# The biomechanical effect of different types of footwear on medial compartment knee loading during stair ascent and descent

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Submitted in Partial Fulfilment of the Requirements of the Degree of Master of Science by Research, January 2018

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# List of abbreviations

The following table describes the significance of various abbreviations used throughout the thesis and the page on which each one is defined or first used is also given.

Abbreviatio	Abbreviation Meaning Page			
TF	tibiofemoral	1		
PF	patellofemoral	1		
PFP	patellofemoral pain	2		
OA	osteoarthritis	2		
ACL	anterior cruciate ligament	2		
PCL	posterior cruciate ligament	2		
EKAM	external knee adduction moment	3		
НТО	high tibial osteotomy	3		
UKA	unicompartmental knee arthroplasty	3		
TKA	total knee arthroplasty	4		
GC	gait cycle	4		
BW	body weight			
EKFM	FM external knee flexion moment			
LWI	VI lateral wedge insole			
DALYs	disability-adjusted life years	6		
FM	mechanical axis of femur	10		
ТМ	mechanical axis of tibia	10		
HKA	hip-knee-ankle	10		
LBA	load bearing axis	11		
GRF	ground reaction force	18		
KAAI	knee adduction angular impulse	19		
K-L	Kellgren-Lawrence			
VAS	Visual Analogue Score			
WOMAC	Western Ontario and McMaster Universities Osteoarthritis Index			
KOOS	Knee Injury and Osteoarthritis Outcomes Score	20		
	continued	on next page		

WHO	World Health Organization	21
MRI	magnetic resonance imaging	
BML	bone marrow lesion	
NSAIDs	non-steroidal anti-inflammatory drugs	
GI	gastrointestinal	
CV	cardiovascular	24
ROM	range of motion	27
EKEM	external knee extension moment	27
NICE	National Institute of Clinical Excellence	30
СОР	centre of pressure	30
EVA	ethylene vinyl acetate	
SD	standard deviation	
3D	three-dimensional	
ASIS	anterior superior iliac supine	
PSIS	posterior superior iliac supine	
DoF	six-degree of freedom	
ICC	intra-class correlation	
CI	confidence interval	50
MDC	minimal detectable change	51
SEM	standard error of measurement	51
EKERM	external knee external rotation moment	52
EKIRM	external knee internal rotation moment 52	
EAIM	external ankle inversion moment	52
EAEM	external ankle eversion moment	52
ANOVA	analysis of variance	74
EMG	electromyography 106	

# Acknowledgements

I am using this opportunity to express my gratitude and appreciation to everyone who had helped me throughout the research programme.

Firstly, I would like to express my deepest gratitude to my supervisors, Dr Anmin Liu and Prof. Richard Jones, for the guidance, encouragement and advice they provided during my research journey. Under their supervision, I am gradually entered into the field of biomechanics from physiotherapy, and realized the importance of using biomechanical interventions to treat musculoskeletal diseases from a perspective of biomechanics.

Secondly, I would like to thank all the participants who sacrificed their invaluable time to take part in my experiments. I would also thank the University of Salford for providing me available facilities and related software to collect and analysis data. I am grateful to staffs in the podiatry clinic, my friends from all over the world and colleagues in my office for providing me lots of help and advices in my study. I am also grateful to the statistician John and my friend Dr Angmorterh Seth who gave me a lot of help in statistics.

Thirdly, I would like to thank Dr Chris Bramah, who worked as a physiotherapist at the University of Salford's running performance clinic, for allowing me to observe him assessing patients and showing me lots of biomechanical assessment and exercise prescription to patients with running-related injuries.

Most importantly, none of this could have happened without the support of my family. I am grateful to my families who have provided me spiritual and emotional support throughout the research project, especially my mother who is always encouraging me to keep moving.

Thanks for all your help and encouragement!

# Abstract

**Introduction:** Biomechanical treatments for knee OA, especially the specially designed footwear and LWIs, are commonly investigated and used during level walking. The specially designed footwear and LWIs have been suggested to potentially prevent, delay or even halt knee OA progression by reducing knee loading during level walking. However, stair walking is more challenging for individuals with knee OA because the medial knee loading is greater than that in level walking, which is usually reflected as the first complaint for early to moderate knee OA patients during stair walking. The investigation of biomechanical load-reduction footwear on medial knee loading during stair walking is limited and there is no consensus on what kind of design parameters would definitely achieve the expected biomechanical effect. The purpose of this work was to investigate the biomechanical effect of the chosen footwear during stair walking.

**Method**: 3D motion analysis was collected on healthy individuals who were randomised to five different footwear conditions (standard shoe, LWI inserted into standard shoe, mobility shoe, Melbourne OA shoe and variable stiffness shoe) during stair ascent and descent. Each participant performed five valid trials of stair ascent and descent for both limbs under each condition. Repeated measures ANOVA and Friedman's ANOVA were used for statistical analysis.

**Result:** Sixteen participants (eight male and eight female) took part in the study. The knee loading variables of the first and second peaks of the EKAM, and KAAI were significantly reduced when using LWI, Melbourne OA shoe and mobility shoe in comparison with the standard shoe during both stair ascent and descent. However, such reductions were not identified in the variable stiffness shoe.

**Conclusion:** The specially designed footwear (LWI, Melbourne OA shoe and mobility shoe) demonstrated to reduce both peak medial knee loading and cumulative knee loading during stair ascent and descent compared with wearing standard shoe. However, the similarly designed variable stiffness shoe did not demonstrate the same biomechanical effects. These results support that the use of specially designed shoes might be useful as a biomechanical treatment in individuals with medial knee OA during stair ascent and descent.

# **Chapter 1: Introduction**

# 1.1. The anatomy of knee joint

The knee joint is the largest and one of the most complicated joint in human body (Englund, 2010). It is composed of two separate joints: the tibiofemoral (TF) joint and the patellofemoral (PF) joint (Goldblatt and Richmond, 2003) (Figure 1-1). The surfaces of these two joints are covered with articular cartilage which provides a low-friction gliding surface to decrease the friction forces. The stability of the knee joint requires static and dynamic stabilizers. The static stabilizer is primarily maintained by the collateral and cruciate ligaments, and the mainly muscular anatomy (quadriceps, hamstrings, and gastrocnemius) provides dynamic stability to the knee joint. Between the TF joint, the medial and lateral meniscus provide shock absorption and stability to the knee.

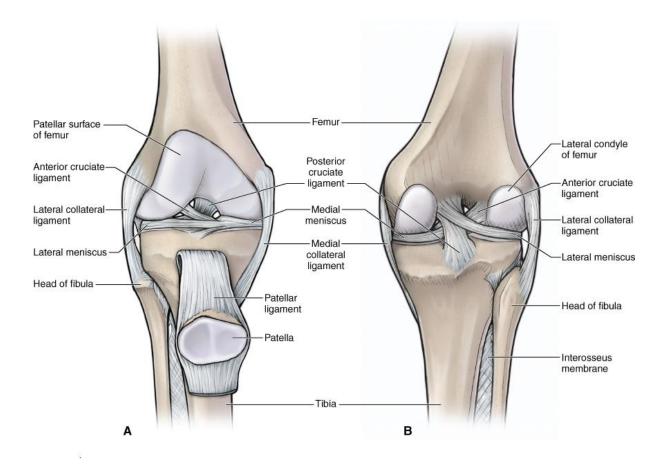


Figure 1-1: The anatomy of the right knee joint. (A) Anterior view of the knee, and (B) Posterior view of the knee) (Dutton, 2012).

The knee plays an important role in human locomotion activities and daily performance. However, patellofemoral pain (PFP), meniscal injuries, anterior and posterior cruciate ligament (ACL and PCL) injuries can decrease both sporting and the level of daily physical activity. These musculoskeletal disorders also have common risk factors for future degenerative disease, such as knee osteoarthritis (OA) particularly when the individual progresses in age.

## 1.2. Definition of knee OA

OA is the most common type of arthritis among older people, defined as cartilage destruction and rebuilding of bone close to the joint (Das and Farooqi, 2008). OA can lead to joint pain, functional impairment and disability (Pouli et al., 2014). It is the fourth leading cause of disability worldwide with its incidence increasing in the last two decades (Woolf and Pfleger, 2003). One of the most commonly affected joints by OA is the knee, and knee OA can lead to functional limitations of lower extremity and is a major cause of disability globally (Guccione et al., 1994, Murray et al., 2012, Dillon et al., 2006).

# 1.3. The prevalence of knee OA

The estimation of knee OA prevalence varies widely in different countries affected by the age and sex of the studied population. In the UK, the prevalence of knee OA in adults aged over 45 years old approaches 18% (Arthritis Research UK, 2013). In the US, about 37% of the population aged over 60 years has radiographic knee OA and 12% has knee OA symptoms while having radiographic features (Fibel et al., 2015, Dillon et al., 2006). In China, the overall prevalence of symptomatic knee OA was 11.1% in adults aged 60-69 years, and it was more common in women (14.7%) than in men (7.5%) (Tang et al., 2016). In Sweden, the prevalence of symptomatic or clinically diagnosed knee OA in adults aged 56-84 years is 15.4% (Turkiewicz et al., 2015). It is estimated that by the year 2025, the prevalence of knee OA will increase by 40% mainly due to the aging of the world population as well as obesity (Woolf and Pfleger, 2003). There is a huge challenge in managing these individuals and with ever decreasing healthcare funds, identifying easy to use and cheap management options is vital.

#### 1.4. The risk factors for knee OA

Knee OA risk factors include both systemic and local biomechanical factors and whilst systemic risk factors (age, sex, genetics, hormones, bone mineral density, race/ethnicity) are generally unmodifiable (Sowers, 2001, Chaganti and Lane, 2011), the local biomechanical factors are modifiable (Chaganti and Lane, 2011, Guilak, 2011, Felson, 2004). These biomechanical factors (higher medial knee loading, knee malalignment, obesity, and muscle weakness) play an important role in both knee injuries and future knee OA. A detailed understanding of the knee biomechanics provides an essential framework to understand and assess the progress of knee OA. In order to relieve pain and improve function in individuals with knee OA, the biomechanical risk factors related to knee OA have increasingly gained attention. One of the primary factors related to the progression of knee OA is increased knee joint load (Andriacchi et al., 2009) and it is widely believed that medial compartment knee OA and its progression are caused by the excessive load on the medial side (Chang et al., 2007). The susceptibility of medial knee OA in Western populations is five to ten times higher than that in lateral knee OA (Felson et al., 2002, Ahlbäck, 1968). This may be caused by approximately 60-80% of compressive loading force transmitted to the medial side of the knee during walking (Chang et al., 2007). Since it is hard to measure the contact stress and joint force on medial knee compartment directly, the external knee adduction moment (EKAM) is a useful surrogate measurement of the relative load on the medial compartment knee and has been correlated with knee OA radiographic severity and severity of disease symptoms (Chang et al., 2015, Andriacchi et al., 2009). This has led to reducing the peak EKAM as a common goal to improve pain and delay the onset and/or progression of medial knee OA (Hunt and Bennell, 2011, Shull et al., 2013).

## 1.5. The management of knee OA

Management of knee OA is broadly divided into surgical and non-surgical treatments that depend on the patient's stage of disease and individual characteristics. The common surgical treatments include:

- arthroscopic surgery,
- high tibial osteotomy (HTO),
- unicompartmental knee arthroplasty (UKA),

• and total knee arthroplasty (TKA).

The common conservative management options include:

- patient education,
- weight control,
- muscle strengthening exercise,
- acupuncture,
- and using biomechanical load reducing treatments.

Biomechanical load-reduction treatments such as knee braces, knee sleeves, insoles and footwear may be effective interventions for medial knee OA, with the primary mechanism to reduce the EKAM (Ramsey and Russell, 2009). There are different types of footwear widely used as a treatment of medial knee OA and many studies have reported that lateral wedge insole (LWI) (Shimada et al., 2006, Hinman et al., 2012), variable stiffness shoe (Erhart et al., 2010a, Erhart et al., 2008), Melbourne OA shoe (Kean et al., 2013, Bennell et al., 2013), and Moleca shoe (Trombini-Souza et al., 2015) could reduce medial knee loading during level walking. Compared with other biomechanical treatments (such as knee bracing, knee sleeves, etc.), using a pair of biomechanical shoes is an inexpensive option for conservative treatment and could be used every day.

# 1.6. The difference between level walking and stair walking

Extensive studies have investigated the kinematics and kinetics of lower limb in stair walking and found that the knee kinetics and kinematics during stair walking are different from that of level walking (Vallabhajosula et al., 2012, Hicks-Little et al., 2011, Protopapadaki et al., 2007, Amirudin et al., 2014). Unlike level walking where a traditional gait cycle (GC) begins with heel strike in healthy people, stair walking partially begins with initial contact with the middle to front part of the foot (Au et al., 2008, Riener et al., 2002, McFadyen and Winter, 1988). The compressive TF forces during level walking were approximately three times body weight (BW) but five times BW during stair walking (Taylor et al., 2004). Compared with level walking, the medial compartment knee loading is about six times greater during stair descent and the maximum external knee flexion moment (EKFM) is about three times greater during stair ascent, and a larger range of knee motion is required during stair ascent and descent (Andriacchi et al., 1980).

The effect of biomechanical load-reduction insoles or footwear during stair walking on knee loading in individuals with medial knee OA have been investigated by some researchers (Alshawabka et al., 2014, Sacco et al., 2012, Moyer et al., 2017, Al-Zahrani et al., 2013). However, no research has compared LWI and different biomechanical footwear during stair walking. Therefore, the main purpose of this thesis was to investigate the biomechanical effect of different types of footwear (including insoles within footwear) on knee medial joint loading during stair ascent and descent.

## **1.7. The framework of this study**

The thesis will firstly include a review (Chapter 2) to the existing literature related to knee OA, the management of knee OA, and the effect of different types of footwear designed to reduce the knee loading to demonstrate the novelty of the study to fill the gap from previous literature. Prior to the primary study on stair walking, the method of data collection and biomechanical analysis will be introduced in Chapter 3, with a between-session reliability pilot study on data quality assurance based on marker placement was performed to ensure the error of the biomechanical outcomes to be minimum so that the reported biomechanical changes after introducing the treatment would not be biased due to the error of measurement. Chapter 4 will investigate the biomechanical effect of different types of footwear on medial knee loading during stair ascent and descent with Chapter 5 presenting a summary to the study and a few considerations for future studies in this area.

# **Chapter 2: Literature review**

## 2.1. The prevalence of knee OA

The lifetime risk of developing knee OA is about 46% (Murphy et al., 2008) and it is estimated that around 10-13% of individuals aged 60 years and over have symptomatic knee OA (Zhang and Jordan, 2010). Van Der Pas et al. (2013) reported that 20.2% community-dwelling residents aged 65-85 years had clinical knee OA among some European countries (Germany, Italy, the Netherlands, Spain, Sweden and the UK). In Spain, 10.2% of the adults aged 20 and over reported symptomatic knee OA in a health survey in 2000 (Carmona et al., 2001).

