bi-directional relationship. The distribution of pressures can provide an insight into mechanical foot function (Kirtley 2006). Plantar pressure data has been used in the assessment of individuals with a range of musculoskeletal conditions such as diabetes and rheumatoid arthritis as the ‘information derived from plantar pressure data can determine and manage the impairments associated with musculoskeletal, integumentary and neurological disorders’ (Orlin and McPoil 2000). Studies have also used this technology to demonstrate significant changes to dynamic foot function within specific footwear and when wearing foot orthoses (Praet et al., 2003; Erdemir et al., 2005; Estivalet and Brisson 2008).

There are a range of measurement devices and technologies available ranging from optical sensors and capacitive sensors to piezo-electric and piezo-resistive sensors. While piezo-electric sensors are noted to be the most accurate, these have not been implemented into a flat plate design. This is one of the two main types of design options: flat-plate systems and in-shoe systems. The flat plate systems such as the RSscan International (Belgium) are mounted in the floor and measure the pressure between the foot and the floor and are most suited to barefoot measures (Cavanagh and Hennig 1982; Kirtley 2006). In-shoe systems such as the Pedar ® (Novel, Munich, Germany) or F-Scan systems (Tekscan, USA) are placed inside the shoe and record pressures between the foot and sole of the shoe (Akhlagi and Pepper 1996). Both these systems and their technologies have their respective advantages and disadvantages for clinical and research use and will be discussed.

One of the noted limitations is the availability of system specific calibration curves. This is however, not the case with the Pedar in-shoe system which offers calibration techniques and equipment to ensure that individual sensors accurately reflect the values of known and applied pressures. The Pedar® system used capacitive sensors and each are calibrated individually using a rubber air bladder applying incremental pressure from 100 to 600 Kilopascals (KPa). Kernozek et al., (1996) stated that this was the most accurate and truly representative calibration technique available. The capacitive systems work on a change in capacitance when two electrical plates are squeezed together. The insoles can have upto 1024 sensors. These have been calibrated and validated in reference studies in healthy adult
populations and normative values for plantar pressure parameters have been generated in different footwear conditions (Kirtley, 2006; Putti et al., 2007). This system can therefore offer particular advantages over pressure platforms, in view of evaluating in-shoe plantar pressure parameters between the foot and shoe/ground interface.

- **Pressure Platforms versus In-shoe Systems**

In-shoe systems are often utilised in research and clinical settings and they have the benefit of, being mobile as opposed to an inbuilt force platform; allowing multiple steps to be recorded in a series which avoids targeting of a platform and permitting an in-shoe PP assessment with the use of foot orthoses which is difficult with platform interface systems (Barnett et al., 2001; Chevalier et al., 2010).

The ease of data collection with a pressure plate system could also be debated as a midgait approach, a two-step or three-step approach would reduce the amount of time needed for data collection. This should be a consideration for individuals with painful joints. In the midgait approach, data is collected after the subject has walked a few steps while in the two-step method; the data is collected from the participant’s second step. When contrasted with the in-shoe system, data can be collected from any step during normal walking. A mean of three steps per foot raises the reliability coefficients over 0.7 (Kirtley 2006) while five to twelve midgait steps per foot are needed for reliable and valid PP data (Mandato and Nester, 1999; Arts and Bus 2011).

Several studies have documented the reliability of measures obtained from F-Scan (Tekscan Inc, Boston, MA) and Pedar in-shoe systems (Martinez-Nova et al., 2007). However, Quesada et al., (1997) found that the Pedar has greater accuracy and repeatability compared with the F-Scan. The Pedar insoles each contain a matrix embedded with 99 capacitive sensors, each with a diameter of 1.5 cm² and a sampling rate of 50 Hertz. The insoles record data in real time similar to pressure platforms but also allow standardisation using templates that divide the foot into anatomical regions of interest. In direct comparison studies, the Pedar ® in-shoe system has been comparable with platform systems such as the Kistler (Switzerland) where pressures reported were slightly higher. This was attributed to an in-built sensitivity threshold of 20 kPa which also accounts for pressure ‘white noise’ and to the different types of footwear used in the study (Barnett et al., 2001). This is an important
consideration as in-shoe systems consistently report higher pressure values because of the footwear design (Chevalier et al., 2010). Greenhalgh and Chockalingam (2006) reported that if a shoe is properly fitted, there is force acting on the dorsal aspect of the foot which results in higher pressures. This could be addressed by documenting footwear characteristics in a study design as this may be a source of detected pressure changes.

- **Choice of Plantar Pressure Parameters**

Previous research studies have used the Pedar ® in disease processes that have an impact on musculoskeletal pathology, such as diabetes and rheumatoid arthritis (Lavery et al., 1997 and Hodge et al., 1999). In diabetic individuals, neuropathic plantar ulcerations occur as a result of repetitive stresses over high pressure areas associated with deformity or functional limitations of joints such as the metatarsophalangeal joints (MPJ’s). As a result, diabetic patients have a higher incidence of plantar ulcers in this particular region and the focus of treatment interventions is reducing these PPs to reduce the risk of acute or chronic ulcerations (Mueller et al., 2008; Drerup et al., 2008). Several studies have shown a relationship between pain, OA and changes in PP patterns (Van Gheluwe et al., 2005; Van der Leeden et al., 2006; Schmiegel et al., 2008). Maly et al., (2002) showed that in a statically assessed varus alignment, there was greater pressure under the lateral foot. Further studies have showed that medial TFJt OA individuals had a more laterally deviated centre of pressure (COP) compared to healthy controls when barefoot and using platform pressure sensors. There was also a significant relationship between pain and a laterally deviated COP in the 25 OA individuals compared to 25 controls (p<0.001) during the midstance phase of gait (Lidtke et al., 2010). The COP measurement is based on a two factors: contact area (spatial) and magnitude of pressure (magnitudinal).

The parameters of interest tend to be either magnitudinal, spatial or temporal. Magnitudinal parameters refer to the size of pressures acting in a particular region such as peak pressure at the lateral heel. Temporal parameters measure the time taken in a particular region of the foot, such as contact time at the medial midfoot. Spatial parameters involve contact between the foot and the sensor and include parameters such as the contact area. Harrison and Hillard (1997) state that a review of the literature often reveals that parameters are rarely defined consistently or interpreted credibly.
Contact area (CA) is a spatial parameter and demonstrates the number of sensors in contact with the foot, particularly during the midstance phase of gait. This is insightful as it might be associated with foot posture characteristics, e.g. a more pronated foot type might have increased contact area in the medial midfoot during midstance than the lateral aspect. It allows comparisons to be made between static measures of FPI and dynamic measures of foot function.

Some examples of temporal parameters are contact time (CT), pressure-time integral (PTI) and force-time integrals (FTI) and have been investigated in the context of foot-function altering devices like foot orthoses where a reduction in the temporal parameters has been observed (Landorf and Keenan, 2000). Contact time (ms) is a temporal PPP and is defined as the time each area of the foot remained in contact with the ground (Pedar insole) during the stance phase of gait. The area beneath the pressure-time curve is referred to as the integral of the curve or impulse (kPa*sec). It enables an understanding of the amount of pressure that has been applied over the duration of foot contact during the stance phase of gait (pressure time integral, PTI). The area beneath the force-time curve is referred to as the integral of the curve or impulse (N*sec) and similar to the PTI, is a measure of the amount of force applied over the duration of foot contact (force time integral, FTI). In a healthy participant with a neutral foot type, the temporal parameters would be expected to fall within normative values in the literature (Putti et al., 2007). In terms of spatial parameters, the researchers found that CA was highest in the rearfoot followed by the midfoot region. Temporal parameters such as CT was longest in the metatarsal regions particularly the hallux. The PTI and FTI were highest in the rearfoot and these correspond with the findings of Kernozek et al., (1996). However, these values could potentially alter in a medial TFJt OA participant. Maximal pressure loading on the lateral aspect of the rearfoot and midfoot and increased contact time in the lateral forefoot (supinated foot) could theoretically increase the knee adduction moment and contribute to medial TFJt OA progression which is in contrast to a prevalent pronated foot posture in medial TFJt OA participants (Levinger et al., 2010). This could suggest age-related and consequent biomechanical compensation as pronation of the rearfoot complex would decrease the knee adduction moment and subsequent medial knee loading (Scott et al., 2007).

The key PP measurements that are alluded to in the knee osteoarthritic literature base have been included in this selection and while COP would have been useful, the Pedar ® in-shoe
system does not record this as it needs a barefoot anatomical representation of the foot in order to gauge medial-lateral movements of the centre of gravity. However, this can be assessed based on pressure (peak pressure) distributions over the entire foot. Peak pressure (kPa) is a magnitudinal PP and represents the highest pressure value recorded by each sensor over the entire stance phase of gait (Orlin and McPoil 2000). Peak pressures are clinically relevant they can be correlated with foot posture groups in normal and OA populations.

CA, CT, PTI, FTI and peak pressures have been identified as the most clinical relevant of all 18 Pedar parameters (Putti et al., 2007). Foot posture could potentially be a confounding variable to PP parameters and this has not been previously considered by normative reference studies in healthy individuals or OA groups. Recent studies have shown contradictory results between foot posture measures and dynamic kinetic data with the need to determine normative values in different participant and pathology-based groups and refine study methodologies (Cavanagh et al., 1997; McPoil and Cornwall 2005; Landorf et al., 2006). For example, Teyhen et al., (2009) showed that there was a relationship between greater arch heights and greater lateral forefoot PP’s. Albensi et al., (1999) also demonstrated that in 17 healthy athletes lower arch height was associated with a greater rearfoot PP. This is direct contrast to findings by Burns et al., (2005) where greater arch heights were associated with greater rearfoot pressures in 70 volunteers of varying pes cavus foot types compared to controls. Foot posture was categorised using the FPI-6. This discrepancy in the literature could be due to a variety of factors: the use of different foot posture assessment tools (arch index versus the FPI-6); varying ages, sample sizes (17 versus 70) and pathological groups (idiopathic pes cavus, neuropathic pes cavus and normal versus normal). More recently, Jonely et al., (2011) found that more pronated foot postures were associated with greater pressures under the hallux and medial mid-foot. The authors also reported a poor to fair association foot posture and PP when using linear regression analysis (hallux ($R^2 = 0.18$), medial forefoot ($R^2 = 0.07$), and medial rearfoot ($R^2 = 0.05$). This could be due to the fact the authors focussed only on the medial column of the foot, thereby potentially excluding vital pressure differences that occurred over the entire foot in different foot postures.

Therefore, by quantifying PP parameters, normative baseline values of these parameters based on foot posture categories (using FPI-6) can be established and used to determine
whether there is a relationship between foot posture and PP measures and furthermore, whether this relationship alters in TFJt OA individuals.
2.4 Conservative Interventions for OA Management

The aims of managing medial TFJt OA involve educating patients on OA pathogenesis; managing pain, improving physical function and; therefore, reducing OA progression and its consequences (Hunter and Felson 2006). In most cases, TFJt OA treatment is an amalgamation of different available options based on the age of participants, health-related quality of life and severity of OA. Figure 3.1 is an illustration of the range of treatments and is similar to the guidance provided by the National Health Services’ Clinical Knowledge Summaries (CKS) which is aimed at frontline healthcare professionals. The purpose of such strategies is to reduce the number of inappropriate surgical referrals, the number of waiting list patients and hence the unnecessary costs to the health service (Public Health Intelligence Team 2007).

The treatment emphasis has often been placed on either pharmacological or surgical therapies but as Figure 2.9 illustrates, this should be aimed at moderate-severe OA individuals. It could be argued that there is an inherent ‘research agenda bias’ which may be a direct response of the lucrative opportunities for pharmaceutical industries (Tallon et al., 2000). Frontline conservative treatments such as foot orthoses would be categorised as non-pharmacological management and has been cited for use in a mild-moderate OA populations by CKS. However, foot orthoses are not mentioned in the illustration and generally receive limited attention in contrast to surgery and analgesics. Foot orthoses are medical devices that are used in conjunction with footwear to support and align the foot and to improve foot function (Wu 1990). Kirby (1998) built on this definition and suggested that an effective FO altered plantar pressure parameters (magnitude and timing) to allow a more normal foot and lower extremity function, thereby reduce abnormal or pathologic loading forces on the lower extremity during gait. In particular, LWOs have been shown to be beneficial in the treatment of medial TFJt OA in terms of improving kinetic and patient-centred outcome scores. They may also be cost-effective in the long term although this has not been established by any longitudinal studies (Llandorf et al., 2004).
2.4.1 The Burden of OA Management

One of the biggest factors affecting the health economy is the burgeoning cost of healthcare provision and musculoskeletal pathology figures for TFJt OA (NICE guidelines 2005). According to the literature, there are almost 70,000 knee replacement surgeries carried out in England and Wales every year. Each replacement procedure costs around £5500 not including aftercare and rehabilitation (Treatment Abroad 2008). While financial costs of an intervention are a key factor, economic costs such as treatment administration and implementation also influence the cost benefit and cost effectiveness of a treatment (Haycox 2009).

When the cost-effectiveness of non-pharmacological and nonsurgical interventions of TFJt OA was evaluated by Pinto et al., (2012), there was only limited evidence available for exercise programmes, acupuncture and lifestyle interventions for treating TFJt OA. From the available research, the authors reported that all studies evaluating exercise interventions found the programmes to be cost effective. However, six out of eleven interventional studies demonstrated a risk of bias for the cost and/or effect components of their cost-effectiveness analysis. Additionally, amongst the conservative interventions, weight loss and regular exercise are difficult for patients to achieve while chronic use of simple analgesics such as paracetamol may have adverse side-effects (Delzell 2012). Laterally wedged foot orthoses have been proposed as a low-cost, low-risk intervention that can provide immediate relief for
early stage TFJt OA symptoms (Hinman et al., 2008; Reeves and Bowling 2011). Despite the cost-benefit and cost-effectiveness of foot orthoses being demonstrated in a few studies (NICE 2008), foot orthoses are still regarded as a 'patient-focussed, evidence-based, expert consensus recommendation for the management of TFJt OA’ by Zhang and colleagues (2008). Foot orthoses, which will be discussed in detail next, offer an attractive management solution of TFJt OA as it is a minimally invasive, is simple and easy for patients to adopt and has limited side-effects.

2.4.2 Foot Orthoses

The focus of orthotic therapy is to directly influence lower limb alignment by altering rearfoot alignment and function (Yasuda and Sasaki 1987). In medial TFJt OA, a lateral wedge placed along the lateral border of the orthoses could evert the rearfoot and has been suggested as an effective treatment to reduce the KAM and delay the progression of the disease (Yasuda and Sasaki 1987).

In a review, Marks and Penton (2004) investigated studies that have used laterally wedged orthoses (LWOs) to specifically influence kinetic, kinematic and patient centred outcome scores. The review found that while the majority of studies were not well designed (limited sample size, no randomisation process and no control groups), there was a statistically significant benefit using LWOs to reduce pain of biomechanical origin in TFJt OA. However, the evidence is conflicting as Reilly et al., (2006) conducted a systematic review and found that the use of LWOs in medial TFJt OA is not supported by the literature. This was echoed by Hinman and Bennell (2009) who confirmed that clinical trials had not been conclusive for several reasons.

The authors made reference to the lack of consideration given to the structure and function of the foot and ankle during gait. This could be a significant factor contributing to the dissonance in the evidence base as different foot postures could influence the effect of the LWOs on lower limb biomechanics and therefore affect loading at the TFJt. LWOs have also shown individual-specific features as they have been most beneficial in those with early mild-moderate medial TFJt OA compared with severe medial TFJt OA (Shimada et al., 2006). The authors’ quantified OA severity by using a radiographic scale; the Kellgren-Lawrence (KL) grading for TFJt OA and did not use symptom-based scores. Table 2.2 presents the KL OA classification system (2011).
There is also a considerable variation in the material design and features of different orthoses used to treat medial TFJt OA which are influenced by personal experience or anecdotal evidence instead of empirical studies (Payne 1998). Lateral wedges of between 5° to 15° have shown beneficial effects (reductions in KAM between 4% - 14%), however, the greater the inclination, the less comfort and tolerance within footwear has been reported (Kerrigan et al., 2002; Reeves and Bowling 2011). Customising lateral wedging based on comfort using a lateral step down test as in Butler et al., (2007) is an option. The authors assessed each participant for the maximal lateral wedging that provides maximal pain relief. Other authors use standardised non-customised LWOs in a treatment group compared to a control group (Hinman et al., 2009; Reeves and Bowling 2011). This allows comparison of different patient groups in a research trial through standardisation of the intervention. It is important as while being regarded as biomechanically effective, LWOs may be difficult to disseminate in traditional public health settings due to a lack of standardisations and hence limited external validity and repeatability of a study (Osteoarthritis Intervention White Paper 2011).

Other differences include the length of the lateral wedging itself. Compared with a full-length insole, lateral rearfoot wedging has not shown significant effect on symptoms, joint space narrowing or on the KAM (Mallierfert et al., 2001; Nester et al., 2003 Pham et al., 2004). Kirby (in Delzell 2012) suggests that a fuller-length LWO has a greater surface area to shift the COP laterally and decrease loading on the medial TFJt. This suggests that the longer the wedge, the greater the leverage afforded by the LWO and subsequently, the greater the influence on shifting the COP laterally. However, while full-length LWOs have been shown

<table>
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<th>Grade</th>
<th>Criteria</th>
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<tbody>
<tr>
<td>0</td>
<td>Normal</td>
</tr>
<tr>
<td>I</td>
<td>Doubtful narrowing of joint space, possible osteophyte development</td>
</tr>
<tr>
<td>II</td>
<td>Definite osteophytes, absent or questionable narrowing of joint space</td>
</tr>
<tr>
<td>III</td>
<td>Moderate osteophytes, definite narrowing some sclerosis, possible joint deformity</td>
</tr>
<tr>
<td>IV</td>
<td>Large osteophytes, marked narrowing, severe sclerosis and joint deformity</td>
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Table 2.2 The Kellgren and Lawrence Classification of OA based on radiographic evaluation of a joint (Schultz 2011).
to be the most effective, the incline in the region of the forefoot would need to be ground smoothly so as to be better accommodated in the footwear and prevent pressure from footwear uppers on the lesser digits. Therefore, an alternative would be a three-quarter length LWO that would account for patient comfort and tolerance (Wallace 2006). A three-quarter length LWO would start proximal to the metatarsal heads and extend to the posterior aspect of the heel as opposed to a full length LWO or a rearfoot LWO (located underneath the lateral aspect of the calcaneus). Three-quarter length LWOs have had limited research attention, however, in order to minimise patient discomfort while maintaining functional control of the rearfoot and midfoot, the revised three-quarter length design could be a valid consideration. This along with a valgus arch support could improve patient comfort and increase compliance.

Another variation to the literature results are the types of footwear used in LWO studies in TFJt OA. While flat shoes with no heels are considered ideal by Toda and colleagues (2002), Fang et al., (2006) found there was a significant improvement observed in knee pain and function using a knee-health related quality of life measure with shock absorbing trainers. The inherent design of some trainers could mean an elevated rearfoot i.e. a slight heel elevation (3 - 5mm). However, conflicting evidence suggests that usual footwear, such as clogs and stability shoes or walking shoes, can increase KAM and thereby medial knee loading (Kemp et al., 2008). The varying effects of footwear on patient outcomes has been considered as having a potential effect on patient compliance by Hinman et al., (2009). However, the resource implication of standardising footwear in an OA population needs equal consideration and is not routine in clinical practice. Therefore, while the influence of footwear can be considered a key factor in determining patient outcomes, these could be considered using an appropriate foot categorisation or assessment tool during the studies.

These differences (foot posture, orthoses design and footwear) could explain the discrepancies in the LWO research findings. LWOs are nonetheless regarded as a beneficial conservative intervention and this is reflected by the fact that LWOs are recommended by 13 out of 14 different guidelines for TFJt OA. This includes guidelines published by the Osteoarthritis Research Society International (OARSI) (Zhang et al., 2008; Hinman et al., 2009). Hinman and colleagues also suggested possible reasons for conflicting findings as a lack of randomised trials with control groups in this research area, lack of reference to footwear choice, justification of orthoses design and clinical lower limb alignment profiles.
• *Foot Orthoses: Proposed Mechanism of Action*

The basic principles of FO prescription are: to realign structures within the foot, to control excessive joint motion or facilitate joints with a limited range and quality of motion and; to redistribute and reduce the magnitude of plantar peak pressure to manage timing of pressures in an area (Menz 2008; Payne et al., 2003). While these foundational principles are generally agreed on, Table 2.3 summarises several paradigms on the basic mechanistic premises of foot orthoses. Kirby (1998) describes two main types of foot orthoses: prescription or customised orthoses and non-prescription or prefabricated orthoses. Both custom and prefabricated orthoses can be either: functional – capable of altering function and the transfer of ground reaction forces through the lower limb - or accommodative – capable of attenuating shock and reducing the magnitudes and temporal loading parameters of pathologically affected gait (Rose et al., 2011).

Within the context of medial TFJt OA, LWOs are often described as functional foot orthoses as lateral wedging increases the lateral surface area available for the transfer of the GRF. However, they could also be described as accommodative as they have been known to reduce the medial plantar loading and redistributing them to the lateral rearfoot (Leitch et al., 2011). LWOs therefore, prolong the lateral shift in the COP and reduce loading on the medial TFJt compartment (Kirby 1992; 2012; Delzell 2012). This has also been demonstrated by Kakihana et al., (2005) and Maly et al., (2002) when using a pressure plate system while Van Gheluwe and colleagues used an in-shoe pressure system and found a similar lateral shift in the COP. Nigg et al., (2003) also suggested this as the functional mechanism of action of LWOs. Incidentally, Nigg (1999) was the original proponent of the ‘preferred motion pathway’ theory whereby the body modulates joint excursions in order to maintain a constant centre of mass during locomotion. LWOs could work within this remit to improve the excursion of the GRF. By altering the direction of the GRF, LWOs could work by reducing the external KAM moment of the knee joint. It would prevent adverse loading on the medial TFJt and allow the transfer of forces along a pathway of least constraints or minimised muscle activity (Nigg 2001; Kirby 2004).

Individuals with TFJt OA have shown demonstrated altered quadriceps function and decreased sagittal plane (knee flexion) during stance compared with controls. This delayed onset of quadriceps activity may implicate force attenuation across the TFJt (Hinman et al., 2002). Another theoretical framework for foot orthoses is the ‘shock attenuation theory’ in
which they act as a shock absorbing interface between the foot and the ground (Whittle 1999; Ball and Afheldt 2002; Groner 2011). LWOs increase pronation of the rearfoot and midfoot and thus may improve shock attenuation during gait. This would present as plantar pressure reductions in the lateral rearfoot and corresponding increases of the medial rearfoot respectively as it reflects the transverse and frontal plane motion of the foot (Nester et al., 2003). This also implicates the ‘plantar pressure reduction and redistribution’ theoretical framework as a mechanism of LWO action. Therefore, the function of LWOs cannot be reduced to one particular theoretical framework due to the overlap of the theories and the research findings themselves.
Theoretical Frameworks | Proponents
--- | ---
‘Preferred Muscle Pathway’ – Foot orthoses work not by realigning skeletal structures, but encouraging lower extremity muscle tuning, thereby reducing soft tissue vibrations and promoting motion along a preferential movement pathway. | Nigg 1997; 1999 and 2001 and Kirby 2006

‘Altered muscle activity’ – FO efficacy and positive outcomes correlated with altered mean electromyographic (EMG) amplitude of proximal and distal lower extremity muscle groups particularly, biceps femoris and tibialis anterior. | Nawoczenski and Ludewig, 1999 and Tomaro and Burdett, 1993

‘Plantar pressure reduction and redistribution’ – Foot orthoses work on the principle of redistributing pressures over the plantar surface of the foot and reducing peak pressures and forces in key areas such as the forefoot and heel. Considerable research conducted in diabetic populations. | Cornwall and McPoil 1997; Redmond et al., 2000; Boulton 2004; Zammit et al., 2008; Chevalier et al., 2010; Lidtke 2010.

‘Kinematic Alterations and Movement Coupling’ – Foot orthoses produced a small reduction in maximal tibial internal rotation in participant groups that were categorised according to foot type. Changes in tibial axis orientation produce a more neutral, or closer to subtalar joint neutral alignment. | Ball and Afheldt 2002; Nawoczenski and Janisse, 2004; Pohl and Buckley 2008; Houck et al., 2009.

‘Shock Attenuation Theory’ – In this theory, Foot orthoses act as a shock absorbing interface between the ground with footwear and the foot. The underlying principle is that the magnitude of the force and the way this force is dissipated through the lower limb can be a contributing factor to overuse injuries. | Pratt 1988; Whittle 1999; Ball and Afheldt 2002; Groner 2011

**Table 2.3** Commonly cited theoretical frameworks underlying orthotic theory and prescription which in some cases tend to overlap such as preferred motion pathway and altered muscle activity theories. Nigg’s theory on preferential motion pathways also extends and compliments the enhanced proprioception theory (Feuerbach et al., 1994; Richie 2007).
Foot Orthoses: Factors for Consideration

Cost

Some authors have discussed the main advantage of prefabricated foot orthoses as their cost benefit compared to custom foot orthoses (Menz 2009; Hawke et al., 2009; Brocklesby and Wooles 2009; Kripke 2009). This, however, is matched by an increase in the shelf-life, longevity and anecdotal (not empirical) improved functional control of custom foot orthoses (Redmond et al., 2000). In actual fact, both foot orthoses are equally clinically effective at reducing pain and improving patient outcome scores for a variety of musculoskeletal pathologies (Redmond et al., 2009).

There is a cost difference with custom foot orthoses which are 3.5 times more expensive at the point of issue and 2.5 times more costly over the entire episode of care in a direct comparison with prefabricated foot orthoses (Redmond et al., 2009). However, it is not possible to recommend one type of FO over the other due to a lack of long-term comparative data as custom foot orthoses might be more effective over time and have a greater cost advantage (Llandorf et al., 2004). A similar argument was noted by Rome et al., (2004) that although custom foot orthoses might initially be more expensive, they seem to result in a higher foot-health related quality of life score and reduced heel pain. Therefore, the use of a particular LWO should also include material cost per unit relative to alternatives available and LWO material composition.

Insole materials that have been shown to have an effect in treating medial TFJt OA have ranged from Poron and Plastazote (foam rubber based) to an Ethyl Vinyl Acetate (EVA) composition (Marks and Penton 2004; Hinman et al., 2008). EVA is a polymer that is malleable and flexible. Due to its chemical composition, it is lightweight, stress-crack resistant and is particularly durable under exposure to different temperatures. Rubber LWOs such as those used by Malliefert et al., (2001) in treating medial TFJt OA is an alternative that is durable and effective. However, as EVA is porous in composition, it is similar to rubber and at a cost level, is cheaper compared to natural rubber. EVA based orthotics range in cost depending on brand and manufacture – Vasyli’s range from £22.99 for an orthotic template while the Slimflex range from £1.90 per unit which is a substantially different pricing bracket. The Slimflex orthoses are made of EVA which is similar to those used in TFJt OA studies by Rubin and Menz (2005) and Hinman et al., (2008). They are commonly used in the NHS due to their longevity and comparative costs as reported in clinical audits.
undertaken by several primary care trusts (Brocklesby and Wooles, 2009; Cameron et al., 2009). In these independent studies, the prefabricated Slimflex have also been evaluated using patient outcome scores and they are worn more (hours per week) and tolerated better (comfort in shoes) compared to custom made orthoses. The cost per prefabricated Slimflex insole is competitive (£1.90 per unit) and is more cost effective than custom made orthoses (by £4.21 per unit). The NHS has frequently used FO interventions and has had effective clinical outcomes across podiatry departments (Fox and Winson, 1994; Rendall and Batty, 1998; Brocklesby and Wooles 2009). This debate is also further compounded by the disparities in type of data collection, types and definitions of foot orthoses used as an intervention and differing study designs (Llandorf and Keenan, 1998 and Clark et al., 2006).

Footwear

When comparing custom and prefabricated foot orthoses, other factors such as longevity, size and shape fit, availability, accommodation within footwear and time available during a consultation play a role in the decision. Patient compliance is also a key factor. Payne (2006) compared the patient compliance in two types of foot orthoses and found that 24.5% preferred the prefabricated FO, 18.4% preferred the custom FO but the majority, 57%, did not have a preference. FO comfort within footwear was comparable in both groups as 83.7% had no preference between the custom or prefabricated FO in their own footwear. Fang et al., (2006) reported an immediate improvement in pain scores when using shock absorbing shoes in conjunction with LWOs. More recently, Barrios et al., (2009) accounted for individual footwear variation by prescribing standardised walking shoes in sixty-six subjection with medial TFJt OA and found that both the LWO and neutral FO group improved when using patient centred outcome scores. Shock absorbing footwear may facilitate shock attenuation and moderate the transfer of excessive loading along the kinetic chain to the medial TFJt. The results suggest that footwear may be a moderating factor in the management of TFJt OA and therefore warrants consideration in research studies focussed on the lower limb.
Health Benefits and Side Effects

There is conflicting evidence for the health benefits and improvement in foot-health related quality of life when using LWOs and evaluated with patient centred outcome scores. Hinman (2008) reported immediate pain relief and an improvement in pain scores over 3 months (p<0.01) in an LWO group while Raiij et al., (2010) found these pain improvements extended over 6 months (p<0.06). Another study has demonstrated a non-significant decrease in the consumption of non-steroidal anti inflammatory drugs with the use of LWOs (Pham et al., 2004). In addition there was increased compliance (71% and 45%; p=0.01) as participants used the treatment LWO significantly longer per week (p=0.006) compared to a knee brace intervention.

Hawke et al., (2008) also report conflicting evidence with regards to side effects and complications with the use of FO interventions. Some of the side effects recorded with the use of foot orthoses in general have been additional foot pain, ankle instability and an increased risk of ankle sprain injuries as well as skin irritation such as blisters, allergies and hyperkeratotic lesions (Dimou et al., 2004, Woodburn et al., 2002 and Burns et al., 2006). There are several methods by which clinicians and researchers alike can monitor these side effects. This includes the use of footwear diaries or journals to record symptoms on a daily or weekly basis and/or having routine appointments to address any issues.
2.5 Patient Outcome Scores

TFJt OA is a slowly progressing and debilitating process and can have a devastating impact on the health-related quality of life (HRQoL) (Fontaine 2008). TFJt OA is characterised clinically by pain, disability and loss of function. Patients report with a diminished ability to perform the basic activities of daily living such as climbing stairs or changing from the sitting to a standing position (Tanner et al., 2007). Due to the chronic nature of the disease and associated clinical outcomes, there is a need to better understand the relationship between measures of patient centred outcome in relation to specific biomechanical factors (lower limb alignment profiles) and conservative interventions (LWOs). Previously, patient outcomes following knee injuries or disorders were based on objective physical findings such as ligamentous laxity, radiographic findings and performance indicators on functional tests. Subjective patient outcome scores such as HRQoL are important as OA causes significant decrements in function and well-being that for patients may be of greater consequence than the disease process itself (Scott 2000). Knee HRQoL measures are of importance to clinicians, researchers and policy makers as they provide an understanding of an individual’s state of health that is quantifiable and comparable with different population groups (Fontaine 2007). Considering disease status and the cost of care, if a conservative alternative such as LWOs could reduce symptoms and increase activities of daily living, it follows that future research should be aligned to this goal.

There are several reliable, responsive and validated scores which encompass these different facets of quality of life and shall be discussed next.

2.5.1 Knee-health related Quality of Life

Knee-health related outcome measures evaluate the influence of TFJt OA on various aspects of activity levels and lifestyles (Bellamy et al., 1997; Naudie et al., 1999).

In 1982, the Western Ontario and McMaster University Osteoarthritis Index (WOMAC) was introduced as an evaluation tool to assess patient outcomes in hip or TFJt OA. The WOMAC contains 24 parameters pertaining to pain, stiffness and physical function. It has been used and validated in a range of musculoskeletal conditions such as rheumatoid arthritis, systemic lupus erythematosus and fibromyalgia (Wold 1999; Ito et al., 2007). The WOMAC is self-administered and takes 12 minutes to complete. It does not require any additional equipment however; it is subject to licensing processing and costs in using the questionnaire for research purposes. It is scored on a Likert-like scale ranging from 0-4 and the higher the scores on the
WOMAC indicate worse patient symptoms and outcomes. While it has demonstrated adequate validity, there is limited evidence regarding the properties of the stiffness subscale and its associated test-retest reliability is low (McConnell et al., 2001). Other studies have also reported a weak factorial validity of the WOMAC pain and physical function sections. This means that the WOMAC is unable to detect changes in physical function when there is a weak relationship between pain and function (Pua et al., 2009). Despite this, the WOMAC is one of the most widely administered self-reported patient outcome measures for the lower extremity symptoms and function in OA (Bellamy 2002).

The Knee Injury and Osteoarthritis Outcome Score (KOOS) was developed as an extension of the WOMAC (Roos and Larsen 2003). The KOOS contains 42 questions and collects data on five knee-specific patient outcome subscales: pain; symptoms such as swelling; disability in activities of daily living (ADL); disability on a level physically more demanding that ADL; and mental and social factors such as awareness and lifestyle changes. It is a Likert-style scoring system which generates a score transformed on a 0 – 100 scale with 0 representing extremely low QoL as a result of knee problems and 100 representing an extremely best QoL as a result of no knee problems. It is self-administered and takes approximately 10 minutes to complete without the need or cost of any license arrangements or equipment. The KOOS is a reliable tool and validation studies have been carried out in different populations with varying degrees of knee disease, durations, age groups and activity levels (Roos et al 1998 and 2003). It is has been evaluated in terms of validity, consistency and applicability to different population groups in terms of age, pathology and ethnic origin (Dieppe et al., 2005; Frobell et al., 2010; Renstrom et al., 2008). A test has convergent validity if it has a high correlation with another test that measures the same construct. Alternatively, divergent validity is demonstrated by a low correlation with a test that measures a different construct (Gravetter and Forzano 2011). The KOOS has demonstrated convergent and divergent construct validity when compared with the 36 item short-form health survey and the Lysholm knee scale (Ware and Sherbourne 1992). The primary differentiation between KOOS and other scores is that KOOS evaluates both the short term and long term symptoms of patients with TFJt OA as opposed to WOMAC which specifically gauges the long term consequences and the Lysholm knee scoring scale which is a short term assessment tool (Tegner and Lysholm 1985).

However, Roos and Lohmander (2003) who developed the KOOS, stated that it retained all items of the WOMAC score (version 3.0) and thus the scores are comparable, especially for
patients outcomes from previous studies that have used the WOMAC in different population groups. Fundamentally, the KOOS is different as it is more sensitive to patients with previous knee injuries such as meniscal damage or anterior cruciate ligament (ACL) damage. The KOOS has further items added to the pain and stiffness subsections and additional subscales (sports and recreation function and knee-health related quality of life) to account for potential injuries. The KOOS also has better sensitivity to recreational activities and sports (better responsiveness) compared with the WOMAC (Roos et al., 2003). As a result of the increased criteria, the KOOS reported larger effect sizes particularly in participants between the ages of 18 – 46 (Roos et al., 1998) and subsequently in an elderly population (aged 43-86) (Roos et al., 2003). This makes the KOOS attractive for use in a clinical research study as its increased sensitivity resulting in larger effect sizes could allow for smaller sample numbers for interventional studies.

The KOOS has been used to evaluate the effectiveness of offloading knee braces in the management of medial TFJt OA (Bennell et al., 2010; Franklin et al., 2010) and the effectiveness of physical therapy and nutritional supplementation (Colker et al., 2002 and Braham et al., 2003). It has also been validated in ACL constructions, total knee replacements studies and most particularly in mild – moderate TFJt OA (Roos and Lohmander 2003).

### 2.5.2 Physical Activity Questionnaires

A lack of physical activity is often considered as an important reason for the increase in chronic diseases such as osteoarthritis and it is thought that in increase in regular physical activity contributes to the prevention of these diseases (WHO 2002).

Physical activity questionnaires are the most widely used, cheapest and most convenient self-reporting instruments used to assess physical activity. Matthews (2002) states that there are different types of measures such as activity logs/journals, recall questionnaires and global self-report. Recall questionnaires contain between 5-15 items and aim to categorise a population sample intro different physical activity groups such as low, moderate and high levels of activity. It can also estimate average energy expenditure for a given week or month based on a participant’s recall of physical activities. Some examples of this type of questionnaire include the short form International Physical Activity Questionnaire (IPAQ) or the Baecke Questionnaire. Other, more detailed questionnaires such as long version of the IPAQ, aim to capture different dimensions of physical activity and identify patterns within the data. The Global Physical Activity Questionnaire (GPAQ) was developed by the WHO and collects
data on the following: work activity, travelling and recreational activities. The GPAQ however was developed more specifically for surveillance studies in developing nations.