#### 2.2. The economic burden of knee OA

Individuals with knee OA are more likely to increase their pain intensity, physical limitations, and functional restrictions with the progression of disease (Sutbeyaz et al., 2007) and the medial knee OA is one of the leading causes of pain and disability among older adults (Favre et al., 2016, Dillon et al., 2006). The limitations of daily activities (such as level walking, stair walking, and squatting) are common complaints to individuals with knee OA (Farr Ii et al., 2013). Knee OA affects not only the patients' infected knee but also their mood and whole life, and ultimately changes their quality of life (Nyvang et al., 2016).

Given the high prevalence of knee OA in the population, its economic burden is large, and knee OA accounts for a high socio-economic burden in the western society (Neogi et al., 2009). Knee OA is a burden not only on individuals but also on healthcare systems and the overall economy (White and Waterman, 2012, Farr Ii et al., 2013). The economic costs of knee OA include direct costs and indirect costs. Direct costs consist of drug and non-drug treatments; indirect costs consist of lost work time, reduced work productivity, caregiver services, premature death as well as disability compensation (Chen et al., 2012).

Knee OA is a primary cause of disability and contributes to 7.5 million disability-adjusted life years (DALYs, representing the number of years lived with disability or lost due to premature death) in people aged over 60 globally (Deveza and Hunter, 2016, Cross et al.,

2014). The economic cost of knee and hip OA in the general population of Spain was  $\notin 4,738$  million in 2007 which represented 0.5% of the gross national product in Spain (Loza et al., 2009). In Italy, the economic burden of a knee OA in 2004 contained: the direct costs added up to  $\notin 934$  and indirect costs came to  $\notin 1236$  for each patient within a year (Leardini et al., 2004). In the Netherlands, the costs of knee-related productivity and medical treatment for knee OA were averaged  $\notin 871$  per patient per month (Hermans et al., 2012). In the UK, the expenditure of total hip and knee replacements was  $\pounds 405$  million in 2000, and  $\pounds 852$  million in 2010 (Chen et al., 2012). According to the National Joint Registry's (NJR) 13th Annual Report, the number of primary knee replacement operations in the UK was 871,472 between 2003 and 2015 and keeps increasing during these years (Figure 2-1) (National joint registry, 2016). As both age and obesity are risk factors for the development of knee OA, it is estimated that the demand for joint replacements will continue to grow.

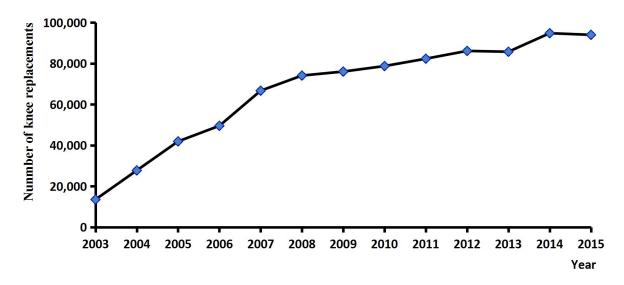


Figure 2-1: The number of annual knee replacements from 2003 to 2015 in the UK (Adapted from (National joint registry, 2016)).

#### 2.3. Risk factors for knee OA

It is necessary to know the risk factors for knee OA before it is possible to identify a treatment for the patients with medial knee OA. The contributing factors for the onset and/or worsening of knee OA are broadly classified into systemic factors and biomechanical factors (Felson et al., 2000). The systemic risk factors include age, sex, genetics, hormones, bone mineral density, race/ethnicity and generally these are unmodifiable (Sowers, 2001, Chaganti

and Lane, 2011). The biomechanical risk factors (altered joint loading), such as obesity, the adduction moment, malalignment, trauma, repetitive stress and muscle strength, play an important role in knee OA onset and/or progression, and may be modifiable (Chaganti and Lane, 2011, Guilak, 2011, Felson, 2004). A short summary of the risk factors is presented below.

#### 2.3.1 Systemic factors

#### 2.3.1.1 Aging

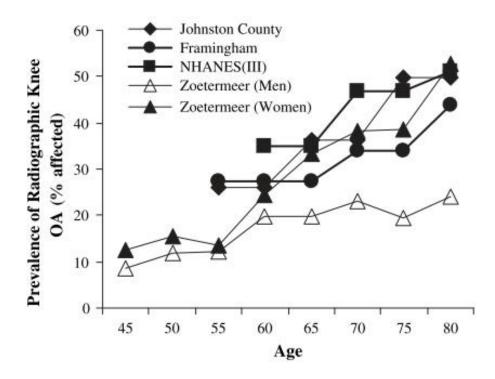


Figure 2-2: The relationship between the prevalence of radiographic knee OA and age. Data were extracted from the following studies: Johnston County (Jordan et al., 2007), Framingham (Felson et al., 1987), NHANES (III) (Dillon et al., 2006), and Zoetermeer (Van Saase et al., 1989). (Figure from (Shane Anderson and Loeser, 2010)).

OA is an age-related disease and it is the most prominent risk factor for the progression of knee OA (Felson et al., 2000, Shane Anderson and Loeser, 2010). The prevalence of radiographic knee OA increases with aging as shown in previous studies (Jordan et al., 2007, Dillon et al., 2006) and the prevalence of radiographic knee OA rose from 26.2% among

those aged 55-64 to approximately 50% among those over 75 years old (Figure 2-2) (Felson et al., 1987, Jordan et al., 2007, Van Saase et al., 1989, Dillon et al., 2006).

#### 2.3.1.2 Genetics and Gender

The genetic factors have been shown to be a determinant of radiographic knee OA and the estimated heritability of knee OA was over 40% (Spector and MacGregor, 2004). Women are more likely to suffer from higher prevalence and greater severity of knee OA than men, especially after menopause (Srikanth et al., 2005). This gender disparity effect on knee OA may be explained by the oestrogen deficiency following menopause (Felson and Zhang, 1998).

#### 2.3.1.3 Geography and nutritional factors

The incidence of symptomatic knee OA in rural areas are more likely to be higher than that in urban areas (Busija et al., 2010). The higher incidence of knee OA in rural areas may be explained by larger proportions of individuals occupied in heavy physical activities and repetitive use. Low calcium intake and low serum levels of vitamin D, which has direct effects upon cartilage metabolism and have been demonstrated to redevelop vitamin D receptors (Felson et al., 2000), appear to be associated with an increased risk for progression of knee OA (McAlindon et al., 1996).

#### 2.3.2 Biomechanical factors

#### 2.3.2.1 Obesity

Obesity represents chronic excess loading (Felson, 2013). Losing a small amount of weight can significantly reduce the risk of knee OA incidence. Felson et al. (1992) found that a reduction in BMI of two or more units (almost five kg) over 10 years could decrease the incidence of developing symptomatic knee OA among medium height women approximately by 50%.

#### 2.3.2.2 Muscle weakness and joint laxity

It is generally accepted that the quadriceps muscle is a primary contributor to dynamic knee joint stability. This may be explained by quadriceps weakness leading to poor neuromuscular control and reducing the ability of knee shock absorption (Slemenda et al., 1998, Lewek et al., 2004). Van der Esch et al. (2006) demonstrated that individuals with knee OA with a high knee varus-valgus joint laxity and low flexor-extensor muscle strength were at highest risk of functional disability.

#### 2.3.2.3 Injury

Knee injury is an important risk factor for early-onset and development of knee OA (Johnson and Hunter, 2014, Lohmander et al., 2007, Muthuri et al., 2011). Individuals with a major knee injury history are 3-6 times more likely to develop knee OA (Felson and Zhang, 1998) and are diagnosed almost 10 years earlier than those without a history of knee injuries (Brown et al., 2006). Felson and Zhang (1998) also reported that approximately 14-25% of the incidence of symptomatic knee OA could be reduced by preventing knee injuries.

#### 2.3.2.4 Repetitive joint stress

It is reported that overload stress on the articular surface could lead to OA in uninjured joints and the physical demanding activities (running, jumping, and squatting, et al.) with repetitive stress on knee joint were more likely to cause early onset of knee OA (Buckwalter et al., 2013). A higher prevalence of knee OA has been found among athletes and this may be caused by repetitive impact loading on the articular surface of the knee joint and thus leading to knee cartilage degeneration (Caine and Golightly, 2011, Frizziero et al., 2012).

#### 2.3.2.5 Malalignment

Lower extremity malalignment has been reported to be associated with the progression of knee OA (Tanamas et al., 2009). The alignment of knee is generally measured by the hip-knee-ankle (HKA) angle, which is at the intersection of the mechanical axis of femur (FM, the line between the centres of hip and knee) and the mechanical axis of tibia (TM, the line between the centres of knee and ankle) (Figure 2-3, A) (Cooke et al., 2007).

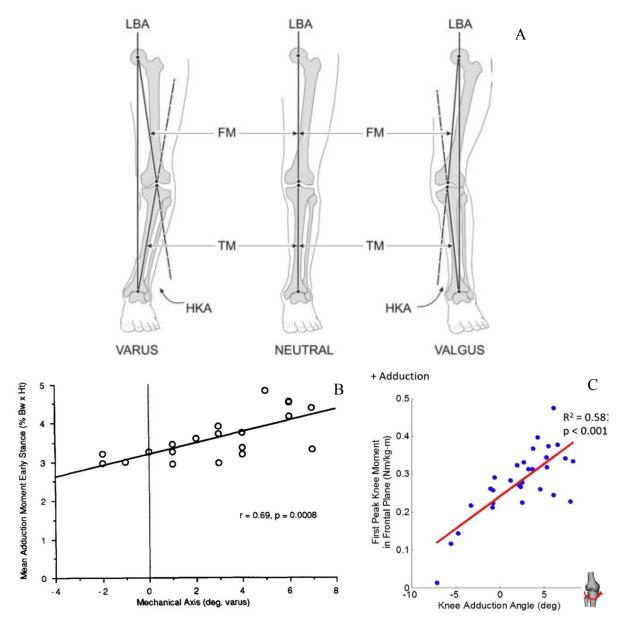


Figure 2-3: The alignment of lower extremity, and the relationship between knee adduction angle (varus angle) and EKAM. (A) The alignment of lower extremity (Cooke et al., 2007), (B) Static knee varus angle (Andrews et al., 1996), and (C) Dynamic knee varus angle (Schmitz and Noehren, 2014).

Neutrally, the load bearing axis (LBA) is defined as the line goes through the hip centre to the ankle centre, and the LBA is coincident with the FM and TM; if the LBA goes through the medial knee, it is called the knee varus (bowlegged); and if the LBA goes through the lateral knee, it is called the knee valgus (knock-kneed) (Figure 2-3 (A)) (Cooke et al., 2007). The higher static and dynamic knee adduction angles (Figure 2-3 (B) and (C)) are, particularly the dynamic knee adduction angle during walking, the more likely will the knee be subject to the higher medial loading (Barrios et al., 2012, Andrews et al., 1996, Schmitz and Noehren,

2014). Andrews et al. (1996) found that individuals with static varus knee alignment had significantly higher peak of the EKAM during early stance phase, but those with knee valgus alignment significantly had lower peak of the EKAM during early stance phase. Furthermore, Barrios et al. (2012) found that the dynamic peak knee adduction angle was better than static radiographic knee alignment to predict the medial knee loading.

# 2.4. Biomechanical knee loading in level walking and stair walking

It is widely believed that the biomechanical risk factors play an important role in the progression of knee OA. Although kneeling and squatting are critical conditions for the knee, level walking and stair walking are the most common daily activities and therefore they are the most focused conditions in all knee OA related researches (Reid et al., 2010). Before discussing the biomechanical knee loading in level walking and stair walking, it is necessary to review the normal level walking and stair walking firstly.

#### 2.4.1 Level walking

Human walking is defined as the repetitive lower limb motions to provide weight transfer while also maintain support. The typical GC is the period from one foot initially contacts the ground to the following initial contact with the ground of the same foot (Perry and Burnfield, 2010). Each GC is divided into stance phase and swing phase: the stance phase (from initial contact to toe-off) accounts for about 60% (62% by some researchers) of the GC when the foot contacts with the ground and the swing phase (from toe off to initial contact) accounts for about 40% (38% by some researchers) of the GC when the foot is in the air (Perry and Burnfield, 2010). Furthermore, the stance phase of GC includes four sub-phases (loading response, mid stance, terminal stance, pre-swing) and the swing phase of GC includes three sub-phases (initial, mid and terminal swing) (Figure 2-4 and Table 2-1) (Levine et al., 2012, Perry and Burnfield, 2010).

The initial contact is the beginning of the loading response and also called heel strike in normal gait. There are two double stance phases during stance phase, the initial double stance period is the loading response and second double stance phase is the pre-swing (Perry and Burnfield, 2010).

Phase	Sub-phase	% GC	Function
	Loading response	0-12%	Loading and weight transfer
Stance	Mid stance	13-31%	Support of entire BW;
phase	Terminal stance	32-50%	centre of mass moving forward
	Pre-swing	51-62%	Unloading and preparing for swing
	Initial swing	63-75%	Foot clearance
Swing	Mid swing	76-87%	Limb advances in front of body
phase	Terminal swing	88-100%	Limb deceleration, preparation for weight transfer

Table 2-1: Level walking GC period and function (from (Rose and Gamble, 2006))

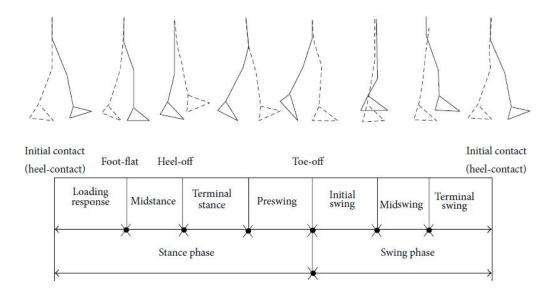


Figure 2-4: Typical GC during level walking (Alam et al., 2014).

#### 2.4.2 Stair walking

Stair walking is one of the most challenging daily activities for older adults due to greater lower limb motions and muscle power needed in comparison with level walking (Startzell et al., 2000). The GC in stair walking is similar to that in level walking, both ascending and descending include stance phase and swing phase (McFadyen and Winter, 1988). During stair walking, the stance phase is the time when the foot is on a step of the stair and the swing phase is the time when the foot is in the air. However, the sub-phases in the stair GC are not identical with level walking GC (Table 2-1 and Table 2-2) (Zachazewski et al., 1993). Generally, healthy individuals walk with the reciprocal step over step pattern (Figure 2-5 (A)) during stair walking where one foot is placed on each step, while individuals with functional

motor disability may walk with the compensatory step by step manner (Figure 2-5 (B)) where both feet placed on the same step before stair ascent or descent (Reid et al., 2007).