The IPAQ is a self assessed questionnaire that evaluates the health of a participant in metabolic minutes per week (energy expenditure). It can be a useful tool when used to evaluate differences in physical functioning between a healthy control group and pathological populations such as the medial TFJt OA population. The IPAQ measure was developed as a response to prevalent global concerns over sedentary lifestyles and the need to standardise measures of activity across different countries. The IPAQ has been evaluated across different populations and was rigorously tested for reliability and validity (Craig et al., 2003).

However, a noted disadvantage to recalled questionnaires such as the IPAQ is that it is subject to recall bias as well as a social desirability bias (the respondents answer according to what will be perceived as favourable). Its advantages are that it is suitable for most population groups (ages 18-65) and it provides a low respondent burden while allowing a relatively easy and convenient mode of data collection (Kurtz et al., 2008). Another advantage of the short form IPAQ however, is in its scoring methods as the participants can be categorised in activity groups of low, moderate or high and this can be further analysed as met-minutes per week. Several researchers have used the IPAQ to evaluate improvements in physical activity associated with improved HRQoL factors for patients with TFJt OA (O’Reilly et al., 1998; Felson et al., 2000; Rosemann et al., 2007). It has also been used to assess the relationship between obesity, QoL and physical activity in primary care patients with TFJt OA (Rosemann et al., 2008). The IPAQ is therefore often used in conjunction with other measures of QoL such as the KOOS questionnaire (Kumar 2010; Newbould et al., 2011).

Pain occurring as a result of TFJt OA can act as an impediment to physical activity due to the bidirectional relationship. It limits a patient’s ability to perform exercise or a physical task and a lack of this activity is associated with an increase in body weight which affects the function and loading of weight bearing joints such as the TFJt (Felson et al., 2000). A decrease in activity also decreases muscle strength and this has been attributed to the development and progression of TFJt OA (Sharma et al., 2003). Therefore, quantifying physical activity with the use of measures such as the IPAQ would allow the categorisation of populations according to health status. This offers a clinically applicable method of quantifying physical activity and monitoring any changes or developments (improvements or decreases), for example when an intervention is administered.
The literature review provides the foundation for this research and the key points are summarised as follows:

- OA is a multifactorial process where mechanical factors play a central role. Abnormal foot posture or a varus oriented knee alignment could contribute to increased loading of the medial TFJt. Yet, clinical lower limb profiles encompassing foot posture and knee alignment have received limited attention in the literature.

- A neutral TFJt alignment or neutral foot type is no longer defined as the structural ideal or a normal lower limb profile. A normal TFJt alignment varies has a reported a range of 170° – 180° ranging from slightly varus to slightly valgus. A normal foot posture varies within a healthy non-pathological population from neutral to slightly pronated (raw FPI score +2 - +4) with an elderly population and OA populations showing a range of pronated normative scores (raw FPI score +4 - +6).

- Clinically applicable methods of evaluating lower limb profiles such as the goniometer and FPI-6 have shown moderate to excellent reliability and good-excellent internal and external validity. Yet, they have received little attention within a TFJt OA context despite also being cost-effective, simple to administer and clinically applicable.

- There is limited information about the relationship between static foot posture and dynamic kinetic determinants such as plantar pressure assessments. Kinetic variables that are magnitudinal, temporal or spatial have not been investigated in relation to lower limb alignment profiles and within the context of normal and OA participants.

- There are a range of conservative interventions for the management of TFJt OA. LWOs have had varying biomechanical and patient-centred effects when evaluated in randomised control trial designs over the past 10 years. Such an evaluation has yet to determine whether foot posture could be a clinical indicator of OA development and if LWOs can be targeted at a specific patient group based on lower limb alignment profiles.

- Within the context of lower limb alignments, LWOs may alter dynamic foot function and this may be reflected in kinetic changes to plantar pressure patterns compared to an OA control group. The influence of foot posture on the effectiveness of LWOs has not been established.
Therefore, on the basis on these key points, sequential studies were designed:

1. Reliability Study:
   Static foot posture may provide evidence of dynamic function and different types of foot postures are linked with lower limb dysfunction and associated pathologies (Mathieson et al., 2004; Valmassy 1996). Static foot posture can be classified using a range of measures. Currently, there is no valid and universally accepted standard for foot posture classification (Razhegi and Bhatt 2002). Static measures of foot posture such as the navicular height and the Foot Posture Index (FPI-6) have previously demonstrated varying reliability from poor – moderate and moderate – excellent respectively. Reliability refers to the consistency of measure and a test has excellent test-retest reliability if the same result is obtained repeatedly when assessed over two time points (Steffen and Seney 2008). Due to the varying reliability findings, before the FPI-6 or NH can be incorporated into a clinical study, its reliability has to be assessed.
   Static goniometric measurements of TFJt alignment has also received limited attention in the literature despite being the most reliable method of evaluating the anatomical axis of the TFJt (Kraus et al., 2005). The intra-rater reliability needs to be assessed before this knee alignment classification technique can be used further in a clinical study. The reliability of dynamic TFJt angles using 2-dimensional video motion analysis also needed to be established.

2. Preliminary Study:
   Normative foot posture in a healthy population varies from neutral to a slightly pronated while a normative TFJt ranges from slightly varus to a valgus alignment (Redmond et al., 2008; Levinger et al., 2010). The purpose of the preliminary study is to identify normative foot posture and normative static and dynamic TFJt alignments in a healthy demographic. These profiles will be assessed using reliable and clinically applicable techniques that will come from the reliability studies in the previous stage. Normal participants over the age of 45 will be recruited based on strict inclusion criteria encompassing medical history, medical status, family history and absence of any biomechanical/gait abnormalities.
Normative plantar pressure measurements will also be established in standardised footwear in order to determine key healthy magnitudinal, temporal and spatial parameters. Static foot posture and function has been associated with dynamic plantar pressure (Molloy 2010; Teyhen 2009; 2011). The establishment of a healthy normal lower limb alignment profile could identify normative lower limb loading mechanisms using both kinetic and kinematic determinants. As such, the study will also explore the relationship between clinically established foot posture profiles and key plantar pressure outcomes. The preliminary study will also provide a normal comparison of anthropometric measures like height, weight and body mass index (BMI) and physical activity (IPAQ).

3. The Knee OA Clinical Study (KOCS):
Lower limb alignment factors such as foot posture and knee alignment have received little attention in the literature (Lidtke 2011). This is despite a known relationship between foot posture and the direction of the GRF suggesting a potentially moderating influence on TFJt loading (Delzell 2012).
This study will primarily identify normative foot posture, TFJt alignment profiles and associated plantar pressure outcomes in an OA group within standardised footwear at baseline. The methods and study protocol will be similar to the preliminary study, to allow direct comparisons between the normal and OA groups.

(1) Randomised Control Trial (RCT)
As a secondary aim, the study will then evaluate LWOs, a conservative intervention that may be influenced by lower limb alignment factors and could account for the conflicting reviews on clinical effectiveness within the literature (Hinman et al., 2009). A RCT with a parallel-group study design will be used to evaluate the kinetic and patient centred outcomes in a LWO treatment and a control group. It will also determine whether a relationship exists between static foot posture, dynamic plantar pressure outcomes and associated patient outcomes in a medial TFJt OA population.
A RCT is a study in which participants are allocated at random to receive one of many clinical interventions. Randomisation ensures that all possible variables are equal between groups and that any significant differences can be attributed to the
intervention and not an unidentified variable (Nystrom et al., 1993). The few RCT’s that have been conducted did not clearly document randomisation procedures, did not provide complete data sets or use standardised clinical patient outcome measures such as the KOOS or WOMAC (Toda et al., 2001; Malliefert et al., 2001; Pham et al., 2004).

Therefore, an RCT will be devised to include these recommendations and the aims are:

- To examine the effects of LWOs on patient centred outcome scores particularly pain, symptoms, activities of daily living, recreational ability and knee-health related quality of life.
- To identify differences in plantar pressure patterns between the treatment group and the control group and explore these within the context of foot posture.

Other factors such as footwear which could also be a predictor of the success of LWOs will be considered with the use of a footwear questionnaire and a daily footwear log throughout the RCT. The results could provide an insight into mechanical alignment factors (foot posture and/or knee alignment), static and dynamic function factors (limb dominance or plantar pressure parameters) and environmental factors (footwear or physical activity levels) that may affect LWO outcomes.
3. Methods

The aim of this chapter is to discuss participant selection, study designs, the data collection methodologies and protocols adopted in the reliability and normal study, the Knee Osteoarthritis Clinical Study (KOCS) and the randomised control trial (RCT). Section 3.1 will address participant selection for the sequence of studies. Section 3.2 will discuss the methodological designs of the studies. Section 3.3 will address anthropometric measures, foot posture assessment, static and dynamic TFJt alignment. Section 3.4 will detail the in-shoe plantar pressure measurement protocols using the Pedar. Finally, Section 3.5 will address the knee-health related quality of life measures, physical activity and the compilation of footwear and medication diaries.

3.1 Participant Selection

3.1.1 Reliability of Key Measures

A convenience or non-probability sample was appropriate for the reliability study as the aim was to establish the reliability of assessment techniques and participants could be recruited conveniently from the Wales Centre for Podiatric Studies and the University staff and student population. Ethical approval was obtained from the CMU Ethics Committee (Appendix 1). The sample size was ten participants (n=10) and all were recruited through email advertisement. They were healthy and did not have any significant previous or current medical/surgical conditions or injuries that would affect anthropometric measures and static foot posture and TFJt alignment evaluation.

The inclusion criteria for the reliability study were:

- Aged 18-4;
- No previous medical or surgical history resulting in knee pain, symptoms such as swelling or lower limb OA;
- No gait abnormalities or foot deformities on visual observation;
- Able to provide informed consent;
- Availability for two data collection sessions (30 minutes each), one week apart.

3.1.2 Normal Study

A power calculation was conducted and based on two previous studies (Reilly et al., 2009; Levinger et al., 2010). These studies suggested that an expected foot posture (using FPI-6) difference of 1.18 with a standard deviation of 2.0 would be expected when comparing foot posture in a healthy and OA group. Hence, using these values and a required power of 0.8 and significance at the 0.05 level suggested that a sample of at least 47 participants would be required to undertake this study. The calculation was conducted using Minitab® release
version 15. Ethical approval (Appendix 1) was obtained from the Cardiff Metropolitan University (CMU) Ethics committee. Participants were recruited from the university staff and student population at CMU and the local community centre: Friends of Insole Court over an eight month data collection period (April 2010 – November 2010). Posters, emails and leaflets were used in order to recruit participants (Appendix 2). The information sheet and consent form for the Normal study is included in Appendix 3 and 4.

The inclusion criteria of the study were:

- over the age of 45;
- no history of knee pain, knee injury or trauma over the past 10 years;
- no history of significant trauma, injury or surgery to the lower limb in the last 20 years;
- no obvious gait abnormality on visual gait analysis;
- Availability for one session (40 minutes).

3.1.3 Knee Osteoarthritis Clinical Study (OA Study) and RCT

The target sample number for the randomised control trial was established at 100 participants (n=50 in the treatment and n=50 in the control group) based on the power calculation previously conducted for the normal study using Minitab®. The sample was also informed by similar foot orthoses interventional studies from the literature where the sample sizes ranged from n = 30 – 91 (Rodrigues et al., 2008; Hinman et al., 2008 and Raij et al., 2010). Ethical approval for the study was obtained from the CMU Ethics committee (Appendix 5). Participants were recruited from the university staff and student population; Wales Centre for Podiatric Studies clinic; local community groups such as Friends of Insole Court and Arthritis Care Wales; and universities based in the Cardiff area. Potential participants were contacted via email, poster distribution, leaflets and the use of screen slides on advertisement monitors across the UWIC campuses (Appendix 6) over an 8 month data collection period (June 2011 – January 2012). Participants were provided with an information sheet detailing the study outline and requirements. Informed consent was then obtained and all data collection was conducted in a gait laboratory at UWIC where only the principal investigator and participant were present. The information sheet and consent form is located in Appendix 7.
The inclusion criteria of the study were:

- over the age of 45;
- history of medial knee pain over the last 1 year;
- no history of significant trauma, injury or surgery to the lower limb in the last 20 years;
- no obvious gait abnormality on visual gait analysis;
- Where available, radiographic evidence of mild –moderate medial knee OA (Kellgren-Lawrence grade I-III). The inclusion criteria of radiographic evidence of knee OA would have been limiting for several factors: patients seek treatment for knee symptom relief and an improvement of functional limitations, not structural deficiencies of the knee specifically;
- Family history of OA;
- American College of Rheumatology (ACR) classification of OA based on physical examination and clinical presentation: Pain in the knee and three of the following; over the age of 50, less than 30 minutes of morning stiffness, crepitus on active motion, bony tenderness, bony enlargement and no palpable warmth of synovium;
- Availability for 5 sessions (initial meeting of 30 minutes, baseline meeting of 45 minutes and 3 subsequent meetings of 25 minutes) over a 3 month period.

All participant information was kept confidential and enclosed in anonymously labelled and individual numbered booklets. These were stored in a locked cabinet in the research office and could only be accessed by the principal investigator.
3.2 Study Design

While randomised control trials (RCT’s) are widely accepted as the most valid method of determining clinical effectiveness of a single intervention such as a drug, the emphasis on adopting the same rigorous approach to non-pharmacological interventions is increasing (Stephenson and Imrie 1998). Campbell and colleagues (2000) advocate a phased approach to the development and evaluation of complex interventions and Figure 3.1 is an illustration of the sequential phases of developing an RCT. While interventions such as laterally wedged orthoses (LWOs) have been evaluated in RCT’s (Phase III) by previous researchers (Toda et al., 2001; Malliefert et al., 2001; Pham et al., 2004, Bennell et al., 2011; ), there has been limited research to support modelling (Phase I) and exploratory trials (Phase II). With particular regard to medial knee OA, there has been limited identification of underlying mechanisms, such as lower limb alignment, which could influence patient outcomes and may be a factor that contributes to the variable efficacy reported with the use of LWOs. Foot posture and its subsequent dynamic mobility is relevant as it affects how forces are transmitted to the TFJt and is associated with knee pain and medial TFJt cartilage degradation (Wada et al., 2001). Subsequently, there is some inconsistency as while some authors associate a varus TFJt alignment with a supinated foot (Cooke et al., 2007), others have found and suggested a more pronated foot type (Levinger et al., 2010). The literature reported has also been inconsistent in the attention to and outcome measures used to evaluate lower limb alignment (Gandhi 2010).

Therefore, a modelling trial would firstly identify the reliability of the key components or underlying mechanisms, i.e. evaluation of lower limb alignment techniques in a pilot study. Its purpose is to evaluate the logistics, gather information, verify procedural skills and evaluate the reliability of results.

Secondly, the exploratory trial would establish the primary (lower limb alignment) and secondary outcome measures (plantar pressure parameters) that are relevant to patients with medial knee OA and establish normative comparisons in a healthy normal group.
In clinical research, there are two types of exploratory studies: experimental and observational. When an investigator assigns a treatment, the study is an experimental one whereas if the opposite is true, it is an observational study. Figure 3.2 is an algorithm for the classification of the types of clinical research (Grimes and Schulz 2002). Observational studies can be either analytical or descriptive. In order to establish normative lower limb alignment profiles and plantar pressure profiles in normal and OA participants, a cross sectional-study design will be adopted. Normal and OA participants will therefore be assessed at one time point. There are several advantages to the use of a cross-sectional study design: it is an effective design to evaluate prevalence and can also identify possible associations or interactions that can be more rigorously evaluated in a larger cohort study or RCT. It does not, however, allow the differentiations between cause and effect or allow us to insight into the sequence of events as it offer a snapshot of a particular time point (Mann 2003). The normal and OA study would allow direct comparisons of lower limb alignment and associated plantar pressure parameters to be made between both normal and OA participants. Flow chart 3.1 provides an outline of one data collection session in the normal study.
Figure 3.2 Algorithm for classification of different types of clinical research (Grimes and Schulz 2002).
Over 45 years, no history of lower limb injury, trauma or surgery. No systemic condition affecting gait on observation. No obvious gait discrepancy.

N=50

Participants are given Information Sheets prior and any questions are addressed. Sign consent form.

Assess physical activity using the IPAQ

Barefoot and remove heavy clothing to measure height (metres) and weight (kgs) to assess BMI (kgs/m²)

Step onto lined paper. Then march on the spot for 20 seconds so as to assume relaxed calcaneal stance position when stepping onto A2 sheet.

Draw outline around the feet. Place retro-reflective markers on the centre of the knee and visually assessed centre of thigh and shin. Assess Foot Posture Index (FPI)

Palpate navicular tuberosity and mark with a pen. Measure distance from ground to the navicular. Navicular height (NH) measured thrice.

Assess limb dominance by kicking a ball.

Measure the TFJt angle using goniometer from markers positioned on skin. Repeat thrice.

Use Quintic 2-dimensional software to assess TFJt alignment on the platform. Repeat measures (dynamic TFJt angle) thrice.

Fit Pedar insoles inside Donnay trainers and record plantar pressure measurements and dynamic (TFJt angles) using Quintic. Measures repeated thrice.

Flow Chart 3.1 The data collection outline of the normal study
There are several issues to consider when conducting RCT’s. They are time consuming and expensive, inefficient for evaluating adverse effects, and are subject to a strict inclusion and exclusion criteria. However, they are the optimal study design for evaluating efficacy, the process of randomisation avoids confounding factors and it may explain a cause and effect relationship (Gossall and Gossall 2006). The OA study will also use an experimental study design as participants with medial TFJt OA will be randomly allocated to a treatment (LWOs) and control group (neutral orthoses) in a RCT using a block randomisation technique. Randomisation is crucial to eliminating selection bias, balancing the study groups in terms of variables and provides a basis for an assumption-free statistical test of group equality. There are different types of randomisation available but block randomisation was chosen as simple randomisation for example, cannot guarantee participant number balances during a trial. Therefore, at any given point in the RCT, when a complete block was used, there were comparable number of participants in the treatment and the control group. A block size of $2 \times 2 = 4$ was used and to avoid further selection bias, random block sizes were generated and implemented (Shen and Lu 2006). The block sequences were generated using a free online randomisation calculator as recommended by Bland (2008).

The RCT will evaluate the effectiveness of LWOs over a three month treatment period using patient centred outcome scores and plantar pressure outcomes. The influence of lower limb alignment profiles on these outcome measures will also be established. Flow Chart 3.2 provides an outline of the data collection sessions in the baseline OA study (cross sectional) and subsequently the RCT design over time. The RCT will adhere to the CONSORT (Consolidated Standards of Reporting Trials) statement in Chapter 6 when reporting the trial’s design, conduct, analysis and interpretation and subsequent result validity.
Inclusion criteria:
Over 45, knee pain for over 6 months lasting no more than 30 minutes at a time + ACR classification of OA; Family history of Knee OA; Radiographic knee OA where available; no history of surgery, trauma or injury to the lower limbs.

Participants are provided with information sheets and are differentiated by a block randomisation method into:

N=50

Assess BMI, foot posture, static and dynamic TFJt alignments and plantar pressure parameters (Pedar). Administer KOOS score and IPAQ. Prescribe LWOs with 5° lateral wedge and medial arch infill.

Assess static and dynamic TFJt alignments, plantar pressure parameters and administer KOOS score and IPAQ.

Assess static and dynamic TFJt alignments, plantar pressures and administer KOOS score and IPAQ.

Assess static and dynamic TFJt alignments, plantar pressure parameters and administer KOOS score and IPAQ.

N=50

Assess BMI, foot posture, static and dynamic TFJt alignments and plantar pressure parameters (Pedar). Administer KOOS score and IPAQ. Prescribe neutral inserts with no postings.

Assess static and dynamic TFJt alignments, plantar pressure parameters and administer KOOS score and IPAQ.

Assess static and dynamic TFJt alignments, plantar pressures and administer KOOS score and IPAQ.

Assess static and dynamic TFJt alignments, plantar pressure parameters and administer KOOS score and IPAQ.

Flow Chart 3.2 The data collection outline of the OA study
3.3 Anthropometric and Lower Limb Alignment Methods

3.3.1 Anthropometric Measures

**Materials:** Participant booklets.

**Methods:** Participants were provided with a participant booklet for each study and were asked to provide details on age, date of birth and contact address. All data collection took place in the Gait Laboratory at the Wales Centre for Podiatric Studies.

A reliable and verified clinical scale was used to assess weight in kilograms (kgs) and the same scale was used throughout the project. A wall mounted height ruler was used to assess height in metres (m) and this was used consistently throughout the project. Weight and height were then noted in the booklet and body mass index (BMI) was calculated from weight in kgs divided by the square of height in m. BMI was then interpreted using the international classification of adult underweight, overweight and obesity according to the WHO (Table 3.1). BMI is considered an international gold-standard of obesity measurement in both men and women and is used to classify adult weight as underweight or overweight. As previous studies have documented a direct relation between musculoskeletal pathologies and body weight; it was a useful parameter to include for its potential effects on foot posture despite conflicting evidence (Davis et al., 1991; Irving et al., 2007; Redmond et al., 2008; Aurichio et al., 2010). It is also relatively inexpensive, easy to administer and clinically applicable. Participant’s height and weight was assessed on every occasion that they came to the gait lab to account for any fluctuation throughout the project.
Table 1.1 The International Classification of BMI (WHO 1995; 2000 and 2002)

<table>
<thead>
<tr>
<th>Classification</th>
<th>BMI (kg/m²)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Principal cut-off points</td>
</tr>
<tr>
<td>Underweight</td>
<td>&lt;18.50</td>
</tr>
<tr>
<td>Severe thinness</td>
<td>&lt;16.00</td>
</tr>
<tr>
<td>Moderate thinness</td>
<td>16.00 - 16.99</td>
</tr>
<tr>
<td>Mild thinness</td>
<td>17.00 - 18.49</td>
</tr>
<tr>
<td>Normal range</td>
<td>18.50 - 24.99</td>
</tr>
<tr>
<td>Overweight</td>
<td>≥25.00</td>
</tr>
<tr>
<td>Pre-obese</td>
<td>25.00 - 29.99</td>
</tr>
<tr>
<td>Obese</td>
<td>≥30.00</td>
</tr>
<tr>
<td>Obese class I</td>
<td>30.00 - 34.99</td>
</tr>
<tr>
<td>Obese class II</td>
<td>35.00 - 39.99</td>
</tr>
<tr>
<td>Obese class III</td>
<td>≥40.00</td>
</tr>
</tbody>
</table>

3.2 Foot Posture and Spatial Gait Assessment

Materials: Foot Posture Index (FPI-version 6) datasheet and reference scoring sheet (Appendix 8); A1 paper sheet; biro; 30 centimetre ruler; protractor; stopwatch and participant booklet.

Methods: Participants were barefoot and wore a pair of shorts for the ease of assessment. They were first asked to stand on an A1 sheet of paper and march on the spot for 20 seconds before stepping onto another sheet of prepared paper. This was done in order to obtain a relaxed calcaneal stance orientation and enabled participants to adopt a more natural stance position to allow foot posture assessment (Redmond et al., 2006; Curran et al., 2006). The participants were always requested to stand still, with their arms by their sides and looking straight ahead. Before the FPI-6 was administered an outline of both feet was drawn onto the A1 paper in order to assess the angle of gait (AOG) and base of gait (BOG). The quasi-static AOG and BOG were determined from methods previously described by Curran and colleagues (2006) and is illustrated in Figure 3.3.
Figure 3.3 Quasi-static AOG and BOG assessments were made using a ruler and protractor.

The FPI-6 was then assessed following palpation and visual observation of 6 anatomical landmarks of each foot: talar head; curves above and below the malleoli; calcaneal inversion/eversion; talonavicular prominence; medial arch height and forefoot transverse plane positioning. Each factor received a score ranging from -2 - +2 and these were noted on the FPI datasheet for each participant. The navicular height was then assessed using a biro to first mark the position of the most prominent aspect of the navicular tuberosity when the subtalar joint was in a relaxed stance position. This method has been described previously by Shrader and colleagues (2005). A ruler was then used to measure the distance between the ground and the marked point in centimetres. This process was repeated three times to get an average NH reading for the left and right foot respectively. Figure 3.4 is an illustration of how NH was measured using this technique.

Limb dominance is often a disregarded characteristic in healthy and pathological gait (Polk and Rosengren 2010). However, gait asymmetries have been linked to limb dominance and a right dominant limb can exhibit more pronated and increased AOG (Sadeghi et al., 2000;
Therefore, LD was also assessed by asking participants to kick a ball and noting which limb was used, a technique utilised by previous researchers (Curran et al., 2005; Brophy et al., 2010). This was performed three times to verify LD in case there was any inconsistency for example if a participant inadvertently altered the limb of choice when kicking the ball.

Figure 3.4 In the first illustration, the NH position is assessed and marked with a biro. Following this, the distance between the ground and the navicular tuberosity prominence is assessed with a ruler.

Walking speed was assessed using a stopwatch that would record the time taken to walk from one end of the gait platform to the other end (an 8 meter distance). This was recorded in the participant booklets three times so that an average walking speed could be documented.

3.3.3 Static and Dynamic TFJt Alignment

Materials: Seven 6.4 mm retroreflective markers (Quintic Consultancy Limited, UK); double sided adhesive tape (Quintic Consultancy Limited, UK); 12 inch goniometer (Physio Supplies Limited, UK); video camera (Panasonic NV-GS230); tripod and cable leads; ruler; Sony Vaio laptop (PCG-XG500 700Mhz P3) with installed Quintic Biomechanics software (version 17 and later updated 18); marker tape for camera arm positioning; participant booklet and biro.

Static Methods: Participants remained in their outlined AOG and BOG while remaining still and looking straight ahead throughout the static assessment phase. Participants remained
relaxed without contracting the quadriceps or hamstrings. It was also ensured that participants stood with their weight equally distributed between the lower limbs (Hinman et al., 2009). The 6.4 millimetre retro-reflective markers were placed along the visual established TFJt using the centre of the patella as a reference point as described by Kraus and colleagues (2005). Seven retro-reflective markers were placed at a distance of 1.5 centimetres from each other; extending up the thigh and down the line of the tibia which could be palpated. A 12 inch goniometer was used to establish the static TFJt angle (to within 1˚). The axis of the goniometer was placed on the centre of the patella as described by Cibere et al., (2004) and Hinman et al., (2009). This placement coincided with the retro-reflective marker in this spot and the arms of the goniometer were extended along the centre of the thigh and along the axis of the lower leg – also mimicking the line already adopted by the retro-reflective markers that were in position. The static TFJt angle was then assessed three times for each TFJt with the goniometer and noted in the booklet. While it is possible to record the visually assessed static TFJt angle before applying the markers, this might not be consistently reliable and could lead to inconsistency when tracked dynamically. The repeated goniometric readings of static TFJt took less than five minutes to assess, thus making it ideal for use within a busy clinical setup.

Dynamic Methods:
Participants then walked along an 8-metre walkway. In order to record their natural gait, participants were asked to walk six lengths on the walkway to reach a comfortable self-selected speed. When the participant had completed three trials, the video camera (Panasonic NV-GS230) was switched on to record the onward approach of participants as they walked towards the camera. The camera was recording data at 50 frames per second in sports mode, as this allows for increased shutter speed and improved automatic focus. Increased shutter speed is important as it allows more detailed image capture and will help in isolating specific frames of interest such as gait midstance. The camera was mounted on a tripod that was adjusted to a height of 30 cms from the ground. Tape markings on the walkway were used to verify the positions of the tripod legs for repeated measures throughout the studies. Three videos were captured for each participant and still images were selected from these videos in order to assess the unshod dynamic TFJt angle. The still image (plus six frames before and six frames after) was selected when the limb of interest (either right or left) was in mid-stance and in the 1 metre outline marked on the platform while the contralateral limb was in swing phase and the body was in an upright position (Figure 3.5). At least twelve frames were chosen as this is the minimum number of frames necessary for automatic digitisation and
marker tracking. The frame number was noted in order to aid in the digitisation process. This is midstance position most reflective of the static TFJt angle and involves the peak of knee joint loading during the gait cycle. It is this reflection of the static TFJt angle that is associated with greater knee adduction moments in participants with medial knee OA (Sharma et al., 1998; Hurwitz et al., 2002; Amin et al., 2004). When these frames were isolated, any unnecessary frames from the start or the end were clipped out and the subsequent file was compressed and saved in an audio video interleave or ‘avi’ format. These were then stored securely using individual participant identification numbers.

Figure 3.5 Identifying the frame (Frame 14) at which the right limb is in midstance while the contralateral limb is in the swing phase.

Digitisation: The digitisation process enables tracking of any part of the body of interest throughout a video recording. Digitisations of the retroreflective markers generates numerical data in the form of co-ordinates, which allows the investigator to determine distance, velocities or angles such as the frontal plane TFJt angle within the frame of interest. In order to begin the digitisation process, a suitable stride which coincided with a marked 1.5 metre
outline on the walkway was identified. The frame numbers relating to the midstance (when the contralateral limb was deemed in line with the limb of interest and weightbearing was solely on one foot) was noted. In order to ensure the stride was appropriate for digitisation, the retroreflective markers had to be clearly visible (adequate lighting and not obscured by clothing or contralateral limb) and the stride had to be typical, i.e. no sudden movements or change in direction, speed or an abnormal movement pattern.

Once three suitable videos were determined per participant, each file was then opened individually and digitised using a created template. The template was saved and kept consistent throughout the project (Figure 3.6). The videos were calibrated for distance using markings on the back wall that were also kept consistent. On clicking the digitisation tab, the video recording speed was selected at 50 frames per second. The frames of interest are then selected and when the markers have been identified, tracking of the TFJt angle begins throughout the frames of interest (Figure 3.7). The Quintic Biomechanics software has the option of adopting a low pass Butterworth filter in order to smooth the data and eradicate any high frequency interference or when noises needed to be separated from the frequency signal (Robertson 2004). This was applied in order to smooth the data. The filter values were then saved. The angular analysis tab was then used to determine the angular displacement of the TFJt and the TFJt angles for the midstance frame was recorded for each participant and for the left and right TFJt respectively (Figure 3.8).
Figure 3.6 A consistent marker template (rctmod1) was used to identify markers 1, 2 and 3 for each participant. This was done using the digitisation feature of the Quintic Biomechanics software.

Figure 3.7 Tracking of the markers from Frame 14 till Frame 26 (a minimum of 12 frames need to be selected for angular analysis) allows TFJt angles for a particular frame of interest to be assessed.
Figure 3.8 The angular analysis tab was used to determine TFJt angles in a specific frame of interest (Frame 14). This was done three times to provide a mean value for TFJt alignment in mid-stance for the left and right foot respectively.
3.4 In-shoe Plantar Pressure Assessment

**Materials:** Level 8-metre walkway; Donnay Footwear (Sizes 4, 5, 6, 7, 8, 10, 11 and 12); Pedar Insoles (Sizes 3, 5, 6, 7, 8, 10 and 12); Pedar Equipment (laptop, Pedar pen drive with software, cable box receiver and power supply); Velcro straps and participant booklets (to note insole and shoe size).

**Methods:** A data collection guide on the use of the Pedar was adhered to so that several factors that may influence in-shoe pressure measurements were thoroughly considered (Novel 2012). An 8-metre walkway located in the Gait Laboratory of the Wales Centre for Podiatric Studies was used consistently through the studies. It was always ensured that the 10 metre cable was out of the way so that participants did not have to walk over or avoid the cable. Participants were then provided with standardised off the shelf neutral running trainers (*Donnay®* International, 27006) with size-matched Pedar® insoles (*Pedar® Munich, Germany*) in the trainers. The Donnay trainers were chosen as a standardised neutral running trainer as previous authors have used this footwear to demonstrate reliability of the Pedar and establish normative plantar pressure parameters in healthy participants (Putti *et al.*, 2007; Ramanathan *et al.*, 2010). Figure 3.9 shows a pair of Size 6 Donnay trainers used for the study.

![Figure 3.9 Size 6 neutral off-the-shelf Donnay trainers.](image-url)
The Pedar® system is comprised of 99 capacitive sensors, each of which have to be individually calibrated. This was done to 500 kPa using a calibration device as recommended by the manufacturer’s manual by the principal investigator. The shoe size and Pedar® insole size was always noted as this was essential in order to generate regional masks in order to analyse the Pedar® insole data. The Pedar® recording equipment was attached via cables that were secured using adhesive tape (to the lower limb) and Velcro straps (just above the last marker onto of each leg). This was undertaken to avoid obscuring the retro-reflective markers from the camera view. The Pedar® insole was inserted into the size-specific shoe and was connected to the Pedar® box. It was ensured that the insole was never pushed forward or sideways within a shoe. This was done by placing the insoles in the correct sized footwear without creasing them and by holding the insole in position as the foot is inserted into the shoe. The Pedar box was then either clipped securely on the rear of the belt or a secure waistband if available.

Participants were then asked to walk three full-lengths of the platform to become accustomed to the cables and the Pedar® recording box fixed to their waistband or belt. The Pedar® was then calibrated (zero measurement check) by asking participants to stand on each foot, to ensure each of the 99 sensors in the insole were functioning prior to each trial. This was always done immediately before data collection. The zero measurement check was performed every time a successive test needed to be conducted for example, three repeats in the Donnay trainers and three repeats in participant’s own footwear.

After this, the participants walked towards the camera at one end of the walkway and this was recorded. Eight steps were collected per straight-line walk and this was repeated three times (24 steps) were recorded at a frequency of 50 Hz. Both the camera and the Pedar® recorded each trial simultaneously with the Quintic recording 3 sets of shod dynamic TFJt angles (Figure 10). The Pedar® records 18 dynamic parameters from the in-shoe system, however, the 5 parameters that have been investigated and grouped according to Redmond and colleagues' (2005) FPI-6 classification categories (highly supinated (-5 to -12); supinated (-1 to -4); neutral (0 to +5); pronated (+6 to +9) and highly pronated (+10 to +12)) for the left and right foot are: contact area (cm²); peak pressure (kPa); contact time (ms); pressure-time integral (kPa/second) and force-time integral (N/second).
For each participant, plantar pressure recordings and TFJt angles were recorded three times using the Pedar and the Quintic software. This was done within the Donnay trainers (normal normative study) and within Donnay trainers and participant’s own footwear (KOCS and the RCT).

The plantar pressure recordings from each participant was taken and converted into select footsteps that would analysed over each trial on the walkway. This was done for each of the 3 sets of data obtained from between the foot-shoe interface. This involved converting the Pedar® sol. file type to a col. file which enabled filtering and analysis of key footsteps. This generated 1950 col. files that were then filtered further based on shoe size and insole size (50 plantar pressure profiles in Donnay trainers in the normal participants; and 100 plantar pressure profiles in Donnay trainers, Donnay and LWOs and Own footwear in the OA participants. Each recording was performed three times in order to calculate mean values for each plantar pressure parameter. Data groups containing participants with the same shoe and insole size were created and this resulted in the production of 5 distinct mask templates for each insole group. The groups were then analysed using the group mask evaluation feature of the Pedar® software and the values were exported into Excel to calculate mean values for each parameter.
The plantar pressure parameters of interest were investigated using a manually created regional mask template for each shoe and insole size and considered body weight (kgs) when determining key measures. Figure 3.11 is a representation of the regional mask template used to analyse the recorded data from each participant, each mask was divided into 6 areas; medial rearfoot, lateral rearfoot, medial midfoot, lateral midfoot, medial forefoot and lateral forefoot (6 masks). These were calculated as a percentage of foot length and width. Data from the digits (toe box) region have been known to yield low values with a high variance. Due to the potential source of error as well as a limited value in recording and analysing this data in context of the study aims, the toe box region was not included in subsequent analysis. The rearfoot and midfoot region were identified as the most important foot masks as firstly, motion of the STJ influence the MTJ (midfoot) and the subsequent flexibility and rigidity of the foot due to the intrinsic relationship between these key joints. Secondly, the coupling linkage between the STJ (rearfoot) and the lower limb influences the transfer of forces along the kinetic chain. The masks were therefore determined in three main regions, rearfoot, midfoot and forefoot. Subsequently, the Mask 5 and 6 (medial and lateral forefoot) were excluded from analysis due to its limited importance in the context of TFJt OA (Lidtke 2011). Cousins et al., (2012) discuss that there is no current consensus in the literature about the definition of foot masks and that segments are analysed based on previous study templates where available or are created and defined to fit the study aims. In this study, six mask areas were defined using percentages on the Pedar group mask creator software. The heel was defined at 30% of the entire length of the foot, the midfoot at 58-60% and the forefoot at 80% as illustrated by Figure 11. This was similar to the protocol described and used by Johnson et al., (2000) and Redmond et al., (2009). Recent studies in normal healthy populations have shown contradictory results for normative values of foot posture measures and dynamic kinetic data in pathological groups hence the need to establish normative values in a normal population group over the age of 45 and comparative OA group (Cavanagh et al., 1997; McPoil and Cornwall 2005; Landorf et al., 2006; Redmond et al., 2008).
Figure 3.11 The 6 mask areas on a right foot as defined using percentages on the Pedar®
groupmask creator tab. Each region was further divided: M1: medial rearfoot; M2: lateral
rearfoot; M3: medial midfoot; M4: lateral midfoot; M5: medial forefoot and M6: lateral
forefoot).
3.5 Patient Centred Outcome Scores

*Materials:* Participant booklets; KOOS scoring sheet; IPAQ scoring sheet and Medication and Footwear Journal.

*Methods:*

3.5.1 Knee Injury and Osteoarthritis Outcome Score (KOOS)

The KOOS questionnaire is self-administered and was included as part of the participant booklet in the Knee Osteoarthritis Clinical Study. Participants were asked to refer to the knee that was most painful in the last week if they had bilateral knee OA or the OA knee (unilateral) when answering the KOOS questions. KOOS values were established at baseline and subsequently at 3 weeks, 6 weeks and 12 weeks. A KOOS scoring sheet (provided in Excel format by Roos and colleagues (2003)) was used in order to determine individual scores for pain, symptoms, activities of daily living, sports and recreation and quality of life where 0 represented worst possible outcomes and 100 corresponded with the best outcomes. Appendix 9 contains a sample KOOS questionnaire which is provided alongside an automated excel score sheet.

3.5.2 International Physical Activity Questionnaire

The fitness levels and physical capabilities of each participant were quantified in the booklet using the International Physical Activity Questionnaire (IPAQ). The IPAQ is a self-administered questionnaire that considers the level of activity (moderate; heavy lifting; walking and sitting) undertaken in a given week. The IPAQ was administered in the normal study and OA study (baseline, 3 weeks, 6 weeks and 12 weeks). Participants were asked to consider the current week in the normal study and (corresponding with KOOS week in the OA study). The IPAQ generates scores as metabolic-minutes per week and is used to classify participants as having low level of physical activity (<600met-mins/week), moderate levels of physical activity (600 – 1500 met-mins/week) or high levels of physical activity (>1500 met-mins/week).

Participants were also asked which sport/activities they participated in weekly along with any resulting injuries or sprains they may have suffered with when younger and this was noted in the booklet as additional information. Any apparent consequent debilitation would exclude participants from the taking part in the study.
3.5.3 Medication and Footwear Diary

In the OA study, participants were provided with a medication diary in order to provide detailed information on any pharmacological interventions that were consumed during the course of the 3 month study. The type of medication, quantity consumed per day and per week was noted for each of the 12 weeks. The medication diary was provided in the same journal as the footwear diary for participant convenience.

The footwear diary documented the type of footwear worn most often during the week, the type of footwear that the orthoses was worn in, number of hours a day and the numbers of days in a week the orthoses were worn. Appendix 10 contains an example of Week 1 in the diary. Participants were each provided with their own booklets that were all returned at the end of the study.
4. Lower Limb Alignment Profiles and Plantar Pressure Measurement: An OA and non-OA Comparative Study

The aim of this chapter is to compare normative values of foot posture, static and dynamic TFJt angles and plantar pressure parameters in a non-OA population with an OA population. It will describe the study outline and discuss the key findings in an OA group and draw comparisons with the non-OA group within the context of foot posture. Section 4.1 will discuss the study background and literature that determine the alternate and null hypotheses including a discussion on the diagnosis of OA. Section 4.2 will discuss the study materials, methodology used and type of data analysis adopted for the results. Section 4.3 covers the study’s key comparative findings of anthropometric data; lower limb alignment profiles and explores the relationship with kinetic in-shoe plantar pressure parameters between the two groups. Section 4.4 will summarise the key findings of the study. Section 4.5 will elaborate on these findings and discuss the results within the context of the literature review of Chapter 2. This section will also discuss the limitations of the study design and finally, Section 4.6 is an executive summary of the chapter.

4.1 Rationale

There has been only limited research suggesting that abnormal lower limb alignment profiles, such as suboptimal foot postures, could be implicated in medial knee OA (Levinger et al., 2010). It has been suggested that lower limb alignment is a part of a ‘web of causation’ however its role as either a sufficient or component cause is yet to be established (MacMahon and Pugh, 1970; Rothman 1976; Sharma et al., 2010). Rearfoot eversion has been associated with a knee valgus alignment that is characteristic of lateral TFJt OA (Gross 1995). However, more recently, it was suggested that rearfoot eversion occurs as part of a pronatory compensatory mechanism in patients with medial TFJt OA rather than lateral TFJt OA patients (Butler et al., 2011). Recent findings by Redmond et al., (2008) and Levinger et al., (2010) showed that in both older participants and those with medial knee OA there is a more pronated foot posture. In the context of recent findings, it is not possible to determine whether the prevalence of a pronated foot type in an OA population is a causative factor or a consequence of medial TFJt pathology. It has been suggested however that a more pronated foot has increased instability and motion particularly of the rearfoot and midfoot during midstance gait. Individuals with medial TFJt OA walk with greater peak external KAM compared with healthy individuals and greater stance phase KAM is associated with and contributes to chronic knee pain and OA progression (Amin et al., 2004; Dyrby et al., 2005; Landry et al., 2007). Knee pain is a clinical characteristic of knee OA patients and Levinger
et al., (2010) found that in a medial TFJt OA group, patients had more mildly pronated foot types compared to healthy participants. As such, foot posture has been cited as both a cause and consequence of TFJt OA (Guo et al., 2007; Lynn et al., 2008; Levinger et al., 2010). As a causative factor, it may affect lower limb alignment and also influence plantar pressure patterns by altering the magnitude and timing of loading forces across the TFJt by affecting the magnitude of the GRF (an increase in the GRF would increase KAM) (Delzell 2012). Currently, the relationship between foot posture and associated loading patterns under the foot is not clear due to the lack of studies investigating the age-related changes in foot structure or altered foot function particularly in older participants (Scott et al., 2007).

Furthermore, as a result of the TFJt OA process, the prevalence of a pronated foot type can alter the direction of the GRF towards the TFJt centre, thereby resulting in a decreased KAM and decrease TFJt loading (Reeves and Bowling 2011). Kul-Panza and Berker (2006) found that pain scores at rest were negatively correlated with peak pressures in the rearfoot (p<0.05) in OA participants and were also significantly lower when compared to healthy controls (p<0.05). This trend of reduced rearfoot pressures during standing and reduced forefoot pressures during walking was also noted by Neugebauer et al., (2007). This suggests that weight bearing changes do occur in OA patients that could be a compensatory mechanism involving altering lower limb alignment in order to minimise rearfoot loading and subsequent medial TFJt loading. Plantar pressure measurements have demonstrated correlations with pain severity as opposed to radiographic severity (Lidtke et al., 2010) and as such, it could be a useful, reliable and valid clinical tool. Further research with non-OA and OA participants and with particular emphasis on the in-shoe plantar pressure assessments of the rearfoot and midfoot at the midstance phase of gait is warranted (Lidtke et al., 2010).

Foot posture and TFJt alignment that have been assessed using clinically applicable methods such as the FPI-6 and goniometric measurements have featured individually only in select studies in a non-OA and OA population, but not in amalgamation (Levinger et al., 2010; Levinger et al., 2012; Riddle et al., 2012). The associated reliability, validity and clinical applicability of these techniques have been compared and contrasted with alternative assessments previously in Chapter 2 (Section 2.3.1 and 2.3.2). The use of 2-dimensional video analysis for TFJt kinematics within the context of knee OA is relevant as it is a tool that is available and affordable to most clinicians and practitioners. The lack of research in this arena is a compounding factor to further understanding the potential biomechanical effects
that lower limb alignment may exert on TFJt OA and its clinical symptoms such as pain (Levinger et al., 2010). The studies that have drawn comparisons between these groups, despite having smaller sample sizes (n= 12-91) have found significant differences in pain and knee health related quality of life outcomes and radiographically established TFJt alignments (Maly et al., 2002; Shimada et al., 2006; Raaij et al., 2010). Another factor is the lack of discussion surrounding the clinical classification of OA in epidemiological studies as researchers subscribe to a range of methods from radiographic to physical and clinical examination techniques. The influence of biomechanical characteristics on symptomatic TFJt OA is more clinically relevant given the significant correlation between these (Lidtke et al., 2010) in addition to the fact that establishing clinical symptoms based on medical history and physical examination is routine clinical practice (Dieppe and Brandt 2003). The studies that have identified differences between OA and non-OA groups used clinical presentation of symptoms, the ACR (American College of Rheumatology) classification system and/or radiographic techniques. Given the heterogeneous nature of OA, a clear understanding and definition of the classification criteria is important to affect a specific patient group such as those with mild-moderate medial TFJt OA and furthermore, to increase the external validity of the research findings.

Diagnosis of OA
Several researchers have alluded to a diagnostic discordance between the evidence of radiographic knee OA and knee pain in knee OA surveys (Peat et al., 2005; Bedson et al., 2008; Neogi et al., 2009). The National Institute for Health and Clinical Excellence (NICE 2008) suggests that the radiographic degenerative process of OA should be conceptually separated from the clinical symptom presentation. 60% of patients who present with radiographic OA based on assessment tools such as the Kellgren-Lawrence (K-L) scale do not present with symptoms such as knee pain (Hochberg et al., 2010). The key criticisms of using the K-L scale are: in order for a diagnosis to be made, there needs to be discernible osteophytic proliferation and joint space narrowing; there are inconsistencies in the interpretation of radiographs and; it is not sensitive enough in the early stages of OA (as there are no detectable osteophytes) (Hochberg et al., 2010).

As a result, symptomatic arthritis which is disease-based and has a clinical presentation is recommended for studies investigating the causes, progression and management strategies for knee OA. Therefore, the inclusion criteria of radiographic evidence of knee OA would have been limiting for several factors: patients seek treatment for knee symptom relief and an
improvement of functional limitations, not structural deficiencies and radiographic outcomes of the knee specifically. The participant’s minimum age was set at 45 because knee joint pain on most days is reported commonly in ages 45 and above in the United Kingdom (Altman et al., 1986; NICE 2008). The Guideline Development Group (GDG) suggested that the suspicion of OA increases in the patient, who is over 45, has persistent joint pain that is associated with functional deficiency and presents with morning stiffness of less than 30 minutes (NICE 2008). It did not require laboratory or radiographic investigations and mimicked the ACR classification which was originally designed to differentiate between inflammatory arthritis and osteoarthritis (Altman et al., 1986). In younger patient groups, there is also a much lower prevalence of radiographic knee OA compared to an elderly population whereas in a 40-80 year demographic, the proportion of radiographic knee OA ranges from 19-30%. Therefore participants had to meet the minimum age criteria of 45 for mild-moderate knee OA. All participants were interviewed for additional factors such as GP diagnosis of unilateral or bilateral knee OA. A standardised clinical assessment was administered for each participant that included a clinical interview with full medical history and family background as well as a physical examination to classify OA according to the ACR classification tree method described by Peat and colleagues (2001 and 2005).

The overall purpose of this chapter was to provide a comparison of clinically established lower limb alignment profiles in a non-OA and OA demographic. Therefore, the main objective of this study was to establish baseline foot posture, spatial gait parameters such as AOG and BOG, static and dynamic TFJt angles and key in-shoe plantar pressure parameters in a non-OA and OA group. The secondary objective was to draw comparisons between the two groups and explore if any differences existed based on foot posture categories.

The following hypotheses were generated for the second objective:

*Alternative Hypothesis* $H_1$: There are significant differences in foot posture, spatial gait parameters and TFJt angles between OA and non-OA participants.

*Null Hypothesis* $H_0$: There are no significant differences in foot posture, spatial gait parameters and TFJt angles between OA and non-OA participants.
**Alternative Hypothesis** $H_1$: There are significant differences in plantar pressure parameters between OA and non-OA participants.

**Null Hypothesis** $H_0$: There are no significant differences in plantar pressure parameters between OA and non-OA participants.
4.2 Study Materials and Methods

Ethical approval for the non-OA student was attained from the Cardiff Metropolitan University Ethics Committee (Appendix 1). Participants were provided with an information sheet and provided written informed consent prior to participation (Appendix 3 and 4). Ethical approval for the Knee Osteoarthritis Clinical Study (OA study) was attained from the Cardiff Metropolitan University Ethics Committee (Appendix 5). Participants were provided with an information sheet and provided written informed consent prior to participation (Appendix 7).

An investigation into the reliability of measures:

Prior to data collection for the OA and non-OA study, a reliability study was conducted to establish the reliability (intra-class correlations (ICC’s) and precision coefficients (standard error of measurement (SEM))) of the key clinical measures: FPI-6, AOG and BOG characteristics and static and dynamic TFJt alignments. The measures were assessed three times on two separate data collection sessions. The studies consisted of 2 males and 8 females with a mean age of 28.8 years (SD ± 11.32). The mean BMI was 24.97 (SD ± 4.7) and the mean IPAQ score was 2760.40 met minutes per week (SD ± 1031.4). This represented a sample with a healthy BMI and moderate-high physical activity levels in a week. All participants were right limb dominant.

The FPI-6 showed excellent reliability between the two sessions (ICC’s for the left foot was 0.98 and for the right foot was 0.81). ICC values for the AOG (left: 0.89 and right: 0.9) and BOG (0.87) also demonstrated excellent ICC’s between the two sessions. When SEM for the AOG was calculated, these were 1.18 and 1.33 for the left and right foot respectively. 95 out of a 100 times, the true score for the left AOG was 7.4° ± 2.36 and for the right AOG was 7.9° ± 2.66. For the BOG, the SEM score was 1.35 and with a 95% CI, the true test score was 14.17 cms ± 2.7.

The reliability of left and right NH was poor (0.26 and 0.16). When the SEM was calculated, these were low at 0.58 and 0.6 for the left and right foot respectively and when using a 95% CI, in 95 out of a 100 the left NH is 5.64 ± 1.10 and the right NH is 5.69 ± 1.2.

The reliability of the static TFJt angle was poor to moderate when assessed with ICC’s (0.42 and 0.2) and moderate to excellent when assessed with Pearson’s (0.45 and 0.78). The reliability of the dynamic TFJt angle was poor to moderate using ICC’s (0.5 and 0.2) and poor to excellent using Pearson’s (0.48 and 0.82). When the SEM was calculated, it was 2.51
and 2.45 for the left and right static TFJt and in 95% of cases, the static left TFJt is 166.09° ± 5.02 and for the right knee was 167.46° ± 4.9. When the SEM was calculated, these were 3.81 and 1.90 for the dynamic left and right TFJt and in 95% of cases, the TFJt angle was 171.91° ± 4.9 and for the right knee was 171.21° ± 3.8.

The study has shown that the FPI-6, AOG and BOG demonstrated excellent intra-rater reliability while the static and dynamic TFJt angles demonstrate moderate-excellent intra-rater reliability in a clinical setting while the NH showed only poor intra-rater reliability. The reliability study also allowed a rehearsal of assessment methods to counteract an experience or learning effect.

Appendix 13 contains a flow chart of participants through the reliability study and three tables with the results of the key clinical measures in week one and week two.

Sample Size and Inclusion Criteria:

Participant’s selection and the inclusion criteria for the non-OA study were presented in the Methods chapter (Chapter 3, Section 3.1.2) while selection and the inclusion criteria for the OA study were presented in the same chapter (Chapter 3, Section 3.1.3). During the non-OA and OA screening process, participants were informed that the study would be carried out one data collection session and would take approximately 40 minutes. Flow chart 1 illustrates the assessments conducted and the flow of participants through the study.

Materials and Equipment Required:

Participant booklets with ID numbers; wall mounted height scale; weighing scale; International Physical Activity Questionnaire; ball (limb dominance); A2 paper; Foot Posture Index guide and score sheet; Seven 6.4 mm retroreflective markers (Quintic Consultancy Limited, UK); double sided adhesive tape (Quintic Consultancy Limited, UK); 12 inch goniometer (Physio Supplies Limited, UK); video camera (Panasonic NV-GS230); tripod and cable leads; ruler; Sony Vaio laptop (PCG-XG500 700Mhz P3) with installed Quintic Biomechanics software (version 17); Level 8-metre walkway; Donnay Footwear (Sizes 4, 5, 6, 7, 8, 10, 11 and 12); Pedar Insoles (Sizes 3, 5, 6, 7 8, 10 and 12); Pedar Equipment (laptop, Pedar pen drive with software, cable box receiver and power supply); Velcro straps and participant booklets (to note insole and shoe size) and biro.

The materials and equipment used in both the OA and non-OA group were similar except for the size of the retroreflective markers used. Instead of the 6.4mm diameter markers, 9.2mm
markers were used in the OA study as the smaller size were no longer being supplied by Quintic Consultancy Limited during the course of the project.

Methodology:

4.2.1 Initial Screening of Participants:
Each participant was allocated individual data booklets for the duration of the study which was marked by numbers and kept by the PI. After receiving the signed consent forms, participants were invited to an initial screening process which took 30 minutes where the study was explained in greater detail and the inclusion criteria was verified. Participants were also asked for their date of birth, full medical history, medication history and family history of knee OA. This was done in order to separate participants into their respective non-OA or OA group dependant on meeting the inclusion criteria.
Participants were also advised to bring a pair of shorts that would aid with data collection for the following session.

4.2.2 Study Protocol:
The protocol for this comparative study has been described previously in the Methods chapter (Chapter 3, Section 3.3) for anthropometric measures, foot posture and spatial gait assessment, static and dynamic TFJt angles and in-shoe plantar pressure measurement.
Both non-OA and OA participants were anonymously labelled with number reference and their age and gender was noted. Their anthropometric characteristics (height and weight) were noted and BMI was determined. Participants were also provided with the IPAQ score to complete at the start of the session. Following this, participants were asked to march on the spot for 20 seconds before standing on an A2 paper while the FPI-6 and spatial gait assessments (AOG and BOG) were administered. Participants remained in their outlined AOG and BOG on the A2 paper and were requested to look straight ahead and keep as still as possible throughout the static assessment phase.
Following this process, seven 6.4 millimetre retro-reflective markers (Quintic Consultancy Limited, UK) were placed along the visual established TFJt using the centre of the patella as a reference point and at a distance of 1.5 centimetres from each other; extending up the thigh and down the line of the tibia which could be palpated. A 12 inch goniometer (Physio Supplies Limited, UK) was used to establish the static TFJt angle (to within 1°). The static TFJt angle was then assessed three times for each knee joint with the goniometer and noted. Participants were then asked to kick a ball so that limb dominance could be determined.
For the dynamic assessment, participants had to walk along the 8-metre walkway for 3 lengths until they reached a comfortable self-selected walking speed. At the end of the walkway, the video camera (*Panasonic NV-GS230*) was mounted on a tripod at a height of 30 cms from the floor with tape markings on the walkway for consistency throughout the study. Three videos were captured for each participant and still images were selected from these videos in order to assess the unshod dynamic TFJt angle as described in Chapter 3 (Section 3.3).

The data collection protocol adopted with the in-shoe plantar pressure measurement is detailed in Chapter 3 (Section 3.4). Post calibration of the insoles, the Donnay shoe size and Pedar insole size per participant was noted in the individual booklets. Once the equipment was clipped securely, connected and checked, participants were requested to stand on one foot at a time in order to conduct the zero measurement check. This was done for each of the three repeat recordings of the in-shoe plantar pressure measurement as participants walked towards the camera. As previously described, eight steps were collected per straight-line walk and three walks (total of 24 steps) were recorded at a frequency of 50 HZ. This was done simultaneously with the shod dynamic TFJt angle recordings using the Quintic Biomechanics software. The digitisation process that was described in Chapter 3 (Section 3.3) was adopted to obtain shod and unshod dynamic TFJt angles.

Flow Chart 4.1 provides an illustration of the flow of participants through the studies.
Participants screened \( n = 120 \)

Non-OA Participants screened \( n = 54 \)

OA Participants included \( (n=100) \) as they met the inclusion criteria (over 45 years, history of medial knee pain for at least the preceding year; no history of significant trauma, injury or surgery to the lower limb; where available radiographic evidence of mild-moderate knee OA (KL scale I-III); Family history of OA; ACR classification of knee OA based on medical history and physical examination.

Non-OA Participants included \( (n=50) \) as they met the inclusion criteria (over 45 years, no history of lower limb injury, trauma or surgery. No systemic condition affecting gait on observation. No obvious gait discrepancy.

Participants provided with information sheet and informed consent obtained.

Physical activity assessed using the IPAQ and barefoot anthropometric measures (height and weight) were determined and used to calculate BMI.

Barefoot march on the spot for 20 seconds and step onto a prepared A3 paper and assume relaxed calcaneal stance position. Draw foot outline and assess foot posture using the FPI-6.

Seven 6.4 mm retroreflective markers were placed on the visually assessed TFJt – this was assessed three times using a goniometer for the left and right TFJt.

Limb dominance assessed by asking participant to kick a ball.

Participants walk barefoot on an 8-metre walkway. Record dynamic TFJt angle with Quintic Biomechanics software from marker reference points on the still images selected representing midstance.

Participants are provided with Donnay neutral trainers with correct sizes Pedar insoles. Connect to Pedar box with Pedar cables and Velcro straps and adhesive. Zero measurement check for the left and right foot respectively. Obtain plantar pressure measurements from three consecutive trials (24 steps in total) and simultaneously record dynamic TFJt angles with Quintic Biomechanics software.

Flow Chart 4.1: Participant flow through the OA and non-OA study
**Data Analysis:**

The results of the study were collated in Excel and analysed using SPSS (version 18). All the data was presented with mean values, standard deviation and range of values found. Correlation is a technique for investigating the relationship between two quantitative variables and is a measure of the strength of the association between the two variables. To determine the relationship or strength of association between static and dynamic TFJt angles, Pearson’s correlation coefficient was used. As the data was checked for normality using the Kolmogorov-Smirnov test (p>0.05), the data was normally distributed and a parametric correlation coefficient was used (Pearson’s). This was interpreted using the Guildford’s (1973) rule of thumb interpretation model. Table 4.1 contains Guildford’s the correlation values and their corresponding interpretations. Additionally, the data for the non-OA and OA groups were analysed for normality individually and these will be presented as such in tables in the results section.

<table>
<thead>
<tr>
<th>Value</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than .20</td>
<td>Less than .20 Slight, almost negligible relationship</td>
</tr>
<tr>
<td>.20 - .40</td>
<td>.20 - .40 Low correlation; definite but small relationship</td>
</tr>
<tr>
<td>.40 - .70</td>
<td>.40 - .70 Moderate correlation; substantial relationship</td>
</tr>
<tr>
<td>.70 - .90</td>
<td>.70 - .90 High correlation; marked relationship</td>
</tr>
<tr>
<td>.90 - 1.00</td>
<td>.90 – 1.00 Very high correlation; very dependable relationship</td>
</tr>
</tbody>
</table>

**Table 4.1 Guildford Correlation Interpretation Model (1965).**

The data was also analysed first using Kolmogorov-Smirnov test to determine if the data was normally distributed (if p> 0.05, then data is parametric or normally distributed). In order to analyse foot posture data with other types of parametric assessments in this study, such as static and dynamic TFJt angles, the FPI-6 was converted into interval scores from its set ordinal pattern. Therefore, the transformed scores were entered into SPSS as logit values. The raw FPI-6 data was converted to parametric, transformed Rasch scores using values provided by a previous study by Keenan et al., (2007) which were derived from previous research data (n=426).

The plantar pressure recordings from each participant were taken and converted into a different format (sol. to col. files) as discussed previously in Chapter 3, Section 3.4. This was done for each of the 3 sets of data obtained from between the foot-shoe interface generating
18 steps (9 steps for the left and right foot respectively) that were isolated and analysed. This was achieved by converting the Pedar® sol. file type to a col. file which enabled filtering and analysis of the 18 footsteps. This generated 450 col. Files (3 sets of data x 150 participants) that were then filtered further based on shoe size and insole size. Data groups containing participants with the same shoe and insole size were created and this resulted in the production of 5 distinct mask templates for each insole group based on shoe and insole size. Each template consists of 6 anatomical regions: Mask 1 (medial rearfoot), Mask 2 (lateral rearfoot), Mask 3 (medial midfoot), Mask 4 (lateral midfoot), Mask 5 (medial forefoot) and Mask 6 (lateral forefoot). This diagram has been presented previously in Chapter 3, Section 3.4 (Figure 11, page 83).

An independent samples t-test is used when comparing the means of normally distributed variables for two independent groups. Independent samples t-tests were used to compare the means of OA and non-OA groups to determine if there were differences between foot posture, spatial gait parameters and static and dynamic TFJt angles. The significance level (alpha) was set at 0.05 with a value of < 0.05 indicating that the alternative hypothesis should be accepted and the null hypothesis rejected. However, the independent t-test assumes the variances of the two groups measured to be equal as if the variances are unequal, this increases the probably of a Type 1 error (false positive). As a result, the Levene’s test for equality of variances needed to be verified in order to assume homogeneity of variance in the two groups. If the results of the Levene’s is statistically non-significant, i.e. p>0.05, it indicates equal variance in the groups despite unequal group sizes. Therefore, prior to running an independent samples t-test, the data was checked for equal variance as there were unequal group sizes (n=50 in the non-OA group and n=100 in the OA group) using the Levene’s test for equality of variances (Fields 2005).

A one-way analysis of variance (ANOVA) was used to determine if there was a significant difference in the mean plantar pressure parameters of the OA and non-OA groups particularly in the medial and lateral midfoot (Mask 3 and 4) and medial and lateral rearfoot (Mask 1 and 2). If any significant differences are found, a Tukey’s post hoc would be used for further analysis (p < 0.05) to determine if foot posture had an effect on plantar pressure parameters.
4.3 Results

The study consisted of 50 participants (mean age: 53.46; SD ± 8.08; range: 45 – 91) and 100 OA participants (mean age: 57.35; SD ± 9.4; range: 42 – 84). Within the OA group, 67 participants presented with OA in both knees (bilateral) with the right knee being most painful in these participants; 23 presented with OA only in the right knee (unilateral) while 10 presented with left knee OA (unilateral).

The mean body mass index (BMI) in the non-OA group was 29.55 (SD ± 6.11) and in the OA group this was 29.53 (SD ± 6.17) indicating an overweight and pre-obese demographic. The non-OA group consisted of 30 females and 20 males. The mean BMI for females was 25.9 (SD ± 0.8) while for males it was 26.2 (SD ± 0.87). This was a non-significant difference (t (48) = 0.24, p = 0.8). While in the OA group there were 61 females and 30 males. The mean BMI for females was 29.56 (SD ± 6.95) and for the males it was 30.18 (SD ± 7.15). This was a non-significant gender difference (t (98) = 0.43, p = 0.66).

The mean IPAQ score in the non-OA group was 3710 met-minutes/week (SD ± 3296) while in the OA group, this score was 3680 met-minutes/week (SD ± 3290) which is suggestive of a highly active cohort.

In the non-OA group, the mean AOG for the left foot was 12.12° (SD ± 5.9, range 4° – 27°) and for the right foot 10.8° (SD ± 6.73, range 2° - 30°). The mean base of gait was 12.79 cms (SD ±3.22, range 6° - 19.50°).

While in the OA group, the mean AOG for the left foot was 10.3° (SD ± 6.04, range 1° – 29°) and for the right foot 10.8° (SD ± 5.36, range 1° – 32°). The mean base of gait was 15.72 cms (SD ± 4.04, range 7° – 25.5°).

When the OA participants were compared to the non-OA participants for age, BMI, IPAQ, left and right AOG and BOG scores, there was a significant differences in the age and BOG (p<0.05). There were no significant differences in physical activity levels (IPAQ), BMI or left and right AOG between the two groups.

Prior to comparing the groups using independent samples t-test, the variance of each group was determined using Levene’s test for equality of variances. The results were non-significant (p>0.05) for age (p=0.98), BMI (p=0.88), AOG (left) (p=0.75) and BOG (p=0.07).
Hence variances in each group were assumed to be equal as a result of the Levene’s test. The exception was AOG (right) for which Levene’s p=0.02. Therefore, equal variances were not assumed for the right AOG and the corresponding t-test results were reported. These results are presented in Table 4.1.

<table>
<thead>
<tr>
<th></th>
<th>Non-OA (n=50)</th>
<th>OA (n=100)</th>
<th>Independent t test</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
<td>t (df) = (p)</td>
</tr>
<tr>
<td></td>
<td>Range</td>
<td>Range</td>
<td></td>
</tr>
<tr>
<td>Age (years)</td>
<td>53.46 (8.08)</td>
<td>57.35 (9.4)</td>
<td>t (148) = 2.49</td>
</tr>
<tr>
<td></td>
<td>45 – 91</td>
<td>42 - 84</td>
<td>(p = 0.01)*</td>
</tr>
<tr>
<td>BMI (kg/m2)</td>
<td>29.55 (6.11)</td>
<td>29.53 (6.17)</td>
<td>t (148) = 0.13</td>
</tr>
<tr>
<td></td>
<td>20.0 – 50.0</td>
<td>20.3 – 50.7</td>
<td>(p = 0.887)</td>
</tr>
<tr>
<td>IPAQ (met minutes/week)</td>
<td>3710 (3296)</td>
<td>3680 (3290)</td>
<td>t (148) = 0.05</td>
</tr>
<tr>
<td></td>
<td>99 – 15,918</td>
<td>0 – 14,130</td>
<td>(p = 0.95)</td>
</tr>
<tr>
<td>Left AOG (°)</td>
<td>12.12 (5.9)</td>
<td>10.3 (6.04)</td>
<td>t (148) = 1.75</td>
</tr>
<tr>
<td></td>
<td>4 – 27</td>
<td>1 - 29</td>
<td>(p = 0.08)</td>
</tr>
<tr>
<td>Right AOG (°)</td>
<td>10.8 (6.73)</td>
<td>10.8 (5.36)</td>
<td>t (80.97) = -0.03</td>
</tr>
<tr>
<td></td>
<td>2 – 30</td>
<td>1 -32</td>
<td>(p = 0.97)</td>
</tr>
<tr>
<td>BOG (centimetres)</td>
<td>12.79 (3.22)</td>
<td>15.72(4.04)</td>
<td>t (148) = 4.46</td>
</tr>
<tr>
<td></td>
<td>6 -19.5</td>
<td>7 – 25.5</td>
<td>(p = 0.0001)*</td>
</tr>
</tbody>
</table>

Table 4.2. Independent t test comparisons of the OA and non OA group for Age, BMI, IPAQ, left and right AOG and BOG scores.

In the non-OA student, the right limb was the dominant limb in 98% (n=49) of participants while in the OA study, the right limb was the dominant limb in 99% (n=99) of the participants.

Foot Posture Characteristics

In the non-OA group the most prevalent foot posture for the left and right foot was mildly pronated (FPI raw score +6 for the left foot and +6.14 for the right foot). Thirty-six percent (n=18) of participants had a neutral left foot, 60% (n = 30) had a pronated left foot and 4% (n = 2) had a highly pronated left foot. The results were similar for the right foot, 36% (n=18) of participants had a neutral right foot, 58% (n=29) had a pronated right foot, and 6% (n=3) had a highly pronated right foot. The most prevalent foot posture in the OA group for the left and
right foot was mildly pronated (FPI raw score +6.08 for the left foot and +6.12 for the right foot). Thirty-seven percent (n=37) of participants had a neutral left foot, 61% (n=61) had a pronated left foot and 2% (n=2) had a highly pronated left foot. The results were similar for the right foot, 36% (n=36) of participants had a neutral right foot, 61% (n=61) had a pronated right foot, and 3% (n=3) had a highly pronated right foot.

When the OA group was compared with the non-OA group, there were no significant differences in foot posture for the left foot (t (148) = 0.25, p = 0.80) and for the right foot (t (148) = 0.05, p = 0.95).

**Static and Dynamic TFJt alignment: mean group differences**

The results of the Kolmogorov – Smirnov test in the non-OA group were consistently non-significant thus showing that the static and dynamic TFJt angles were normally distributed, i.e. parametric. These results are presented in Table 4.3.

<table>
<thead>
<tr>
<th>N = 50 (Non-OA group)</th>
<th>Mean (±SD)</th>
<th>Standard Error of the Mean</th>
<th>95% Confidence Interval (CI)</th>
<th>Kolmogorov-Smirnov Z (p value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Static Left TFJt angle (°)</td>
<td>165.03 (±4.43)</td>
<td>0.62</td>
<td>150.33 – 175</td>
<td>0.728 ( = 0.67)</td>
</tr>
<tr>
<td>Static Right TFJt angle (°)</td>
<td>166.95 (±4.9)</td>
<td>0.69</td>
<td>157.00 – 176.0</td>
<td>0.576 ( = 0.89)</td>
</tr>
<tr>
<td>Dynamic Left TFJt angle (unshod) (°)</td>
<td>167.65 (±3.25)</td>
<td>0.46</td>
<td>157.63 – 174.72</td>
<td>–</td>
</tr>
<tr>
<td>Dynamic Right TFJt angle (unshod) (°)</td>
<td>168.94 (±3.31)</td>
<td>0.47</td>
<td>159.96 – 176.22</td>
<td>–</td>
</tr>
<tr>
<td>Dynamic Left TFJt angle (shod) (°)</td>
<td>167.75 (±2.67)</td>
<td>0.38</td>
<td>160.55 – 173.74</td>
<td>–</td>
</tr>
<tr>
<td>Dynamic Right TFJt angle (shod) (°)</td>
<td>169.01 (±3.25)</td>
<td>0.46</td>
<td>159.05 – 175.41</td>
<td>–</td>
</tr>
</tbody>
</table>

Table 4.3. The mean, standard error of the mean, 95% CI and results of the Kolmogorov-Smirnov Z test for the static and dynamic shod and unshod TFJt angles.
The results of the Kolmogorov-Smirnov test for the OA group were consistently non-significant too thus showing that the static and dynamic TFJt angles were normally distributed, i.e. parametric. The only exception was the dynamic shod left TFJt angle ($p < 0.05$). These results are presented in Table 4.4.

<table>
<thead>
<tr>
<th>N = 100 (OA group)</th>
<th>Mean ($\pm SD$)</th>
<th>Standard Error of the Mean</th>
<th>95% Confidence Interval (CI)</th>
<th>Kolmogorov-Smirnov Z (p value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Static Left TFJt angle (°)</td>
<td>163.80 ($\pm$ 4.27)</td>
<td>0.43</td>
<td>152 – 175</td>
<td>0.08 (= 0.05)</td>
</tr>
<tr>
<td>Static Right TFJt angle (°)</td>
<td>164.51 ($\pm$ 4.81)</td>
<td>0.48</td>
<td>151.66 – 175</td>
<td>0.07 (= 0.20)</td>
</tr>
<tr>
<td>Dynamic Left TFJt angle (unshod) (°)</td>
<td>165.38 ($\pm$ 6.00)</td>
<td>0.60</td>
<td>151.58 – 179.24</td>
<td>0.05 (= 0.20)</td>
</tr>
<tr>
<td>Dynamic Right TFJt angle (unshod) (°)</td>
<td>164.97 ($\pm$ 5.41)</td>
<td>0.54</td>
<td>150.55 – 173.59</td>
<td>0.07 (= 0.20)</td>
</tr>
<tr>
<td>Dynamic Left TFJt angle (shod) (°)</td>
<td>166.22 ($\pm$ 5.18)</td>
<td>0.52</td>
<td>147.77 – 179.86</td>
<td>0.12 (= 0.001)*</td>
</tr>
<tr>
<td>Dynamic Right TFJt angle (shod) (°)</td>
<td>165.15 ($\pm$ 5.37)</td>
<td>0.54</td>
<td>147.96 – 179.51</td>
<td>0.05 (= 0.20)</td>
</tr>
</tbody>
</table>

Table 4.4. The mean, standard error of the mean, 95% CI and results of the Kolmogorov-Smirnov Z test for the static and dynamic shod and unshod TFJt angles in the OA group.