Condition	Phase	Period	% GC
	Stance	Weight acceptance	0-17%
Ascending	phase	Pull up	18-37%
Stair		Forward continuance	38-65%
	Swing	Foot clearance	66-82%
	phase	Foot placement	83-100%
	Stance	Weight acceptance	0-14%
Descending	phase	Forward continuance	15-34%
Stair	P	Controlled lowering	35-68%
	Swing	Leg pull through	69-84%
	phase	Foot placement	85-100%

Table 2-2: Stair GC period (from (Zachazewski et al., 1993, McFadyen and Winter, 1988))

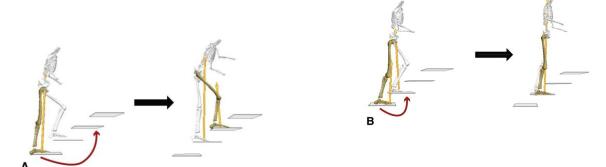


Figure 2-5: (A) Step over step stair ascent, and (B) Step by step stair ascent (Aldridge Whitehead et al., 2014)

## 2.4.2.1 Ascending stair GC

The stance phase of ascending stair GC (approximately 65% of stair GC) can be divided into three sub-phases: (1) weight acceptance, (2) pull-up, and (3) forward continuance; the swing phase (35% of GC) divided into two sub-phases: (4) foot clearance, and (5) foot placement (Figure 2-6 and Table 2-2) (Novak et al., 2010, Zachazewski et al., 1993).

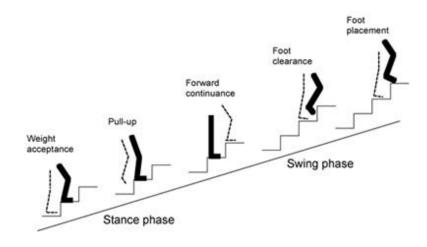


Figure 2-6: The GC of stair ascent (Novak et al., 2010)

(1) The first sub-phase of stair ascent is weight acceptance and occupies about 17% of the stair GC. Unlike level walking which using typical heel strike, the natural initial contact during stair ascent is the midfoot or forefoot strike (Au et al., 2008, Riener et al., 2002, McFadyen and Winter, 1988). During this phase, the ankle becomes more dorsiflexed (approximately 15°) whilst the hip and knee are in flexion position to prevent pelvic drop and prepare to pull up the body (Novak et al., 2010).

(2) Most of the progression made during stair ascent happens in the pull-up phase (vertical thrust phase) which represents the time of 18-37% of the stair GC. During this phase, the muscles of hip extensor, knee extensor, and the ankle plantar flexor concentrically contract to pull the body up and lift the other side foot into the air (McFadyen and Winter, 1988, Zachazewski et al., 1993).

(3) Forward continuance phase is the last stage of stance phase and occupies 38-65% of stair GC. After ascending one step, the forward progression will still continue by firing the muscles of hip extensor and knee extensor (Novak et al., 2010).

(4) Foot clearance occupies 66-82% of stair GC. During this phase, the lower limb is raised to clear the intermediate step by hip flexion, knee flexion and ankle dorsiflexion (McFadyen and Winter, 1988, Andriacchi et al., 1980).

(5) Foot placement occupies 83-100% of stair GC. During this period, the swing lower limb is positioned for foot placement on the next step (McFadyen and Winter, 1988, Zachazewski et al., 1993).

#### 2.4.2.2 Descending stair GC

The stance phase of descending stair GC, which accounts for approximately 68% of the stair GC, is also divided into three sub-phases: (1) weight acceptance, (2) forward continuance, and (3) controlled lowering; the swing phase can be divided into two sub-phases: (4) leg pull through, and (5) foot placement (Figure 2-7 and Table 2-2) (Novak et al., 2010, Zachazewski et al., 1993). Ascending stair requires higher demand for concentric muscle activities of lower limb to lift the body mass against gravity. Meanwhile, descending stair has higher demand for eccentric muscle activities of lower limb to control the lowering of the body (Costigan et al., 2002, McFadyen and Winter, 1988, Novak et al., 2010).

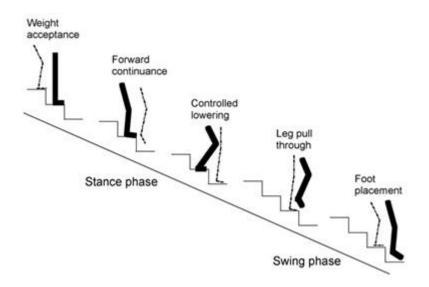


Figure 2-7: The GC of stair descent (Novak et al., 2010)

(1) Weight acceptance occupies 0-14% of stair GC. Like stair ascent, using initial midfoot or forefoot contact at the beginning of weight acceptance (Au et al., 2008, Riener et al., 2002, McFadyen and Winter, 1988). When the foot starts to accept the BW and this weight is transferred to the leg as the opposite foot lifts off the step (McFadyen and Winter, 1988, Zachazewski et al., 1993).

(2) Forward continuance occupies 15-34% of stair GC. During this period, the ankle continues to increase dorsiflexion to start the single limb support and move the body forward (Novak et al., 2010, McFadyen and Winter, 1988).

(3) Most of the progression happens in the controlled lowering phase which occupies 35-68% of stair GC (Zachazewski et al., 1993, Riener et al., 2002). During this period, the knee starts

to flex and reach the maximum degree of flexion (Zachazewski et al., 1993, Novak et al., 2010) and the foot also starts to dorsiflex and reach maximum degree of dorsiflexion (Andriacchi et al., 1980) at the same time to move the body's mass from a higher position and lower onto the support limb (Novak et al., 2010).

(4) Leg pull through occupies 69-84% of the GC. The swing limb is pulled forward by ankle plantarflexion during this phase.

(5) The foot placement occupies 85-100% of stair GC and prepares for the next weight acceptance (McFadyen and Winter, 1988, Zachazewski et al., 1993).

#### 2.4.3 The difference between level walking and stair walking

Firstly, unlike level walking where a traditional GC begins with heel strike in healthy people, both stair ascent and descent partially begins with a midfoot or forefoot strike (Au et al., 2008, Riener et al., 2002, McFadyen and Winter, 1988).

Secondly, the kinematics of stair ascent and descent are distinguished from that of level walking (Riener et al., 2002). Compared with level walking, stair ascent and descent require greater ROM of lower limb to negotiate stair (Andriacchi et al., 1980, Riener et al., 2002). The requirement of maximal knee flexion was considerably greater during both ascending (approximately 94°) and descending (approximately 91°) than during level walking (approximately 60°); the maximal ROM of ankle was greater during both ascending (approximately 43°) and descending (approximately 61°) than during level walking (approximately 25°) (Protopapadaki et al., 2007, Perry and Burnfield, 2010). However, the maximal hip ROM in sagittal plane was smaller during descending (approximately 25°) than ascending (approximately 58°) and level walking (approximately 41°) (Riener et al., 2002, Perry and Burnfield, 2010).

Thirdly, compared with level walking, the difficulty in stair walking for early to moderate knee OA patients is their first complaint (Costigan et al., 2002). This may be explained by the changes in knee kinetics and kinematics during stair walking being different from level walking. The compressive TF forces during level walking averaged approximately three times BW, stair walking averaged approximately five times BW (Taylor et al., 2004). Compared with level walking, the medial compartment knee loading could be six times

greater during stair descent and the maximum EKFM could be three times greater during stair ascent, and a larger range of knee motion would be required during stair walking (Andriacchi et al., 1980).

#### 2.4.4 Biomechanical knee loading assessment

The excessive mechanical load on knee joint has adverse effects on the development and progression of knee OA (Miyazaki et al., 2002). The medial compartment of the knee is more likely to be affected by OA than the lateral compartment (Felson et al., 2002, Ahlbäck, 1968) and this caused by approximately 60-80% of compressive loading force transmitted to the medial side of the knee during walking (Chang et al., 2007). It is difficult to measure the TF contact forces in vivo directly and thus surrogate measures are used to infer the knee loads (Hall et al., 2016). One of the best ways to assess the medial TF contact force is to measure the EKAM which is the product of the moment arm and the value of ground reaction force (GRF) in frontal plane (Hinman and Bennell, 2009) (Figure 2-8). The EKAM is a valid and reliable surrogate of dynamic medial knee loading during walking (Birmingham et al., 2007), and correlates to knee pain (Hurwitz et al., 2000) and radiographic disease severity (Kean et al., 2012).

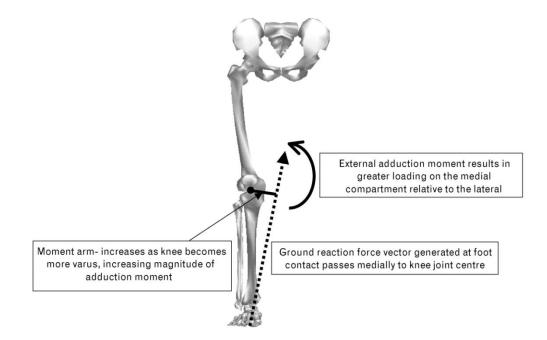


Figure 2-8: The representation of the EKAM (Hinman and Bennell, 2009).

Generally, the EKAM has two peaks (the 1<sup>st</sup> and 2<sup>nd</sup> peaks of the EKAM, Figure 2-9), and the first peak of the EKAM is usually higher than the second peak of the EKAM and used as a proxy measure of medial knee loading (Barrios et al., 2012, Baliunas et al., 2002, Hurwitz et al., 2002). The first peak of the EKAM is in the early stance (0–50% of stance phase) and the second one is in the late stance (51–100% of stance phase) (Thorp et al., 2006). It is reported that the risk of knee OA progression will increase by 6.46 times when every 1% increases in the EKAM (Miyazaki et al., 2002). Therefore, the treatment target is to lower the peak of the EKAM and Schmitz and Noehren (2014) found that the most effective way to reduce the first peak of the EKAM was to reduce the dynamic knee adduction angle in frontal plane, and followed by lowering the value of the vertical GRF.

However, Walter et al. (2010) found that reduction in the first peak of the EKAM did not guarantee the reduction in the medial knee contact force due to an increase in the peak of the EKFM, and suggested that it is better to predict the medial knee loading by using both the first and second peaks of EKAM and the peak of the EKFM. Trepczynski et al. (2014) also suggested that the peak of the EKFM need to be taken into consideration when predicting the medial knee contact force during over-flexed knee activities (such as stair walking, squatting and sit-to-stand).

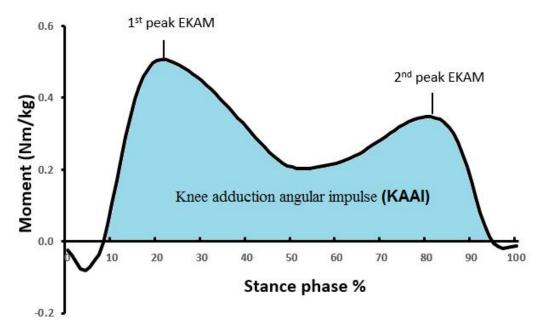


Figure 2-9: The first and second peaks of the EKAM, and KAAI.

The knee adduction angular impulse (KAAI, Figure 2-9), which represents the cumulative knee adduction loading over the stance phase (the area under the knee adduction moment

curve and above zero line, Figure 2-9), was firstly proposed by Thorp et al. (2006). The KAAI has been used as a complementary assessment to the peaks of the EKAM to measure knee loading since the first or second peak of the EKAM only represents a single time point during stance phase and cannot reflect the overall stance phase (Thorp et al., 2006). Additionally, the KAAI is more sensitive to detect the mild knee OA from the moderate knee OA than the first and second peaks of the EKAM (Thorp et al., 2006) and has been regarded as a cause for the medial cartilage volume loss (Bennell et al., 2011a). The individuals with medial knee OA have higher KAAI and peak EKAM than those without knee OA, and both of the peak EKAM and KAAI increased with Kellgren-Lawrence (K-L) grading (Thorp et al., 2006, Linley et al., 2010).

It is difficult for early to moderate knee OA patients when climbing stairs compared with level walking (Costigan et al., 2002). This may come from the differences of the knee kinetics and kinematics between the stair walking and level walking. Studies have revealed that individuals with medial knee OA have higher EKAM during stair walking than level walking; the highest peak of the EKAM was during stair descent followed by stair ascent and the lowest was level walking (Guo et al., 2007).

## 2.5. Clinical assessment of knee OA

Individuals with knee OA demonstrate clinical signs either from a pain perspective and/or a radiological perspective. This allows clinicians to determine the severity of the disease and a short overview of this is presented below.

#### 2.5.1 Pain

Pain is the most common presentation of knee OA, but it is difficult to accurately measure the pain, as one's pain score is different from another's even though in a similar disease status (Lakkireddy et al., 2015). A simple, common way of measuring pain is using the Visual Analogue Score (VAS) with a scale of one to ten. However, the most validated measures for assessing knee pain and function is the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) which is the most widely used disease specific questionnaire (Bellamy et al., 1997). The WOMAC, which was developed for elderly individuals with OA, is composed of 24 items and divided into three parts (function, pain and stiffness). The Knee Injury and Osteoarthritis Outcomes Score (KOOS) which is based on the WOMAC Arthritis

Index has been introduced in the OA literature (Roos et al., 1998). The KOOS is intended for adults with knee injury and/or knee OA, and can be used to monitor disease progression and outcomes following conservative and non-conservative interventions (Roos et al., 1998). The KOOS, which is free of charge and translated into more than 45 different language versions, has been used for clinical and research purposes internationally and is now becoming the most used instrument (Collins et al., 2016).

## 2.5.2 X-ray

The radiograph remains the most widely used tool in the diagnosis and grading of knee OA, although more advanced imaging techniques are available. Standard standing anteroposterior and lateral views of knee in extension are routinely used. Kellgren-Lawrence (K-L) grading scale (Table 2-3 and Figure 2-10) is the most often used and World Health Organization (WHO) accepted radiological classification system for the diagnosis of knee OA (Wright and Group, 2014, Lakkireddy et al., 2015, Kellegren and Lawrence, 1957). Although the radiography is the most common diagnosis choice for individuals with knee pain, the degree of disagreement between clinical criteria and the radiological classification of OA is high in the early stages (Lakkireddy et al., 2015, Hannan et al., 2000).

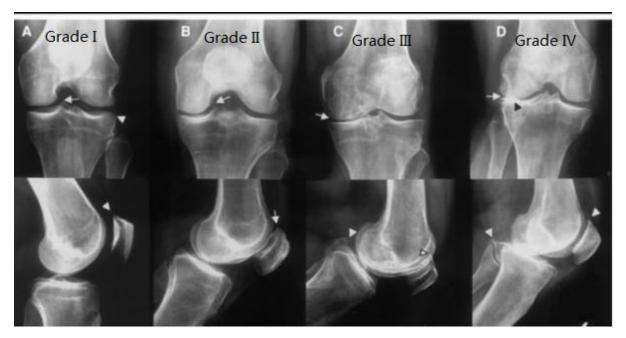


Figure 2-10: The grades of knee OA (Link et al., 2003).