Prior to using the independent t-test, variances were checked using Levene’s test to account for unequal group sizes. The results were non-significant i.e. equal variances assumed for static TFJt left ($p=0.87$) and static TFJt right ($p=0.54$). However, the result were significant i.e. equal variances not assumed for dynamic left TFJt (unshod) $p = 0.001$, dynamic right TFJt (unshod) $p=0.001$, dynamic left TFJt (shod) $p = 0.001$ and dynamic right TFJt (shod) $p = 0.004$. Therefore, the corresponding results for the independent samples was presented in Table 4.5.
When the static and dynamic TFJt angles of the OA group were compared with the non-OA group using independent t-tests, the results showed significant differences for the left and right unshod dynamic TFJt, the right static TFJt and right shod dynamic TFJt ($p<0.05$). There was a moderately significant differences between the groups when the dynamic left TFJt angle was compared ($p = 0.051$) and no significant differences when the static left TFJt was compared ($p>0.05$). The non-OA group showed significant higher static and TFJt angles compared with the OA group suggesting a more valgus alignment in the OA group and a more neutral alignment in the non-OA group. Table 4.5 presents this data.

<table>
<thead>
<tr>
<th></th>
<th>Non-OA (n=50) Mean (±SD)</th>
<th>OA (n=100) Mean (±SD)</th>
<th>Independent t test t (df) = ($p$)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Static Left TFJt angle (°)</strong></td>
<td>165.03 (±4.43)</td>
<td>163.80 (± 4.27)</td>
<td>t (148) = 1.64 ($p = 0.10$)</td>
</tr>
<tr>
<td><strong>Static Right TFJt angle (°)</strong></td>
<td>166.95 (±4.9)</td>
<td>164.51 (±4.81)</td>
<td>t (148) = 2.91 ($p = 0.004$)*</td>
</tr>
<tr>
<td><strong>Dynamic Left TFJt angle (unshod) (°)</strong></td>
<td>167.65 (±3.25)</td>
<td>165.38 (±6.00)</td>
<td>t (146.9) = 2.99 ($p = 0.003$)*</td>
</tr>
<tr>
<td><strong>Dynamic Right TFJt angle (unshod)</strong></td>
<td>168.94 (±3.31)</td>
<td>164.97 (±5.41)</td>
<td>t (141.96) = 5.53 ($p = 0.0001$)*</td>
</tr>
<tr>
<td><strong>Dynamic Left TFJt angle (shod) (°)</strong></td>
<td>167.75 (±2.67)</td>
<td>166.22 (±5.18)</td>
<td>t (145.96) = 2.37 ($p = 0.01$)*</td>
</tr>
<tr>
<td><strong>Dynamic Right TFJt angle (shod) (°)</strong></td>
<td>169.01 (±3.25)</td>
<td>165.15 (±5.37)</td>
<td>t (141.6) = 5.42 ($p = 0.0001$)*</td>
</tr>
</tbody>
</table>

Table 4.5. Results of the independent t test when comparisons of static and dynamic TFJt angles were made between the OA and non-OA group.
In-Shoe Plantar Pressure Analysis: A comparison between OA and non-OA groups

A one-way ANOVA was used to determine if any differences existed between the OA and non-OA group in the midfoot (Mask 3 and 4) and rearfoot (Mask 1 and 2) contact area (CA), contact time (CT), peak pressure (PP), pressure time integrals (PTI) and force time integrals (FTI). The results are presented for each of these parameters sequentially.

Contact Area (cm²)

The CA for both the left and right midfoot was significantly greater in the OA group compared with the non-OA group (p<0.001). When these differences were explored further using Tukey’s post-hoc analysis, foot posture was found to have a significant effect on CA particularly in the midfoot region (medial and lateral) for a pronated foot type (p<0.05). There was greater CA in a pronated OA foot compared with a non-OA foot (p = 0.041 and p = 0.007) for the medial and lateral midfoot respectively. In the right foot, a significant difference was found in the medial midfoot region (p = 0.018) with greater CA in the OA neutral foot compared with a non-OA neutral foot.

Paired t-tests were conducted to determine if the difference in medial and lateral CA in OA individuals was significant (p<0.05). For CA in the left midfoot, there were significant differences between the medial and lateral regions (t (99) = 15.81, p< 0.0001). For CA in the right midfoot, there were significant differences between the medial and lateral regions (t (99) = 17.03, p<0.0001). For CA in the left rearfoot, there were no significant differences between the medial and lateral regions (t (99) = 1.74, p = 0.08). For the right rearfoot too, there were no significant differences between the medial and lateral regions (t (99) = 1.78, p = 0.07).
Table 4.6. The ANOVA results for contact area for the left and right foot when the non-OA and OA group were compared.

**Peak Pressure (kPa)**

The PP for both the left and right midfoot and the left lateral rearfoot was significantly greater in the OA group compared with the non-OA group \( (p<0.05) \). This is demonstrated in Table 4.7. When these differences were explored further using Tukey’s post-hoc analysis, foot posture was found to have a significant effect on PP particularly in the medial midfoot region of a pronated foot type \( (p<0.05) \). There was greater PP in the pronated OA group compared with the pronated non-OA group for the left \( (p = 0.04) \) and right foot \( (p= 0.03) \) respectively. There was also a significantly greater PP in the medial rearfoot in a pronated OA group \( (p = 0.04) \) compared with the pronated non-OA group.
Paired t-tests were conducted to determine if the difference in medial and lateral PP in OA individuals was significant (p<0.05). For PP in the left midfoot, there were no significant differences between the medial and lateral regions (t (99) = -0.71, p=0.47). For PP in the right midfoot, there were no significant differences between the medial and lateral regions (t (99) = 0.03, p=0.97).

For PP in the left rearfoot, there were no significant differences between the medial and lateral regions (t (99) = 1.55, p = 0.12). For the right rearfoot, there was a significant difference between the medial and lateral regions (t (99) = 2.75, p = 0.006).

<table>
<thead>
<tr>
<th>PP (kPa)</th>
<th>Non-OA Mean (SD±)</th>
<th>OA Mean (SD±)</th>
<th>ANOVA F value (significance)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PP Mask 1 left (medial rearfoot)</td>
<td>213.38 (72.18)</td>
<td>225.37 (37.87)</td>
<td>1.68 (0.196)</td>
</tr>
<tr>
<td>PP Mask 2 left (lateral rearfoot)</td>
<td>212.72 (56.70)</td>
<td>233.74 (53.92)</td>
<td>4.74 (0.03)*</td>
</tr>
<tr>
<td>PP Mask 3 left (medial midfoot)</td>
<td>99.45 (81.78)</td>
<td>152.52 (56.63)</td>
<td>20.61 (0.0001)*</td>
</tr>
<tr>
<td>PP Mask 4 left (lateral midfoot)</td>
<td>124.85 (67.89)</td>
<td>148.46 (45.25)</td>
<td>6.13 (0.014)*</td>
</tr>
<tr>
<td>PP Mask 1 right (medial rearfoot)</td>
<td>203.03 (78.38)</td>
<td>216.58 (42.16)</td>
<td>1.8 (0.182)</td>
</tr>
<tr>
<td>PP Mask 2 right (lateral rearfoot)</td>
<td>210.61 (69.53)</td>
<td>232.42 (57.41)</td>
<td>4.013 (0.47)</td>
</tr>
<tr>
<td>PP Mask 3 right (medial midfoot)</td>
<td>95.09 (84.55)</td>
<td>151.68 (57.24)</td>
<td>22.39 (0.0001)*</td>
</tr>
<tr>
<td>PP Mask 4 right (lateral midfoot)</td>
<td>120.37 (81.42)</td>
<td>151.89 (55.19)</td>
<td>7.48 (0.007)*</td>
</tr>
</tbody>
</table>

Table 4.7. The ANOVA results for peak pressure for the left and right foot when the non-OA and OA group were compared.
Contact Time (ms)

The CT for both groups are presented in Table 4.8 and the results of the ANOVA found no significant differences between the OA and non-OA group ($p>0.05$).

<table>
<thead>
<tr>
<th>CT (ms)</th>
<th>Non-OA Mean (SD±)</th>
<th>OA Mean (SD±)</th>
<th>ANOVA F value (significance)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CT Mask 1 left (medial rearfoot)</td>
<td>794.71 (1630.05)</td>
<td>636.45 (384.84)</td>
<td>0.79 (0.37)</td>
</tr>
<tr>
<td>CT Mask 2 left (lateral rearfoot)</td>
<td>791.98 (1630.28)</td>
<td>640.70 (381.36)</td>
<td>0.72 (0.39)</td>
</tr>
<tr>
<td>CT Mask 3 left (medial midfoot)</td>
<td>795.13 (1629.00)</td>
<td>650.22 (381.36)</td>
<td>0.66 (0.41)</td>
</tr>
<tr>
<td>CT Mask 4 left (lateral midfoot)</td>
<td>846.32 (1621.05)</td>
<td>698.24 (363.51)</td>
<td>0.70 (0.40)</td>
</tr>
<tr>
<td>CT Mask 1 right (medial rearfoot)</td>
<td>195.72 (1656.14)</td>
<td>765.92 (1173.30)</td>
<td>0.016 (0.90)</td>
</tr>
<tr>
<td>CT Mask 2 right (lateral rearfoot)</td>
<td>805.93 (1662.69)</td>
<td>768.25 (1171.89)</td>
<td>0.02 (0.875)</td>
</tr>
<tr>
<td>CT Mask 3 right (medial midfoot)</td>
<td>804.88 (1662.76)</td>
<td>748.95 (1165.62)</td>
<td>0.05 (0.81)</td>
</tr>
<tr>
<td>CT Mask 4 right (lateral midfoot)</td>
<td>877.71 (1652.41)</td>
<td>815.41 (1160.94)</td>
<td>0.06 (0.79)</td>
</tr>
</tbody>
</table>

Table 4.8. The ANOVA results for contact time for the left and right foot when the non-OA and OA group were compared.
Pressure Time Integral (kPa/sec)

The PTI for both groups are presented in Table 4.9 and the results of the ANOVA found no significant differences between the OA and non-OA group ($p>0.05$).

<table>
<thead>
<tr>
<th>PTI (kPa/sec)</th>
<th>Non-OA Mean (SD±)</th>
<th>OA Mean (SD±)</th>
<th>ANOVA F value (significance)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PTI Mask 1 left (medial rearfoot)</td>
<td>205.79 (1035.72)</td>
<td>75.30 (39.74)</td>
<td>1.46 (0.23)</td>
</tr>
<tr>
<td>PTI Mask 2 left (lateral rearfoot)</td>
<td>173.54 (805.5)</td>
<td>88.65 (117.05)</td>
<td>0.98 (0.32)</td>
</tr>
<tr>
<td>PTI Mask 3 left (medial midfoot)</td>
<td>178.83 (1043.93)</td>
<td>56.18 (45.22)</td>
<td>1.27 (0.26)</td>
</tr>
<tr>
<td>PTI Mask 4 left (lateral midfoot)</td>
<td>168.71 (846.79)</td>
<td>63.69 (29.82)</td>
<td>1.41 (0.23)</td>
</tr>
<tr>
<td>PTI Mask 1 right (medial rearfoot)</td>
<td>209.54 (1078.68)</td>
<td>78.15 (75.96)</td>
<td>1.36 (0.25)</td>
</tr>
<tr>
<td>PTI Mask 2 right (lateral rearfoot)</td>
<td>202.55 (993.17)</td>
<td>87.89 (85.95)</td>
<td>1.21 (0.27)</td>
</tr>
<tr>
<td>PTI Mask 3 right (medial midfoot)</td>
<td>182.28 (1073.89)</td>
<td>56.93 (40.89)</td>
<td>1.26 (0.26)</td>
</tr>
<tr>
<td>PTI Mask 4 right (lateral midfoot)</td>
<td>200.81 (1071.61)</td>
<td>86.79 (153.54)</td>
<td>1.00 (0.37)</td>
</tr>
</tbody>
</table>

Table 4.9. The ANOVA results for pressure time integral for the left and right foot when the non-OA and OA group were compared.
**Force Time Integral (N/sec)**

The FTI for both groups are presented in Table 4.10 and the results of the ANOVA found no significant differences between the OA and non-OA group ($p>0.05$).

<table>
<thead>
<tr>
<th>FTI (N/sec)</th>
<th>Non-OA Mean (SD±)</th>
<th>OA Mean (SD±)</th>
<th>ANOVA F value (significance)</th>
</tr>
</thead>
<tbody>
<tr>
<td>FTI Mask 1 left (medial rearfoot)</td>
<td>33.64 (189.26)</td>
<td>7.70 (3.04)</td>
<td>1.73 (0.19)</td>
</tr>
<tr>
<td>FTI Mask 2 left (lateral rearfoot)</td>
<td>27.40 (145.38)</td>
<td>8.36 (4.59)</td>
<td>1.59 (0.21)</td>
</tr>
<tr>
<td>FTI Mask 3 left (medial midfoot)</td>
<td>30.13 (207.51)</td>
<td>4.20 (3.88)</td>
<td>1.44 (0.23)</td>
</tr>
<tr>
<td>FTI Mask 4 left (lateral midfoot)</td>
<td>29.52 (168.79)</td>
<td>9.76 (5.62)</td>
<td>1.26 (0.26)</td>
</tr>
<tr>
<td>FTI Mask 1 right (medial rearfoot)</td>
<td>32.65 (183.54)</td>
<td>10.71 (11.25)</td>
<td>1.57 (0.21)</td>
</tr>
<tr>
<td>FTI Mask 2 right (lateral rearfoot)</td>
<td>36.15 (183.54)</td>
<td>12.40 (13.68)</td>
<td>1.53 (0.22)</td>
</tr>
<tr>
<td>FTI Mask 3 right (medial midfoot)</td>
<td>27.09 (185.36)</td>
<td>4.07 (2.84)</td>
<td>1.42 (0.23)</td>
</tr>
<tr>
<td>FTI Mask 4 right (lateral midfoot)</td>
<td>40.99 (249.74)</td>
<td>11.08 (15.46)</td>
<td>1.32 (0.25)</td>
</tr>
</tbody>
</table>

Table 4.10. The ANOVA results for force time integral for the left and right foot when the non-OA and OA group were compared.
4.4 Summary of Results

- When independent t-tests were used to compare the OA and non-OA group, age and BOG was significantly higher ($p = 0.01$ and $p = 0.0001$) in the OA group.
- Ninety-nine OA participants had a dominant right limb and this was comparable with the non-OA group of which 98% (n=49) had a dominant right limb.
- The most prevalent foot posture was mildly pronated for both the left and right foot (61% for each foot). The mean FPI for the left foot was +6.08 and for the right foot was +6.12. The most prevalent foot posture was mildly pronated for both the left and right foot (60% and 58% respectively). The mean FPI for the left foot was +6 and for the right foot was +6.14. There were no significant differences between OA FPI and non-OA FPI for the left foot ($p = 0.80$) or for the right foot ($p =0.95$).
- The mean static TFJt angle for the OA group ranged from 165.03˚ – 166.95˚ and the mean dynamic TFJt angle ranged from 167.65˚ - 169.01˚ and this was similar to the non-OA group where the mean static TFJt angle ranged from 164.81˚ - 167.89˚ and the mean dynamic TFJt angle ranged from 167.4˚ – 170.48˚. These corresponded with a genu valgus alignment of the knee.
- When the OA group was compared with the normal group, there were highly significant differences in the static right TFJt angle ($p = 0.004$); the dynamic unshod left TFJt angle ($p = 0.01$); dynamic unshod right TFJt angle ($p = 0.0001$); dynamic shod left TFJt angle ($p = 0.051$) and the dynamic shod right TFJt angle ($p = 0.00001$).
- There were highly significant plantar pressure differences between the OA and normal group when contact area and peak pressure were analysed particularly in the midfoot region ($p<.0.01$). Post-hoc analysis showed significant difference particularly between a pronated foot type of OA and normal participants ($p<0.05$). A greater loading area and greater peak magnitude of loading in an OA pronated foot suggests that static foot posture may influence dynamic plantar pressure loading patterns in an OA individual compared to a normal individual. There were no significant differences in contact time, and pressure-time integrals and force-time integrals ($p>0.05$).
4.5 Discussion

The primary aim of this study was to determine normative values of foot posture, spatial gait parameters and static and dynamic TFJt alignment profiles in an OA and non-OA population. The results of the study showed that 98% of participants had either a neutral foot posture (37% and 36% for the left and right foot respectively) or a pronated foot posture (61%) with 2% demonstrating a highly pronated left and right foot. The mean OA static and dynamic TFJt angles were found to be a valgus alignment and was subsequently further compared with the non-OA group.

The secondary aim was to determine if there were any differences between the OA and non-OA group and explore if any differences existed based on foot posture categories. The results showed that there were statistically significant differences between the static and dynamic TFJt alignments and plantar pressure parameters, particularly when based on foot posture categories. Therefore the alternate hypothesis was accepted and the null hypothesis was rejected.

4.5.1 Foot Posture

Despite the availability of clinically applicable and reliable foot posture assessments, there have been limited studies that have assessed foot posture in an OA population (Levinger et al., 2010; Reilly et al., 2009) in a relatively small sample size (n=20 – 32). The more recent study reported that people with medial compartment TFJt OA demonstrated a significantly pronated foot type compared to control participants (FPI: +2.46 vs. +1.43, p = 0.02). Reilly and colleagues (2006) reported a significant difference in rearfoot posture with the OA group who exhibited a more everted rearfoot, which, along with dorsiflexion of the ankle and abduction of the forefoot comprises foot pronation. It has been suggested previously that increased pronation may alter the magnitude and/or direction of the GRF, thereby influencing the KAM and medial TFJt loading (Reeves and Bowling 2011; Levinger et al., 2012). From a mechanical viewpoint, altered kinematics and associated kinetics (specifically, in-shoe plantar pressure) in one joint of the kinetic chain can subsequently influence the mechanics of other joints in the linkage (Kepple et al., 1997). Therefore, assessing foot posture and its associated variables can suggest alternate mechanisms in OA individuals that are different from non-OA participants and can be specifically targeted for treatment.
In this study, 81% of participants had a mildly pronated left and right foot as indicated using the FPI-6. These raw FPI scores were +6.08 and +6.12 for the left and right foot respectively. When these results are compared with previous studies of OA participants, there was a difference in the interpretation of the results. Levinger et al., (2010) reported raw FPI scores of +4 - +5 in an OA group compared with a normal FPI score of +2 and +3. This study found that OA participants (n=100) had a more pronated foot type when interpreted using the FPI-6 categorisation (Redmond et al., 2001). However, when compared with the non-OA group, there were no significant differences in foot posture as both groups were mildly pronated with raw FPI scores of +6 - +7 (left foot: p = 0.80; right foot: p = 0.95). Despite having the same inclusion criteria for age (over the age of 45), the OA group (mean age: 57.35; SD ± 9.4) were significantly older (p = 0.01) than the normal group (mean age: 53.46; SD ± 8.08).

Age could be a determining factor in this study as previous normative data by Redmond et al., (2008) suggests that a more pronated foot posture of +5 is demonstrable in an older population (over the age of 60) compared to those under the age of 60 with a raw FPI score of +4. The authors also suggest that in the presence of pathology, a more pronated posture should be expected and this could explain the pronated foot posture in this OA group.

Ageing has been linked with musculoskeletal changes and altered gait patterns. In a study by Rudolph et al., (2007) comparing various age groups with a medial knee OA group, the middle aged and older adults (ages 40 – 80 years) had comparable movement patterns to the younger control group. As age-related muscle laxity occurs, participants must alter their movement and muscle activity patterns in order to maintain a certain level of subtalar joint function (Banks and McGlamry 2001). Therefore, a weakness of the supinatory muscles, such as the flexor digitorum longus but particularly the tibialis posterior, and a corresponding laxity of the deltoid ligament could explain the prevalent pronated foot posture in the healthy demographic in this study. The function of the deltoid ligaments is to limit talar abduction, stabilise the ankle against plantar flexion, external rotation and pronation. It also prevents a valgus stress on the subtalar joint. A weakness of the deltoid ligament could be a factor as it is during ageing that there is an increase in the rigidity and subsequent brittleness of the collagen fibres. This process is deleterious to optimal joint functioning during gait and could result in a prevalent pronated foot type. Another explanation could be one suggested by Hintermann et al., (2003) as previous injuries such as an eversion trauma associated with running down the stairs or landing on an uneven surface. While this could contribute to a
prevalent pronated foot posture in the sample, all participants were screened and excluded from the studies if they had a history of sprains or injuries to the lower limb.

Another factor that might contribute to the prevalence of a pronated foot type is modern footwear, such as trainers, with their ever increasing shock absorbing properties, anti-pronatory mechanisms, specific weight, fit and material composition (McDougall 2009; Rossi 2011). This has resulted in altered muscle strength and increased elasticity of the foot which could have contributed to an increase prevalence of the pronated foot (Graff 2011). While the effects of footwear have been acknowledge by researchers (Putti et al., 2007; Ramanathan et al., 2010), the prevailing foot postures, their associated lower limb profiles and in-shoe plantar pressure measurements should be documented in different pathological groups for reference.

The participants in this study had a dominant right limb (98%) and this may have contributed to a mildly pronated right foot posture as suggested by Polk and Rosengren (2010). The authors found that dominant right limbs were markedly abducted however the authors did not use static foot posture assessment methods such as the FPI-6. Therefore, while the abduction of the forefoot could have been affected, it is one of six anatomical features considered by the FPI-6. Furthermore, the results of this study found no significant differences between left and right foot suggesting that limb dominance did not have an effect on prevalent foot postures or on the angle of gait (AOG).

There were no significant differences in BMI between the two groups. Aurichio et al., (2011) reported flatter feet in obese women and more pronated feet in obese men indicating a relationship between high BMI values (> 30 kg/m²) and foot postural characteristics. This echoes work by Riddiford-Harland (2000) where individuals with higher BMI’s have lower arches, a broader midfoot and flatter feet. A criticism of these findings is the use of footprint measures and as such, it is possible that the effect of body adiposity on measures such as arch height could affect the validity of outcome measures. However, as both groups presented with mildly pronated foot postures using the FPI-6 and an overweight BMI, there was no statistical significance on comparison.
4.5.2 Angle of Gait and Base of Gait

The results of this study found that BOG in an OA and non-OA population was significantly different \( (p = 0.0006) \) finding that an OA individual presents with a significantly higher BOG. This could occur to increase the support base and therefore improve stability of the body (Miller \textit{et al.}, 2008; Kumaresan and Kavithayini 2012). Although BOG is a static parameter, it is an objective and reliable clinical assessment tool (Curran \textit{et al.}, 2006) and its role in pathological conditions such as medial TFJt OA has been suggested but rarely adopted. The results are significant in the context of the GRF, whose magnitude is determined by the position of the foot relative to the position of the body’s centre of gravity. The GRF is equal in magnitude and opposite in direction to the force the body exerts on the floor through the foot (Nordin and Frankel 2001). Therefore, if the foot is further away from the centre of gravity, an increased pronation combined with a greater body mass would affect the direction of the GRF and produce a greater ground force vector (a composite of the KAM). Figure 4.1 illustrates this concept in a non-OA and OA lower limb suggesting a mechanism for abnormal TFJt loading. In such a cross sectional study design, it is not possible to ascertain cause and effect, however a relationship can be inferred by the significantly higher BOG noted in the OA group. An increased BOG has also been known to cause an increase in the GRF magnitude particularly in overweight gait which would subsequently increase the KAM and medial TFJt loading (Sheehan \textit{et al.}, 2012) thus explaining the significant differences in BOG in the symptomatic TFJt OA group.
The results were not significantly different however, in AOG for the left or the right foot ($p = 0.08$ and $p = 1.0$ respectively). The AOG which is also referred to as the foot progression angle (FPA) or angle of turnout (AOT) has been particularly significant ($p<0.05$) in mild-moderate knee OA individuals as an increase in AOG has been associated with a decrease in pain and a decrease in the magnitude of peak KAM (Guo et al., 2007; Rutherford et al., 2008). An increase in the AOG can be associated with an abducted foot which is a composite of a pronated foot type, thereby suggesting that an increase in pronation may reduce KAM and the clinical symptoms of TFJt OA. However, the results of the study found no significant differences in AOG or FPI for the left and right foot when comparing OA and non-OA participants. In this study, the mean values of AOG ranged from $1^\circ$ – $32^\circ$ which is similar to values reported by Curran et al., (2006) ($6^\circ$ - $28^\circ$) and Bryant (2001) ($0^\circ$ - $15^\circ$).
4.5.3 Static and Dynamic TFJt Alignment

A varus or valgus alignment of the knee is assumed to correlate with TFJt OA however; it is unknown whether such a malalignment precedes the development of symptomatic and radiographic OA or whether it occurs as a result of OA (Sharma et al., 2003). Alternatively, Brouwer et al., (2007) suggests a bidirectional relationship between alignment and OA. In a cross sectional study design such as this, it is not possible to determine a cause and effect relationship however the differences in static and dynamic TFJt alignment in an OA and non-OA group can infer a relationship between lower limb structure and function and the presentation of clinical symptoms and medial TFJt OA. The OA values of static TFJt alignments ranged from 163.80° - 166.95° while the OA dynamic TFJt angles range from 164.97° - 169.01°. When these results were compared with non-OA TFJt angles, there were significant differences (p<0.05) in static and dynamic TFJt angles for both the left and right foot with the exception of the static left TFJt angle (p = 0.10).

Non-OA participants had significantly greater TFJt angles than OA participants indicating a closer to neutral alignment compared with a slightly valgus alignment. People with medial TFJt OA have been shown to display genu varus TFJt alignments when assessed using radiographic techniques (McWilliams et al., 2010; Sharma et al., 2010). It has been suggested that genu varum alignment could lead to compensatory foot pronation (Riegger-Krigh and Keysor 1996) and Van Gheluwe et al., (2005) showed that a simulated genu varum and a genu valgum would increase the subtalar joint pronation moment during the contact phase. This would result in a prevalent pronated foot posture during dynamic function which can viably be inferred from static foot postural assessments of a static pronated foot type (Guichet et al., 2003; Levinger et al., 2010). Furthermore, the eversion of the rearfoot is linked with internal tibial rotation due to the coupling mechanism and an abnormally pronated foot could present with excessive internal tibial rotation. This may delay the natural external tibial rotation as the knee begins to extend during the stance phase of gait (Bellchamber and Bogert 2000). However, while this could increase torsional stresses on the TFJt, it could also prevent full TFJt extension and act as a compensatory mechanism of reducing medial TFJt loading and subsequently pain. This extension limitation would also be compounded by weakened extensors, the quadriceps (rectus femoris, vastus intermedius, and vastus lateralis and vastus medialis) that is often reported in medial TFJt OA participants (Teichtahl et al., 2003; Segal and Glass 2011). As weak quadriceps may become fatigued easily, the subsequent poor neuromuscular control could reduce shock absorption during the early stance phase (Herzog
et al., 2003). Excessive pronation of the foot, characterised by subtalar joint pronation and eversion of the calcaneus, could therefore compensate for the quadriceps deficit in shock absorption with prolonged or excessive pronation at the distal lower limb level during midstance (Livingston and Mandigo 2003). This could explain the prevalent mildly pronated foot postures in both groups and is consistent with the author’s findings. The discrepancy in the results could be due to different classification techniques, a range of assessment methods used and reliability of goniometric assessment.

Goniometric findings of anatomical alignment of the TFJt while being a cost-effective and clinically applicable method of ascertaining alignment in the frontal plane, was recently found to be indicative of only 20% of radiographically assessed lower limb alignment (Riddle 2011). Riddle found that in medial TFJt OA participants, a valgus alignment was evidence in 24.6% of the participants (n = 69) which is similar to findings reported in this study. Previous research (Cibere et al., 2004; Kraus et al., 2005) does also offer an alternative conclusion as goniometric assessments have demonstrated good – excellent reliability and correlations with full limb radiographic mechanical alignment. Surrogate measures of establishing TFJt alignment as opposed to the traditional ‘gold standard’ radiograph are important as alignment has been significantly correlation with pain ($p<0.01$) and with a lack of physical functioning when assessed using patient-centred outcome scores ($p<0.01$). Furthermore, static TFJt alignment (mechanical axis) is more closely correlated with KAM ($R=0.74$, $p<0.001$) than with radiographic measures of OA, FPA or pain scores (Hurwitz et al., 2002).

4.5.4 In-Shoe Plantar Pressure Measurement

An in-shoe plantar pressure assessment offers the most direct method of examining the interface between the ground and the foot. There have been a range of studies that have documented a relationship between knee OA, pain and changes in plantar pressure (Hassan et al., 2001; Kul-Panza et al., 2006; Lidtke et al., 2010; Leitch et al., 2011). Lidtke (2010) reported that in medial TFJt OA there was a greater lateral loading compared with a more central centre-of-pressure distribution pattern in healthy controls ($p<0.001$). The authors also stated a correlation between loading and the severity of pain as opposed to radiographic severity. The dynamic function of the foot during gait could thus exert a mediating effect on the TFJt OA by increasing lateral loading and attempting to reduce KAM and subsequent
adverse loading. This may indicate that dynamic plantar loading is reflective of clinical symptoms of knee OA as opposed to radiographic parameters as these may not be clearly obvious in mild-moderate knee OA patients. As foot posture and its potential effects on plantar pressure have been established in healthy participants where more pronated feet have been associated with greater medial midfoot pressures (Jonely et al., 2011), it was necessary to explore OA plantar pressure parameters within the context of foot posture. The same five parameters of contact area, peak pressure, contact time, pressure-time integrals and force-time integrals were examined in both groups. The four masks (medial and lateral rearfoot and medial and lateral midfoot) were selected as these are key areas which determine magnitude and timing of plantar loading that is eventually transferred along the kinetic chain to the TFJt (Lidtke 2011).

Contact Area
The mean contact area (cm², CA) in the OA group was significantly greater in lateral midfoot compared to the medial midfoot for the left foot and right foot respectively (p <0.0001). When the OA participants were further compared with the non-OA group, CA was significant greater in the medial midfoot (p<0.001) and further to this, a pronated OA foot demonstrated greater CA compared to a non-OA pronated foot. This suggests that foot posture can affect in-shoe plantar pressure assessments as suggested by previous authors (Lidtke et al., 2011; Levinger et al., 2010). A more pronated foot type would increase the surface area through which ground reaction forces can be dissipated while greater loading in the lateral midfoot could occur to alleviate adverse medial TFJt loading. The results of greater lateral loading echoes findings by Lidtke et al., (2010) where OA participants had a more lateral COP trace during gait than healthy matched controls.

Previous researchers (Putti et al., 2007) have reported the largest CA in the rearfoot region followed by the midfoot, whereas in this study OA participants demonstrated greater CA in the midfoot region which is indicative of decreased rearfoot contact, perhaps as a compensatory mechanism. Due to subtalar joint pronation, the midfoot may undergo increased pronation in order to attain a plantigrade foot and this echoes findings of Barrios et al., (2009). The authors found that knee malalignment (varus or valgus) could result in compensatory alterations to lower limb function. In a valgus knee, the calcaneus is everted at foot strike and thus, further pronation could be facilitated in order to redistribute the significantly increased lateral loading of the OA midfoot. Riberio et al., (2011) showed that
in pregnant women, plantar loads, particularly CA, was redistributed from the rearfoot to the midfoot which could increase dynamic stability during locomotion. As participants in the OA study had a significantly higher BMI compared with the non-OA group, this could account greater midfoot CA compared to rearfoot CA as a wider foot would imply a greater surface area of foot in contact with the Pedar insoles.

**Peak Pressure**

The PP or magnitude of peak pressure can have an effect on the magnitude of the GRF and therefore determine KAM. Lidtke et al., (2010) found that the plantar centre of pressure in medial TFJt OA have a higher lateral loading component. Therefore, greater loading of the lateral aspect of the rearfoot and possible the midfoot would be expect in TFJt OA patients compared with the midfoot. This would place greater pressure on the medial aspect of the TFJt (Currie 2010). In this study, PP in the right rearfoot was significantly higher in the lateral region (232.42 kPa) compared with the medial region (216.58 kPa) \((p=0.006)\). This difference was not significant in either left or right midfoot \((p=0.47 \text{ and } 0.12)\) and the left rearfoot region \((p=0.97)\). Limb dominance could be a factor as 99 participants were right limb dominant while 90 participants had OA predominantly in their right knee. A healthy gait is often considered to be a series of symmetrical motion patterns and asymmetries in gait have been used to explain differences in balance and propulsion abilities in the lower limbs (Ledebt et al., 2004). Polk and Rosengren (2010) found that in thirty-six healthy volunteers, the dominant right limb generated greater medial forces and lower lateral forces and impulses. However, the participants in this study had greater laterally directed forces which could be a cause or consequence of medial TFJt OA. The prevalence of medial TFJt OA however, has been suggested to be greater in a non-dominant limb compared with a dominant knee. For example, professional football players have a significantly increased risk of injury and early OA in the non-dominant limb (Krajnc et al., 2010). Nishimura et al., (2012) also showed that 49.2% of 1239 participants developed unilateral OA in the contralateral knee over a five year period which suggests that in the absence of a history of knee trauma such as fractures, there is an almost even prevalence of OA in either limb. Eckstein et al., (2002) found that while limb dominance did not determine cartilage morphology in healthy participants, there were significant difference in thigh musculature which were positively correlated with TFJt cartilage volume \((p<0.01)\). This indicates that the contralateral limb would be more at risk of cartilage degradation and subsequent OA pathological processes. Therefore, the dominant right limb in 90 OA participants may be physiological more able to
regulate TFJt loading by redirecting plantar forces more laterally than a medial or central pressure distribution pattern. This could be a compensatory mechanism to manage clinical symptoms and reduce the progression of medial TFJt OA.

When the OA participants were compared with the non-OA group, there were significant differences noted in the left lateral rearfoot ($p=0.03$), left medial and lateral midfoot ($p=0.0001$ and 0.014 respectively) with greater peak pressures in the OA group. In the right foot, there were significant differences in the medial and lateral midfoot ($p=0.0001$ and $p=0.007$ respectively) with greater peak pressures in the OA group. The peak pressure ranges for the midfoot region ranged from 148.46 kPa - 152.52 kPa. When these differences were explored further within the context of foot posture, a pronated foot type was found to exhibit greater PP medially in the midfoot for both the left ($p=0.04$) and right foot ($p=0.03$) when compared with the pronated normal group. A pronated OA foot therefore, had greater peak pressures affecting a greater contact area compared to a normal foot. Jonely et al., (2011) found that in healthy participants, lower arch foot postures were associated with greater peak pressures particularly under the medial midfoot ($p<0.05$) however the strength of this relationship was only poor to fair. One factor that should be considered according to Arnold et al., (2010), is body mass as the effect increasing body mass has on PP during gait is inconclusive and that specifically, comparisons between an asymptomatic population and a matched pathological group is lacking.

As discussed previously, the OA group had a significantly greater BMI compared with the normal group ($p=0.0006$). Vela and colleagues (1998) reported that there were statistically significant increases in peak pressure in the rearfoot and midfoot with additional loading of subjects while Arnold (2010) found that only the rearfoot region was sensitive to changes in body mass compared with the forefoot region. This trend was observed in the lateral rearfoot of the OA group compared with the non-OA group and could be explained by altered lower limb alignment due to pathological TFJt changes. During normal gait for example, the rearfoot region (lateral aspect of the calcaneus) is the first contact surface with the ground during the stance phase followed by the midfoot and the forefoot. As the initial point of contact, this aspect of the lower limb may not be functionally able to adapt to increasing loading pressure which could explain the increase in rearfoot loading with an increased BMI. The increases in midfoot loading in this study can also be compared with Birtane and Tuna (2004) who suggested that increase loading forces limit the ability of the medial longitudinal
arch to dissipate such increased forces, and thus there is an increased plantar contact area within the midfoot as compensation. The findings of this study also echo the work of Hills et al., (2001) who found significant differences in midfoot loading when biomechanically evaluating obese and non-obese adults.

**Contact time**

The mean contact time (CT) in the midfoot and rearfoot of an OA foot were not significantly different to a non-OA foot (p>0.05). There were no significant differences between CT between the left and right foot (p>0.05). This suggests that while contact area and magnitude of pressure was significantly different in the two groups, the amount of time spent in the medial and lateral aspect of the foot was no significantly different. An explanation for this could be as a result of ground surface and comparable footwear used for both studies (neutral Donnay trainers). Tessutti et al., (2007) suggested that rigid surfaces such as concrete would produce smaller CT’s and increase plantar pressure variables in all foot regions while surfaces considered compliant would produce greater CT’s. Therefore, when compared with Putti’s findings of CT ranging from 450 – 550 ms, the greater CT in this study could be explained due to different ground surfaces (not documented by Putti) and by a younger age group (mean age 34.4 years).

Age and presences of pathology could contribute to an increased CT in an OA population as Al-Zahrani and Bakheit (2002) showed that participants with OA demonstrated significantly reduced walking speed, a reduced stride length and a prolonged stance phase compared to healthy control subjects. Other authors have also reported decreased walking speed and longer time spent in double support in elderly and OA individuals compared with controls (Hulet et al., 1996; Hurwitz et al., 1997; Bejek et al., 2005). The presence of pathology could have explained a prolonged contact time due to an analgesic response however the results of this study do not support this. A possible explanation is that participants in the previous studies who had demonstrable altered gait mechanics also presented with more severe TFJt OA (Kellgren and Lawrence Score of 3-5 or Hospital for Special Surgery Knee Score of <70 indicating poor – fair outcomes). This is in contrast to the OA participants in this study who presented with mild symptomatic TFJt OA.
Pressure Time Integral and Force Time Integral

The PTI values in the OA participants in the left foot ranges from 56.81 kPa·second – 88.65 kPa·second while for the right foot, the PTI ranged from 56.93 kPa·second – 87.89 kPa·second. The FTI values ranged from 4.20 N·second – 9.76 N·second for the left foot and 4.07 N·second – 12.40 N·second for the right foot. When compared with the non-OA group, there were no significant differences in PTI or FTI for either the left or right foot (p>0.05).

This suggests that the pressure and force distribution over time was not affected by the presence of OA and foot posture outcomes. The overall in-shoe plantar pressure patterns suggest that despite an increase in CA and PP, the amount of time spent in each region of the foot did not increase or decrease in an OA group. This is in contrast with the thoughts of Harrington (2005) who stated that when pain and discomfort is present, the affected lower limb will bear less weight and have a decreased stance phase duration whereas the contralateral unaffected limb has a corresponding shortened swing phase. Weight bearing on the non-affected OA limb would therefore be prolonged and is a protective mechanism. However, there was no difference in pressure or force distributions over time despite a highly significant increase in peak pressures in the OA foot and in particular, the medial aspect of the midfoot.
4.5.5 Limitations

The sample size of 100 OA and 50 non-OA participants was determined from power calculations using means and standard deviations from previous researchers as discussed previously in the methods chapter (Chapter 3, Section 3.1.2). While the difficulty encountered recruiting non-OA participants was significant compared with recruiting medial knee OA participants, the inclusion of participants based on physical examination, medical history and clinical presentation without the evidence of radiographic evidence in all individuals could be a limitation. Although the debate between clinical symptoms and radiographic OA has been discussed, the inclusion of participants with radiographically verified Kellgren-Lawrence grades of I-III (mild-moderate OA) could have made the study more comparable to previous research studies using these techniques. However, the prohibitive cost, time and resource allocation as well as specialist equipment required made this method clinically inapplicable and inappropriate within this research setting.

As the results of the study in OA participants was compared with normal participants within the context of foot posture, a more considered approach of recruiting participants with a range of foot postures, particularly a supinated foot posture would have provided a better insight into the effect of a range of foot postures on kinematic and kinetic knee outcomes. Despite the results reflecting previously established prevalence of a mildly pronated foot posture being the norm in a healthy population and a mildly pronated foot posture in a medial TFJt OA group, it would have been insightful to include a supinated foot posture category. Although there is limited reliability and validity associated with different methods of static foot posture assessments (Morrison and Ferrari 2009), the inclusion of further measures such as arch index and navicular drop (pending intra-class reliability studies) would have provided a triangulation strategy for a more accurate gait analysis.

Another limitation to the study could be the degree to which the neutral Donnay trainers were laced up for each participant. While shoe make and model was kept consistent through the study and shoe size was accounted for in every participant in order to generate Pedar outcomes, it was not possible to regulate how tightly or loosely laces the shoes were during data collection. Fiedler et al., (2011) found that loose lacing styles produce smaller peak and plantar pressure changes (by 3% and 6.5% respectively) and particularly, the perceived in-shoe displacement increased when compared to more securely fastened footwear. While
participants were advised to comfortably tighten their laces, it is not possible to regulate the effect this may have on plantar pressure outcomes.

Another limitation of this study that was noted was that walking speeds were not recorded and these are known to have an effect on plantar pressure parameters such as peak pressure, where greater walking speeds are associated with higher peak pressures particularly in the rearfoot (Segal et al., 2004). This could be a factor to consider particularly in the next stage of the study where orthotic intervention could redistribute peak pressures and cadence would have to be a noted covariant.

**Future Considerations**

While neutral Donnay trainers were used for data collection, it would have been a useful exercise to document the type and make of the most commonly worn footwear by participants in this study. This would have been useful for the next stage of this study where the effect of orthoses on kinetic plantar pressure parameters could be determined in neutral trainers as well as own footwear. The next phase could consist of using a footwear assessment tool such as that described by Barton et al., (2009) which would consider footwear factors such as fit, age of shoe, material composition and cushioning. The documentation of footwear characteristics as well as type of footwear worn should be a consideration for future research trials as footwear can have a significant impact on plantar pressure assessments as well as influence medial TFJt loading. In an OA population, footwear guidelines have been suggested by the National Institute for Health and Clinical Excellence (2008) as well as the Osteoarthritis Research Society International however the findings are limited, often conflicting and are of poor methodological quality (Fang et al., 2009). Therefore, in the absence of definitive footwear recommendations, it would be of interest to researchers and clinicians to document the type of footwear OA patients wear most often in a given week as well as the type of footwear they prefer to place the orthoses into. This can be accounted for with a footwear diary.

Another factor that was highlighted by this study is the walking speed or cadence. Previous researchers have commented increasing walking speeds could increase the peak pressure under the heel and medial aspect of the forefoot region. Additionally, contact time increases with higher walking speed as well as a reduction of force-time and pressure-time integrals at faster speeds (Rosenbaum et al., 1994; Taylor et al., 2004). Therefore, with the use of a stopwatch, the walking speeds of participants in the future trial will be measured and noted.
This would provide an additional insight that could potentially affect plantar pressure parameters over time. The time taken to walk along the 8 metre platform and any changes to this timing would also be a useful indication of functional capability, along with the IPAQ, in the subsequent studies.
4.6 Conclusion

The primary purpose of this study was to establish foot posture, spatial gait parameters, static and dynamic TFJt angles and associated kinetic in-shoe plantar pressure parameters in an OA group while the secondary aim was to determine if any differences existed between a normal and an OA group.

The results showed that there were significant differences between static right TFJt angles and left and right dynamic shod and unshod TFJt angles with the greater values recorded in a normal group suggesting a closer to neutral alignment in this group. The results also supported the alternate hypothesis as there were significant differences in key plantar pressure parameters such as contact area and peak pressure between OA and normal groups. Even though foot posture did not differ between the two groups, it exerted a significant effect on plantar pressure distribution patterns with the more pronated foot demonstrating greater midfoot contact area and greater midfoot peak pressures.

This study demonstrates that foot posture (as determined using the FPI-6) can influence in-shoe plantar pressure parameters and potentially subsequent mechanical alignment and dynamic lower limb function. Therefore, foot posture could be considered a clinical indicator of knee OA mechanisms. To this end, foot orthoses and footwear modifications have been suggested as a conservative treatment of knee OA despite limited RCT in this area (Shimada et al., 2006; Baker et al., 2007; Sharma et al., 2008). To comprehend the effect of interventions such as LWO’s and the interactions between these, foot posture and associated patient-centred and kinetic outcomes, RCT’s including foot posture and function in this population is necessary.
5. Laterally Wedged Orthoses in Medial Knee Osteoarthritis: A Randomised Control Trial

The aim of this chapter is to present the results of the randomised control trial and discuss the key findings and differences, if any, between the treatment and the control group. It will describe the RCT outline and discuss the key findings in an OA group over a three month time period and will discuss these within the context of foot posture and static BOG. Section 5.1 will introduce the RCT background and the alternate and null hypotheses. Section 5.2 will discuss the study materials, methodology used and type of data analysis adopted for the results. Section 5.3 covers the RCT’s key findings of anthropometric data, lower limb alignment profiles and associated kinetic in-shoe plantar pressure parameters of the treatment and control group. Section 5.4 will summarise the key findings of the study. Section 5.5 will elaborate on these findings and discuss the results within the findings of previous research (Chapter 2) and previous findings (Chapter 4). This section will also discuss the limitations of the study design and finally, Section 5.6 is an executive summary of the chapter.

5.1 Rationale

Conservative interventions such as laterally wedged orthoses (LWOs) and their effect on knee alignment, plantar pressure parameters and patient-centred outcome scores warrant further research investigation (Hinman and Crossley 2007). The literature review (Chapter 2) found that malalignment within the lower limb has been suggested as a biomechanical contributor to knee OA development and progression (Heegard et al., 2001; Lee et al., 2003 and Hintswimmer et al., 2005). There have been several theoretical explanations, such as the presence of suboptimal foot postures and an increased foot progression angle demonstrating an effect on KAM, a clinical indicator of TFJt OA development (Guo et al., 2007; Rutherford et al., 2008; Levinger et al., 2010).

Chapter 4 demonstrated that although foot posture was not significantly different in the OA and normal group, a pronated OA foot posture had greater in-shoe plantar pressure contact area and peak pressure compared to a pronated normal foot. There were highly significant differences with a greater CA in the lateral midfoot and a greater PP in the lateral rearfoot in the OA group (p<0.01). This suggests that foot posture and subsequent dynamic function can have an influence on dynamic loading however the modification of foot posture and its effects on clinical symptoms is yet to be established. This is relevant to the use of LWOs whose mechanism of action is an amalgamation of plantar pressure redistribution, an increase in the pronation of the STJt which would alter the direction and magnitude of the GRF and which would act as a shock absorbing mechanism during midstance (Whittle 1999; Ball and
Afheldt 2002; Nester et al., 2003; Zammit et al., 2008). To date, there has been no research investigating foot posture and associated in-shoe plantar pressure parameters in an OA population. Despite previous evidence purporting that abnormal foot postures have a significant effect on medial and lateral midfoot and rearfoot CA and PP and, an increased risk of lower extremity overuse injuries (Kaufman et al., 1999; Chuckpaiwong et al., 2008).

The studies in the previous chapters also discussed the significant differences in the static spatial parameters of gait particularly the base of gait (BOG) where OA individuals had an increased BOG compared with the normal group suggesting a modified static stance position that may increase postural and dynamic stability but also act to increase TFJt loading by affecting the KAM (Sheehan et al., 2012). The results suggest that foot posture and spatial gait characteristics could potentially influence clinical outcomes however, the evidence base for the use of LWOs have rarely accounted for these factors (Chapter 2, Table 2.1: LWO RCT reviews from 2001 – to date). It could also explain the variation of and inconsistent findings in the existing literature reviews of LWOs leading to a Cochrane review suggesting there is only silver level evidence for the use of LWOs as a viable treatment option for medial knee OA (Brouwer et al., 2007). The review however, did not address the impact of footwear choice on patient outcomes. The potential effect of footwear has only been acknowledged more recently (Fang et al., 2009; Shakoor et al., 2010) and is a conflicting factor because often, the ‘ideal shoe’ recommended by clinicians is based on anecdotal evidence or clinical preference (Landry 2011). Furthermore, differences in footwear choices could explain the inconsistent findings previously described in LWOs clinical trials.

The few RCT’s that have been conducted have also been limited by small sample sizes, short intervention periods, the use of suboptimal lateral wedge designs (heel wedges as opposed to three-quarter or full-length) and the inclusion of patients with more severe TFJt OA (Pham et al., 2004; Baker et al., 2007; Barrios et al., 2009). As they remain advocated by 13 out of 14 international guidelines on the management of knee OA (Zhang et al., 2008), it is important to understand their potential mechanism of action. The potential influence of factors such as foot posture or footwear on patient centred outcomes and in-shoe plantar pressure measurements needs to be considered in future LWO RCT’s (Hinman 2012, Levinger et al., 2012).
The aim of this RCT was to evaluate the differences in clinical outcomes such as pain, health-related quality of life and in-shoe plantar pressure parameters in the treatment compared with the control group.

The following hypotheses for patient-centred outcomes score and kinetic outcomes were generated for the RCT:

**Hypothesis H1**: There is a difference in patient centred outcome scores such as pain and knee health-related quality of life between LWOs and a neutral insert in an OA population.

**Null Hypothesis H0**: There is no difference in patient centred outcome scores such as pain and knee health-related quality of life between LWOs and a neutral insert in an OA population.

**Hypothesis H2**: There is a difference in patient in plantar pressure parameters between LWOs and a neutral insert in an OA population.

**Null Hypothesis H0**: There is no difference in plantar pressure parameters between LWOs and a neutral insert in an OA population.

The differences, if any, can then be further explored using sub-group analysis based on foot posture (neutral, pronated and highly pronated) and spatial gait characteristics (AOG and BOG). As previously discussed, footwear choice could have an effect on the primary and secondary outcomes and as such, warrant further investigation.
5.2 Study Materials and Methods

Ethical approval for the OA study and RCT was obtained from Cardiff Metropolitan University Ethics Committee (Appendix 5). Participants were provided with an information sheet and provided written informed consent prior to participation in the initial screening and subsequent trial.

Sample Size and Inclusion Criteria:
Participant’s selection and inclusion criteria for the study are presented in the methods chapter (Chapter 3, Section 3.1.3). During the initial screening, participants were informed that the first session would take approximately 40 minutes while the subsequent 3 sessions at 3 weeks, 6 weeks and 12 weeks from the first session would take approximately 30 minutes. Flow chart 6.1 demonstrates the movement of participants through the RCT and the types of assessments conducted at each session of data collection.

Participant Randomisation:
As discussed in Chapter 3 (Section 3.2 Study Design), participants will be randomised into parallel groups using a block randomisation technique with block sizes of 2 x 2 = 4. This technique was chosen in order to ensure that at every stage of the recruitment, there were equal participant numbers in the treatment and control group. Shen and Lu (2006) also recommended using this type of technique as selection bias is avoided and furthermore, the block sequences themselves were not generated by the principal investigator.

Materials and Equipment Required:
The materials and equipment used in this study are similar to those presented in Chapter 5 (Section 5.2.1).

Methodology:
5.2.1 Initial Screening of Participants:
The initial screening of participants was detailed in Chapter 4 (Section 4.2.1).

5.2.2 Repeat Sessions and Assessments:
Following the baseline meeting (0 weeks) which was detailed in Chapter 4 (Section 4.2.2), participants were then seen at 3 weeks, 6 weeks and 12 weeks from baseline. The KOOS
questionnaire and the IPAQ score were administered in each of these sessions. Participants were then asked to adopt the same position as the foot outlines on the A1 sheets from baseline and retroreflective markers were placed on the visual assessed TFJt angle. Participants were then asked to walk along the 8 metre walkway so that the dynamic TFJt angle with their own footwear and orthoses could be ascertained at 12 weeks. This would be compared to baseline findings of dynamic TFJt angles. Simultaneously, plantar pressure assessments were also recorded using the same footwear choice that was used in the first session (worn most during the week and over the 12 month period). Three recordings of dynamic shod TFJt were noted and in-shoe pressure measurements using the Pedar® were also recorded for three lengths of the walkway. From each of these walks, 3 midgait steps for the left and right foot were selected and analysed using the Pedar® analysis function.

The walking speed was assessed using a stop watch to record the amount of time taken (seconds) to walk from one end of the gait platform to the end (8 meter platform).
Assessed for Eligibility (n=120)

Not randomised (n=2)
Declined to participate in a randomised trial

Eligible participants (n=107)

Gave informed consent and randomised (n=105)

Baseline:
Anthropometric measures; FPI; static and dynamic TFJt alignment and plantar pressure parameters recorded three times. Footwear & Medication Diary provided.

Allocated to control group (n=52)

First follow up (n=51, 98%)
Discontinued (n=1)
Reasons: 1 withdrawal, non-compliance (footwear)

Second follow up (n=49, 94%)
Discontinued (n=2)
Reasons: 1 unable to contact and 1 withdrawal due to lack of improvement

Third follow up (n=48, 92%)
Discontinue (n=1)
Reasons: Withdrawal due to lack of improvement

Allocated to treatment group (n=53)

First Follow up (n=53, 100%)

3 weeks:
Repeat Measures: static and dynamic TFJt alignment and plantar pressure parameters recorded three times.

Second follow-up (n=52, 98%)
Discontinued n=1
Reasons: Unable to contact

6 weeks:
Repeat Measures: static and dynamic TFJt alignment and plantar pressure parameters recorded three times.

Third follow up (n=52, 98%)

12 weeks:
Repeat Measures: static and dynamic TFJt alignment and plantar pressure parameters recorded three times. Footwear & Medication Diary collected.

Ineligible (n=13)
- 8 participants had a medical history of inflammatory conditions (bursitis, chondromalacia patellae)
- 5 could not attend clinic for a straight 3 month period.

52 treatment participants and 48 control participants were analysed at baseline, 3 weeks, 6 weeks and 12 weeks.

Flow Chart 5.1 Participant Flow through the RCT
Data Analysis:

The results of the study were collated in Excel and analysed using SPSS for Windows package (version 19). Participant characteristics in the treatment and control group will be presented for anthropometric data (age, BMI and IPAQ), foot posture and spatial gait parameters. These will be compared using independent t-tests for the two groups prior to intervention being provided. Pearson’s correlation coefficient was used to determine the relationship between static and dynamic TFJt angles at baseline and for an association over the 3 month time period. They were interpreted using the Guildford model as described in Chapter 4. In order to use parametric analysis, data were analysed using the Kolmogorov-Smirnov test to determine if the data were normally distributed (>0.05). Foot posture scores were converted into Rasch transformed scores provided by Keenan et al., (2007).

Compliance was assessed from the footwear diary in addressing the number of hours orthoses were worn in every week of the 12 week period. This was collated in excel and analysed using the Bonferroni correction where the adjusted p values is 0.05 divided by 12 (total weeks in the study). This would reduce the chance obtaining a false-positive or type 1 error that would occur if multiple paired t-tests were used. Therefore, using this correction the statistical power of this comparison would be tested at the 0.004 level (Fields 2005; Napierala 2012). Medication usage will also be assessed over the 3 month period for changes over time and if there was a significant difference from baseline measures pre-intervention to post-intervention at 3 months. The differences will also be considered using the Bonferroni adjusted p value of p=0.004.

The KOOS scores and IPAQ questionnaires were tallied in excel using pre-designed KOOS excel scoring sheets (Roos 2003) and IPAQ scoring ranges as described in Chapter 4. These values will be described and analysed in the treatment and control groups respectively for significant differences over the 12 weeks. A 2 by 4 ANOVA will be used to find any significant differences between the groups and these will be further evaluated using a Tukey’s post hoc analysis at the p< 0.05 level. The minimal clinically important change (MIC) is the smallest change scored needed for an effect of an intervention to be considered as clinically significant and relevant. The recommended MIC for the KOOS score is 8-10 points on the KOOS scale (Roos and Lohmander 2003). These will be reported in both the treatment and control groups.
In-shoe Plantar Pressure Measurement

In-shoe plantar pressure parameters were interpreted using the same regional masks used to analyse pressure patterns from the previous study comparing OA and non-OA groups. Walking speed during in-shoe plantar pressure measurements was recorded using a stopwatch and inputted into excel, averaged over three occasions for each time point and imported into SPSS.

Inter limb analysis will be conducted using paired samples t-tests in order to determine if there are any differences between the left and right limb during walking. The group sizes are assumed to be equal subsequent to testing using Levene’s test for equality of variance which will be reported. Bejek et al., (2006) found that in unilateral OA, compensatory mechanisms occurred within the affected limb itself. Richardson and Higginson (2011) found no significant differences between OA unaffected knees compared with healthy knees while Metcalfe et al., (2012) found that overall peak loading is the same in both the OA affected knee and the OA unaffected knee. Therefore, as both affected and unaffected limbs are comparable and a homogenous sample of unilateral and bilateral knees was used in this study, pending evaluation with the inter-limb analysis, the dominant limb (right) will be selected for further comparisons. Therefore, if the result of the inter-limb analysis was significant and maintained over time, then these would be explored within the context of the affected and unaffected OA limbs.

A repeated measures ANOVA was used in order to identify differences between the treatment and the control groups and look for differences (p<0.05) in kinetic variables at baseline, 3 weeks, 6 weeks and 12 weeks. The within-subjects variables are time and masks while the between-subject factors are grouping (treatment and control). The anatomical regions of interest will be dictated by findings from the previous study which showed significant differences in masks 1 – 4 (medial and lateral rearfoot and medial and lateral midfoot regions) in contact area and peak pressure at baseline. Therefore, any differences between the treatment and control group will be explored using repeated measures ANOVA in these parameters and additionally in contact time, pressure-time integrals and force-time integrals. Any significant differences in the groups will also be explored within the context of foot posture groups (neutral, pronated, highly pronated) and static BOG.

The potential influence of footwear (own footwear when compared with neutral Donnay trainers) will be analysed using an ANOVA and post hoc analysis will be used to determine
specific differences in plantar pressure parameters and in specific regions of the foot using masks (Mask 1: medial rearfoot, Mask 2: lateral rearfoot, Mask 3: medial midfoot, Mask 4: lateral midfoot). The analysis will be conducted in both the treatment and control groups respectively and will consider the four time points of baseline, 3 weeks, 6 weeks and 12 weeks.
5.3 Results

Anthropometrics

The RCT consisted of 100 participants: 52 in the treatment group and 48 in the control group. The mean age of the participants in treatment group was 57.62 years (SD ±10.27). Their mean BMI was 29.34 kg/m\(^2\) (SD ± 5.99) and their baseline IPAQ score was 3897.44 met-minutes/week (SD ±3626.11) which is defined as being a highly active cohort. The mean AOG for the left foot was 10.05 (SD ± 5.74) and for the right foot 10.30 (SD ± 5.35). The mean BOG was 15.38 (SD ± 4.12).

The mean age of participants in the control group was 57.06 years (SD±8.46). They had a mean BMI of 29.63 kg/m\(^2\) (SD ±6.36) and a mean baseline IPAQ score of 3444.89 met-minutes/weeks (SD ± 2904.65) which is also defined as being a highly active cohort. The mean AOG for the left foot was 10.62° (SD ± 6.40) and for the right foot was 11.39° (SD ± 5.37). The mean BOG was 16.09 cms (SD ± 3.95). This data is presented in Table 5.1.

<table>
<thead>
<tr>
<th></th>
<th>Treatment</th>
<th>Control</th>
<th>Independent t test</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>SD±</td>
<td>Range</td>
</tr>
<tr>
<td>Age (years)</td>
<td>57.62</td>
<td>10.27</td>
<td>44 - 84</td>
</tr>
<tr>
<td>BMI (kg/m2)</td>
<td>29.26</td>
<td>5.99</td>
<td>20.3 - 50.70</td>
</tr>
<tr>
<td>IPAQ (met</td>
<td>3897.44</td>
<td>3626.11</td>
<td>0 - 14130</td>
</tr>
<tr>
<td>minutes/week</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Left AOG (°)</td>
<td>10.05</td>
<td>5.74</td>
<td>0.0 - 25</td>
</tr>
<tr>
<td>Right AOG (°)</td>
<td>10.30</td>
<td>5.35</td>
<td>0.0 - 32</td>
</tr>
<tr>
<td>BOG (cms)</td>
<td>15.38</td>
<td>4.12</td>
<td>7.00 – 25.5</td>
</tr>
</tbody>
</table>

Table 5.1. The mean age, body mass index, physical activity scores at baseline, left and right AOG and BOG for the treatment and control groups.
When independent samples t-tests were conducted on the baseline data of both groups, there were no significant differences between age ($t(98) = 0.29, p = 0.76$), BMI ($t(98) = 0.47, p = 0.64$) or with baseline IPAQ scores ($t(98) = 0.68, p = 0.49$). There were no significant differences in left AOG ($t(98) = 0.46, p = 0.63$), right AOG ($t(98) = 1.01, p = 0.31$), and BOG ($t(98) = 0.87, p = 0.38$).

An independent-samples t-test was conducted to compare the differences in BMI and IPAQ between the 39 male and 61 female participants. Although BMI scores were slightly higher for men (30.18 kg/m$^2$, SD±7.15) than for women (29.57 kg/m$^2$, SD±6.95), ($t(99) =0.43, p=0.67$) and baseline IPAQ scores were also higher for men (4118.18, SD±3638.48) than for women (3400.21; SD±3046.61), ($t(98) = 1.06, p=0.29$), there were no significant gender difference in the BMI or baseline IPAQ scores.

The right limb was the dominant limb in 99% of the cohort. Sixty seven participants had symptomatic OA in both knees with the right knee being worse; twenty three participants had symptomatic OA in the right knee alone and ten participants presented with symptoms in their left knee alone.

**Foot Posture Characteristics**
The most prevalent foot posture in the treatment OA group for the left and right foot was mildly pronated (FPI raw score for the left foot +6.05 and +6.05 for the right foot). 21 participants (40.3%) in this group had a neutral left foot, 30 participants (57.6%) had a pronated left foot and 1 (1.92%) had a highly pronated left foot. 20 participants had a neutral right foot, 31 participants had a pronated right foot and 1 participant had a highly pronated right foot.

For the control OA group, a mildly pronated foot was also prevalent as the mean raw FPI score for the left foot was +6.10 and +6.18 for the right foot. 16 participants (33.3%) had a neutral left foot, 31 participants had a pronated left foot and 1 participant had a highly pronated left foot. 16 (33.3%) participants had a neutral right foot, 30 participants had a pronated right foot and 2 participants had a highly pronated right foot. When the groups were compared, there were no significant differences in FPI scores for the left foot ($t(98) = 0.15, p = 0.87$) or the right foot ($t(98) = 0.39, p = 0.69$).
As presented and discussed in the previous chapter, the results of the OA study were found to be non-significant when using the Kolmogorov-Smirnov test thus indicating the goniometric and dynamic TFJt angles were normally distributed, i.e. parametric. The results of the static and dynamic TFJt angles of the treatment OA group and the control OA group were compared using independent t-tests. The baseline results are presented in Table 5.2 for static, unshod dynamic and shod in Donnay trainers.

The results showed no significant differences between the static and dynamic TFJt angles of the treatment and control groups (p>0.05).

<table>
<thead>
<tr>
<th></th>
<th>Treatment OA (n=52) Mean (±SD)</th>
<th>Control OA (n=48) Mean (±SD)</th>
<th>Independent t test t (df) = (p)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Static Left TFJt angle (°)</td>
<td>163.70 (±4.56)</td>
<td>163.91 (±3.97)</td>
<td>t (98) = 0.24, p = 0.8</td>
</tr>
<tr>
<td>Static Right TFJt angle (°)</td>
<td>164.52 (±5.57)</td>
<td>164.49 (±3.88)</td>
<td>t (98) = 0.03, p = 0.97</td>
</tr>
<tr>
<td>Dynamic Left TFJt angle (unshod) (°)</td>
<td>166.28 (±5.86)</td>
<td>164.4 (±6.05)</td>
<td>t (98) = 0.157, p = 0.11</td>
</tr>
<tr>
<td>Dynamic Right TFJt angle (unshod) (°)</td>
<td>165.69 (±5.93)</td>
<td>164.18 (±4.73)</td>
<td>t (98) = 1.4, p = 0.16</td>
</tr>
<tr>
<td>Dynamic Left TFJt angle (shod) (°)</td>
<td>167.12 (±4.92)</td>
<td>165.29 (±5.32)</td>
<td>t (98) = 1.78, p = 0.07</td>
</tr>
<tr>
<td>Dynamic Right TFJt angle (shod) (°)</td>
<td>165.47 (±6.20)</td>
<td>164.82 (±4.39)</td>
<td>t (98) = 0.60, p = 0.54</td>
</tr>
</tbody>
</table>

Table 5.2. Static and Dynamic TFJt angles for the treatment and control group at baseline for the right and left limb.
5.3.1 Patient Centred Outcome Score

Pain scores: mean group differences over time

Pain scores in the groups were recorded using the self-administered KOOS questionnaire. The pain scores at the four time points (0, 3, 6 and 12 weeks) for the treatment and control group are presented in figure 5.1.

When a repeated measures ANOVA was used, it was determined that there were no significant differences between the two groups (p=0.675). However, significant differences were recorded within each group over time (p<0.01). The difference in treatment pain scores over 3 months was 11.9 while for the control group, this was 5.62. The mean percentage increase in the treatment group was 14.9%, while in the control group it was 7.5%. In the treatment group, there was a significant improvement in pain scores between baseline and 3 weeks (p<0.05, p=0.03); baseline and 6 weeks (p<0.05, p=0.001) and baseline and 12 weeks (p<0.05, p=0.001). While pain reduced over time, there was no significant reduction between 6 weeks and 12 weeks (p>0.05). In the control group, there were significant improvements in pain scores between baseline and 3 weeks (p<0.05, p=0.037); baseline and 6 weeks (p<0.05, p=0.004) and baseline and 12 weeks (p<0.05, p=0.038). The biggest reduction in pain occurred between baseline and 3 weeks while between 3 weeks to 12 weeks there was no significant change (p>0.05).

When considering the MIC for pain, there was a clinically significant improvement in pain scores in the treatment group and not in the control group.

![KOOS Pain Subscale](image)

Figure 5.1. KOOS Pain scores in the treatment and control group at baseline, 3 weeks, 6 weeks and 12 weeks.
When the pain scores of the treatment and control group were analysed within the context of foot posture and static BOG, the results were not significant (p>0.05) indicating that there was no effect of static foot posture (p = 0.09) or static BOG (p = 0.53) on pain scores at baseline.

**Health related quality of life: mean group differences over time**

**Symptoms:**
The KOOS questionnaire also produced data on four other aspects of quality of life: symptoms, activities of daily living (ADL), recreation and overall quality of life (QoL). The symptom scores at the four time points for the treatment and control group are presented in figure 5.2.

A repeated measures ANOVA found no significant differences between the treatment group and the control group at the p<0.05 level (p=0.26). There were significant differences noted within the treatment and control groups over time. The difference in treatment symptom scores over 3 months was 9.86 and in control symptom scores were 6.29. The mean percentage increase in the treatment group was 12.4%, while in the control group it was 8.5%. There was a significant improvement in the symptom score in the treatment group between baseline and 3 weeks (p<0.05, p=0.002), baseline and 6 weeks (p<0.05, p=0.001) and baseline and 12 weeks (p<0.05, p=0.01). Significant changes occurred between baseline and 3 weeks and not between subsequent time points. There were significant improvements in the symptom score of the control group between baseline and 3 weeks (p<0.05, p=0.006); baseline and 6 weeks (p<0.05, p=0.001) and baseline and 12 weeks (p<0.05, p=0.019). The most significant improvement in symptoms experienced occurred between baseline and 3 weeks.

When considering the MIC for symptom improvement, there was a clinically significant improvement in pain scores in the treatment group and not in the control group.
When symptom scores of the treatment and control group were analysed within the context of foot posture and static BOG, there were no significant differences indicating there was no effect of static foot posture (p = 0.76) or static BOG (p = 0.63) over time.

**Activities of Daily Living**

The activities of daily living (ADL) score was also analysed for difference between the treatment and control groups. The mean ADL scores are presented in figure 5.3. There was no significant difference between the two groups at the p<0.05 level with p=0.433. However, there were significant improvements in the ability to perform activities of daily living such as climbing stairs or getting into and out of bed. In the treatment ADL, there was a mean difference of 9.96 over 3 months while in the control group there was a mean difference of 7.92. The mean percentage increase in the treatment group was 12.12%, while in the control group it was 10.06%. In the treatment group, there was a significant improvement between baseline and 3 weeks (p<0.05, p=0.023); baseline and 6 weeks (p<0.05, p=0.001) and baseline and 12 weeks (p<0.05, p=0.001). The most significant improvement in ADL for both the treatment and control group was noted between baseline and 3 weeks. In the control group, there were also significant improvements between baseline and 3 weeks (p<0.05,
p=0.01); baseline and 6 weeks (p<0.05, p=0.002) and baseline and 12 weeks (p<0.05, p=0.004).

When considering the MIC for ADL, there was a clinically significant improvement in pain scores in the treatment group and not in the control group.

![KOOS ADL Subscale](image)

**Figure 5.3.** Treatment and Control mean values for KOOS ADL subscale at baseline, 3 weeks, 6 weeks and 12 weeks.

When ADL scores of the treatment and control group were analysed within the context of foot posture and static BOG, there were no significant differences suggesting there was no effect of static foot posture (p = 0.67) or static BOG (p = 0.99) over time.

**Recreational Activities**

The recreational activities score determines the ability of an individual to perform function, sport and recreational abilities. This data is presented in figure 5.4. There were no significant differences between the treatment group and the control group at the p<0.05 level (p=0.73). In the treatment recreational scores, there was a difference of 16.94 compared to the control group’s 11.98. The mean percentage increase in the treatment group was 22.04%, while in the control group it was 16.14%. With the treatment orthoses, there were significant improvements in the KOOS recreation subscale outcome between baseline and 3 weeks.
(p<0.05, p=0.001); baseline and 6 weeks (p<0.05, p=0.001) and baseline and 12 weeks (p<0.05, p=0.001). With the control orthoses, there were also significant improvements compared to baseline at 3 weeks (p<0.05, p=0.004), at 6 weeks (p<0.05, p=0.005) and at 12 weeks (p<0.05, p=0.001). The most significant differences for both groups were between baseline and 3 weeks.

When considering the MIC for recreational activities, there was a clinically significant improvement in pain scores in the treatment group and in the control group.

![KOOS Recreation Subscale graph](image)

**Figure 5.4** Treatment and Control group changes in recreational activities at baseline, 3 weeks, 6 weeks and 12 weeks.

When symptom scores of the treatment and control group were analysed within the context of foot posture and static BOG, there were no significant differences indicating there was no effect of static foot posture (p = 0.84) or static BOG (p = 0.98) over time.

**Quality of Life**

The final subsection of the KOOS questionnaire is the quality of life (QoL) measures. There were no significant differences between the treatment and control group at the p<0.05 level (p=0.48). There was greatest improvement in the treatment group over 3 months with a mean QoL score difference of 20.48 and for the control group the score was 6.98. The mean percentage increase in the treatment group was 26.02%, while in the control group it was
9.9%. The mean values are presented in figure 5.5. In the treatment group, there were significant improvements in the QoL between baseline and 3 weeks (p<0.05, p=0.001), baseline and 6 weeks (p<0.05, p=0.001) and baseline and 12 weeks (p<0.05, p=0.001). The significant improvement in QoL for the treatment group was noted for 6 weeks. In the control group, there were significant QoL improvements too between baseline and 3 weeks (p<0.05, p=0.002), baseline and 6 weeks (p<0.05, p=0.001) and baseline and 12 weeks (p<0.05, p=0.023). The QoL was significantly improved between baseline and 3 weeks and did not further improve beyond this time point.

When considering the MIC for overall QoL, there was a clinically significant improvement in pain scores in the treatment group and not in the control group.

![Figure 5.5](chart.png)

**Figure 5.5** Treatment and Control group changes in QoL at baseline, 3 weeks and 6 weeks.

When symptom scores of the treatment and control group were analysed within the context of foot posture and static BOG, there were no significant differences indicating there was no effect of static foot posture (p = 0.65) or static BOG (p = 0.81) over time.
5.3.2 In-Shoe Plantar Pressure Measurements

The in-shoe plantar pressure data was analysed using a repeated measures ANOVA with a two by four method using time points and mask regions (1-4) as the within subject variables and group allocation (treatment or control) as the between subject factor. Although the right limb was dominant in 99% of the cohort and 90% of the participants presented with OA being worse in the right knee, inter-limb analysis was conducted using an ANOVA followed by paired sample t-test to determine if there were differences between the left and right limb for each participant. The data was also tested for equality of variances in order to assume homogeneity of variance in the inter-limb analyses. The results were statistically non-significant (p>0.05) indicating that there was equal variance.