Grade	Definition		
0	No radiologic features of OA		
Ι	Doubtful narrowing of joint space and possible osteophytic lipping		
II	Definite osteophytes and possible narrowing of joint space		
III	Moderate multiple osteophytes, definite narrowing of joint space, some sclerosis and possible deformity of bone contour		
IV	Large osteophytes, marked narrowing of joint space, severe sclerosis, and define deformity of bone contour.		

Table 2-3: Kellgren-Lawrence (K-L) grading scale

#### 2.5.3 Magnetic resonance imaging

Magnetic resonance imaging (MRI) is a non-invasive imaging measurement and has been successfully used to detect the changes of articular cartilage (Recht et al., 2001, Eckstein et al., 2001, Kornaat et al., 2005, Peterfy and Genant, 1996). MRI can visualize several knee OA related pathological features, including not only the volume of cartilage change, the structure of the meniscus, the joint effusion and synovitis, but also the subchondral bone marrow lesions (BMLs) (Kornaat et al., 2005, Hayashi et al., 2001), which are not easily detected by the traditional X-ray (McCauley et al., 2001). Although it has advantages in the diagnosis of knee OA, the MRI is not usually recommended as the initial screening tool and routine assessment for knee OA since its high cost.

# 2.6. Management of knee OA

With the increasing of aging population and rising obesity throughout the world, it is expected that the burden of knee OA on healthcare system will increase dramatically and globally (Cross et al., 2014). Given this background, the effective management of knee OA is becoming increasingly important globally. More than 50 treatment methods are available to manage knee OA, but most of them are aimed to alleviate symptoms (Zhang et al., 2007). Treatments are broadly divided into conservative and non-conservative surgical interventions that depend on the disease stage and characteristics of the patients. It is important to use a multi-disciplinary approach to treat knee OA as effectively as possible, especially for the patients who do not want to receive surgery. The non-operative initial treatment includes self-management strategies (losing weight, strengthening exercises, etc.) and solving

biomechanical problems via knee bracing or foot orthoses (Nejati et al., 2015, Snijders et al., 2011).

#### 2.6.1 Self-management

Self-management, which emphasize on teaching skills, has become increasingly popular in the management of chronic diseases (Walker et al., 2003). Weight control is one of the top priority of conservative treatment to knee OA (Jevsevar, 2013). As described before, both gaining weight and decreased muscle strength can lead to increase knee loading. Obesity is a strongly modifiable risk factor for the development of knee OA and weight loss should be addressed as part of the management of knee OA (Litwic et al., 2013, Blagojevic et al., 2010). However, a recent systematic review showed that self-management education programmes have little benefit to individuals with knee OA (Kroon et al., 2014).

#### 2.6.2 Exercise

The muscle strengthening has played an important role in the management of knee OA (Fransen et al., 2015). Fransen et al. (2015) reports that land-based therapeutic exercise is beneficial to improving both knee pain and quality of life for individuals with knee OA. The combination of exercise and weight loss has greater reductions in knee loading than either treatment alone for overweight people with knee OA (Messier et al., 2013). However, it is difficult for patients to adhere to both exercise and weight loss in the long term (Jones et al., 2013a). Lim et al. (2008) found that quadriceps strengthening exercise did not have any effect on medial knee loading. Additionally, Bennell et al. (2010) found that the hip muscles strengthening could alleviate pain and improve function among individuals with medial knee OA, but it did not reduce the medial knee loading.

# 2.6.3 Pharmacological management of knee OA

There is neither a known cure for knee OA nor effective pharmacological interventions to slow disease progression (Carr, 2001). Pharmacological treatment aims to relieve knee pain, which is one of the earliest symptoms of the disease, and the simple analgesics (such as paracetamol and non-steroidal anti-inflammatory drugs (NSAIDs)) were widely used (Park et al., 2016, Snijders et al., 2011). Unfortunately, none of the drugs used for knee OA has convinced structural disease modifying efficacy (Bennell et al., 2012), and drug treatment is

associated with adverse side effects (Stacy et al., 2006, Lazzaroni and Bianchi Porro, 2004). Paracetamol has been recommended for the initial treatment for mild and moderate knee OA (Zhang et al., 2008), but the latest evidence showed that paracetamol might be less effective and might have greater risks (such as gastrointestinal (GI) adverse events and multi-organ failure) than previously thought (McAlindon et al., 2014, Kielly et al., 2017). NSAIDs are associated with an increased risk of serious GI, cardiovascular (CV), and renal injury (Chou et al., 2012). Additionally, pain improvement as the result of drug consumption is accompanied by an increase in the EKAM, which could indicate an increase in medial knee loading (Fantini Pagani et al., 2012, Henriksen et al., 2006).

### 2.6.4 Acupuncture

Acupuncture therapy has gained popularity in treating OA globally (Hou et al., 2015, Jong et al., 2012) and proved beneficial in the relief of pain from OA (Manheimer et al., 2010). The mechanisms of acupuncture analgesia have been widely explored and the endogenous opiate mechanism and descending inhibitory mechanism are accepted (Pomeranz and Chiu, 1976, Takeshige et al., 1992, Hou et al., 2015, Kim et al., 2013). Generally, the treatment of acupuncture can address muscle imbalance and fascial tension and reduce inflammation and pain in the early stage of OA (Tukmachi et al., 2004, Vas et al., 2004, Hou et al., 2015, Williamson et al., 2007). However, Hinman et al. (2014a) compared the effect of needle acupuncture and laser for chronic knee pain among individuals with knee OA for three months and found that neither laser nor needle acupuncture was better than sham laser for pain relieve or function improvement.

### 2.6.5 Intra-articular injections

Intra-articular injections are preferred as the last conservative treatment for knee OA, if other conservative treatments are ineffective. Intra-articular corticosteroids have direct action on nuclear steroid receptors and thus interrupting the inflammatory and immune cascade at several critical levels (Ayhan et al., 2014). However, a 2-year clinical trial on individuals with symptomatic knee OA using intra-articular triamcinolone and saline in two groups showed that greater cartilage volume loss happened in corticosteroids group and no significant difference in knee pain between them (McAlindon et al., 2017). Given the potential side effect, the intra-articular injections may not be merited in long term treatment of knee OA.

# 2.6.6 Operative treatment for knee OA

Although surgical treatments for knee OA include arthroscopy, HTO, UKA and TKA, the best management of knee OA is still controversial. The management of medial knee OA aims to improve pain, physical function and quality of life (Longo et al., 2015). Both the HTO and UKA are the established treatment for moderate medial knee OA. TKA is the method of choice for symptomatic advanced knee OA. Moderate grade stages of knee OA require an individualized approach and are more based on patient's choice and expertise of the consulting surgeon.

# 2.6.6.1 Arthroscopic surgery

Knee OA arthroscopic surgery is an operative treatment which inserts an arthroscope into the knee joint and examines inside of the knee and the main purpose of this treatment is to remove and/or repair any damaged articular surfaces (such as cartilage fragments and osteophytes) (Kirkley et al., 2008). However, studiesreported that arthroscopic surgery did not have additional benefits to individuals with knee OA when compared with conventional physical and medical therapy (Kirkley et al., 2008, Alshami, 2014). Additionally, the intervention of arthroscopic surgery is not effective for knee OA and the treatment efficacy for knee pain and physical function is similar to knee capsule injections of saline, joint lavage, and sham surgery (Moseley et al., 2002, Deyle et al., 2012, Laupattarakasem et al., 2008).

# 2.6.6.2 High tibial osteotomy

The HTO is recognized as a surgical treatment for medial knee OA, especially the younger individuals with varus aligned knee (Rossi et al., 2011, Bonasia et al., 2014). A recent metaanalysis study of the gait changing after HTO reported that the surgery of HTO not only reduced the EKAM, but also increased the walking speed and stride length (Lee et al., 2017). As described before, the higher static and dynamic knee adduction angles were more likely to be associated with higher medial knee loading (Barrios et al., 2012, Andrews et al., 1996, Schmitz and Noehren, 2014). Therefore, individuals with varus aligned knee are associated with overload on the medial TF compartment. Hunt et al. (2006) suggested that the measurement of the dynamic knee adduction angle could be performed before planning the HTO. The intention of the HTO is to redistribute loads on the knee in individuals with medial knee OA and its mechanism is through the mechanical axis of the lower extremity laterally shifted from the medial compartment knee (Bonasia et al., 2014). The opening (medial, Figure 2-11 (A)) and closing (lateral, Figure 2-11 (B)) wedge HTO techniques are most commonly used to treat medial knee OA. The closing wedge HTO was first proposed by Jackson and Waugh (1961) and then further popularized by Coventry (1965). The closing wedge HTO has advantages over opening wedge HTO which includes faster healing, quicker to weightbearing, and fewer problems of patella baja; however, compared with the opening wedge HTO, the closing wedge HTO has its own disadvantages including fibular osteotomy or proximal tibiofibular joint dislocation, lateral muscle detachment, possible of peroneal nerve injury, and more challenging for subsequent TKA (Bonasia et al., 2014). Additionally, the disadvantages of opening wedge HTO include the need for bone grafting, higher rates of nonunion and risk of collapse (Harris et al., 2013, Ferruzzi et al., 2014, Rossi et al., 2011, Bonasia et al., 2014).





Figure 2-11: The radiograph of HTO for medial knee OA. (A) Opening wedge HTO, and (B) Closing wedge HTO) (Brouwer et al., 2006a)

# 2.6.6.3 Unicompartmental knee arthroplasty

The UKA is a surgical procedure that replaces medial or lateral compartment of the knee. The UKA has several advantages over conventional TKA which include minimal access surgery, reduced blood loss, larger knee range of motion (ROM), rapid recovery as well as reduced hospital stay (Lyons et al., 2012, Saldanha et al., 2007, Newman et al., 2009). The individuals with UKA are more likely to have normal EKFM and external knee extension moment (EKEM) in the sagittal plane compared with individuals with TKA, partly due to the presentation of the ACL in the UKA (Chassin et al., 1996). Additionally, individuals who received UKA are more likely to forget their artificial knee joint and be happier with their daily life (Zuiderbaan et al., 2017). The UKA was performed frequently among patients aged 60-64 years, while the HTO was performed most frequently among patients aged 40-44 years (Zhang et al., 2010). However, the EKAM in individuals with UKA was larger than that in individuals with TKA due to the residual varus alignment (Chassin et al., 1996). Meanwhile, Koskinen et al. (2008) did not recommend the UKA to treat unicompartmental knee OA, due to the finding that the UKA had no longer survival than TKA and no cost-benefit over TKA.

# 2.6.6.4 Total knee arthroplasty

The TKA has been regarded as a good option for the treatment of progressive knee OA and its intention is to correct the knee alignment and replace articular surfaces with a pair of artificial knee joint parts (Horikawa et al., 2015, Aglietti et al., 1999). A systematic review found that the TKA could reduce the EKAM and the maximal knee adduction angle (Sosdian et al., 2014). The TKA has long been considered the gold standard in treating knee OA because of its demonstrated predictability, durability, and effectiveness in the treatment of knee pain and improvement of function (Colizza et al., 1995, Diduch et al., 1997, Lyons et al., 2012, Aglietti et al., 1999). Compared with the UKA, the TKA had higher postoperative complications, but had lower revision rates with approximately five years' follow-up (Arirachakaran et al., 2015). However, 15-20% of the patients, who experienced functional limitation of walking, are not satisfied with their TKA (2015, Wylde et al., 2007, Nyvang et al., 2016). The factors which are related to this dissatisfaction are a subject of widespread research. The knee surgeries involve certain risk of complexities and are a burden to the healthcare system and have higher postoperative complications. The adverse outcomes of TKA include fractures, joint stiffness, postoperative ileus, ligamentous instability, arterial lacerations, amputations, deep vein thrombosis, pulmonary embolus, deep wound infections

and even death (Solomon et al., 2006, SooHoo et al., 2006, Pinaroli et al., 2009, Parvizi et al., 2008, Abularrage et al., 2008). Additionally, Orishimo et al. (2012) found that the EKAM was still high at one year after TKA, despite the static knee alignment was corrected; and suggested that the dynamic knee adduction angle could be measured to predict the recurrence of the pre-surgical knee varus deformity.

When summarizing the operative management for medial knee OA, it is clear that the varus alignment and dynamic loading are being treated in order to reduce the individual's pain and also to increase function. Whilst the conservative treatments aforementioned (exercise, acupuncture, pharmacological treatment, etc.) treat the clinical symptoms unfortunately the mechanical impairments persist and thus treatments that offer both a clinical and mechanical advantage, non-operatively, are essential.

# 2.6.7 Biomechanical treatments for medial knee OA

Biomechanical factors are associated with the pathogenesis of knee OA, although the causes of knee OA are complicated (Andriacchi and Mündermann, 2006, Yamaguchi et al., 2015, Block and Shakoor, 2010). Because local mechanical forces influence the initiation and progression of knee OA, load-modifying treatments are particularly appealing because of their acceptable costs and less adverse side effects compared with other pharmacological and operative treatments (Jones et al., 2013a).

An excessive EKAM not only has been associated with the severity and progression of radiographic knee OA but also with severity of knee pain (Fibel et al., 2015). Henriksen et al. (2014) reported that the relative odds of knee OA progression were increased by 1.9 times when each a unit increased in the peak EKAM (% BW\*Ht). In order to reduce the EKAM in individuals with medial knee OA, either the GRF lever arm or the value of GRF should be reduced. Biomechanical treatments (knee braces, knee sleeves, foot orthoses, etc.) are potentially effective interventions for medial knee OA and will be briefly reviewed next.

In order to delay or decrease knee surgeries, non-pharmacological approaches are considered the cornerstone of knee OA management and the biomechanical treatments to medial knee OA have gained more attentions recently.

#### **2.6.7.1 Knee braces and sleeves**

Unloader or off-loader knee braces have been used in knee OA patients to modulate mechanical stress on the symptomatic joint compartment and shift load from the affected compartment to the non-affected compartment (Laroche et al., 2014). Additionally, other mechanisms of knee braces may improve the stability, proprioception and warmth of the knee joint (Hunter, 2015). Valgus braces can unload the medial knee loading in patients with medial knee OA by reducing EKAM and a change in the alignment of the thigh and shank (Petersen et al., 2016). The clinical effects of valgus braces have been shown to be pain reduction and other biomechanical effects include increased walking speed, step length, and/or gait symmetry (Schmalz et al., 2010, Petersen et al., 2016). The cost-effective unloader braces treatment for knee OA has been shown to delay the requirement for surgery (Lindenfeld et al., 1997, Pollo et al., 2002, Horlick and Loomer, 1993). The impairment of proprioception in knee joint has been regarded as one of local factors in the initiation and progression of radiographic knee OA (Knoop et al., 2011, Sharma, 1999). Additionally, proprioceptive impairments could lead to knee pain and/or limitation of daily activities in knee OA patients (van Dijk et al., 2006, Bennell et al., 2003). The knee bandages may improve the proprioceptive accuracy of the knee joint by the stimulation of skin receptors around the knee (Knoop et al., 2011). Knee sleeves may improve the knee joint proprioception by providing warmth and compression to the knee joint (Miller et al., 2005, Perlau et al., 1995). Chuang et al. (2007) found that individuals with knee OA using knee sleeves improved their balance ability in both static and dynamic conditions when compared with those without sleeves. These relatively simple and inexpensive sleeves can be commonly recommended for individuals with medial knee OA to improve balance ability.