The results of the ANOVA found that there were differences in the left and right foot at baseline in the treatment group (p = 0.01) but not in the control group (p=0.60). The significant differences in the treatment group were identified. The results for the treatment group at baseline are presented in Table 5.3.
<table>
<thead>
<tr>
<th>Treatment Pairs (Parameter, Foot and Mask) N=52</th>
<th>Mean</th>
<th>Standard Deviation (±SD)</th>
<th>Std. Error of the Mean</th>
<th>t (df) = , p =</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Left</td>
<td>Right</td>
<td>Left</td>
<td>Right</td>
</tr>
<tr>
<td>CALeft1– CARight1</td>
<td>15.13</td>
<td>20.99</td>
<td>2.85</td>
<td>3.10</td>
</tr>
<tr>
<td>CALeft2– CARight2</td>
<td>15.43</td>
<td>20.69</td>
<td>1.81</td>
<td>3.09</td>
</tr>
<tr>
<td>CALeft3– CARight3</td>
<td>20.03</td>
<td>19.44</td>
<td>6.30</td>
<td>6.48</td>
</tr>
<tr>
<td>CALef4 – CARight4</td>
<td>28.64</td>
<td>27.66</td>
<td>6.98</td>
<td>6.37</td>
</tr>
<tr>
<td>PPLeft1 – PPRight1</td>
<td>198.61</td>
<td>198.57</td>
<td>43.72</td>
<td>42.96</td>
</tr>
<tr>
<td>PPLeft2 – PPRight2</td>
<td>216.65</td>
<td>234.19</td>
<td>36.75</td>
<td>71.17</td>
</tr>
<tr>
<td>PPLeft3 – PPRight3</td>
<td>177.88</td>
<td>175.97</td>
<td>77.00</td>
<td>70.56</td>
</tr>
<tr>
<td>PPLeft4 – PPRight4</td>
<td>156.99</td>
<td>147.58</td>
<td>54.55</td>
<td>53.62</td>
</tr>
<tr>
<td>CTLLeft1 – CTRight1</td>
<td>621.95</td>
<td>651.89</td>
<td>311.35</td>
<td>214.44</td>
</tr>
<tr>
<td>CTLleft2 – CTRight2</td>
<td>631.15</td>
<td>658.46</td>
<td>306.38</td>
<td>232.37</td>
</tr>
<tr>
<td>CTLleft3 – CTRight3</td>
<td>657.11</td>
<td>639.98</td>
<td>310.95</td>
<td>185.07</td>
</tr>
<tr>
<td>CTLleft4 – CTRight4</td>
<td>687.05</td>
<td>690.57</td>
<td>312.73</td>
<td>185.53</td>
</tr>
<tr>
<td>PTILeft1– PTIRight1</td>
<td>66.47</td>
<td>67.97</td>
<td>26.04</td>
<td>21.00</td>
</tr>
<tr>
<td>PTILeft1– PTIRight1</td>
<td>73.35</td>
<td>89.08</td>
<td>24.55</td>
<td>68.54</td>
</tr>
<tr>
<td>PTILeft1– PTIRight1</td>
<td>64.19</td>
<td>63.63</td>
<td>26.93</td>
<td>33.15</td>
</tr>
<tr>
<td>PTILeft1– PTIRight1</td>
<td>76.06</td>
<td>67.34</td>
<td>71.68</td>
<td>32.35</td>
</tr>
</tbody>
</table>
The differences were subsequently analysed at 3 weeks, 6 weeks and 12 weeks in the treatment group for the specific parameters, contact area 1 and 2 (medial and lateral rearfoot); peak pressure 2 (lateral rearfoot); force-time integral 1 and 2 (medial and lateral rearfoot). These results for the treatment group over the 12 weeks are presented in Table 5.4.

### Table 5.3

<table>
<thead>
<tr>
<th>Treatment Pairs (Time Point, Parameter, Foot and Mask)</th>
<th>Mean</th>
<th>Standard Deviation (±SD)</th>
<th>Std. Error of the Mean</th>
<th>t (df) = , p =</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Left</td>
<td>Right</td>
<td>Left</td>
<td>Right</td>
</tr>
<tr>
<td>3 weeks</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CΑLeft1–CΑRight1</td>
<td>15.17</td>
<td>20.05</td>
<td>2.14</td>
<td>3.49</td>
</tr>
<tr>
<td>CΑLeft2–CΑRight2</td>
<td>15.03</td>
<td>19.28</td>
<td>1.72</td>
<td>3.71</td>
</tr>
<tr>
<td>PPLLeft2 – PPRight2</td>
<td>240.65</td>
<td>239.43</td>
<td>63.66</td>
<td>54.07</td>
</tr>
<tr>
<td>FTILeft1–FTIRight1</td>
<td>7.78</td>
<td>9.51</td>
<td>6.11</td>
<td>4.09</td>
</tr>
<tr>
<td>FTILeft2–FTIRight2</td>
<td>10.11</td>
<td>11.08</td>
<td>7.52</td>
<td>5.08</td>
</tr>
<tr>
<td>6 weeks</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CΑLeft1–CΑRight1</td>
<td>14.42</td>
<td>19.14</td>
<td>1.96</td>
<td>3.48</td>
</tr>
</tbody>
</table>

Table 5.3. The mean values, SD, and Standard error of mean and t-test results for the treatment group at baseline (CA: contact area; PP: peak pressure; CT: contact time; PTI: pressure-time integral; FTI: force-time integral) masks. (Mask 1: medial rearfoot, Mask 2: lateral rearfoot, Mask 3: medial midfoot, Mask 4: lateral midfoot)
The results of the inter-limb analysis showed consistently higher values for the right dominant OA limb compared to the left limb. As the right limb was dominant in 99% of participants with 90% presenting with worse medial TFJt OA symptoms in the right limb too, this limb was isolated for further evaluation. The results were analysed for significant differences between the treatment and control group over time and were then explored within the context of static foot posture and static BOG. These will now be presented.

Contact Area (cm$^2$)

The mean values for contact area (CA) for the right foot in the treatment and control group over the 3 month period are presented in table 5.5. When these were analysed for significant
differences using repeated measures ANOVA’s, there was no difference in the groups over time (p =0.46) and no significant differences in masks between the groups (p = 0.50), but there was a significant difference between the CA in each mask over three months (p<0.01).

<table>
<thead>
<tr>
<th>CA (cm²)</th>
<th>Treatment Mask 1 Mean (±SD)</th>
<th>Treatment Mask 2</th>
<th>Treatment Mask 3</th>
<th>Treatment Mask 4</th>
<th>Control Mask 1 Mean (±SD)</th>
<th>Control Mask 2</th>
<th>Control Mask 3</th>
<th>Control Mask 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>20.66 ±3.13</td>
<td>19.79 ±3.29</td>
<td>17.91 ±6.31</td>
<td>25.4 ±7.4</td>
<td>20.29 ±3.30</td>
<td>19.57 ±3.08</td>
<td>17.78 ±7.14</td>
<td>25.30 ±7.09</td>
</tr>
<tr>
<td>3 weeks</td>
<td>20.05 ±3.49</td>
<td>19.28 ±3.71</td>
<td>17.92 ±5.22</td>
<td>26.32 ±7.05</td>
<td>19.00 ±3.37</td>
<td>18.14 ±3.23</td>
<td>17.44 ±7.01</td>
<td>24.35 ±6.32</td>
</tr>
<tr>
<td>12 weeks</td>
<td>16.61 ±2.87</td>
<td>15.21 ±2.41</td>
<td>18.65 ±5.62</td>
<td>25.60 ±7.21</td>
<td>17.01 ±3.73</td>
<td>15.9 ±3.38</td>
<td>17.22 ±6.96</td>
<td>22.65 ±7.01</td>
</tr>
</tbody>
</table>

**Table 5.5.** The mean CA values for the treatment and control group over 12 weeks.

When this difference was further explored using Tukey’s post-hoc analysis, the results showed that in the treatment group, this effect was significant (p=0.001) compared to the control group (p=0.19). The results over time in the treatment group are presented in Table 5.6.

The most significant differences were noted in the rearfoot regions (Masks 1 and 2) with a highly significant decrease in medial rearfoot CA from baseline to 12 weeks and between 3 weeks and 12 weeks and 6 weeks and 12 weeks. In the lateral rearfoot, the CA also decreased significantly from baseline to 6 weeks and baseline to 12 weeks. This suggests overall reduced CA in the rearfoot when participants were wearing the orthoses with self-selected footwear.
<table>
<thead>
<tr>
<th>Mask</th>
<th>Timepoints</th>
<th>Tukey’s post-hoc (Significance, p value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medial Rearfoot (Mask 1)</td>
<td>0 weeks – 12 weeks</td>
<td>0.08</td>
</tr>
<tr>
<td></td>
<td>3 weeks – 6 weeks</td>
<td>0.01*</td>
</tr>
<tr>
<td></td>
<td>6 weeks – 12 weeks</td>
<td>0.0001*</td>
</tr>
<tr>
<td>Lateral Rearfoot (Mask 2)</td>
<td>0 weeks – 12 weeks</td>
<td>0.09</td>
</tr>
<tr>
<td></td>
<td>3 weeks – 6 weeks</td>
<td>0.06</td>
</tr>
<tr>
<td></td>
<td>6 weeks – 12 weeks</td>
<td>0.0001*</td>
</tr>
<tr>
<td>Medial Midfoot (Mask 3)</td>
<td>0 weeks – 12 weeks</td>
<td>0.252</td>
</tr>
<tr>
<td></td>
<td>3 weeks – 12 weeks</td>
<td>0.539</td>
</tr>
<tr>
<td></td>
<td>6 weeks – 12 weeks</td>
<td>0.225</td>
</tr>
<tr>
<td>Lateral Midfoot (Mask 4)</td>
<td>0 weeks – 12 weeks</td>
<td>0.119</td>
</tr>
<tr>
<td></td>
<td>3 weeks – 12 weeks</td>
<td>0.97</td>
</tr>
<tr>
<td></td>
<td>6 weeks – 12 weeks</td>
<td>0.31</td>
</tr>
</tbody>
</table>

**Table 5.6.** Tukey’s post hoc analysis of the treatment group with differences over time in contact area.
**Peak Pressure (kPa)**

The mean values for peak pressures (PP) for the treatment and control group are presented in Table 5.7. When these were analysed for significant differences using repeated measures ANOVA’s, there was no difference in the groups over time (p =0.893) and no significant differences in masks between the groups (p = 0.135), but there was a significant difference between the PP in each mask over three months (p<0.01).

<table>
<thead>
<tr>
<th>PP (kPa)</th>
<th>Treatment Mask 1 Mean (±SD)</th>
<th>Treatment Mask 2</th>
<th>Treatment Mask 3</th>
<th>Treatment Mask 4</th>
<th>Control Mask 1 Mean(±SD)</th>
<th>Control Mask 2</th>
<th>Control Mask 3</th>
<th>Control Mask 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>204.07 ±47.71</td>
<td>229.34 ±76.02</td>
<td>159.32 ±79.42</td>
<td>158.58 ±67.64</td>
<td>191.11 ±36.03</td>
<td>191.22 ±37.35</td>
<td>159.83 ±80.94</td>
<td>148.87 ±54.99</td>
</tr>
<tr>
<td>3 weeks</td>
<td>214.66 ±44.45</td>
<td>239.43 ±54.07</td>
<td>160.13 ±86.20</td>
<td>163.65 ±71.51</td>
<td>193.73 ±34.95</td>
<td>201.05 ±43.01</td>
<td>148.57 ±67.37</td>
<td>150.24 ±66.65</td>
</tr>
<tr>
<td>6 weeks</td>
<td>211.51 ±52.80</td>
<td>201.43 ±73.56</td>
<td>164.07 ±83.30</td>
<td>183.30 ±88.21</td>
<td>193.38 ±45.30</td>
<td>186.79 ±53.44</td>
<td>155.56 ±74.01</td>
<td>153.59 ±68.9</td>
</tr>
<tr>
<td>12 weeks</td>
<td>221.93 ±71.25</td>
<td>242.90 ±65.67</td>
<td>177.73 ±114.73</td>
<td>159.29 ±65.60</td>
<td>200.87 ±43.03</td>
<td>222.27 ±58.02</td>
<td>147.35 ±81.71</td>
<td>162.39 ±77.29</td>
</tr>
</tbody>
</table>

*Table 5.7* The mean PP values in the treatment and control group over 12 weeks.

When this difference was further explored using Tukey’s post-hoc analysis, the results showed that in the treatment group, this effect was non-significant (p=0.15) compared to the control group (p=0.03). The results over time in the control group are presented in Table 5.8.

The most significant differences were noted in the lateral rearfoot regions (Mask 2) with a highly significant increase in PP between baseline to 12 weeks and between 3 weeks and 12 weeks and 6 weeks and 12 weeks. In the medial midfoot, the PP also decreased significantly from baseline to 3 weeks but there were no significant differences between subsequent time points. PP in the lateral rearfoot was significantly increased in OA participants with the neutral orthoses compared with the LWO treatment group suggesting the LWO could have prevented an increase in lateral rearfoot PP, thus maintaining an offloading effect on the lateral rearfoot.
<table>
<thead>
<tr>
<th>Medial Rearfoot (Mask 1)</th>
<th>Tukey’s post-hoc (Significance, p value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 weeks - 3 weeks - 6 weeks - 12 weeks</td>
<td>0.37 0.11 0.07</td>
</tr>
<tr>
<td>3 weeks - 6 weeks - 12 weeks</td>
<td>0.53 0.23</td>
</tr>
<tr>
<td>6 weeks - 12 weeks</td>
<td>0.56</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Lateral Rearfoot (Mask 2)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>0 weeks - 3 weeks - 6 weeks - 12 weeks</td>
<td>0.01* 0.92 0.0001*</td>
</tr>
<tr>
<td>3 weeks - 6 weeks - 12 weeks</td>
<td>0.10 0.002*</td>
</tr>
<tr>
<td>6 weeks - 12 weeks</td>
<td>0.001*</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Medial Midfoot (Mask 3)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>0 weeks - 3 weeks - 6 weeks - 12 weeks</td>
<td>0.02* 0.18 0.64</td>
</tr>
<tr>
<td>3 weeks - 6 weeks - 12 weeks</td>
<td>0.43 0.96</td>
</tr>
<tr>
<td>6 weeks - 12 weeks</td>
<td>0.48</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Lateral Midfoot (Mask 4)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>0 weeks - 3 weeks - 6 weeks - 12 weeks</td>
<td>0.52 0.58 0.19</td>
</tr>
<tr>
<td>3 weeks - 6 weeks - 12 weeks</td>
<td>0.96 0.46</td>
</tr>
<tr>
<td>6 weeks - 12 weeks</td>
<td>0.54</td>
</tr>
</tbody>
</table>

**Table 5.8** Tukey’s post hoc analysis of the treatment group with differences over time in peak pressure.
Contact Time (ms)

The mean values for contact time (CT) for the treatment and control group are presented in Table 5.9. When these were analysed for significant differences using repeated measures ANOVA’s, there was no difference in the groups over time (p =0.127), no significant differences in masks between the groups (p = 0.663) and no significant differences between the PP in each mask over three months (p=0.16).

![Table 5.9. The mean CT values in the treatment and control group over 12 weeks](image-url)
**Pressure Time Integral (kPa/sec)**

The mean values for pressure-time integrals (PTI) for the treatment and control group are presented in Table 5.10. When these were analysed for significant differences using repeated measures ANOVA’s, there was no difference in the groups over time (p = 0.202), no significant differences in masks between the groups (p = 0.206) and no significant differences between the PP in each mask over three months (p=0.08).

<table>
<thead>
<tr>
<th>PTI (kPa/sec)</th>
<th>Treatment Mask 1 Mean (±SD)</th>
<th>Treatment Mask 2</th>
<th>Treatment Mask 3</th>
<th>Treatment Mask 4</th>
<th>Treatment Mask 1 Mean (±SD)</th>
<th>Control Mask 2</th>
<th>Control Mask 3</th>
<th>Control Mask 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>78.80 ±49.91</td>
<td>96.81 ±108.09</td>
<td>67.26 ±51.51</td>
<td>103.71 ±231.16</td>
<td>66.14 ±19.40</td>
<td>66.82 ±22.57</td>
<td>59.18 ±30.32</td>
<td>67.00 ±41.88</td>
</tr>
<tr>
<td>3 weeks</td>
<td>73.99 ±38.25</td>
<td>85.85 ±48.08</td>
<td>62.79 ±42.98</td>
<td>95.58 ±158.86</td>
<td>70.78 ±43.41</td>
<td>77.05 ±65.32</td>
<td>61.09 ±58.69</td>
<td>84.04 ±144.2</td>
</tr>
<tr>
<td>6 weeks</td>
<td>75.75 ±51.94</td>
<td>76.60 ±46.17</td>
<td>56.15 ±31.87</td>
<td>70.22 ±47.48</td>
<td>74.63 ±62.59</td>
<td>66.75 ±37.04</td>
<td>56.70 ±31.51</td>
<td>93.04 ±213.1</td>
</tr>
<tr>
<td>12 weeks</td>
<td>102.28 ±107.58</td>
<td>141.55 ±188.74</td>
<td>77.73 ±79.35</td>
<td>86.11 ±61.95</td>
<td>75.73 ±59.25</td>
<td>96.64 ±118.3</td>
<td>53.69 ±31.58</td>
<td>72.37 ±54.39</td>
</tr>
</tbody>
</table>

**Table 5.10.** The mean PTI values in the treatment and control group over 12 weeks.
Force Time Integral (N/sec)
The mean values for force time integrals (FTI’s) for the treatment and control group are presented in Table 5.11. When these were analysed for significant differences using repeated measures ANOVA’s, there was no difference in the groups over time (p =0.64) and no significant differences in masks between the groups (p = 0.63), but there was a significant difference between the PP in each mask over three months (p=0.01).

<table>
<thead>
<tr>
<th>FTI (N/sec)</th>
<th>Treatment Mask 1 Mean (±SD)</th>
<th>Treatment Mask 2</th>
<th>Treatment Mask 3</th>
<th>Treatment Mask 4</th>
<th>Control Mask 1 Mean(±SD)</th>
<th>Control Mask 2</th>
<th>Control Mask 3</th>
<th>Control Mask 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>10.68 ±6.08</td>
<td>11.70 ±8.16</td>
<td>4.99 ±4.21</td>
<td>12.16 ±23.96</td>
<td>10.10 ±2.94</td>
<td>9.55 ±3.52</td>
<td>4.60 ±2.87</td>
<td>8.46 ±5.19</td>
</tr>
<tr>
<td>3 weeks</td>
<td>9.51 ±4.09</td>
<td>11.08 ±5.08</td>
<td>4.19 ±3.12</td>
<td>10.60 ±15.34</td>
<td>9.92 ±6.02</td>
<td>10.45 ±8.19</td>
<td>4.28 ±3.42</td>
<td>9.36 ±10.95</td>
</tr>
<tr>
<td>6 weeks</td>
<td>19.50 ±30.18</td>
<td>9.58 ±4.63</td>
<td>5.06 ±4.16</td>
<td>6.77 ±4.76</td>
<td>12.77 ±15.96</td>
<td>8.90 ±5.52</td>
<td>4.49 ±3.11</td>
<td>9.12 ±18.29</td>
</tr>
<tr>
<td>12 weeks</td>
<td>11.08 ±12.23</td>
<td>12.98 ±13.37</td>
<td>5.73 ±7.75</td>
<td>10.15 ±8.67</td>
<td>9.56 ±6.63</td>
<td>9.84 ±7.72</td>
<td>4.04 ±3.20</td>
<td>8.5 ±7.43</td>
</tr>
</tbody>
</table>

Table 5.11. The mean FTI values in the treatment and control group over 12 weeks

When this difference was further explored using Tukey’s post-hoc analysis, the results showed that in the treatment group, this effect was significant at the 0.05 level compared to the control group (p=0.35). These results over time in the treatment group are presented in Table 5.12.

The most significant differences were noted in the medial rearfoot region (Mask 1) with a highly significant increase in FTI from 3 weeks to 6 weeks of the study (p=0.03) and in the lateral rearfoot (Mask 2) there were significant differences in FTI between 6 weeks and 12 weeks (p=0.04). Finally, there was also a significant increase between 6 weeks and 12 weeks in the lateral midfoot region (p=0.007).
<table>
<thead>
<tr>
<th>Mask</th>
<th>Time Period</th>
<th>Tukey’s post-hoc (Significance, p value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medial Rearfoot (Mask 1)</td>
<td>0 weeks – 3 weeks</td>
<td>0.15</td>
</tr>
<tr>
<td></td>
<td>- 6 weeks</td>
<td>0.06</td>
</tr>
<tr>
<td></td>
<td>- 12 weeks</td>
<td>0.80</td>
</tr>
<tr>
<td></td>
<td>3 weeks - 6 weeks</td>
<td>0.03*</td>
</tr>
<tr>
<td></td>
<td>- 12 weeks</td>
<td>0.32</td>
</tr>
<tr>
<td></td>
<td>6 weeks - 12 weeks</td>
<td>0.08</td>
</tr>
<tr>
<td>Lateral Rearfoot (Mask 2)</td>
<td>0 weeks – 3 weeks</td>
<td>0.57</td>
</tr>
<tr>
<td></td>
<td>- 6 weeks</td>
<td>0.08</td>
</tr>
<tr>
<td></td>
<td>- 12 weeks</td>
<td>0.53</td>
</tr>
<tr>
<td></td>
<td>3 weeks - 6 weeks</td>
<td>0.08</td>
</tr>
<tr>
<td></td>
<td>- 12 weeks</td>
<td>0.34</td>
</tr>
<tr>
<td></td>
<td>6 weeks - 12 weeks</td>
<td>0.04*</td>
</tr>
<tr>
<td>Medial Midfoot (Mask 3)</td>
<td>0 weeks – 3 weeks</td>
<td>0.17</td>
</tr>
<tr>
<td></td>
<td>- 6 weeks</td>
<td>0.20</td>
</tr>
<tr>
<td></td>
<td>- 12 weeks</td>
<td>0.19</td>
</tr>
<tr>
<td></td>
<td>3 weeks - 6 weeks</td>
<td>0.20</td>
</tr>
<tr>
<td></td>
<td>- 12 weeks</td>
<td>0.19</td>
</tr>
<tr>
<td></td>
<td>6 weeks - 12 weeks</td>
<td>0.46</td>
</tr>
<tr>
<td>Lateral Midfoot (Mask 4)</td>
<td>0 weeks – 3 weeks</td>
<td>0.73</td>
</tr>
<tr>
<td></td>
<td>- 6 weeks</td>
<td>0.15</td>
</tr>
<tr>
<td></td>
<td>- 12 weeks</td>
<td>0.60</td>
</tr>
<tr>
<td></td>
<td>3 weeks - 6 weeks</td>
<td>0.09</td>
</tr>
<tr>
<td></td>
<td>- 12 weeks</td>
<td>0.85</td>
</tr>
<tr>
<td></td>
<td>6 weeks - 12 weeks</td>
<td>0.007*</td>
</tr>
</tbody>
</table>

**Table 5.12.** Tukey’s post hoc analysis of the treatment group with differences over time in FTI.
5.3.3 The Influence of Foot Posture

When the key plantar pressure parameters were analysed within the context of foot posture based on FPI-6 scores using multivariate analyses, there were no significant effects of foot posture on the parameters over time (p= 0.80) or effect of foot posture on regional masks between treatment and control groups (p=0.70). When static BOG was included in the multivariate analyses, there were no significant effects of static BOG on the parameters over time (p=0.84) or effect of static BOG on regional masks between the treatment and control groups (p=0.55).

5.3.4 The Influence of Footwear

The in-shoe plantar pressure measurements were recorded in neutral Donnay trainers and self-selected footwear that participants wore consistently through the 12 weeks study and whose use was recorded with a footwear diary. The type of footwear worn by participants in both the treatment and control groups are presented in pie chart 1. The type of footwear worn by the treatment group and control are presented in Table 5.13. The average age of the shoes was 9 months while the predominant composition of the shoe uppers was leather (77%) and the rest were synthetics (23%) and the outsole was made from rubber in 99% of footwear with 1% being a plastic sole. 94% of shoes did not have an elevated heel counter, while 1% had a heel height of 0.5 centimetres, 4% had a heel height of 1 centimetre and 1 had a heel height of 2 centimetres. There were no significant difference in footwear characteristics between the treatment and control group for age of shoe (F (99) = 0.05, p = 0.81) or the heel height (F(99) = 0.63, p = 0.43) using independent samples t-test.

<table>
<thead>
<tr>
<th>Footwear Type</th>
<th>Treatment</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Walking Shoe</td>
<td>26</td>
<td>25</td>
</tr>
<tr>
<td>Athletic Shoe</td>
<td>8</td>
<td>8</td>
</tr>
<tr>
<td>Oxford Shoe</td>
<td>5</td>
<td>1</td>
</tr>
<tr>
<td>Moccasin</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Boot</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Court Shoe</td>
<td>10</td>
<td>12</td>
</tr>
</tbody>
</table>

Table 5.13. Footwear type worn in the treatment and control groups during the RCT.
**Donnay Trainers versus Self-selected Footwear**

When an ANOVA was conducted, it was established that there was an effect of footwear (Donnay and self-selected) on plantar pressure parameters \((p = 0.06)\), but no significant effect of shoe types (walking, athletic, oxford, court shoe, etc) on key parameters and specific anatomical masks \((p = 0.54)\).

The relationship between footwear and plantar pressure was further explored using Tukey’s post-hoc analysis for specific differences. Table 5.14 presents the mean CA, PP, CT, PTI and FTI in the neutral Donnay trainers and self-selected footwear along with the results of the post-hoc analysis showing an effect of footwear on CA in both groups.

<table>
<thead>
<tr>
<th>Footwear Type</th>
<th>Contact Area (Std. Error) (cm²)</th>
<th>Peak Pressure (Std. Error) (kPa)</th>
<th>Contact Time (Std. Error) (ms)</th>
<th>Pressure-Time Integral (Std. Error) (kPa/sec)</th>
<th>Force-Time Integral (Std. Error) (N/Sec)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Donnay and Orthotic (n=100)</td>
<td>21.88 (0.45)</td>
<td>183.73 (4.14)</td>
<td>647.215 (17.78)</td>
<td>69.38 (3.01)</td>
<td>8.65 (0.30)</td>
</tr>
<tr>
<td>Self-Selected and Orthotic (n=100)</td>
<td>20.95 (0.44)</td>
<td>181.74 (4.89)</td>
<td>735.20 (60.59)</td>
<td>77.03 (7.34)</td>
<td>9.11 (0.78)</td>
</tr>
</tbody>
</table>

Table 5.14. Plantar pressure parameters in Donnay and orthotic and Self-selected footwear and orthotic showing a significant difference in contact area.

The results were further analysed within the context of specific anatomical masks, and the results showed that there were significant differences in CA of mask 2 (lateral rearfoot, \(p = 0.05\)), mask 3 (medial midfoot, \(p = 0.002\)) and mask 4 (lateral midfoot, \(p = 0.002\)) with greater CA in the neutral Donnay trainers compared with own footwear in each of these masks. A significant effect of footwear was also noted in mask 3 (medial midfoot, \(p = 0.04\)) with a greater PP in the neutral Donnay trainers compared with own footwear.
Footwear in Treatment Group compared with Control Group

When footwear was further analysed between the two intervention groups using an ANOVA with footwear style and masks as variables, the results found that there was significant differences in the CA of the treatment group (p=0.02) but not in the control group (p=0.42). As a significant difference was found in the treatment group, a post hoc analysis was conducted in order to determine the specific anatomical foot regions where the CA was different i.e. masks. The results of the treatment group CA were therefore further analysed using post-hoc analysis and these results are presented in Table 5.15.

<table>
<thead>
<tr>
<th>Footwear Style</th>
<th>N number</th>
<th>Mean</th>
<th>Standard Error of Mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>Walking</td>
<td>26</td>
<td>21.17</td>
<td>0.653</td>
</tr>
<tr>
<td>Athletic/Trainer</td>
<td>8</td>
<td>23.74</td>
<td>1.38</td>
</tr>
<tr>
<td>Oxford Shoe</td>
<td>5</td>
<td>17.66</td>
<td>1.69</td>
</tr>
<tr>
<td>Moccasin</td>
<td>1</td>
<td>20.24</td>
<td>1.32</td>
</tr>
<tr>
<td>Boot</td>
<td>2</td>
<td>24.37</td>
<td>2.40</td>
</tr>
<tr>
<td>Court Shoe</td>
<td>10</td>
<td>21.19</td>
<td>1.07</td>
</tr>
</tbody>
</table>

Table 5.15. Mean CA for each footwear style in the treatment group.

The results showed significant differences in mask 3 (medial midfoot) where trainers had the greatest CA in athletic/trainer style footwear compared to walking shoes (p<0.01), oxford style shoes (p<0.01) and court shoes (p<0.01) but not boots (p=0.06) or moccasin shoes (p=0.32). There were no differences in the control group when footwear was used as a variable. The results suggest that in the treatment group, the LWOs and footwear had an effect on CA in the medial midfoot suggesting that footwear styles could influence in-shoe loading patterns and subsequent loading of the medial TFJt.

When the results of the treatment and control group were analysed using footwear and the KOOS outcome scores (pain, symptoms, activity of daily living, recreation and overall quality of life), the results found no significant effect of footwear (p=0.74) and no interaction between KOOS scores, treatment and control group and footwear style (p=0.82). When time
(baseline, 3, 6 and 12 weeks) were added as variables, there was a non-significant interaction (p=0.48). The KOOS outcome scores for the treatment and control group for each footwear style over time has been included in Appendix 14.

**Walking Speed**

The walking speed in the treatment and control group are presented in Table 5.16 at baseline, 3 weeks, 6 weeks and 12 weeks. When a repeated measures ANOVA was conducted, there was a significant effect of time (p=0.0001) and a significant difference between treatment and control groups (p=0.0001).

<table>
<thead>
<tr>
<th>Time point</th>
<th>Treatment walking speed (seconds)</th>
<th>Control walking speed (seconds)</th>
<th>Repeated Measures ANOVA significance</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean (±SD)</td>
<td>Mean (±SD)</td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>8.84 (±1.81)</td>
<td>9.47 (±2.37)</td>
<td>0.14</td>
</tr>
<tr>
<td>3 weeks</td>
<td>7.82 (±1.66)</td>
<td>9.20 (±2.39)</td>
<td>0.001*</td>
</tr>
<tr>
<td>6 weeks</td>
<td>7.73 (±1.58)</td>
<td>9.26 (±2.24)</td>
<td>0.0001*</td>
</tr>
<tr>
<td>12 weeks</td>
<td>7.77 (±1.59)</td>
<td>9.32 (±2.33)</td>
<td>0.0001*</td>
</tr>
</tbody>
</table>

Table 5.16 The mean walking speed in the treatment and control group with results of the repeated measures ANOVA.

The post-hoc results demonstrated that in the treatment group, there were significant reductions in walking speed from baseline to 3 weeks, 6 weeks and 12 weeks (p=0.0001). In the control group, the results demonstrated that there was a significant reduction in walking speed from baseline to 3 weeks (p=0.003), but not subsequently at 6 weeks (p=0.05) and 12 weeks (p=0.14).

**Compliance and Medication Usage**

Through the 3 month course of the RCT, 5 participants dropped out of the study: 2 unable to contact and 3 due to non-compliance (lack of improvement and footwear accommodation). 4 participants were in the control group and 1 participant dropped out from the treatment group. Compliance was assessed using a booklet to document the daily use of the treatment or the control orthoses and was tabulated as hours worn per week. The type of medication and
dosage was also recorded per week and tallied for each group. The number of hours the orthoses were worn per week and the medication intake (in milligrams) was also documented. This is presented in Table 5.17.

Table 5.18 presents the results of the ANOVA using the Bonferroni correction with an adjusted p value of 0.004. The mean compliance hours for the treatment group were 37.63 hours per week and for the control group was 36.78 hours per week. This was a non-significant difference (p = 0.55). The results also showed that despite the overall decrease in medication levels in the treatment group (305.77 milligrams) and the control group (18.7 milligrams) over 3 months, the results were non-significant (p=0.48).

<table>
<thead>
<tr>
<th>Week</th>
<th>Treatment Compliance (hours per week)</th>
<th>Medication (n=  ) (milligrams)</th>
<th>Control Compliance (hours per week)</th>
<th>Medication (n=  ) (milligrams)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Week 1</td>
<td>31.7</td>
<td>707.69</td>
<td>29</td>
<td>268.7</td>
</tr>
<tr>
<td>Week 2</td>
<td>35</td>
<td>632.69</td>
<td>33.6</td>
<td>177.08</td>
</tr>
<tr>
<td>Week 3</td>
<td>37.25</td>
<td>1021.63</td>
<td>35.6</td>
<td>131.25</td>
</tr>
<tr>
<td>Week 4</td>
<td>36.38</td>
<td>725.96</td>
<td>36.5</td>
<td>316.67</td>
</tr>
<tr>
<td>Week 5</td>
<td>34.69</td>
<td>676.92</td>
<td>38</td>
<td>314.58</td>
</tr>
<tr>
<td>Week 6</td>
<td>37.38</td>
<td>630.76</td>
<td>37.9</td>
<td>233.33</td>
</tr>
<tr>
<td>Week 7</td>
<td>39.28</td>
<td>642.3</td>
<td>37.04</td>
<td>302.08</td>
</tr>
<tr>
<td>Week 8</td>
<td>39.46</td>
<td>486.53</td>
<td>37.75</td>
<td>114.58</td>
</tr>
<tr>
<td>Week 9</td>
<td>40.17</td>
<td>576.92</td>
<td>39.4</td>
<td>254.16</td>
</tr>
<tr>
<td>Week 10</td>
<td>39</td>
<td>563.46</td>
<td>37.39</td>
<td>229.16</td>
</tr>
<tr>
<td>Week 11</td>
<td>40.11</td>
<td>590.38</td>
<td>38.85</td>
<td>229.16</td>
</tr>
<tr>
<td>Week 12</td>
<td>41.21</td>
<td>401.92</td>
<td>40.4</td>
<td>250</td>
</tr>
</tbody>
</table>

Table 5.17 Treatment and control group compliance and medication intake in each week of the 12 week trial.
<table>
<thead>
<tr>
<th></th>
<th>Treatment vs. Control ANOVAs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compliance</td>
<td>F (23) = 0.3741, p = 0.55</td>
</tr>
<tr>
<td>Medication</td>
<td>F (23) = 0.51, p = 0.48</td>
</tr>
</tbody>
</table>

Table 5.18 ANOVA results with the revised Bonferroni corrections (p = 0.004) between the treatment and control group.
5.4 Summary of Results

- The RCT recruited 105 participants and 100 were retained for the duration of the RCT. There were no significant differences in the treatment or control group for age (p=0.76), BMI (p=0.64), IPAQ (p=0.49), left AOG (p=0.63), right AOG (p=0.31) and BOG (p=0.38). There were no significant gender differences either (p>0.05).
- In the OA treatment group, the most prevalent foot posture was a mild-moderate pronation (raw FPI score of +6.05 and +6.05 for the left and right foot) and in the OA control group, the most prevalent foot posture was also mild-moderately pronated (raw FPI score of +6.10 and +6.18 for the left and right foot).
- While there were no significant differences between treatment and control groups for pain, symptoms, activities of daily living, recreational ability and quality of life (p>0.05), there was significant differences within the groups over time (p<0.01) particularly a reduction of pain scores in the treatment group between 0 - 6 weeks and in the control group between 0 – 3 weeks. There was also significant MIC in pain, symptom improvement, activities of daily living and QoL in the treatment group but not in the control group.
- There were highly significant differences in plantar pressure within the OA treatment group compared to the OA control group (p=0.001). This was noted in the medial and lateral rearfoot masks with a decrease in CA over 12 weeks. In the OA control group, there was an increase in PP (p=0.03) particularly in the lateral rearfoot compared with the OA treatment group. This suggests the LWO may have had an offloading effect on the lateral rearfoot in the treatment group.
- Foot posture or static BOG did not have an effect on patient centred outcome scores or in-shoe plantar pressure parameters (p>0.05).
- There was a significant effect of footwear on plantar pressure parameters (p=0.06) in the treatment group but no effect of shoe type on plantar pressure parameters in specific masks (p=0.54). CA was significantly greater in the Donnay trainers in the lateral rearfoot (p=0.05) and medial (p=0.002) and lateral midfoot (p=0.002) compared with own footwear.
- There were significant reductions in walking speed in the treatment group over time (p=0.0001). There were no significant differences in medication intake or compliance between the treatment and control groups.
5.5 Discussion

The main aim of this study was to identify a difference in patient centred outcome scores in the treatment group and the control group. In the RCT, these were assessed using the Knee Injury and Osteoarthritis Outcome score (KOOS) which comprised of pain, symptoms, activities of daily living, recreational ability and overall quality of life. While there were overall improvements of each of the five subscales of the KOOS, there were no significant differences between the treatment and control group. Therefore the null hypothesis stating that there were no differences in patient centred outcome scores was accepted while the alternate hypothesis was rejected.