Despite the benefits of using valgus braces, using knee braces has some disadvantages: they can significantly reduce maximal knee flexion during GC and result in reduced foot clearance and a shorter stride (Gaasbeek et al., 2007, Richards et al., 2005) as well as these may not be appropriate in the long term for those with peripheral vascular disease, those who are morbidly obese, or those prone to skin irritation (Brouwer et al., 2006b). Squyer et al. (2013) also found that the most common reasons for preventing individuals with medial or lateral knee OA using the knee brace were that the brace was too uncomfortable (did not fit well) to accelerate the symptoms, too heavy and too hard to take part in activities. Additionally, a previous Cochrane review reported that the benefits of valgus knee braces for treating medial

knee OA was uncertain due to limited controlled trials were published (Duivenvoorden et al., 2015).

There were no significant differences between using valgus brace and LWI treatments to medial knee OA; however, compared with knee braces treatment, the LWI treatment was more acceptable among individuals with medial knee OA (Fu et al., 2015, Jones et al., 2013b, Fantini Pagani et al., 2012). Similarly, Fitzgerald (2005) found that the compliance with LWI treatment was over 90%, but compliance for the valgus knee loading brace was only about 50%. Therefore, whilst braces do appear to have positive elements, the overall costs, low usage and also aesthetics other devices which increase wear time would be more favorable.

### 2.6.7.2 Footwear and lateral wedge insoles

The UK's National Institute of Clinical Excellence (NICE) guidelines recommend footwear and insoles to be a part of the conservative management of knee OA (National Institute for Health and Care Excellence, 2014). The biomechanical treatments of footwear and LWI are both cheap and effective; therefore they could be utilized widely and regularly. Different types of biomechanical footwear are widely used to treat knee OA and can be broadly divided into LWI (worn within a shoe) (Hinman et al., 2012, Hinman et al., 2008b, Hinman et al., 2009, Jones et al., 2014, Chapman et al., 2015), variable stiffness shoe (Fisher et al., 2007, Erhart-Hledik et al., 2012, Boyer et al., 2012, Erhart et al., 2010b, Jenkyn et al., 2011), Melbourne OA shoe (Kean et al., 2013, Van Ginckel et al., 2017, Bennell et al., 2013, Hinman et al., 2014b, Hinman et al., 2016), and the mobility shoe (Shakoor et al., 2013, Shakoor et al., 2008, Jones et al., 2015).

# (i) Lateral wedge insole

LWIs are orthotic devices placed within the shoes, also designed to decrease EKAM and therefore to reduce medial knee loading. It was Tomatsuri et al. (1975) who firstly proposed to use LWI to treat medial knee OA. The mechanism of EKAM reduction caused by LWI was a reduction in knee adduction moment arm (Fantini Pagani et al., 2012) and a laterally shifted Centre of Pressure (COP) (Kakihana et al., 2005). Similarly, medial wedge insoles could reduce lateral knee loading for individuals with lateral knee OA (Rodrigues et al., 2008). The use of LWI for individuals with medial knee OA is a very appealing treatment

because of its acceptable price, simple intervention, and absence of adverse effects (Zhang et al., 2008, Campos et al., 2015), and have been a recommended management strategy in numerous international clinical guidelines for medial knee OA (Lewinson et al., 2014). Individuals with medial knee OA had greater compliance with LWI (71%) than that with brace (45%) during six months' treatment (van Raaij et al., 2010). A recent meta-analysis of randomized trials demonstrated that there was no significant improvement in pain when using the LWI compared with neutral comparator insole (Parkes et al., 2013). The reductions in pain may be relatively small when using LWI, but a small improvement in pain could generate large public health benefits. Meanwhile, this small reduction in pain is also linked with positive biomechanical effects.

The differences among LWIs used in research and clinical treatment are mainly their length and inclination angle. The full-length LWIs (wedged from heel to the forefoot) have been demonstrated beneficial effect on medial knee loading (Kakihana et al., 2005, Kerrigan et al., 2002, Hinman et al., 2008a, Crenshaw et al., 2000). In contrast, the heel-length LWIs (rearfoot wedge) have been proved no effect on medial knee loading (Maly et al., 2002, Hinman et al., 2008a, Nester et al., 2003). The probable reason is that the full-length LWI has longer moment arm because of its extension to the lesser metatarsal heads and increases the subtalar joint valgus moment when compared with heel-length LWI (Hinman et al., 2008a). Additionally, if the individual does not have a distinct heel strike, the sweet spot of the heellength LWI will be missed (Hinman et al., 2008a). Biomechanical studies have been performed using different inclinations of LWIs ranging from 3° to 12° (Kerrigan et al., 2002, Kakihana et al., 2004, Arnold et al., 2016). The most common inclination angle of LWI was five degrees, because higher inclination of LWI would cause greater discomfort and thus decreasing the compliance by individuals with medial knee OA (Arnold et al., 2016, Butler et al., 2007). Kerrigan et al. (2002) showed that wearing 10° LWI further reduced the EKAM; however, it was associated with varying degrees of discomfort. LWI with medial support and without medial support was also used to treat individuals with medial knee OA. The typical LWI has no medial support (Hinman et al., 2009), and the medial support LWI can be divided into custom medial supported LWI (Hunt et al., 2017) and off-the-shelf medial supported LWI (Jones et al., 2015). Hunt et al. (2017) compared the LWIs with and without custom medial arch support for individuals with medial knee OA and found that the LWI with medial support improved foot pain and function for individuals with medial knee OA

and pronated feet. Jones et al. (2015) found that both the typical LWI and off-the-shelf medial supported LWI reduced the medial knee loading similarly, but the medial supported LWI improved pain more. However, the long term clinical effect of LWI has not been proven with null effects seen in trials (Bennell et al., 2011, Baker et al., 2007). One of the potential reasons for this is the biomechanical non-response to the treatment. Despite recommendations in several guidelines (Zhang et al., 2007), approximately 20-30% of patients with medial knee OA have no or even an adverse biomechanical response (Chapman et al., 2015, Hinman et al., 2012, Kakihana et al., 2005).

Whilst LWIs are a convenient choice, the concept of having these in every pair of daily used footwear is an interesting idea and researchers in the United States and Australia have developed shoes with the mechanism of an LWI as an integrated system. One type of these shoes was called the variable stiffness shoe (Fisher et al., 2007, Erhart-Hledik et al., 2012, Boyer et al., 2012, Erhart et al., 2010b, Jenkyn et al., 2011), and the Melbourne OA shoe (Kean et al., 2013, Van Ginckel et al., 2017, Bennell et al., 2013, Hinman et al., 2014b). Additionally, another type of barefoot-mimicking walking shoe, the mobility shoe, was also used to reduce the medial knee loading (Shakoor et al., 2013, Shakoor et al., 2008, Jones et al., 2015).

### (ii) Variable stiffness shoe

The variable stiffness shoe, on which the lateral side of sole was stiffer than the medial side and the sole was made of ethylene vinyl acetate (EVA), was developed by Stanford University. The stiffness ratio of lateral side to medial side ranged from 1.2 to 1.6 in previous studies (Erhart et al., 2010a, Jenkyn et al., 2011, Erhart et al., 2010b, Erhart-Hledik et al., 2012, Teoh et al., 2013, Boyer et al., 2012, Erhart et al., 2008, Fisher et al., 2007). Fisher et al. (2007) found that the higher stiffness ratio of lateral side to medial side of sole, the greater EKAM would be reduced. The variable stiffness shoe could reduce EKAM not only in healthy individuals (Fisher et al., 2007) but also in individuals with medial knee OA (Erhart et al., 2008, Erhart-Hledik et al., 2012). The variable stiffness shoe could reduce medial knee loading immediately (Erhart et al., 2010a) and sustain the reduction in a long time (Erhart et al., 2010b). The mechanism of EKAM reduction caused by variable stiffness shoe was the COP medially shifted and a reduction in the magnitude of medial-lateral GRF component (Jenkyn et al., 2011). The finding of the medially shifted COP position in Jenkyn's study was not consistent with the expected theory that the COP laterally shifted to reduce the EKAM. However, all these previous studies only compared the effect of variable stiffness shoe on medial knee loading with constant stiffness shoe or variable stiffness shoe with different lateral to medial side stiffness ratio, and no researchers have compared the variable stiffness shoe with LWI, Melbourne OA shoe and mobility before (Fisher et al., 2007, Erhart et al., 2008, Erhart et al., 2010a, Erhart et al., 2010b, Jenkyn et al., 2011).

### (iii) Melbourne OA shoe

The Melbourne OA shoe (Gel Melbourne OA, ASICS Oceania Pty. Ltd.), which was developed and manufactured by Melbourne University and ASICS company, has integrated both a variable stiffness midsole and LWI with the idea this can significantly reduce medial knee loading immediately (Kean et al., 2013, Van Ginckel et al., 2017, Bennell et al., 2013, Hinman et al., 2014b, Hinman et al., 2016). The previous studies showed that the Melbourne OA shoe could reduce medial knee loading during walking when compared with control shoe (Asics Oceania) for individuals with medial knee OA (Kean et al., 2013, Bennell et al., 2013). However, Hinman et al. (2016) performed a randomized controlled trial study using Melbourne OA shoe to treat individuals with medial knee OA for six months, the effect of which was assessed by comparing the results with that from the conventional walking shoe, and found that pain and function improvement found in Melbourne OA shoe group.

#### (iv) Mobility shoe

The mobility shoe (a type of lightweight flexible shoe) has a series of grooves on the sole at crucial flexion points, which mimic natural barefoot walking (Shakoor et al., 2008, Shakoor et al., 2013). It has demonstrated that the inexpensive flexibility shoe could reduce medial knee loading immediately (Shakoor et al., 2008) and in longer term (Shakoor et al., 2013). However, the mobility shoe used in previous study showed no reduction in medial knee loading, though immediate knee pain and feeling of comfort significantly improved (Jones et al., 2015).

One of the common threads in biomechanics research literature of insoles and footwear is that the majority of the studies are conducted on a level ground. The difficulty in stair climbing for individuals with mild to moderate knee OA is their first complaint when compared with level walking (Costigan et al., 2002). More importantly, stair walking is more challenging for individuals with medial knee OA because the medial knee joint loading is about six times greater during stair descent than during level walking, and the maximum EKFM during stair ascent is about three times greater than level walking (Andriacchi et al., 1980). Pain has been the first complaint in individuals with medial knee OA during stair ascent and descent, devices should also be examined to whether reduce this loading during these activities (Costigan et al., 2002). Whilst there is an increase in the studies investigating this common daily activity (Vallabhajosula et al., 2012, Hicks-Little et al., 2011, Protopapadaki et al., 2007, Amirudin et al., 2014), few of them have investigated the effect of footwear on stair walking (Alshawabka et al., 2014, Sacco et al., 2012, Moyer et al., 2017, Al-Zahrani et al., 2013). Alshawabka et al. (2014) reported that LWI could reduce the EKAM during ascending and descending stairs among individuals with medial knee OA and Sacco et al. (2012) compared the Moleca shoe with heeled shoe and barefoot and found that the Moleca shoe could decrease knee loading during stair descent in knee OA patients. Al-Zahrani et al. (2013) and Moyer et al. (2017) found that a valgus knee brace and LWI combined could significantly reduce knee loading during stair walking. However, there is no study which has compared the different footwear available for individuals with knee OA when ascending or descending stairs. Different types of footwear may differ in their effect on dynamic knee loading during stair walking and thus understanding which type of footwear reduces medial knee loading best during stair walking may provide the most efficient biomechanical treatment guideline to medial knee OA. To gain a better understanding of footwear effect on medial compartment knee loading during stair walking is meaningful in this first step.

# 2.7. Summary of the review and the focus of this study

Although many different types of footwear have been developed as treatments for medial knee OA, the comprehensive studies on them are still very limited. There is no consensus on what a design feature would definitively result in the expected biomechanical effect for the knee OA. Therefore, the purpose of this work was to investigate the biomechanical effect of the five different footwear conditions (standard shoe, LWI inserted into standard shoe, mobility shoe, Melbourne OA shoe and variable stiffness shoe) on medial knee loading during stair ascent and descent. The primary null hypothesis was that there would be no significant difference in the first and second peaks of the EKAM, and KAAI between the different conditions. However, one of the primary methodological considerations is accurate

marker placement and therefore it was important to ensure that repeatable placement was achieved. In this way, before the main study started, a test-retest reliability pilot study during level walking was conducted to make sure the model, the marker placement and motion capture system which we used were reliable enough to examine the kinematics and kinetics for healthy participants in gait laboratory during different time intervals.

# Chapter 3: Biomechanical method and test-retest reliability pilot study

# 3.1. Instrumentation

# 3.1.1 Cameras and force plates setting

The environment for the work was the Podiatry Clinic's gait laboratory at the University of Salford, Salford, M6 6PU, UK. Kinematic data were collected for the lower limbs using 14 Qualisys OQUS<sup>TM</sup> infra-red motion capture cameras, Qualisys AB, Sweden) at a sampling rate of 100 Hz (Figure 3-1), and four force plates (AMTI: Advanced Mechanical Technology Incorporation, Watertown, USA, model BP600400, Figure 3-2) embedded flush in the ground were used to measure the GRF at a frequency of 1000 Hz. In our study, only force plate 2 and 3 (Figure 3-2) were used to collect data as the interlaced stair used in the following primary study must be installed in these two force plates.

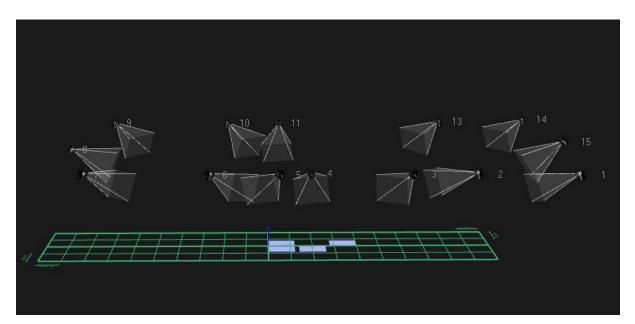


Figure 3-1: The location of the fourteen OQUS<sup>TM</sup> infra-red cameras and the four integrated AMTI force plates.