The secondary aim of the study was to identify differences in plantar pressure parameters between LWOs and neutral inserts in an OA population. The results demonstrated that there were highly significant differences in plantar pressure parameters particularly in contact area and peak pressure in the rearfoot and midfoot regions of the right foot. Therefore, the alternate hypothesis stating that there is a difference in plantar pressure parameters between the treatment and control group was accepted and the null hypothesis was rejected.

**Anthropometric: Patient Group Characteristics**

The mean age of participants in the treatment group was 57.62 years and in the control group, it was 57.06 years. There were no significant differences at baseline between the treatment and control groups in age (p=0.76), BMI (p=0.81), IPAQ (p=0.49), left AOG (p=0.63), right AOG (p=0.31) and BOG (p=0.38). This suggests that the block randomisation method that was adopted was effective in producing a treatment and control group that were similar at baseline and that any change in patient centred outcome scores or plantar pressure parameters could be a result of the treatment or neutral orthotic. Block randomisation ensured that, all participants had the same chance of be allocated to the treatment or control group; the likelihood of receiving either was equal regardless of what point in the study the participant was recruited and; it ensured that at any given recruitment time point, participant numbers in the treatment and control group were comparable (Altman 1991; Friedman et al., 2010).

There were 61 women and 39 men in the study which reflects the work of Sharma and Berenbaum (2007) where the overall female/male ratio for OA was roughly 2:1. There are several reasons for the greater incidence of knee OA in women such as biomechanical and hormonal. The prevalence of knee OA increases significantly post-menopause and has been linked with decreased oestrogen levels. Reduced levels of oestrogen could affect the balance
of matrix degradative enzymes and thus initiate OA pathogenesis. However, this relationship is not conclusive as for instance there have been conflicting findings of the protective relationship that oestrogen may exert on the articular cartilage and; a lack of randomised controlled trials investigating this relationship (Nevitt et al., 1996; Spector et al., 1997; Von Muhlen et al., 2002; Lee et al., 2003; Sharma and Berenbaum 2007).

Physical activity levels were determined using the IPAQ which was self-administered at baseline, 3 weeks, 6 weeks and 12 weeks and there were no significant differences between the groups in IPAQ scores (p=0.49). This is relevant as the amount and type of physical exercise could have influenced the effect of the orthoses as activity levels determine TFJt loading (Bennell et al., 2011). However, as there were no differences in physical activity levels, it is unlikely that IPAQ had an effect on the primary and secondary outcome measures in the RCT.

The participants in the study were also predominantly right limb dominant (99%). Twenty three participants had unilateral right knee OA with 67 participants presenting with symptoms in both knees where the right knee was worse. Ten participants had unilateral left knee OA. While previous authors have suggested different pathogenetic processes for unilateral and bilateral knee OA such as knee injury, this was considered as participants who had previous history of knee injury or trauma such as meniscal tears, ligament ruptures or femoral fractures were excluded from the study. Additionally, Appendix 15 contains the results for when the ten participants with unilateral left knee OA were excluded from the analysis and the results of the study were maintained suggesting that in participants where the right knee is worse (symptomatically speaking), there is still no difference between in-shoe plantar pressure measurements between the left and right foot.

**Lower Limb Alignment: Foot Posture and Static and Dynamic TFJt Alignment**

As discussed previously, people with medial knee OA have demonstrated more pronated foot postures compared to asymptomatic controls (Levinger et al., 2010; Reilly et al., 2006). Foot posture in the OA treatment and control group were mild-moderate pronated left and right foot with raw FPI scores ranging from +6.05 – +6.18. This is comparable with more recent findings by Levinger et al., (2012) who reported a more everted foot type in medial TFJt OA. The authors suggest that this everted position of the rearfoot could be a compensatory adaptation in relation to the tibia in order to allow the foot to be plantigrade. The pronation
allows the medial foot to contact the ground in order to alter the direction of the GRF and therefore reduce overall KAM on the TFJt (Riegger-Krugh and Keysor 1996). This has also been noted in the in-shoe plantar pressure assessments in Chapter 5 (Section 5.5), where contact area in the medial midfoot of the OA group was significantly greater (p<0.001) than normal participants and in particular where a pronated OA foot demonstrated greater CA compared to a normal pronated foot. Therefore, when foot posture is assessed in the context of associated in-shoe plantar pressure parameters, the mechanisms of loading of the foot and subsequently lower limb are relevant.

The static and dynamic TFJt alignment in the treatment and control group were compared and no significant differences were noted (p>0.05). The dynamic TFJt angles were recorded in barefoot and in neutral Donnay trainers. The lack of significant findings suggests that the effect of laterally wedged or neutral orthoses on the frontal plane TFJt is limited or is difficult to establish when using goniometric assessments. This could be due to a lack of sensitivity or validity issues as discussed in Chapter 2 (Section 2.3.2). However, this was not a surprising result as LWOs have previously had no effect on radiographic measures of the TFJt joint in a seven year follow-up study, suggesting that LWOs may not actually alter or mediate TFJt OA (Tohyama et al., 1991). However, radiographic measures of TFJt space narrowing is only weakly associated with the symptomatic presentation of TFJt OA and as a result, any improvement in symptoms may be independent of frontal plane knee alignment changes in the short term (Bruyere et al., 2002; Rubin and Menz 2005).
5.5.1 Patient Centred Outcome Scores

Patient-centred outcome scores are relevant in conditions such as TFJt OA. OA can reduce physical functioning, social mobility and overall quality of life (QoL) which is arguably more significant than the progression of the disease itself (Fontaine et al., 2007). OA can impact on a variety of physical and psychological health domains, and knee health-related QoL’s provide a broad picture of this effect. The KOOS (Knee Injury and Osteoarthritis Outcome Score) and the WOMAC (Western Ontario and McMaster University Osteoarthritis Index) are QoL’s which have been used to determine the clinical effectiveness of LWOs in previous RCT’s over the short, mid and long term (Pham et al., 2004; Rubin and Menz 2005; Rodrigues et al., 2008; Hinman et al., 2008).

When evaluating the validity of a study, the clinical and statistical significance of the findings should be considered (Bhardwaj et al., 2004). The minimally important clinical significance or MIC for the KOOS score has been reported as 8-10 points on the KOOS scale. When the results of the study were interpreted using the recommended MIC value, the results found that there was clinically significant and relevant improvements in pain, symptoms, ADL and overall QoL in the treatment group but not in the control group. This suggests that the study was adequately powered to detect meaningful clinical differences. The clinical relevance of this finding is interesting given that while statistically there was no difference between the treatment and control groups, there was an effect of time as well as an overall improvement in both groups. The statistical relevance and impact of time will now be discussed in more detail.

The results of this RCT found that there were no significant differences in pain (p=0.67), symptoms (p=0.26), activities of daily living (ADL) (p=0.43), recreational ability (p=0.73) or overall quality of life (p=0.48) in the treatment group compared with the control. This is similar to findings by Pham et al., (2004) who found that in 156 participants (mean age 64.8 years), there was no significant difference between groups in global assessments of disease activity and WOMAC subscales such as pain, stiffness and function at 24 months post-intervention. The results also echo recent findings by Bennell and colleagues (2011) where LWOs did not have a significant effect on medial tibial articular cartilage volume or QoL parameters such as pain, stiffness and function in 200 medial knee OA participants over a 12 month period. The authors suggested that LWOs may have a limited effect on structural and
symptomatic outcomes in knee OA. However, this is contradictory to findings by reviewers such as Brouwer et al., (2007) and authors such as Rubin and Menz (2004) and Rodriguez et al., (2008) who did report improvements at 3 weeks, 6 weeks and 8 weeks when using patient-centred outcome scores such as the visual analog scale (VAS) and WOMAC. This suggests a time dependant effect where LWOs may have a short term beneficial effect particularly in participants with mild-moderate medial TFJt OA.

The control orthoses such as the one used in this RCT could have demonstrated an effect on KOOS scores from baseline to 3 weeks as they may have had a shock absorbing characteristics and thus provided symptom relief (Kemp et al., 2008; Raiij et al., 2010). Previous research has demonstrated a decrease in the KAM when wearing a neutral or control orthotic which suggests a potential biomechanical benefit (Wallace 2006). Shiba et al., (1995) found significant reductions in the GRF using simple foam inserts. Within the context of the shock attenuation theory and preferred motion pathway (discussed in Chapter 2, Table 2.3), the control orthoses could have reduced soft tissue vibrations, improved cushioning and thus comfort. This could explain the decrease in pain scores in the control group. It could also contribute to the lack of differences between the treatment and control groups however; the trends within each group over time were significant and will now be discussed.

Treatment and Control Group Differences

The discrepancy between the treatment and control group could be explained by several factors: compression of materials; subjective patient response; the design of LWOs; type of outcome measures used; the effect of time and the placebo and Hawthorne effect.

- Compression of Materials

LWOs are often made from lightweight materials such as EVA and as such may need to be replaced frequently in order to maintain their wedged structures and sustain their biomechanical effect on the lower limb. In this study, the participants used the same insole from baseline through the study and it is possible that the biomechanical effects of LWOs decline over time with compression due to daily use (Hinman et al., 2009). This was reiterated by Hinman and colleagues (2009) who found that LWO degradation does not occur over the short term (4 weeks) however, the study was a short-term design and did not measure symptomatic relief in the twenty participants at baseline and 4 weeks.
**Subjective Patient Response**

Another explanation is rooted in the suggestion that a patient’s response or experience of immediate pain and symptom relief with LWO could be used to predict long-term benefit (Delzell 2011). Specific OA participants, for example, those with mild to moderate medial TFJt OA are more likely to respond better to treatment in the short term and report pain improvements during walking at three months (Hinman et al., 2008). Therefore, while the RCT design may attempt to remove all confounding variables from the treatment and control groups, the subjective response of each participant to the LWOs is individual and could account for differences in outcome measures.

**The Design of LWOs**

The differences in design characteristics of the LWOs could also be a factor explaining the differences in this study with previous work. Kirby (2011) and others (Reeves and Bowling 2011; Baliunas et al., 2002) highlighted the importance of full-length LWOs to ensure that the centre of pressure could be redirected laterally along an increased lateral surface area that will reduce loads on the medial TFJt compartment. While a full-length wedge has had a demonstrable beneficial effect, studies using rearfoot wedges have had no significant effect on symptoms or progression over time (Maly et al., 2002; Nester et al., 2003; Pham et al., 2004). This study used a modified ¾ length LWO design in order to improve comfort within the toe box region of the footwear as a recent suggestion by Wallace (2006). Comfort and fit within the shoe was considered as Bennell et al., (2011) showed that participants who are prescribed LWOs are more likely to have difficulties with footwear accommodation and rated full-length LWOs are less comfortable and have more side-effects when compared with a control orthoses. It is this difference in LWO design that could account for the improvement in pain and other symptoms experienced by the treatment group in this study.

**Type of Outcome Measures used**

The type of outcome measures being used to evaluate effectiveness is another factor as while some studies have reported a lack of improvement to patient-centred outcome scores such as Pham et al., (2004), the study reported a reduction in consumption of anti-inflammatory agents as well as better compliance and tolerance in the treatment group. Another predictor of
improvement is an initial reduction in peak KAM, which is experienced by most participants but not all in LWO studies (Hinman et al., 2008).
Therefore, the results of the RCT treatment and control need to consider these factors because while there was no significant group differences, there was a significant effect of time (p<0.001) on outcome scores.

- *The Effect of Time*
While there was no significant group difference however, there was a significant effect of time (p<0.001) on outcome scores.

*Pain Scores*
The difference in treatment pain scores was 11.9 points on the KOOS scale while in the control group this was 5.62 points. This represented an improvement of 14.9% and 7.5% respectively. In the treatment group, the most significant improvements occurred between baseline and 6 weeks and between baseline and 12 weeks (p=0.001). In the control group, while a significant reduction in pain occurred between baseline and 3 weeks, there were no significant improvements from 3 weeks to 12 weeks. This suggests that while the treatment group continue to improve significantly up to 6 weeks, the control group did not improve post the 3 week time point. This is comparable with findings of Rubin and Menz (2004) who found overall reductions in pain when using a VAS at 3 weeks and 6 weeks post-intervention. The authors reported that the greatest reductions occurred in those with less severe OA and suggested that future studies include larger sample numbers, a longer follow-up period and a control group for comparison.

*Health Related Quality of Life Scores*
When the other KOOS subscales were analysed, the results showed that there were significant improvements in both the treatment and control groups for symptoms, ADL, recreational ability and overall QoL. The most significant improvements were noted between baseline and 3 weeks for symptomatic relief, ADL and recreational ability. However, in overall QoL there was the greatest improvement in the treatment group with a mean improvement of 20.48 points while for the control group this was 6.98 point which represented an improvement of 26.02% and 9.9% respectively. In addition, in the treatment group, the greatest improvements occurred from baseline to 6 weeks while in the control
group this was between baseline and 3 weeks. Some of the reasons for these trends are the design of the LWOs itself or the placebo effect.

- **Placebo Effect**

Another explanation could be that improvements in KOOS scores could have been due to the placebo effect (Hernborg and Nilsson 1977 in Rubin and Menz 2005). The placebo effect is defined as ‘the measurable, observable, or felt improvement in health not attributable to an actual treatment’. It is governed by the patient’s psychological willing and positive thinking of benefit as opposed to an actual benefit (Eustice 2011). In studies which involve pain control participants, the placebo effect is suggested to be responsible for a 30% improvement in clinical symptoms (Turner *et al.*, 2004). Therefore, the improvement in the control group of 7.5% - 16.14% could be viably attributed to this effect.

However, the results of the treatment group in this study could also be attributed to the placebo effect using Turner’s (2004) 30% cut-off point. Although the non-significant differences between the treatment and control groups are similar to previous findings (Wallace 2006; Bennell *et al.*, 2011), some authors have reported within treatment group improvements in pain scores of 33% - 58% over a 12 week intervention period (Rubin and Menz 2006; Wallace 2006).

The improvement in pain scores and overall QoL scores in this study could also be attributed to the Hawthorne effect. This is the experimental effect where a participants’ knowledge of being studied or involved in a research project results in a significant positive effect on the reported outcomes (Mayo 1933; Draper 2012). However, it has been countered that in any research study involving an intervention which may have benefits for a participant, there will always been a human propensity to be motivated, to adapt and to potentially improve (Draper 2012). In this study, there may have been indirect causal factors involved. These are feedback that participants could note from their footwear/medication journals over the 12 weeks; the selection of footwear prior to study participation or; changes to goals and beliefs about action induced by the experimental situation. This was an anecdotal observation and could have been addressed by interviewing participants after the trial for personal goals, lifestyle changes, or their perspective on the researchers or trial expectations (Adair 1984). This would explain the discrepancy in patient outcome scores in LWO trials and perhaps should be a consideration of future research.
While both the Hawthorne and placebo effect have been considered as part of the discussion of the RCT results, it is worth considering the clinically relevant findings of MIC in the treatment group alone and not in the control group. From a practitioner’s perspective, the results are appealing as LWOs are cost- and clinically effective and could therefore be a viable conservative treatment option for medial TFJt OA (Leung 2001).
5.5.2 In-Shoe Plantar Pressure Measurement

There have been a few studies that have evaluated the effect of LWOs on in-shoe plantar pressure assessments in medial knee OA patients (Leitch et al., 2011) and in healthy subjects (Gheluwe et al., 2004; Erhart et al., 2008). However, to date, there have been no RCT’s with large sample numbers investigating this relationship at baseline and any changes that may occur over time. In-shoe plantar pressure assessments in key parameters such as contact area and peak pressures offer the most direct assessments of the foot and ground interface and particularly between the foot, orthotic and shoe and the ground.

An inter-limb analysis was conducted in order to ascertain whether there were any compensatory mechanisms occurring in the non-dominant limb during normal gait. Previous research has demonstrated that there is an increased risk of knee injuries and subsequent OA development in the non-dominant limb of professional football players (Krajnc et al., 2010). This can be explained as the non-dominant TFJt in professional footballers undergoes greater torsional and compressive stresses particularly in defender and striker positions (Faude et al., 2006) and as a result, there is an increased risk of acute injury and second OA. However, Wong and colleagues (2007) demonstrated that in soccer players, the overall peak plantar pressure of the dominant foot is always greater than the non-dominant foot. However, the effect of limb dominance on in-shoe plantar pressure measurements in OA participants who are not professional athletes has been limited. The results of the inter-limb analysis from this study found that there were significant differences between the left and right foot in the treatment group but not in the control group. This suggests that there was more variation between the left and right foot that could be attributed to the LWOs as this was the main difference between the groups. At baseline, there was greater CA and FTI in the right foot medial and lateral rearfoot compared to the left foot. There was also significantly greater PP in the right lateral rearfoot compared to the left lateral rearfoot. This could be explained as there is greater loading and demand on the dominant limb during gait and this could result in OA development and progression. However, if a participant presents with an analalgic gait pattern, then less weight is borne by the affected or painful dominant limb. In support of this contrast, Harrington (2005) states that weight bearing on the non-dominant or non-affected side is prolonged and produces a characteristic gait pattern with uneven strides of varying duration. When the results of the inter-limb analysis were explored at the 3 weeks time point, the increase was only maintained in the CA but not in PP or FTI parameters. At 6 weeks,
there was increased PP and FTI in the left foot as opposed to the right foot but at 12 weeks, this trend reversed back to the right foot demonstrating greater CA, PP and FTI in the rearfoot.

The inter-limb analysis therefore showed there was a variation in plantar pressure outcomes for the left and right foot in the treatment group. One explanation for this could be leg length discrepancy, a common biomechanical problem that could affect foot loading patterns during walking as demonstrated by Perttunen et al., (2004) and could also be a predisposing factor for musculoskeletal disorders (Gurney 2002). However, while asymmetrical lower limbs (structural or functional leg length discrepancies) are common occurrences in a clinical setting, those participants with an obvious or pathological gait abnormality resulting in a leg length discrepancy were excluded from the OA study during the screening process. Gait asymmetry or limb dominance (laterality) has been the subject of numerous investigations which have shown that it is simply reflective of natural functional differences between the lower limbs. In order to simplify data collection and analysis, gait symmetry is often assumed and there have been conflicting evidence on the relationship between functional gait asymmetry and limb dominance (Sadeghi et al., 2000). For example, Sharma and colleagues (2001) reported that the incidence of medial and lateral OA progression in an OA population, i.e. not elite sportspeople, was similar in the dominant and non-dominant limb. Eckstein and colleagues (2002) also concurred and stated that limb dominance does not explain side effects differences in AC morphology and instead suggested that muscle mass i.e. the quadriceps could have a significant effect. However, this study was conducted in fifteen health participants and as such, is a limitation of the contrast with an OA group. However, based on the literature available on cartilage morphology and pathological presentation of symptoms, it can be assumed that in an OA population, the dominant limb which is usually the right limb has worsened symptoms and is also potentially reflective of the contralateral, non-affected OA limb. Another factor that warrants discussion is the fact that clinical presentation of symptoms which was used as the diagnostic criteria in the RCT does not always correlate with radiographic presentation of medial TFJt OA symptoms. For example, participants could present with OA in an affected limb and while they may not present with pain in the contralateral limb, they may in fact present with radiographic evidence of joint space narrowing and osteophytic proliferation (Dieppe 2003). The chronic and progressive nature of OA needs to be considered as Hochberg et al., (2010) reported that 62% of participants who presented with Grade 0 or ‘doubtful’ presence of OA using the KL scale, went on to
develop the condition within ten years. Therefore, although the RCT was longitudinal, the chronic nature of OA is a confounding variable.

The overall results of the inter-limb analysis suggests therefore that while there were variations between the right foot and left foot within the treatment group, this pattern was not consistent or maintained over the 12 week trial. The greater CA, PP and FTI in the right foot at baseline could be explained by right limb dominance and therefore greater demands placed on the limb. The results do however suggest that there were limited compensatory mechanisms at work in the contralateral or non-OA limb. This reflects the work of Metcalfe et al., (2012) who found that overall peak TFJt loading is the same in both the OA affected limb and contralateral limb suggesting they are comparable. This also echoes the work of Liikavainio et al., (2007) who found no asymmetry between the left and right limbs in either kinetic or kinematic parameters including in-shoe plantar pressure measurements during normal walking in patients with knee OA. A consideration however, is that the offloading mechanism of the LWO could have precipitated greater variation and movement in the treatment group whilst this effect was not significant in the control group. On the basis of the above findings, the dominant right limb which also presented with worsened knee symptoms was used to direct the subsequent analysis.

**Contact Area**

The results of the study found that there was no difference in contact area (CA) in the treatment or the control group (p>0.05). However, while there was no interaction between the groups over time (p=0.46) or masks between the groups (p=0.50), there was a significant difference between the CA in each mask over time (p<0.01). When these results were analysed further, it was in the treatment group that the results were most significant (p=0.001) with a significant decrease in medial and lateral rearfoot CA between baseline and 12 weeks. This suggests an overall decrease in CA in the rearfoot with LWOs compared to baseline. The rearfoot complex and in particular, rearfoot kinetics are important as Nester et al., (2003) reported that LWOs primarily effects the rearfoot and that as soon as the heel leave the ground, LWOs have a minimal influence (Wallace 2006). Therefore, the eversion of the rearfoot along with a reduced CA could occur in OA patients to compensate for a weakened quadriceps that does not provide adequate shock absorption during early contact phase (Rice et al., 2011).
As there is a statistically significant correlation between increased pain and a lateral orientation of centre of pressure, the results suggest that a decrease in CA could have contributed to an improvement of symptoms such as pain as noted in the KOOS subscales (Lidtke et al., 2010).

**Quadriceps Muscle Strength and Activity**

The decrease in rearfoot CA could result in an increase in peak pressures in the rearfoot which although not significant (p=0.15), was noted in the treatment group. The decrease in rearfoot CA could decrease the vertical GRF at early midstance and reduce KAM at the medial TFJt (Waetjen et al., 2011). This could either occur to compensate for an over-pronated foot posture and function where there is increased stresses on the medial TFJt or could be a consequence of symptomatic TFJt OA. When the TFJt moves from slight flexion to extension in early midstance, pain could act as a trigger to reducing rearfoot CA and thus decrease loading of the medial TFJt (Nester et al., 2002). Previous authors have also linked this pain to disuse atrophy and a reflex inhibition of the quadriceps muscles, which could account for the prevalent finding of weakened quadriceps muscles in an OA population (O’Reilly et al., 1997; Fitzgerald et al., 2004). The reduced rearfoot CA could contribute to this cycle where the quadriceps are not needed to function to capacity resulting in a decrease overall force production (Liikavainio et al., 2009).

**Footwear**

Another factor that may have contributed to this trend is the footwear choices of participants. Gradual heel elevations such as those present in walking shoes, court shoes or athletic shoes (89% of participants) could cause a decrease in rearfoot CA as demonstrated by Luximon et al., (2012). Kerrigan et al., (1998) showed that heel elevations caused greater compressive forces on the medial TFJt when compared with barefoot walking. When considering walking shoes and athletic shoes, the elevated heel counter, designed for cushioning and improved shock absorption, could have the same effect as a low heel. Therefore, even though only the footwear with a noticeable heel (of over 0.5cms) were recorded in this study, the 94% without noticeable heel counters but built in elevations may have had an influence on plantar pressure parameters such as CA.
Walking Speed
Walking speed could also explain the decrease in CA in the treatment group as walking speed significantly increased (p=0.0001) with time in this group compared with the control group. Burnfield et al., (2004) showed that in healthy older adults, increased walking speeds caused a decrease in CA which also corresponded with an increase in peak pressures in the heel or rearfoot region. Increased walking speeds could alter initial CA from the rearfoot to the midfoot region of the foot (Ho et al., 2010). Although there were no statistically significant increases in the midfoot CA, there was an increase of midfoot CA over time which could explain the decreasing CA in the rearfoot.

This shift of CA from the rearfoot to the midfoot could occur at higher walking speeds as the midfoot is more capable at adapting to changes in forces and may aid in shock absorption in gait. The medial longitudinal arch plays an important role at shock absorption than knee flexion and extension during the early stance phase (Guo et al., 2006; Ho et al., 2010).

Peak Pressure
The results of the study found that there was no difference in peak pressure (PP) in the treatment or the control group (p>0.05). However, while there was no interaction between the groups over time (p=0.89) or masks between the groups (p=0.14), there was a significant difference between the CA in each mask over time (p<0.01). When these results were analysed further, it was in the control group that the results were most significant (p=0.03) with a significant increase in lateral rearfoot PP between baseline and 12 weeks.

This suggests that in OA participants with the neutral orthoses there was a significant gradual increase in PP in the lateral rearfoot compared with the treatment group with LWOs. The LWOs could have reduced the PP particularly in the lateral rearfoot of the treatment group as an increased lateral rearfoot pressure has been associated with knee pain (Delzell 2011). As people with medial knee OA contact the ground with a more everted rearfoot position than healthy normal individuals, it follows that the LWOs exert some control over rearfoot PP distribution than the neutral orthoses (Levinger et al., 2012).

As the GRF magnitude is also determined by the magnitude of PP, in the OA control group, a significant increase in PP could be attributed to the lack of LWOs. These could have prevented an increase in the GRF and subsequently the KAM affecting the medial TFJt.
Contact time, Pressure Time Integral and Force Time Integral

The results showed no significant differences between the treatment and control group and no significant effect of time (p>0.05) for contact time, pressure time integrals and force time integrals. This suggests that LWOs did not have an effect on loading time or pressures and forces acting over time on the right foot. The overall plantar pressure trends in the OA group showed decreased rearfoot CA in the treatment group and an increased rearfoot PP in the control group; however neither orthoses influenced temporal plantar pressure parameters. This is contradictory to Harrington’s (2005) assertions that in the symptomatic OA limb, there would be a decrease in stance phase duration and a potential decrease in CT of the ipsilateral foot. Therefore, while LWOs and the neutral orthoses reduced overall pain and improved the knee-health related QoL, the inserts did not influence plantar pressure timings during normal gait.
5.5.3 The Influence of Foot Posture on Outcome Scores

The results showed that static foot posture and static BOG did not have an effect on the in-shoe plantar pressure parameters over time or between the treatment and control groups. Foot posture could alter the alignment and dynamic function of lower limb in medial knee OA. The inconclusive results of previous RCT’s investigating LWOs could be as a result of the variation in foot postures between participants. A pronated foot type could produce a reduced CA and reduced CT in the rearfoot during heel strike and also produce prolonged pronation during midstance with the aid of LWOs. The amalgamation of this effect may alter the GRF and reduce the KAM to improve patient outcomes. Although the results of this RCT found no significant effects of static foot posture on these outcomes, an explanation could be due to the lack of clear classification of foot posture using the FPI-6. Previous research (Redmond et al., 2008) have classified those with a foot posture (raw FPI score of +4) as being mildly pronated even though according to Redmond’s (2005) classification that raw FPI scores of 0 - +5 were neutral, +6-+9 was pronated and +10 - +12 was highly pronated.

5.5.4 The influence of Footwear

Systematic reviews on footwear types for medial knee OA patients have been inconclusive due to the lack of high-quality clinical trials. Fang et al., (2006) found there was a significant improvement observed in knee pain and function using a knee-health related quality of life measure with shock absorbing trainers. However, conflicting evidence suggests that usual footwear, such as walking shoes, can increase medial knee loading (Kemp et al., 2008). When four types of footwear; clogs, stability shoes and walking shoes and flip flops were evaluated, clogs and stability shoes increased the KAM (considered an important clinical OA risk factor) by 15% compared to barefoot while flat walking shoes and flips flops were not significantly different. This finding is alarming, considering stability shoes and walking shoes are often recommended as ideal footwear for OA patients (Landry et al., 2011). Footwear was not standardised over the course of the RCT. The reasons for this were due to the lack of resources and funding available to provide every participant with a standardised pair of shoes for the trial. Also, patient compliance in LWO trials as a result of footwear compliance has been a noted issue in the literature (Hinman et al., 2009). Therefore in order to increase patient compliance, as is customary in clinical podiatric practice, participants self-selected footwear choices and these were noted at baseline. Beyond baseline, the effect of a variety of footwear was minimised by recording type of shoe worn everyday for the 12 week period in
the footwear diary. The effect of footwear, particularly in the treatment group, is an insightful finding of this study. The amalgamated effect of walking shoes and LWOs as an effective treatment intervention warrants discussion considering contrasting evidence suggesting flexible, flat footwear produces improved patient outcomes (Shakoor et al., 2013).

**Footwear Choice**

While footwear choice has received limited attention in the LWO literature, it might explain the discrepancy in patient outcomes in interventional studies. In the only block randomised RCT, Barrios and colleagues (2009) used LWOs and standardised walking shoes in the treatment group and neutral orthoses in the control group. The results found that there was a significant improvement in the treatment group pain, stiffness and functional ability scores at 1 month (p<0.001) and at 1 year (p<0.001) and in the control group at 1 year (p=0.017). The authors thus recommended walking shoes alongside LWOs. In this RCT, the most prevalent shoe worn during the 3 month study was a walking shoe (51%) while 22% preferred a court shoe and 16% preferred an athletic shoe. These (walking shoe and court shoe) were the main shoe types recorded by participants and when compared with the neutral Donnay trainers, there was significant difference in CA (p<0.001) between the footwear.

When footwear were analysed further, trainers or athletic footwear demonstrated the greatest CA in the medial midfoot region when compared with walking shoes, oxford shoes and court shoes. There was no difference in plantar pressure parameters in the control group which is insightful as the results suggests that the combined effect of LWO’s and footwear have a tangible and significant effect on CA and could explain the MIC effect in patient outcome scores in the treatment group. As demonstrated in Appendix 14 however, when KOOS scores were analysed within the context of footwear, there were no significant interactions (p=0.82). The KOOS scores for pain, symptoms, ADL, recreational activities and overall QoL in participants with athletics shoes was comparable to those with walking shoes, oxford shoes and court style shoes. However, while this was the case for both the treatment and control group, there were clinically significant changes demonstrated by the MIC values in the treatment group only. Therefore, the results suggest that any of these footwear types could be advocated alongside LWOs in order to improve pain, symptom, ADL and overall QoL outcomes. There are several explanations that should be considered.
An increase in CA in the medial midfoot could have several ramifications on the lower limb kinetic chain. An increased CA in the medial midfoot would medialise loading forces and result in an altered GRF vector. Previous research has demonstrated that there is a lateralisation of the GRF that is associated with medial TFJt OA (Leitch et al., 2011). Lidtke et al., (2010) found that greater lateral loading particularly during the contact and midstance gait phases was correlated with severity of pain. The authors concluded that loading patterns at the foot and ankle level were linked with medial TFJt OA. Within the context of this study’s findings, the decreased distance between this line vector and the centre of the TFJt would reduce the KAM and consequently reduce medial TFJt loading. As a result, pain and symptom presentation in the treatment group would improve as was demonstrated by the KOOS scores.

The role of the midfoot region in medial TFJt OA has not received much attention in the literature despite suggestions that midfoot plantar pressure distributions and peak pressure could affect the TFJt (Barrios et al., 2009). Chen and colleagues (2003) found that when compared with younger, healthy control groups, people with knee OA had significantly greater loading forces in the midfoot region during midstance. An increased CA in the medial midfoot could maintain pronation during the midstance phase and act as an extra shock absorbing mechanism to reduce TFJt loading. This effect, when combined with the shock absorbing properties of certain types of footwear such as trainers or walking shoes could explain the clinically significant improvements in the treatment group and to a lesser extent, even in the control group (footwear effect alone). However, it was difficult to account for type of footwear in each of the groups as they were randomly block allocated at the start of the trial. Furthermore, participants chose their own footwear and then noted this choice in their footwear diaries.

Design of Heel Counter and Arch Support
The results showed that there was a greater CA in the Donnay trainers compared with the self-selected footwear. There are two main explanations for this: the difference in design features of the heel counters and the arch support within the footwear. The Donnay trainers are a neutral shoe with a relatively thin sole which offers limited shock absorption compared to walking shoes which are made from a polymerized soles which have wider, rigid and more padded heel counters. Shoe sole composition has a significant effect on compression and shear strains on the tibia with embedded heel air cells in walking shoes that can be protective
against shearing and compressive stresses on the lower limb (Milgrom et al., 2001). Walking shoes and athletic shoes tend to differ to neutral Donnay trainers in their outer sole and midsole (combinations or prefabricated) designs and a more contoured midsole design could improve balance and stability of the midfoot region (Porter and Schon 2007).

In the RCT, all removable foot beds and arch supports were removed from footwear and replaced with the either LWOs or neutral orthoses. However, the specific arch design in each footwear type could have varied and though shoe style, age, heel height and material composition was recorded, the specifications such as anti-pronatory or anti-supinatory control elements were not recorded in this study. These features could have had an effect as previous research has shown that motion control and stability footwear have increased medial midfoot support which in turns has improvement stability of the lower limb by decreasing foot pronation (Hintermann et al., 2002). The most common types of footwear such as the walking shoes, court shoes and athletic shoes could have had anti-pronatory control features of two types: a denser material such as polyurethane (PU) could have been built in to the medial aspect of the midsole as well as the heel counter to control excessive pronation and alterations to the shoe’s outer sole to limit pronation of the rearfoot and midfoot (Porter and Schon 2007).

Therefore, a combination of a more contoured foot bed along with anti-pronatory or motion control features of the self-selected footwear could have resulted in decreased CA in the lateral rearfoot (p=0.05), medial (p=0.002) and lateral midfoot (p=0.002) compared with the neutral Donnay trainers. Although footwear has rarely been considered in the literature on conservative knee OA interventions, it could well account for the discrepancy in findings of LWO effectiveness in OA populations as indicated by this RCT (Toda and Tsukimura 2008). Furthermore, in an email on the 20th of February, 2012 R. Hinman stated that while the results of her 2009 clinical trial of LWOs was non-significant, she believed that a major factor for this was the variability of shoes that participants wore over the course of the year.
Limitations

The type of footwear worn by each participant was kept consistent throughout the study and was recorded in the footwear diary for every day of the 12 weeks of the RCT. However, one of the limitations of this study is the regulatory effect that footwear may have had on patient centred outcome scores as well as kinetic outcomes. There are two main limitations associated with this point: it was difficult to compare different footwear types with each other within the treatment and control groups due to small sample sizes wearing a particular type of shoe and; the generalisibility of the results is difficult as footwear was a confounding variable. The relatively small sample size wearing a particular type of footwear was due to difficulties in patient recruitment over time and the funding available for the project. However, only a few studies (Yoda and Tsukimura 2007; Barrios et al., 2009) attempted to standardise footwear along with the intervention. They found that while heeled footwear decreased the efficacy of LWOs, flat footwear without heels and walking shoes significantly improved knee OA patient outcomes over the short and long term. Therefore, despite the neutral Donnay trainers being consistent throughout this research, standardised footwear recommendations could have also provided better outcomes and allowed more effective comparisons to be made between participant groups. While this would have been ideal, the limitations with regards to funding and provision of footwear prevented standardisation for the 100 participants over the trial period.

Another limitation of the study was the use of the KOOS outcome score compared with other patient centred outcome measures such as the VAS or WOMAC. The KOOS was chosen for both its short term and long term validity and would have served as a useful comparison with future long-term studies using this outcome score. However, while comparisons can be drawn between this RCT and other RCT’s that have used the WOMAC, it would have been better comparable if similar techniques were used.

The generalisibility of this study is limited by the short duration of the RCT and further research is required in order to evaluate the long-term effectiveness of LWOs along with appropriate standardised footwear. However, the aim of the study was to determine if there were any differences between the treatment and control groups and to explore the potential effect of foot posture, static BOG and footwear on the key outcomes.

Given the findings of an effect of LWOs on outcome scores and the fact that OA is a progressive, chronic condition, a 12 week intervention period could be considered as limited in predicting the long-term effects of LWOs on a patient’s clinical outcomes. However, the
results do suggest that LWOs could be a potential cost effective and useful short-term treatment strategy for medial TFJt OA.

The long term ramifications of the condition are also relevant as any potential health hazards or side effects could be identified and minimised. Reilly (2009) noted that with long term LWO use, the lack of re-supinatory motion of the midfoot could result in side-effects along the lower limb kinetic chain and could even have an adverse effect of TFJt loading. This concern was also echoed by Reeves and Bowling (2011) who reported that LWOs increased the ankle eversion moment by 93% and could be lead to ankle instability and sprains. While the participants in this study did not report any side-effects, it is possible that continued long-term use may have been detrimental.
5.6 Conclusion

The main purpose of this RCT was to determine if there were any differences in patient centred outcome scores between the treatment (LWO) and control (neutral) group while the subsequent aim was to determine if there was any difference in key plantar pressure parameters between the groups.

The results showed that while there was an overall improvement in each of the five subscales of the KOOS, there were no statistically significant differences between the treatment and control group.

The significant improvements in pain, symptoms, activities of daily living, recreational ability and overall quality of life, along with significant increased in walking speed and altered contact area and peak pressure in the rearfoot and midfoot region of treatment (LWO) participants were positive. These were verified when using MIC values that found clinically significant findings in the treatment group. The improvements in pain and functional scores had a linear pattern and continued to improve throughout the 12 weeks. In order for an OA treatment to be deemed effective, it must affect biomechanical lower limb loading to minimise GRF and subsequently reduce the KAM, while also reducing pain and improving physical function. The direct effect of static foot posture and function on dynamic kinetic outcomes has demonstrated a relationship in an OA population previously, and may have contributed to the improved patient outcome scores. These trends were noted in both the treatment and control groups but were most significant in the treatment group.

This suggests that LWOs could be effective at improving outcome scores in a non-invasive and cost-effective way however, foot posture did not have any effect on the outcomes. The evidence for the use of LWOs is therefore inconclusive. As footwear did have a mediating effect on outcome scores, further research is warranted to determine whether a combined approach of LWOs and standardised footwear could prove more effective at conservatively managing medial knee OA.
6. Discussion, Clinical Implications and Conclusions

The aim of this chapter is to provide an overall discussion on the important findings and conclusions drawn from each of the previous studies: the reliability study, the normal study, the comparison between the OA and normal groups and finally, the randomised controlled trial. Section 6.1 will address the key themes emerging through the thesis and discuss these. Section 6.2 discusses the strengths and limitations of the thesis structure, the rationale, the designs of the studies and confounding factors which may explain key findings. Section 6.3 makes suggestions for future research work in this area. Finally, Section 6.4 concludes the main outcomes of this study within the context of the public health problem that is knee OA. It will emphasise on the advances made in the current literature and provide evidence for conservative treatments and contribution to clinical understanding.

6.1 Overall Discussion

The proposed relationship between foot posture and the development of chronic conditions such as medial TFJt OA has been alluded to only in the more recent literature (MacAuley and Bes 2007; Menz 2008; Levinger et al., 2010). TFJt OA can occur as a result of excessive loading of the articular cartilage particularly in the medial compartment where specific gait mechanics such as the KAM has been associated with OA progression as well as patient outcomes (Sharma et al., 2010). Foot posture is relevant to this association as it could alter the mechanical alignment and subsequent function of the lower limb. Static foot posture has been associated with in-shoe plantar pressure measurements where a more pronated foot type has been associated with greater pressures under the medial midfoot region and greater peak forefoot abduction and peak rearfoot eversion in healthy participants (Barton et al., 2011; Jonely et al., 2011).

However, to date, while no research study has explored the relationship between static foot posture and the KAM, an abducted foot has been shown to significantly reduce the KAM in mild-moderate medial TFJt OA (Rutherford et al., 2008; Lynn et al., 2008). These studies were based on the hypothesis that rotating the foot externally or abduction would increase the lateralisation of the centre of pressure (which determines the GRF), thereby reducing the distance between the GRF and the TFJt centre. This would reduce the lever arm magnitude and therefore alter the KAM (Hunt 2012). This suggests that spatial gait characteristics such as AOG and BOG could be indicative of medial TFJt loading despite a lack of research. Furthermore, while the relationship between foot posture and the KAM remains to be determined, recent research suggests its potential clinical significance should not be
discounted. Whether a pronated foot type is a cause or consequence of medial TFJt OA remains inconclusive however, the interdependence between static foot posture and knee mechanics is more certain (Lafortune et al., 1994; Souza et al., 2009; Gross et al., 2011). While pronation is normal, a more pronated foot type can lead to internal tibial rotation which, if prolonged over time, can increase medial TFJt loading due to the coupling mechanism which was discussed in Chapter 2 (Section 2.2 in Normal Foot Posture and Function). Therefore, the potential effect of foot posture on clinical symptoms and in-shoe plantar pressure measurements of medial TFJt OA patients needed to be investigated. Furthermore, as conservative interventions such as altering foot position when externally rotating the foot to reduce KAM, has a positive effect on patient outcomes, the influence of static foot posture on these outcomes needed to be determined. If foot posture is clinically relevant, it could be a potential indicator of TFJt OA that has not been accounted for in knee intervention studies using conservative treatments such as LWOs. The effect of foot posture and its dynamic effect within footwear also needed to be studied as these factors could explain the inconclusive findings of LWO intervention studies in a Cochrane review (Brouwer et al., 2007), but more positive findings of Barrios and colleagues (2009) when using standardised walking shoes and LWOs.

6.1.1 The relationship between tibiofemoral joint alignments, foot posture and foot function in normal and OA groups

The categorisation of lower limb alignment profiles and the associated reliability and validity of available techniques has been critically appraised in Chapter 2 (Section 2.3). The clinical applicability of these methods have also been evaluated within the context of suitability, practicality, expense and specialist resources that are required to adopt these methods as these can also be a limitation in routine practice. In this research (Chapter 4), foot posture assessed using the Foot Posture Index (FPI-6) had excellent intra-rater reliability while static and dynamic frontal plane tibiofemoral joint (TFJt) assessments had more fair-moderate intra-rater reliability. However, the low standard error of measurement (SEM) associated with the FPI-6 indicates only a small deviation of errors and confirms the FPI-6 as a reliable clinical tool. The TFJt assessment methods had a higher error of measurement (SEM) indicating that it may need to be interpreted cautiously in a clinical setting. In-shoe plantar pressure assessments have been evaluated longitudinally and have been repeatedly valid, reliable and consistent (Murphy et al., 2005; Martinez-Nova et al., 2007; Hurkmans et al., 2006). Kernozek et al., (1996) suggested that at least eight steps needed to be averaged in order to
achieve excellent reliability and as a result, this study recorded nine steps for each foot. Putti and colleagues (2007) also established normative values for key plantar pressure parameters in normal, healthy participants within neutral Donnay trainers and this was used as a comparative benchmark for the normal and OA groups in this research. A key finding of the reliability studies described in Chapter 4 (Section 4.2) was the predictive ability of the statically assessed TFJt alignments to predict the dynamic TFJt by 41% and 58% for the left and right foot and which was also significant in week two (p<0.05). As static alignment can account for 50% of the variability of KAM, the potential influence of TFJt alignment on subsequent patient outcomes warrants investigation (Hurwitz et al., 2002; Barrios et al., 2009). It is also due to the coupling mechanism with the link between foot posture and function and the lower limb that lower limb alignment profiles encompassing foot posture and TFJt alignment needed to be established. This was done in a sequential process whereby firstly, normal participants were recruited in order to establish normative alignment profiles and kinetic outcomes and subsequently, OA participants were recruited in order to make comparisons with the already established and matched non-pathological group.

Normal Participants
The normal group was recruited based on probability sampling using power calculations described in detail in the methods section (Chapter 3, Section 3.1.1). Participants (n=50) were over the age of 45 as 20% of adults in the 45-64 age group have symptomatic knee OA (Cecchi et al., 2008) and OA is not common among people under the age of 45 (Altman 1986 and Oliveira et al., 1995 in Murphy et al., 2008). There were difficulties associated with recruiting participants who had no history of knee pain, injury or trauma and no history of lower limb injuries or surgeries in the over-45 population. The normal participants were assessed for foot posture, lower limb alignment profiles and kinetic outcomes and these were then compared with previous findings in the literature. The most prevalent foot posture (60% of participants) was a mildly pronated foot posture (raw FPI scores of +6 and +6.14). However, while these findings echoed previous research of a pronated foot type in an older adult population, further explanations of the findings were discussed such as an effect of age, ageing-related changes, body weight and physical activity, gender and footwear adaptations (Chapter 4, Section 4.5). However, a normative baseline needed to be established as even minor variations in FPI scores could increase the risk of altered biomechanics and have an effect on pathologies such as medial TFJt OA (Levinger et al., 2010). There were no significant differences in static or dynamic TFJt alignments based on foot posture, but a
valgus orientation of the knee which was found in this largely pronated population was discussed within the context of internal tibial rotation and external femoral rotation. However, the predominant valgus TFJt alignment is similar to previous research (Scuderi 2006; Cooke et al., 2007) while others have reported an almost neutral alignment in normal populations (Moreland et al., 1987; Cooke et al., 2003). Foot posture did have a significant effect on contact area (CA) in the medial midfoot region where a pronated foot posture was associated with an increase in CA compared with a neutral right foot. The results suggest that prolonged pronation of foot in midstance could alter the directional arm of the GRF and increase the internal tibial rotation. A more flexible foot is a mobile adaptor that could enhance balance, stability and shock absorption in non-pathological participant groups.

During gait, the intensity of the ground impact is mediated by shock-absorbing reactions of the foot and ankle, knee and hip joints. Motion patterns therefore occur simultaneously during the loading response of gait to minimise adverse loading along the kinetic chain. This begins with the ankle plantar flexing and the TFJt is slightly flexed to absorb shock (Trew and Everett 2005). Flexion of the TFJt is restrained by the quadriceps and occurs as a reaction to the heel rocker initiated by floor contact. This is because the heel rocker rolls the foot into plantar flexion and as the tibialis anterior decelerates foot drop, it can draw the tibia forward. The eccentric contraction of the quadriceps then extends the progression of tibia to advancing the thigh (Perry and Burnfield 2010). Some of the loading force is absorbed by the thigh muscle mass which can have detrimental consequences as older individuals have a reduced quality and quantity of fast-twitch and slow-twitch muscle fibres and altered ligament and cartilage composition (Macaluso and Vito 2003). Therefore, a weakness in the quadriceps muscles could be compensated for by a pronated foot type which would facilitate the necessary shock absorption.

**OA Participants**

The next phase of the research involved recruiting OA participants in order to investigate lower limb alignment and kinetic outcomes at baseline for direct comparisons with the normal group. As these participants would eventually be recruited for the randomised controlled trial investigating LWOs in a treatment and control group, the sample size from the normal informed the OA sample size (n=100). Participants were over the age of 45 with a history of medial knee pain for the past year at least with no significant trauma, injury or surgery to the lower limb. All participants also reported on their family history of OA along with the American College of Rheumatology (ACR) classification of OA based on physical
examination and symptom presentation. This was presented in Chapter 3 (Section 3.1.3) with detailed discussions on symptomatic OA versus radiographic OA in Chapter 4 (Section 4.1, Diagnosis of OA). There has been a noted discordance between clinical and radiographically-defined OA in the previous literature due to varying definitions of pain and the nature of the OA study groups (Bedson and Croft 2008). While non-conservative treatment options such as total knee replacements are considered on the basis of and are evaluated through radiographic techniques (Dandy and Edwards 2003), Dieppe and Brandt (2003) suggest that in patients without serious or severe loss of physical function, radiographic evaluation is not only rarely prescribed but it has a limited clinical value within the context of OA. Symptomatic OA with clinical symptom presentation is recommend for studies investigating management strategies such as LWOs for knee OA treatment. Furthermore, the effect of foot posture and the treatment intervention on clinical symptoms and subsequent patient-centred scores is arguably more relevant than the structural progression of OA itself (Scott 2000).

The results showed a mildly pronated foot posture with no significant differences between the normal and OA group (p>0.05). While foot posture did not effect static or dynamic TFJt alignment, the normal group had significantly higher TFJt angles which suggested a more neutral alignment compared to a more valgus alignment in OA participants. Foot posture did have an effect on CA and peak pressure (PP) in the midfoot region (p<0.01). The results showed while both groups had a mildly pronated foot type, the OA pronated group demonstrated greater loading area and a greater PP in the midfoot region. Previous researchers have demonstrated that increased body weight caused redistribution of plantar loads such as increased medial midfoot CA which may occur to increase dynamic stability during gait. The OA participants had a significantly greater BMI compared to the normal group (p=0.0006). The increases in midfoot PP could also have an effect on the elasticity of the medial longitudinal arch and its ability to dissipate loading forces effectively, therefore an increase CA in this region could occur as compensation. Also, a reduced quadriceps weakness in participants with TFJt OA could result in decreased shock absorption during midstance. As a result, a pronated foot posture could provide an increased surface area available for compensatory shock absorption instead of the eccentric contraction and loading of weakened quadriceps (Perry and Burnfield 2010).

The concept of ‘envelope of function’ could also be applied in order to gain an insight into the effect of a pronated foot posture on loading in the medial TFJt. The knee has the capacity to assimilate and distribute loads within an optimal envelope of function (Kulkarni 2009).
However, with altered loading mechanisms due to malalignment, the excessive loading or supraphysiological loading would affect the equilibrium of the articular cartilage and bone as discussed in Chapter 2 (Section 2.1) and lead to the progression of the OA process. As a pronated foot may be a consequence of medial TFJt OA and occur to improve shock absorption, it may also reduce the excessive loading on the TFJt and move the knee from a supraphysiological state to an optimal one in terms of loading.

6.1.2 The effect of laterally wedged orthoses on patient centred outcome scores

The OA group was block randomised into the treatment group (n=52) which received the 5° LWOs and the control groups (n=48) which received the neutral orthoses. A randomised controlled trial (RCT) design was used as it is the most rigorous method of determining whether a cause-effect relationship exists between a treatment and patient and kinetic outcomes (Kendall 2003). The RCT was designed using the CONSORT and this 25-item check list is presented in Appendix 1. The clinical effectiveness of the LWOs and neutral orthotic was established using knee-health related quality of life (QoL) scores and in-shoe plantar pressure assessments at baseline, 3 weeks, 6 weeks and 12 weeks. The effect of foot posture on patient outcomes in such an intervention could be relevant as the LWOs mechanism of action is: an amalgamation of plantar pressure redistribution; an increased pronation of the STJt and; an improved shock absorbing mechanism during initial contact (Whittle 1999; Ball and Afheldt 2002; Nester et al., 2003; Zammit et al., 2008). Previous research has also found that abnormal foot posture have contributed to abnormal rearfoot and midfoot CA and PP and an increased risk of lower limb extremity injuries (Chuckpaiwong et al., 2008). However, despite this potential relationship, no research study has investigated foot posture and associated in-shoe plantar pressure parameters in an OA population. Therefore, the results of the RCT were also analysed within the context of foot posture categories. It may explain the inconclusive evidence on the clinical effectiveness of LWOs in previous RCT’s (Brouwer et al., 2007; Hinman et al., 2009; Bennell et al., 2011). The results of the RCT found that there was no significant difference in FPI scores between the treatment and control group. There was no significant differences between the groups for pain, symptoms, activities of daily living, recreational ability and QoL (p>0.05), however there were significant improvements in both groups over time (p<0.05). In the treatment group, there most significant reduction in pain scores occurred in the first 6 weeks while in the control group, most significant reductions occurred in the first 3 weeks.
While there were no statistically significant differences between the treatment and control group, there were, however, clinically relevant differences between them. The MIC for pain, symptoms, ADL and overall QoL suggest that the LWOs did have an effect on patient outcomes. Copay et al., (2007) stated than an MIC is conceptually important as it represents a change that would be considered ‘meaningful and worthwhile by the patient’, so much so that they would consider receiving or maintaining the intervention when given the choice. This is relevant as the KOOS scores for 4 of the 5 QoL outcomes were within or exceeded the MIC thresholds as identified by Roos and Lohmander (2003).

The overall conclusions are that LWOs had non-statistically significant but clinically relevant effect on patient centred outcome scores with noted improvements in pain and overall QoL. The improvements in the control group could be explained by the Hawthorne effect in which participants improvements are linked to their inclusion and awareness of the research environment as opposed to the LWOs. This could be the cause of inconclusive findings of LWO effectiveness despite improvements in both the control and treatment groups in previous studies (Wallace 2006; Rubin and Menz 2006).

6.1.3 The effect of laterally wedged orthoses on in-shoe plantar pressure measurements

There was however, a highly significant difference in plantar pressure between the groups (p=0.001). In the treatment group, the CA decreased over time in the medial and lateral rearfoot (p=0.0001) while in the control group, PP increased significantly over time (p=0.0001). These results suggest that the LWOs may have prevented an increase in PP over time which occurred in the control group. This could have altered the magnitude of the GRF, which may have had an effect on the KAM and subsequently could explain the significant improvements in all knee-health related QoL subscales in the treatment group. There were no significant effects of foot posture on the patient and kinetic outcomes (p>0.05). However, one factor that may have contributed to a decrease in rearfoot CA is footwear choices of participants. While baseline comparisons with the normal group were made in standardised neutral Donnay trainers, in the 12 week RCT, participants used the intervention within their own footwear. Their footwear choices were recorded for every day of the 12 week period and each footwear specification or type was used as a covariate in the analysis of in-shoe plantar pressure data. It is possible that even gradual heel elevations that exist as a design feature in walking, athletic and court shoes could have caused a decrease in rearfoot CA (Luximon et al., 2012). Therefore, footwear in conjunction with LWOs could have had a significant impact on outcomes in this RCT as well as previous studies, although only one previous RCT
accounted for footwear (Barrois et al., 2009). It could be argued that footwear may exert more of an effect on patient and kinetic outcomes than foot posture and function.

The results of the RCT also showed that in self-selected footwear, lateral rearfoot and midfoot CA was decreased significantly compared with the neutral Donnay trainers (p<0.05). This could be accounted for due to differences in design features of various heel counters and arch supports within footwear. While the Donnay trainers had a thinner sole at the heel area which offered limited shock absorption, walking shoes and athletic shoes have thicker soles with more padded heel counters that could act as a slight heel. Therefore, while affording improved shock attenuation, the elevated heel of the footwear could have also reduced CA in the rearfoot. As increased heel heights has been shown to increase compressive stressed of the medial TFJt by 23% compared with barefoot (Kerrigan et al., 1998), it follows that even sensible and often recommended footwear options such as walking shoes or stability shoes could be detrimental (Kemp et al., 2008; Shakoor et al., 2010). Shakoor and colleagues (2006) even demonstrated that sensible walking shoes resulted in a 14% increase in dynamic loading of the TFJt compared with barefoot walking in OA patients. They recommended footwear that was flat but also lightweight and flexible. This could offer an additional benefit of increased sensory input from a foot that was minimally insulated as opposed to a well-insulated foot such as in a walking shoe during ground contact. The increased sensory feedback is thought to initiate neuromuscular mechanisms which may minimise adverse loading and could have a protective function for the lower limb (Nurse and Nigg 2001). This overlaps with the ‘preferred muscle pathway’ theoretical framework which suggests that the effectiveness of foot orthoses are due to lower extremity muscle tuning which reduces adverse muscle vibrations and encourages motion along a preferred pathway (Nigg 1997; 1999 and Kirby 2006). Thus, this argument could be extended to include footwear as foot orthoses are always worn in conjunction with often recommended footwear choices such as stability shoes, trainers or walking shoes. The potential effect therefore of foot posture on outcomes such as QoL could be limited as a result of self-selected footwear.

A key finding of the RCT was that the combined effect of footwear and LWOs could have had an effect on KOOS scores and had a significant effect on in-shoe plantar pressure measurements. The results found that in treatment participants, trainers demonstrated greater CA in the medial midfoot region compared with walking shoes, oxford shoes or court shoes. These differences could not be accounted for by foot posture and suggest an alternative
mechanism for reducing knee symptoms in OA. Firstly, the medialisation of pressure in the midfoot region would alter the GRF and subsequently reduce KAM and TFJt loading. Secondly, a more pronated foot type or a prolonged pronation could act as an additional shock absorptive mechanism. When combined with the in-built shock absorption of an athletic shoe, the treatment group would have had better KOOS outcomes regardless of static foot posture. It is difficult to draw comparisons with the evidence base on OA footwear choice due to the lack of research (Shakoor et al., 2010). On the other hand, footballers’ boots have been researched relatively extensively. Livesay et al., (2006) showed that less numerous cleats were ideal for more adhering playing surfaces while studded boots are considered safer for play and considering in-shoe plantar pressure distribution (Bentley et al., 2012). The authors found that bladed boots could potentially increase loading under the lateral aspect of the foot and predispose the foot to injuries and furthermore could affect the TFJt (Bentley et al. 2012). While this study consisted of twenty nine healthy male volunteers from football teams, it is interesting to note two points. The increased loading on the lateral aspect of the foot has been linked with medial TFJt OA development (Delzell 2011); and professional footballers have a 40-80% chance of knee OA development as a result of high intensity activity over a prolonged period (training hours and match seasons) (Kuijt et al., 2012).

This research addressed calls for further investigation into foot posture and associated kinetic characteristics in pathological groups such as medial TFJt populations (Redmond et al., 2008). There was a lack of knowledge on the relationship between static foot posture and dynamic function that has been demonstrated by in healthy and patellofemoral pain syndrome patients (Barton et al., 2011), but not in medial TFJt OA. The discussion therefore on whether foot posture has a role to play in medial knee osteoarthritis is warranted based on recent research findings as well as the results of this research study. In particular, the role of foot posture on dynamic rearfoot and midfoot in-shoe plantar pressure assessments has been demonstrated in comparisons between the normal and the OA group. An improved understanding of foot posture in people with medial TFJt OA could inform our decisions on the type of foot orthoses and footwear modifications that may not only be clinically effective, but also more effective than current conservative treatment options. However, while foot posture did explain key differences between the pathological and non-pathological groups, it did not have an effect on patient outcomes and kinetic outcomes over time in the RCT in either group. This could be indicative of an adaptive response where the effect of the orthoses was not maintained over the 12 week intervention period. The significant relationships noted
particularly in the OA group at baseline in neutral Donnay trainers were not maintained in non-standardised footwear such as walking shoes. The variation in footwear style used could have therefore had more of an impact on outcomes scores and could have diminished the role and subsequent effect of foot posture. The role of LWOs was significant with an improvement in pain scores of 14.9% and overall QoL by 20.5% in the treatment group versus 7.5% and 7% respectively in the control group. The significant improvement in the control group also could be due to the influence of a neutral orthoses as demonstrated by previous research (Shiba et al., 1995; Wallace 2006) as well as more accommodating footwear choices. Participants in both groups admitted being more aware of and making sensible footwear choices throughout the trial however, this was only anecdotal. A key finding of this research is that the role of footwear in medial TFJt OA and optimal footwear choices needs to be evaluated as it could enhance the clinical effectiveness of LWOs and other conservative interventions (Eustice 2008; Radzimski et al., 2012).

Levinger et al., (2012) stated that there is an unclear relationship between foot function and knee OA due to the lack of quality research studies. Their recent results showed that there was altered foot kinematics, such as a more everted rearfoot, in knee OA which also had an effect on the internal rotation of the tibia. This study suggests that foot posture had an effect on kinetic outcomes particularly in the rearfoot and midfoot and along with footwear, could explain the clinical effectiveness of LWOs. Therefore, further research is needed in order to ascertain the relationship between foot posture and footwear but, foot posture itself cannot be undermined as a clinical indicator for knee OA. The link between kinetic outcomes and patient centred outcome scores also warrants attention as a change in rearfoot and midfoot function could affect medial TFJt loading and subsequent clinical symptoms.
6.2 **Strengths and limitations of the thesis**

**Strengths**

This thesis has a number of strengths and perhaps the most significant of these is the application of two research methods involving deductive and inductive approaches. An inductive research approach is one in which observations and exploratory methods are used to generate a tentative hypothesis that addresses a theory. On the other hand, a deductive research approach is one which is hypothesis driven based on an existing theory and is used to generate evidence from which a conclusion is drawn by either accepting or rejecting the null or alternative hypotheses (Burney 2008; Blaikie 2009). These were often used in combination. The comparative study (Chapter 4) was an example of both: an inductive research approach was used as the primary aim of the study was to establish lower limb alignment profiles in healthy participants in order to identify if any relationships existed between foot posture and static and dynamic TFJt alignment. A deductive research approach was also adopted as the secondary aim was based on the hypotheses that there may have been a difference in alignment profiles and kinetic outcomes between foot posture groups. A similar approach was also used in the comparative study between normal and OA participants (Chapter 4, Section 4.1) where inductive reasoning was used as the primary aim of the study was to establish baseline normal and OA lower limb alignment profiles, spatial gait parameters and kinetic outcomes. Deductive reasoning was also used as the secondary aim was strongly driven by the hypotheses that there may have been differences between the groups in key parameters. The study benefited from a combined approach as at the start of the research project, inductive reasoning was used significantly as there was limited research evidence available for the role of foot posture and associated kinetic outcomes in medial TFJt OA (Levinger et al., 2010; Leitch et al., 2011; Reeves and Bowling 2011; Levinger et al., 2012) and a lack of evidence on the role of foot posture in the clinical effectiveness of LWOs. This is the logic or reasoning used where a clinician or researcher may have to build an understanding of the unclear link between foot posture and medial TFJt OA as opposed to starting with key principles and theories and making deductions from these. Deductive reasoning was particularly useful in the RCT (Chapter 5, Section 5.1) where a hierarchy of statements and evidence are generated by either proving or disproving a hypothesis, such as did the LWOs have a clinically significant effect on patient outcomes compared to the neutral orthoses. Therefore, as more research evidence was gathered through the course of the study, more robust conclusions were drawn from the deductive research approach (Burney 2008).
A battery of clinical measures were used in order to establish lower limb alignment profiles and associated in-shoe plantar pressure measurements in both the normal and OA groups. These were: easy to administer, time efficient and inexpensive, which makes them attractive for use in routine clinical settings. Curran (2008) showed that the sensitivity, specificity and predictive value of clinical measures are enhanced when they are used in collaboration. As there was a significant relationship between foot posture and CA and PP that could explain the distribution of loading at the rearfoot and midfoot in OA participants, there is potential for use of this combination of standardised measures in further studies highlighting the clinical appeal.

Another strength was the use of both patient-centred outcomes and biomechanical outcomes such as in-shoe plantar pressure assessments in evaluating the effectiveness of LWOs compared with neutral orthoses. This has been a noted limitation in previous researches which have focussed on singular outcomes and thus offered little insight into the potential mechanism of action of LWOs and their potential effect on dynamic lower limb function (Mallierfert et al., 2001; Pham et al., 2004; Rubin and Menz 2005; Raiij et al., 2010; Bennell et al., 2011). These studies either did not consider or did not include footwear in their research papers. As footwear has been found to exert a significant impact on kinetic outcomes (Chapter 6, Section 6.5) and an effect on patient outcomes and KAM in more recent research (Barrios et al., 2009; Shakoor et al., 2010), the neutral Donnay trainers that were standardised allowed direct comparisons to be made with previous non-pathological groups (Putti et al., 2007) and allowed direct comparison of the normal and OA groups in this study (Chapter 6).

The design of the RCT could also be considered a strength of this thesis as it addressed calls from a Cochrane review by Brouwer and colleagues (2007) who suggested that the lack of well-designed RCT’s could account for the silver level evidence for the use of LWOs despite it being recommended in 13 out of 14 international guidelines on the management of knee OA (Zhang et al., 2008). Therefore, the CONSORT statement was used to inform the design of the RCT. While the limitations of the RCT were acknowledged (Chapter 7, Section 7.5), a CONSORT 25-item checklist was used to report the results in a clear and comprehensive way and a flow diagram of progress through the four stages of the RCT was included (Chapter 7, Section 7.2, Flow Chart 1). This study also contained the first RCT in which patient outcomes and in-shoe plantar pressure outcomes were evaluated and the results demonstrated a statistically non-significant effect of foot posture and a statistically significant effect of footwear on kinetic outcomes.
Limitations

This thesis has a number of limitations and perhaps the most significant within the context of research findings was the non-standardisation of footwear over the 12 week RCT. While a strict standardised protocol was performed for all studies and the interventions were made to a strict template, the variation in footwear could have significantly affected the results. Only one previous researcher evaluated footwear alongside an intervention (Barrios et al., 2009) and did so in sixty six participants. While footwear was considered in the design stages of the RCT, it was cost prohibitive to this research study to provide cost-free interventions as well as footwear options. This could have been compounded by individual demands for varying footwear styles based on personal preference, occupation and weather considerations.

Another limitation was that a range of foot postures from highly supinated to the highly pronated foot type was not represented in the participant samples. This could have had an effect on the results as participants with highly supinated feet may have responded differently to LWOs however, participants were recruited based on clinical symptoms of medial TFJt OA rather than foot posture types. While a pronated foot posture is the most prevalent foot type in an older adult and a medial TFJt OA population (Redmond et al., 2008; Levinger et al., 2010; 2012), the effect of a range of foot postures on clinical outcomes could have explained the variation in LWO effectiveness in the research.

The use of clinical symptom presentation in order to recruit participants may also be a weakness. The homogeneity of participants in the OA group could affect the validity of the study as not all participants may have had mild-moderate or early stage medial TFJt OA based on subjective patient reports of pain severity and location. Early stage OA as determined by the Kellgren Lawrence scale does not always predict pain and as such, its use as a valid OA rating system warrants discussion. However, Dieppe and Brandt (2003) have argued that in the early stages of OA: radiographic evaluation not routine; it is not recommended as an outcome measure for conservative interventions and; its clinical applicability is limited due to the cost, time and specialist resources required and within the context of clinical or symptomatic knee OA (NICE 2008). Clinical symptoms could be useful clinical indicators as they are already used as clinically applicable diagnostic tools. While traditionally, health outcomes have been evaluated using quantitative changes in health characteristics or the cost of provision, there has been a shift towards the patient’s perspectives and the effect an intervention may have on health, physical functioning, emotional and social mobility (Fontaine 2012). This strongly suggests that any intervention
should focus on patient-centred outcome scores first while subsequently identifying the biomechanical processes by which pain reduction occurs.

Following on from this point, the evaluation of the patient’s perspective using qualitative research methods could have provided more meaningful data for example, on compliance issues or any side effects associated with LWOs that has been reported in previous research (Brouwer et al., 2005). This particular limitation was noted during the data collection stage of the RCT. Some participants would note in their respective footwear and medication diaries how their knee felt on a particular day or during a particular week. Some of these included were; the weather, a change in physical activity in one week that could not be evaluated by the IPAQ or using the clutch in the car. However, while this would have provided a more holistic perspective of the patient responses, it would have limited contribution to the specific aims and focus of this research study. It could be the focus for future research evaluating footwear modifications or orthotic therapy in knee OA.

The intervention time period of 12 weeks is considered short term and given the chronic nature of OA, could be viewed as a limitation of this study. However, aims of this research were to establish normative values of OA and normal lower limb alignment profiles and further determine if there was a mediating effect of foot posture, static BOG or footwear on OA clinical outcomes. The studies were not aimed at the long-term evaluation of foot posture and knee alignment as previous OA research has shown that the volume of medial tibial cartilage or static TFJt does not significantly change over the short, mid- or long term (Brouwer et al., 2007; Bennell et al., 2011) and the same has been suggested for foot posture (Redmond et al., 2008). As the RCT results show that there was no effect of foot posture or static BOG but a highly significant effect of footwear. This could be considered by future studies which specifically evaluate the mid to long term effects of footwear modifications alongside LWOs.
6.3 Considerations for Future Research

This thesis has presented and identified various research areas where further investigation is warranted in order to increase the present knowledge and understanding on the relationship between the foot and the lower limb in medial TFJt OA. Whilst there are several possibilities, some of the key research areas include:

- An investigation of a range of foot posture on kinetic outcomes in medial TFJt OA:

  This would be aimed at addressing our limited understanding of the foot posture and establish whether it may potentially be a clinically relevant indicator of TFJt OA initiation and progression. A cross-sectional research study could be used to determine what effect different types of foot postures could have on lower limb alignment, kinetic and kinematic outcomes in medial TFJt OA. Participants would be recruited in a longitudinal study design similar to the Framingham Knee Osteoarthritis Study (Felson 1990) where participants were assessed over a thirty five year period for key risk factors such as gender, knee injury, occupation, etc. The inclusion criteria would include foot posture criteria with supinated, highly supinated, neutral, pronated and highly pronated groups. This could identify if certain foot postures could respond more effectively to specific treatments such as footwear modifications or foot orthoses and whether foot posture occurs as a precursor to or as a result of medial TFJt OA development.

- The appropriate type of footwear for medial knee osteoarthritis (OA): improving biomechanical and patient-centred outcomes:

  While footwear is a potential conservative treatment, recommendations are currently based on anecdotal evidence or conflicting findings about the ideal footwear, e.g. sole thickness or flexibility.

  A mixed methods research approach could be used to achieve the key goals: establish footwear recommendations/findings by researchers through a systematic review and meta-analysis of the existing literature; establish key footwear styles/design features recommended by 200 (non-probability, convenience sample) front-line health care professionals via a semi-structured questionnaire and; identify key footwear features that both normal and OA participants consider essential via a series of moderator-led focus groups. These would provide additional qualitative feedback on the effects of the interventions on various aspects of QoL and other factors that may influence it.
The amalgamation of these results will determine the types of footwear to be investigated in an exploratory footwear trial to determine the best outcome scores (kinetic, kinematic and patient-centred). A 6 month cross-over trial could then be conducted in 30 OA participants trialling their own footwear versus the optimal footwear that reduces the peak knee adduction moment (KAM) and affects the knee-health related quality of life using an instant feedback gait analysis system. This research would provide a foundation for future clinical trials evaluating footwear characteristics and improving joint loading mechanisms in knee OA patients.
OA of the medial TFJt is a major source of physical disability and reduced QoL in developed countries such as the United Kingdom (Hunter et al., 2002). Due to an increased life expectancy and the obesity epidemic, our ageing populations are faced with the burgeoning public health problem that OA has inevitably become (Russell and Hamill 2010). Pain management strategies and individual holistic assessments have been recommended and conservative interventions, such as LWOs, can address both these priorities (NICE 2008). Understanding the LWOs mechanism of action and effect on the lower limb could provide focussed evidence-based treatment strategies for pain management. The role of foot posture was discussed throughout this thesis and the significant findings of foot posture effecting kinetic outcomes in both normal and OA patients, suggests that it could be an important, albeit previously underrated, clinical indicator of knee OA patient outcomes.

More significantly, the combined effect of footwear alongside LWO use in an OA participant group has been insightful. The results of the RCT demonstrated that there were clinically significant improvements in the treatment when using MIC thresholds despite the lack of statistically significant differences between the groups. Footwear has rarely been considered or standardised in similar RCT designs. Their combined effect with LWOs could be understood, improved and finally implemented as an effective management to improve OA patient outcomes by reducing pain, managing symptoms and improving QoL. The findings support the use of LWOs as a conservative, non-invasive, and cost-effective and low-risk as a treatment strategy compared to pharmacological or surgical interventions (Pinto 2012).

Medial TFJt OA is becoming more prevalent in a working-age demographic (aged 45 – 65) due to lifestyle factors, occupation, previous lower limb injury (due to a range of aetiologies) and other previously discussed factors. As a consequence, it is necessary to firstly understand the mechanism of action and influence of lower limb alignment factors on TFJt OA outcomes. Secondly, the use of this knowledge to develop frontline treatment options that can be viably considered for maintaining and improving TFJt structure and patient outcomes as opposed to more invasive options. The research concluded that while foot posture can affect in-shoe plantar pressure measurement, it is the combined effect of LWOs and footwear that have a mediating effect on symptomatic TFJt OA such as pain and quality of life. The suggested mechanism of action was an altered shock absorbing mechanism as a result of a
prevalent pronated foot types and the orthoses. Foot pronation could have also altered the magnitude and direction of the GRF which could have had an impact on TFJt loading and subsequent patient outcomes. The research also concluded that while standardised footwear was used for all data collection sessions, self-selected footwear had a significant mediating effect on patient outcomes. The influence and role of footwear alongside LWO should be considered as viable conservative treatment options for medial TFJt OA.
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