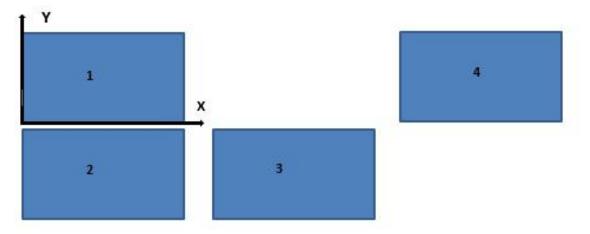


Figure 3-2: The position and orientation of the four force plates.

# 3.1.2 System calibration and lab coordinate system set up

The system calibration incorporates data derived from the force plate and data generated from the camera measurement system. The well set and synchronized force plates with the camera system provide an accurate measurement of the motion data of tracking markers and GRF data.

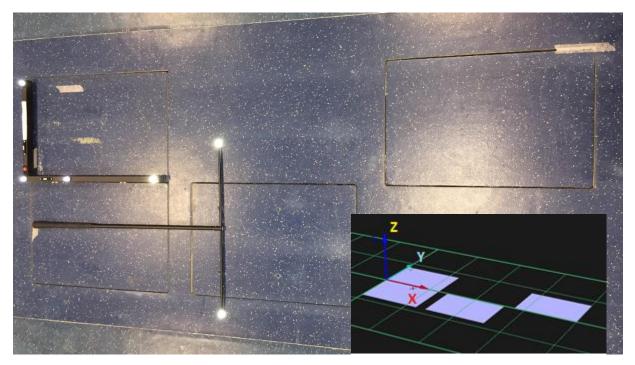


Figure 3-3: The L-frame, the calibration wand and the laboratory coordinate system.

Before data collection, the camera system was calibrated by the method of wand calibration which used a calibration kit consisting of an L-shaped metallic reference structure and a calibration wand. The L-frame contains four markers: two markers are attached to form the X-axis and another two markers determine the Y-axis (Figure 3-3). The L-frame was placed at the original corner of force plate 1 with both frames aligned with the two sides of the force plates, the L-shaped reference structure determined the laboratory coordinate system. In this study, X-axis was set as anterior-posterior, Y-axis was set along medial lateral direction and Z-axis was the vertical axis. The calibration wand (with two markers on both ends of the wand, the distance between the two markers was exactly 601.7 mm, Figure 3-3) was waved inside the measurement volume in all three directions for 60 seconds. This is to ensure that all of the space of data capture (Figure 3-4) will be calibrated with the wand that has an accurate distance. The calibration would be passed once the calibration results (capture points of each camera) achieved a certain level. During this study in the lab, the standard deviation (SD) of the wand (601.7mm) was normally less than one mm.

$\checkmark$	Calibration pa	has				
< '	calibration pa	sseu				
Camera re	sults					
Camera re	sults	1000000 - 200				
Camera	X (mm)	Y (mm)	Z (mm)	Points	Avg. residual (mm)	
)1	6146.91	-2546.60	2312.91	1562	0.38682	
)2 )3 )4	4141.55	-2535.25	2338.84	1106	0.42094	_
13	2865.08	-2472.83	2314.31	567	0.62761	=
14	832.30	-2396.82	2322.38	604	0.45913	
)5	220.12	-2510.53	2327.79	427	0.37453	
)6	-1187.81	-2525.82	2331.82	754	0.44143	
17	-3663.99	-2541.90	2352.79	1584	0.52748	
)8	-4339.84	114.31	2238.02	1404	0.54374	
)9	-3686.15	2551.31	2335.54	953	0.57299	
						-

Figure 3-4: Calibration results of a successful calibration (with only nine cameras' data shown).

# 3.1.3 CalTester calibration

Any errors occurred in the parameter settings of the force plates can lead to incorrect values of joint kinetics. In order to assess the measurement accuracy of the force plate 2 and 3 and ensure their settings in the laboratory coordinate system (the exact position and orientation), a CalTester device (which consists of a rod with two conical tips, five wands with retroreflective markers, a force application bar and a base plate, Figure 3-5) was used by the

researcher after camera calibration and before test. The CalTester test procedure is as described below:

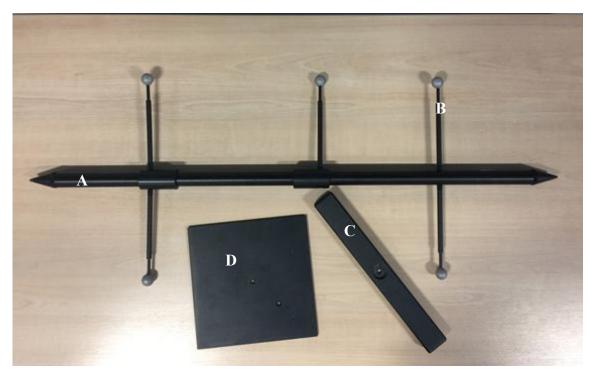


Figure 3-5: The tool of CalTester. (A) CalTester rod with two conical tips, (B) Wand with reflective marker, (C) Force application bar, and (D) Force base.

- Placing the base plate on the force plate and zero the force plate;
- Placing the CalTester rod in the centre of base plate's divot and press down firmly on the bar over the top of the rod with a load of at least 100 N;
- Keeping the CalTester rod aligned vertically and motionless during the trial and at least last for one second;
- Then moving the upper portion of the rod from vertical to 30 degrees from vertical, back to vertical and then 30 degrees in the opposite direction in either the frontal or sagittal direction and no less three seconds (Figure 3-6);
- Repeating the test at least three trials in force plate 2 and 3, respectively.



Figure 3-6: The CalTester rod was used to apply forces to the force plate

Once the data collected in force plate 2 and 3, the data were processed in the software of CalTesterPlus and the force plates setting errors, i.e. the orientation error of the GRF vector and the location error of the COP would be automatically calculated. The results presentation is shown as Figure 3-7 (as an example, the results of force plate 2 were showed). The results of force plate 2 indicated a  $0.52^{\circ}$  error in the force orientation and (1.87 mm, -3.69 mm, 1.6 mm) error in the location of the COP (X, Y, Z). The force plate 3 got a force orientation error of  $0.64^{\circ}$  and (2.28 mm, -2.87 mm, 1.06 mm) error in the location of the COP (X, Y, Z).

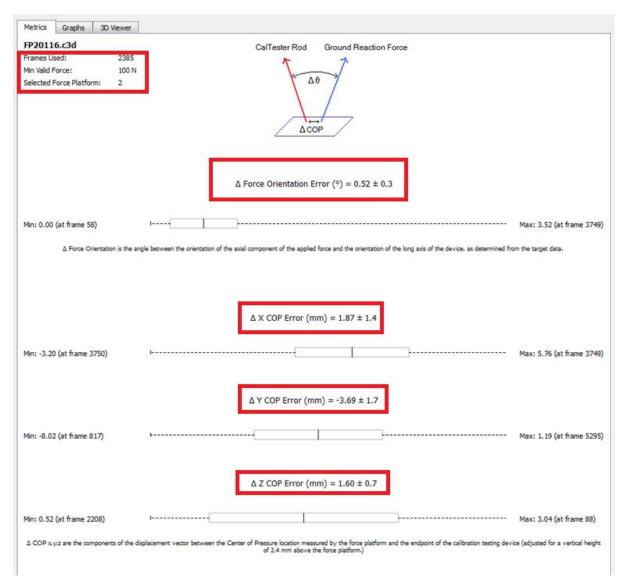


Figure 3-7: The CalTester report of the force plate 2.

# 3.2. Kinematic and kinetic data collection

# 3.2.1 Background

Knee OA is a primary cause of pain, disability and healthcare expenditure globally (Favre et al., 2016, Dillon et al., 2006). With the increasing of aging population and rising obesity worldwide, it is expected that the burden of knee OA on healthcare system will increase dramatically (Cross et al., 2014). Given this background, the effective management of knee OA is becoming increasingly important. Conservative treatments, especially the biomechanical interventions to medial knee OA have gained more attentions recently. To gain a better understanding of biomechanical treatments for knee OA, it is necessary to

monitor the longitudinal change and assess treatment effect by using the three-dimensional (3D) motion analysis.

However, the reliable measurement of knee kinematics and kinetics is crucial for academic gait research and clinical decision-making for knee OA. One of the largest sources of error in gait analysis is inaccurate and inconsistent marker placement and therefore a test-retest reliability pilot study was performed in the first instance to ensure the investigator's reliability. Many researchers investigated the reliability of kinematics and kinetics of knee (Robbins et al., 2013, Birmingham et al., 2007), but to our knowledge, no one focused on the reliability of both the pre-intervention and post-intervention of LWI to knee joint. Hence, this study respectively investigated the reliability of pre-intervention and post-intervention of LWI between the first and second gait test sessions. This was to ensure that the data collected in the primary study were not confounded by inaccurate marker placement. The following sections detail the protocol for the repeatability study.

# 3.2.2 Marker placement

In order to calculate 3D joint kinetics and kinematics, the spatial reconstruction of the body segments was needed. To accomplish this, a set of spherical retro-reflective markers were used to track the movement of the body segment. In this study, forty retro-reflective markers (Figure 3-8 (B) and (C)) were placed on top of the participant's pelvis and lower limbs directly or fixed on the rigid clusters (thermoplastic pads). Anatomical markers were placed on the anterior superior iliac spines (ASIS), posterior superior iliac spines (PSIS), iliac crests, greater trochanters, the medial and lateral femoral epicondyles, the medial and lateral malleoli, 1<sup>st</sup>, 2<sup>nd</sup> and 5<sup>th</sup> metatarsal heads and posterior of calcaneus. Four rigid tracking marker clusters (Figure 3-8 (A)), which was made by gluing the makers on thermoplastic pads, were strapped to the distal third of the shanks and thighs. In order to reduce the relative movement between the markers and skin, the Calibrated Anatomical System Technique (CAST) protocol was used to minimize the displacement errors (Cappozzo et al., 1995).

The accuracy of marker placement determines the accuracy in determining the joint of angles and moments. The pelvis and lower limb anatomical landmarks can be easily palpated in leaner participants, but it is challenging to palpate the landmarks in obese participants with a thick soft tissue layer, especially around the pelvis. It is imperative to follow the same guidelines to place the markers on landmarks. All the markers were placed in standing position because the markers on the skin will move relative to the bone as the participant transcends from sitting or lying to standing (Baker and Hart, 2013). The detailed guidance of marker placement is as follows:

- Pelvic marker placement: the ASIS are located by bringing thumbs bilaterally up from below and locking into the notch of the pelvis. Once the ASIS palpated, then the markers are placed symmetrically at the same time; some participants have dimples in the skin over-riding the PSIS; look for these first. Otherwise, palpating for the place where you can hook your thumbs bilaterally just caudal to the bony protuberance of the PSIS. Iliac crests are palpated bilaterally and two markers are placed symmetrically on the overlying skin at the uppermost margin of each iliac crest.
- Thigh marker placement: the greater trochanters are located by placing thumbs bilaterally on the lateral aspect of the iliac crests and moving down on the thigh with the middle fingers and then asking participant internally and external rotate the leg and have the feeling of greater trochanter tip move beneath the skin, and then placing the markers on the greater trochanters bilaterally at the same time. The markers are placed on the medial and lateral epicondyles of the femures and the marker clusters are strapped to the distal third of the thighs.
- Knee, ankle and foot marker placement: medial and lateral femoral epicondyle of the thighs, medial and lateral malleolus of the shanks, and marker clusters are strapped to the distal third of the shanks. Foot markers are placed on the heads of the 1<sup>st</sup>, 5<sup>th</sup> metatarsals and posterior of calcaneus over the shoe, and the distal tip of the shoe (2<sup>nd</sup> metatarsal).



Figure 3-8: Anatomical and technical reflective markers. (A) Passive reflective marker and cluster marker, (B) and (C) Location of the markers and clusters.

# 3.2.3 Data collection

### 3.2.3.1 Participants recruited

The Research Governance and Ethics Committee at the University of Salford approved the study (HSCR16-65, Appendix A). All participants were recruited from the University of Salford staff and student population by posters. Prior to each testing, the inclusion criteria for the study needed to be confirmed. All participants were classed as healthy participants if they were over 18 years of age and had no serious disease and injury which would affect their movement. Participants were excluded if they sustained an illness and an injury within the previous six months or had any neurological or musculoskeletal impairment which would affect their diffect their movement. Each participant signed an informed consent form as per the ethical approval from the University of Salford Ethics Committee.

The test-retest sessions for each participant were finished within an interval of one week and at least one day apart. In order to maximize generalizability, participants were asked to wear their own shoes (shod), a T-shirt and a pair of shorts to expose their lower limbs in order to allow the cameras to capture markers during trials. Two conditions: a control condition (shod) and an intervention condition (shod with a pair of 5° LWI, Figure 4-3) were tested. The 5° LWI is the off-the-shelf insole (with material properties of Shore A 70) and designed by the University of Salford. The reasons why the off-the-shelf LWIs being used in our study are 5° are that greater wedging is less comfortable to the wearer and difficult to accommodate within a normal shoe (Bennell et al., 2011b). Prior to data collection, all participants had five minutes to practice to get familiar with the walking condition.

# **3.2.3.2** The test procedure

Individuals were asked to change into shorts and T-shirt, and markers were applied as previously explained. Once this was completed, an initial static standing trial on the force plate was performed to determine body mass, calibrate relevant anatomic landmarks and establish joint centres (Hunt et al., 2011).

Increases in walking speed between conditions could affect joint angles and moments. Robbins and Maly (2009) reported that the magnitude of the EKAM would increase with a faster walking speed. The potential change in speed was taken into account in the pilot study as each participant was asked to perform three trials between the wireless timing gates (Brower Timing Systems, USA, Figure 3-9) at a self-selected speed, and the walking time was recorded by the timing gates. The mean time was calculated based on the recorded time of the trials and was used to monitor the walking speed. In order to minimize the speed effect on the subsequent kinetic gait analysis, the trial that had a walking time within an error of  $\pm 5\%$  was included in the analysis.



Figure 3-9: Qualysis system and the wireless timing gates (Brower Timing Systems, USA).

Then each participant completed a minimum of five valid trials consisting of two-directional level walking sequentially under each condition, at a self-selected walking speed. A valid trial was defined as the participant walked naturally and landed the whole foot on the force plate and the walking speed was within an error of  $\pm 5\%$ .

# **3.2.4 Data processing**

A Butterworth fourth order low-pass filter with a cut-off frequency of 6 Hz and 25 Hz for kinematic and analogue data, respectively was used to remove the high frequency noise of the signal. The minimum threshold value of force plates was set to 20 N for gait detection and thus any signal value below this threshold was not recognized as the start of a stance. In this way,

Visual3D automatically determines common events related to gait analysis such as initial foot strike and foot-off during gait.

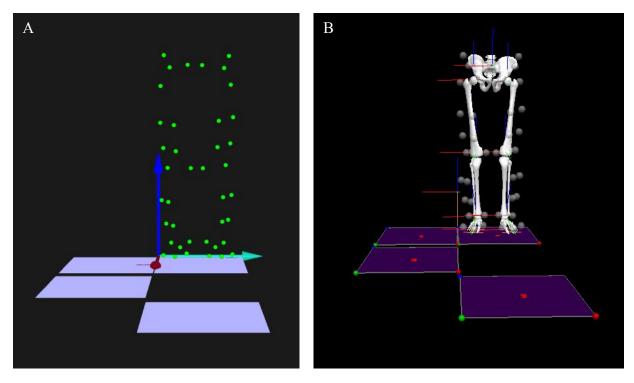


Figure 3-10: (A) The digitized static markers in QTM<sup>TM</sup>, and (B) The linked segments model in Visual3D<sup>TM</sup>.

After data collection, the passive reflective markers were labelled and then automatically digitized in the software of Qualisys Track Manager ( $QTM^{TM}$ ) (Qualisys AB, Sweden) (Figure 3-10 (A)). Gaps less than 10 frames in trajectory were filled using a polynomial interpolation cubic spline. After labelling, all digitalized data were exported to C3D files with dynamic trials using the top 10 frames (from range 1-10 of the exported frames) as its zero force baseline.

# 3.2.5 The kinematic modelling

The exported C3D files from QTM<sup>TM</sup> software were streamed and further processed in the Visual3D<sup>TM</sup> (C-Motion, USA, V6) software for data modelling and analysis. A static trial was used to create the six-degree of freedom (6 DoF) rigid segmental lower limb model (Figure 3-10 (B)) in each condition. The 6 DoF model could be used to determine all three linear or translational movements (vertical, medial-lateral and anterior-posterior) and three rotational

or angular movements in three planes (sagittal, frontal and transverse) but the translational movements at the joint were not our focus and they were not presented. The participant's height (m) and mass (kg) were entered and then the 6 DoF model was assigned to dynamic files in the same condition. The pelvis, thigh, shank and foot segments were modelled by determined the proximal and distal joint/radius and the tracking markers as illustrated in Table 3-1. In order to process kinematic data bi-directionally, the virtual laboratory was set up which changes with the direction of walking.

Segment	Proximal joint/radius	Distal joint/radius	Tracking markers			
Pelvis	<ul><li>-Right anterior superior iliac</li><li>spine</li><li>-Left anterior superior iliac</li><li>spine</li></ul>	<ul> <li>-Right posterior superior iliac</li> <li>spine</li> <li>-Left posterior superior iliac</li> <li>spine</li> </ul>	*			
Thigh	-Hip joint centre -Greater trochanter	-Medial femoral epicondyle -Lateral femoral epicondyle	Thigh cluster pad (4 tracking markers)			
Shank	-Medial femoral epicondyle -Lateral femoral epicondyle	-Medial malleolus -Lateral malleolus	Shank cluster pad (4 tracking markers) calcaneus marker, markers on the heads of metatarsal 1 <sup>st</sup> , 2 <sup>nd</sup> and 5 <sup>th</sup>			
Foot	-Medial malleolus -Lateral malleolus	-the head of the 1 <sup>st</sup> metatarsal -the head of the 5 <sup>th</sup> metatarsal				
Virtual foot	-Medial malleolus floor -Lateral malleolus floor	-the head of the 1 <sup>st</sup> metatarsal floor -the head of the 5 <sup>th</sup> metatarsal floor	calcaneus marker, markers or the heads of metatarsal 1 <sup>st</sup> , 2 <sup>nd</sup> and 5 <sup>th</sup>			

Table 3-1:	Visual3D <sup>TM</sup>	model	segments
------------	------------------------	-------	----------

Note: The \* denotes the anatomical pelvic markers were used as tracking markers to track the movement of the pelvis.

In the Visual3D software, the coda pelvis model was used to build the pelvis segment that determined by both anterior and posterior superior iliac spine (Figure 3-11 (A)). The hip joint centre was determined mathematically by the positions of the ASIS and PSIS markers with the use of regression equation which proposed by Bell et al. (1990). The joint centre of the knee was determined to be the midpoint of the distance between the medial and lateral epicondyles of the femur. The joint centre of the ankle was determined to be the midpoint of the distance from the medial to lateral malleolus. Then the left thigh segment was created by using the left hip centre, left greater trochanter and left medial, lateral femoral epicondyles

and four tracking markers (Figure 3-11 (B)) and the right thigh segment was also built. In the same way, both shank segments were built by using the medial and lateral epicondyles, medial and lateral malleoli and four tracking markers in each side. Similarly, both foot segments were built by using the medial and lateral malleoli, the 1<sup>st</sup> and 5<sup>th</sup> metatarsal and tracked by the four track markers on the foot.

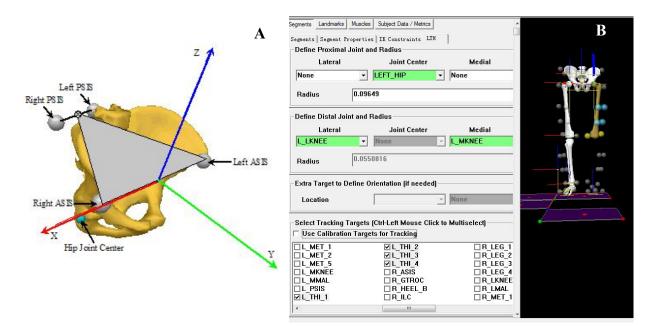


Figure 3-11: (A) The creation of Visual3D pelvis (<u>https://www.c-motion.com</u>), and (B) The creation of left Visual3D thigh.

# 3.2.6 The calculations of the joint angle, joint moment and KAAI

The angle between segments was calculated using the cardan sequence X-Y-Z (X represents flexion/extension; Y represents abduction/adduction and Z represents internal/external rotation) according to the relative position between the segments (Table 3-2). Internal moments cannot be measured directly as they are produced by the muscles and ligaments of each joint. Mathematically, the internal moments are equal and opposite to the external moment which can be calculated with inverse dynamics. In this way, the moments used in this study, were expressed as the external moments (Table 3-2) and the knee moments were resolved into the proximal coordinate system (segment coordinate system, Figure 3-12). The joint moments also were normalized to body mass and reported in Nm/kg and GRF normalized to body weight and reported in \*BW.

parameters	parameters Plane		reference segment/ coordinate system	Period <sup>#</sup>	Positive (+ve)	
	Sagittal	Shank	Thigh	Gait cycle	Flexion +ve	
Knee angle	Frontal	Shank	Thigh	Gait cycle	Adduction +ve	
	Transverse	Shank	Thigh	Gait cycle	Internal + ve	
Ankle	Frontal	Virtual	Shank	Stance phase	Inversion + ve	
angle	Fiontal	foot	Shank	Stance phase		
Knee	Sagittal Shank		Thigh	Stance phase	Extension +ve	
moment	Frontal	Shank	Thigh	Stance phase	Adduction +ve	
moment	Transverse Shank		Thigh	Stance phase	Internal + ve	
Ankle	Frontal	Foot	Shank	Stance phase	Inversion + ve	
moment	Tiontai	1000	Shank	Stance phase		
	Sagittal Foot		Virtual Lab*	Stance phase	Anterior +ve	
GRF	Frontal Foot		Virtual Lab	Stance phase	Medial +ve	
	Transverse	Foot	Virtual Lab	Stance phase	Vertical +ve	
СОР	Frontal	Foot	Virtual foot**	Stance phase	Lateral +ve	

Table 3-2: Conventions for gait measures

Notes: Virtual lab \* (laboratory) frame was set up which changes with the direction of walking and to collect kinematic data bi-directionally. Virtual foot\*\* is the foot segment with respect to the virtual lab used to achieve a zero ankle angle. # Gait cycle: from initial foot strike to the following foot strike. Stance phase: from initial foot strike to toe-off.

As described previously, there are two peaks in the EKAM. The effect of a treatment will be assessed based on the change of the value of first and second peaks of the EKAM (1<sup>st</sup> and 2<sup>nd</sup> peaks of the EKAM, Figure 2-9). Additionally, due to the first or second peak of the EKAM only represents a single time point during stance phase and cannot reflect the overall stance phase, the KAAI over the stance phase (Figure 2-9) was also calculated. The KAAI was the integration of the normalised EKAM (positive, Figure 2-9) in stance phase with the unit of Nm/Kg\*s.

Data Name	L_Knee_Moment	Model Based Item Properties Use Negative
Folder	ORIGINAL	
Result Folder will a Joint Moment: Resolution Coordii the lab or a segme Normalization is by	nate System defines the moment relative ent.	to Joint / (Segment)
		Resolution Coordinate System

Figure 3-12: Resolving the joint moment in a segment coordinate system.

# 3.3. A pilot study of test-retest reliability

# 3.3.1 The assessment of data quality

Intra-class correlation (ICC) is commonly reported in the between-session relative reliability of 3D gait analysis with associated 95% confidence intervals (95% CI) (Weir, 2005). In gait reliability studies (Bechard et al., 2011, Monaghan et al., 2007, Robbins et al., 2009), the ICC of the discrete waveform variables (including KAAI, peak knee moments, etc.) in healthy participants varied from 0.61 to 0.97. However, even high values of ICC could disguise measurement errors that could be judged as clinical importance (Luiz and Szklo, 2005). McGinley et al. (2009) suggested that the absolute magnitude of measurement error and distribution-based change indexes should be calculated, such as the standard error of measurement (SEM) and the minimal detectable change (MDC) at a 95% CI respectively. The SEM values were calculated in their original units to determine absolute reliability. The MDC describes the amount of change that is not likely due to chance variation and allows us to determine whether an observed change between assessments is truthfully due to a treatment rather than the measurement error. In the pilot study, the ICC, SEM and MDC were used to assess the test-retest reliability.

#### **3.3.2 Data analysis of the pilot study**

The key parameters selected in our study were based on previous studies which included all the kinematic and kinetic knee data in sagittal, frontal and transverse planes (Robbins et al., 2013, Birmingham et al., 2007). As described previously, the walking speed and GRF could affect the knee loading, such as the reduced GRF could result in a lower knee moment. Considering the first or second peak of EKAM only represents a single time point during stance phase and cannot reflect the overall stance phase of GC, thus the reliability of speed, GRF, and KAAI will be assessed. The LWI can change the ankle eversion angles and moments in previous studies (Alshawabka et al., 2014, Forghany et al., 2010), the reliability of ankle angles and moments in frontal plane will also be assessed. Therefore, a comprehensive assessment of 27 biomechanical outcomes was performed to check the test-retest reliability, which included 24 key discrete parameters (Table 3-3), three other parameters: KAAI, speed and stance phase time. Such a study is normally performed in only one condition (e.g., barefoot or normal shoe). However, it was deemed appropriate to assess the data quality when an intervention is worn, thus the reliability was performed on both the shod and LWI conditions.

The kinematic, kinetic and force-plate data were normalized to 101 (0-100) points representing the GC or stance phase, and processed as described previously. The selected key discrete parameters (Table 3-3) were based on an average of maximum/minimum peak values across the five valid trials for each participant during early stance phase (or GC) and/or late stance phase (or GC) as described in Table 3-3, and then an average of the peak values across all participants were calculated for each condition. The position for taking the value of each discrete parameter was marked on the variation curve of the joint angles and moments showed in Figure 3-13~15.

UKFS	
Discrete	
number	Definition of the discrete numbers
1	Peak knee flexion angle in stance phase
2	Peak knee flexion angle in swing phase
3	Peak knee adduction angle in stance phase
4	Peak knee abduction angle in stance phase
5	Peak knee internal rotation angle in stance phase
6	Peak ankle eversion angle in stance phase
7	Peak ankle inversion angle in stance phase
8	Peak external knee extension moment (EKEM) in early stance phase
9	Peak external knee flexion moment (EKFM) in early stance phase
10	Peak external knee extension moment (EKEM) in late stance phase
11	Peak external knee flexion moment (EKFM) in late stance phase
12	The first peak of the external knee adduction moment (1 <sup>st</sup> peak EKAM) in early
	stance phase
13	Minimum external knee adduction moment (trough EKAM) in middle stance
10	phase
14	The second peak of the external knee adduction moment (2 <sup>nd</sup> peak EKAM) in
	late stance phase
15	Peak external knee external rotation moment (EKERM) in stance phase
16	Peak external knee internal rotation moment (EKIRM) in stance phase
17	Peak external ankle eversion moment (EAEM) in stance phase
18	Peak external ankle inversion moment (EAIM) in stance phase
19	Peak of the posterior ground reaction force
20	Peak of the anterior ground reaction force
21	Peak of the lateral ground reaction force
22	Peak of the medial ground reaction force
23	The first peak of the vertical ground reaction force (1st Peak GRF)
24	The second peak of the vertical ground reaction force (2 <sup>nd</sup> Peak GRF)

Table 3-3: Description of the discrete parameters for knee and ankle angles, moments and GRFs

# **3.3.3 Statistics**

Statistical analysis was conducted using IBM SPSS Statistics 23 (IBM, Armonk, NY, USA). ICC with 95% CI was calculated. For the purpose of analysis, the ICC values greater than 0.9 indicate excellent reliability, those between 0.75 and 0.9 indicate good reliability, those between 0.5 and 0.75 indicate moderate reliability and those below 0.5 are indicative of poor reliability (Portney and Watkins, 2000). SEM and MDC were also calculated. The MDC and SEM were based on SD and calculated as following formulas:

SEM=SD ×  $\sqrt{(1-ICC)}$  (Harvill, 1991),

MDC=SEM × 1.96 ×  $\sqrt{2}$  (Haley and Fragala-Pinkham, 2006),

SD is the standard deviation of the pooled average scores (mean of session one and session two) from all participants (de Vet et al., 2006).

# 3.3.4 The results of the pilot study

Fourteen participants were recruited in this study and the characteristics of participants were shown in Table 3-4.

Variable	Value*
Subjects (n)	14
Gender (M/F)	8/6
Age (years)	32±5 (24-43)
Height (m)	1.66±0.08 (1.55-1.79)
Body Mass (kg)	62.67±13.53 (46.4-82.4)
BMI (kg/m <sup>2</sup> )	22.54±3.81 (19.4-33.4)

Table 3-4: Participants characteristics

\*Value is the Mean±SD (range) unless otherwise indicated. BMI= body mass index

In this study, the test-retest reliability of knee angles and moments between two sessions in both wearing shod and LWI were assessed in sagittal, frontal and transverse planes. The ICC values and their 95% CI, SEM and MDC were shown were shown in Table  $3-5\sim7$ .

# 3.3.5 The kinematic and kinetic results

The Figure 3-13~15 showed the joint angles in a GC, and the joint moments and GRFs in a stance, both of which were normalized and presented in percentage of a GC and stance. The

two curves in each figure (Figure 3-13 and Figure 3-15 (A-C) were in shod condition; Figure 3-14 and Figure 3-15 (D-F) were in LWI condition) represent the mean results of both limbs from the 14 participants in the first session test (red line) and second session test (dashed black line). The numbers in the figures indicate the discrete numbers listed in Table 3-3.

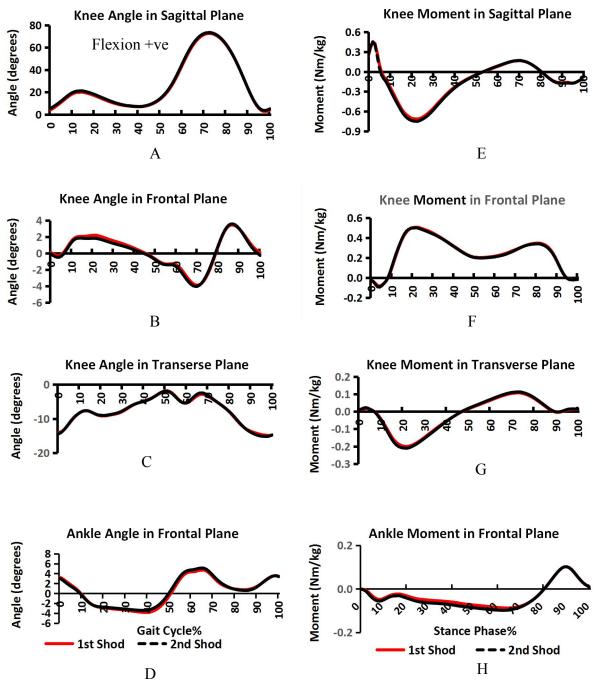


Figure 3-13: The averaged knee and ankle angles (A-D) during GC and moments (E-H) during stance phase for the first session test (red line) in shod condition (own shoes) and second session test (dashed black line) in the same condition.

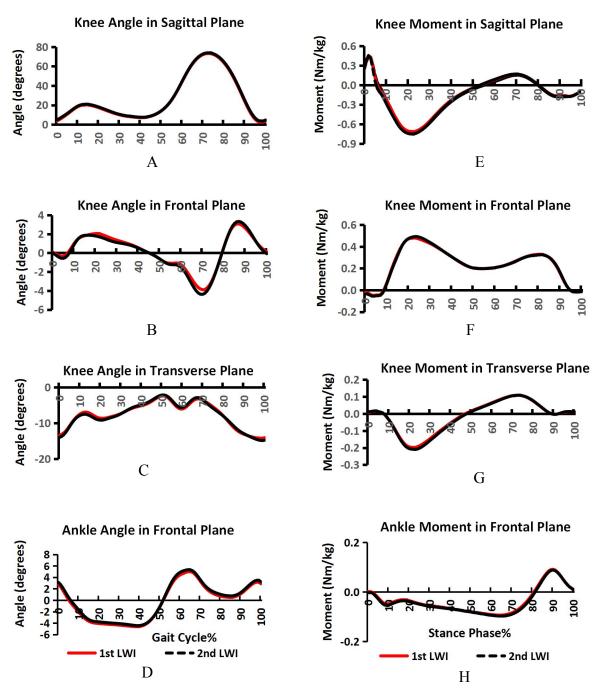


Figure 3-14: The averaged knee and ankle angles (A-D) during GC and moments (E-H) during stance phase for the first session test (red line) in LWI condition and second test (dashed black line) in the same condition.

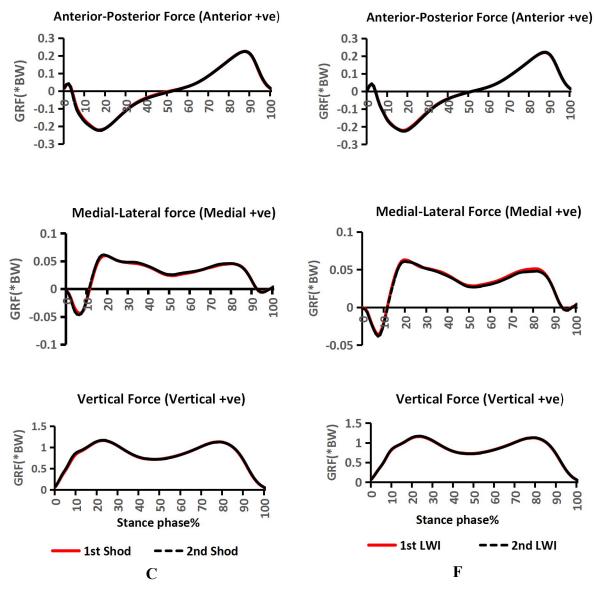


Figure 3-15: The averaged GRFs in sagittal, frontal and transverse plane, in shod (own shoe) condition (A-C) and LWI condition (D-F) during stance phase. (The red line represents the first session test and the dashed black line represents the second session test)

# 3.3.5.1 Test-retest reliability of the knee and ankle kinetics and kinematics

The results demonstrated a good to excellent repeatability in knee moments in three planes when wearing both the shod (ICC: 0.82-0.96) and LWI (ICC: 0.90-0.97) during level walking between sessions of different days. The test-retest reliability of external ankle moments in frontal plane was also from good to excellent in shod walking (ICC: 0.87-0.94) and LWI walking (ICC: 0.91-0.93), respectively. The test-retest reliability of knee angles between two sessions was from good to excellent in shod walking (ICC: 0.82-0.94) and LWI walking (ICC: 0.83-0.93), with the exception of the moderate test-retest reliability in peak knee abduction

angle in stance phase (ICC =0.75) (Table 3-6). The test-retest reliability of ankle angles between sessions was also from good to excellent in shod walking (ICC: 0.85-0.87) and LWI walking (ICC: 0.87-0.89). Additionally, the test-retest reliability of the KAAI was excellent in both conditions (ICC > 0.92). The SEM of knee angle was  $1.5^{\circ}$  in shod walking and  $1.59^{\circ}$  in LWI walking (Table 3-6). The MDC values of the first and second peaks of EKAM were 0.05 Nm/kg and 0.06 Nm/kg respectively in shod walking, and 0.06 Nm/kg for both peaks in LWI walking. Additionally, the MDC values of the KAAI were 0.02 Nm/kg\*s and 0.03 Nm/kg\*s in shod walking and LWI walking, respectively. The variation pattern of mean values, SD, SEM and MDC of the joint angles and moments between test sessions in both conditions were presented in Table 3-5~7.

# **3.3.5.2** Test-retest reliability of walking speed and stance phase time and GRFs

The test-retest reliability of walking speed and stance phase time were excellent in both the shod and LWI conditions (ICC >0.92). The walking speed was slightly higher during the second test than the first test ( $1.39\pm0.09$  and  $1.38\pm0.11$  m/s, respectively) and LWI condition ( $1.39\pm0.11$  and  $1.37\pm0.11$  m/s, respectively), while the stance phase time was almost the same when wearing shod ( $0.63\pm0.03$  and  $0.63\pm0.02$  seconds, respectively) and LWI ( $0.63\pm0.03$  and  $0.63\pm0.03$  seconds, respectively). The test-retest reliability of GRFs in anterior/posterior, medial/lateral and vertical component were illustrated in Table 3-7, which demonstrated good to excellent test-retest reliability in both conditions (ICC >0.89).

	Own shoe insole (shod)					Lateral wedge insole (LWI)								
Variables	Mean (SD)		95% CI				Mean (SD)			95% CI				
v ariables	First test	Second test	ICC	Lower Bound	Upper Bound	SEM	MDC	First test	Second test	ICC	Lower Bound	Upper Bound	SEM	MDC
Peak EKEM in early stance	0.52 (0.13)	0.52 (0.13)	0.95	0.89	0.98	0.03	0.08	0.53 (0.13)	0.54 (0.13)	0.96	0.91	0.98	0.03	0.07
Peak EKFM in early stance	0.73 (0.25)	0.77 (0.26)	0.96	0.92	0.99	0.05	0.14	0.74 (0.25)	0.76 (0.23)	0.97	0.93	0.99	0.04	0.12
Peak EKEM in late stance	0.18 (0.11)	0.18 (0.11)	0.91	0.79	0.96	0.03	0.09	0.17 (0.11)	0.17 (0.12)	0.94	0.86	0.97	0.03	0.08
Peak EKFM in late stance	0.21 (0.06)	0.22 (0.06)	0.92	0.81	0.97	0.02	0.05	0.21 (0.06)	0.22 (0.06)	0.94	0.85	0.97	0.01	0.04
First Peak EKAM	0.55 (0.14)	0.55 (0.14)	0.98	0.95	0.99	0.02	0.05	0.51 (0.13)	0.51 (0.13)	0.97	0.93	0.99	0.02	0.06
Trough EKAM	0.19 (0.04)	0.18 (0.05)	0.84	0.63	0.93	0.02	0.05	0.18 (0.05)	0.18 (0.06)	0.92	0.81	0.97	0.01	0.04
Second peak EKAM	0.36 (0.08)	0.35 (0.08)	0.93	0.84	0.97	0.02	0.06	0.35 (0.07)	0.35 (0.08)	0.90	0.77	0.96	0.02	0.06
Peak EKIRM	0.11 (0.02)	0.12 (0.03)	0.82	0.58	0.92	0.01	0.03	0.11 (0.03)	0.11 (0.03)	0.90	0.76	0.96	0.01	0.03
Peak EKERM	0.21 (0.07)	0.22 (0.07)	0.89	0.76	0.95	0.02	0.06	0.20 (0.07)	0.22 (0.07)	0.91	0.79	0.96	0.02	0.06
KAAI (Nm/Kg*S)	0.16 (0.03)	0.16 (0.03)	0.94	0.86	0.97	0.01	0.02	0.15 (0.03)	0.15 (0.03)	0.92	0.83	0.97	0.01	0.03

Table 3-5: The test-retest reliability of knee joint moments (Nm/kg) in sagittal, frontal and transverse planes

		C	)wn sho	e insole (sho	d)		Lateral wedge insole (LWI)							
Variables	Mean (SD)			95% CI				Mean (SD)		95% CI		6 CI		
v artables	First test	Second test	ICC	Lower Bound	Upper Bound	SEM	MDC	First test	Second test	ICC	Lower Bound	Upper Bound	- SEM	MDC
Peak knee flexion angle in stance phase	20.27 (5.45)	21.38 (5.34)	0.94	0.87	0.98	1.33	3.70	20.49 (5.40)	21.20 (5.22)	0.95	0.88	0.98	1.21	3.75
Peak knee flexion angle in swing phase	72.89 (3.89)	73.69 (3.74)	0.89	0.76	0.95	1.29	3.57	73.51 (3.63)	74.07 (3.95)	0.87	0.70	0.94	1.31	3.63
Peak knee adduction angle in stance phase	3.14 (2.38)	3.02 (2.84)	0.87	0.70	0.94	0.86	2.37	3.04 (2.45)	2.94 (2.83)	0.83	0.60	0.93	1.01	2.80
Peak knee abduction angle in stance phase	2.79 (2.73)	3.27 (2.72)	0.82	0.59	0.92	1.16	3.22	2.78 (2.63)	3.16 (2.75)	0.75	0.42	0.89	1.31	3.64
Peak knee internal rotation angle in stance phase	15.59 (3.76)	15.86 (5.13)	0.84	0.64	0.93	1.50	4.17	15.07 (3.97)	15.78 (4.92)	0.84	0.62	0.93	1.59	4.40
Speed (m/s)	1.38 (0.11)	1.39 (0.09)	0.98	0.93	0.99	0.01	0.04	1.37 (0.11)	1.39 (0.11)	0.97	0.88	0.99	0.02	0.06
Stance phase time (s)	0.63 (0.03)	0.63 (0.02)	0.92	0.82	0.97	0.01	0.02	0.63 (0.03)	0.63 (0.03)	0.92	0.81	0.97	0.01	0.02

# Table 3-6: The test-retest reliability of knee joint angles (Degree) in sagittal, frontal and transverse planes

		Owr	n shoe i	nsole (shoc	l)	Lateral wedge insole (LWI)								
Variables	Mear	n (SD)		95%	6 CI			Mea	n (SD)		95%	6 CI		
Variables	First test	Second test	ICC	Lower Bound	Upper Bound	SEM	MDC	First test	Second test	ICC	Lower Bound	Upper Bound	SEM	MDC
Peak EAEM (Nm/Kg)	0.15 (0.10)	0.16 (0.10)	0.87	0.71	0.95	0.03	0.09	0.15 (0.10)	0.16 (0.11)	0.91	0.79	0.96	0.03	0.09
Peak EAIM (Nm/Kg)	0.14 (0.10)	0.15 (0.12)	0.94	0.85	0.97	0.03	0.08	0.13 (0.09)	0.13 (0.11)	0.93	0.83	0.97	0.03	0.08
Peak ankle eversion angle (Degrees)	4.55 (2.32)	4.2 (2.41)	0.85	0.66	0.94	0.93	2.57	5.42 (2.35)	5.18 (2.11)	0.87	0.70	0.94	0.76	2.11
Peak ankle inversion angle (Degrees)	5.52 (2.92)	5.91 (2.17)	0.87	0.71	0.95	0.78	2.16	5.01 (2.81)	5.68 (2.46)	0.89	0.76	0.95	0.82	2.26
Peak medial GRF (*BW)	0.07 (0.02)	0.07 (0.02)	0.89	0.75	0.95	0.01	0.02	0.07 (0.02)	0.07 (0.02)	0.91	0.79	0.96	0.01	0.01
Peak lateral GRF (*BW)	-0.05 (0.02)	-0.06 (0.02)	0.92	0.82	0.97	0.01	0.02	-0.04 (0.02)	-0.04 (0.02)	0.97	0.92	0.99	0.00	0.01
Peak anterior GRF (*BW)	0.23 (0.03)	0.23 (0.03)	0.92	0.81	0.97	0.01	0.02	0.22 (0.03)	0.22 (0.03)	0.93	0.84	0.97	0.01	0.02
Peak posterior GRF (*BW)	-0.23 (0.04)	-0.23 (0.04)	0.95	0.89	0.98	0.01	0.03	-0.23 (0.05)	-0.23 (0.04)	0.96	0.92	0.99	0.01	0.02
1st Peak vertical GRF (*BW)	1.17 (0.06)	1.18 (0.06)	0.95	0.89	0.98	0.01	0.04	1.18 (0.07)	1.18 (0.06)	0.92	0.81	0.97	0.02	0.05
2nd Peak vertical GRF (*BW)	1.13 (0.05)	1.13 (0.04)	0.92	0.82	0.97	0.01	0.04	1.13 (0.05)	1.13 (0.05)	0.95	0.88	0.98	0.01	0.03

Table 3-7: The test-retest reliability of ankle moments, angles and GRFs

#### **3.3.6** The discussion of the pilot study

This is the first test-retest reliability study that the joint angles and moments of the knee and ankle were assessed under both the shod and LWI conditions. The results of walking speed and stance phase time in this study, as in previous studies (Kadaba et al., 1989, Fernandes et al., 2016), showed high degree of repeatability between two sessions in both walking with shod and LWI. This high repeatability may come from the walking time of each trial was monitored by the timing gates and controlled within an error of  $\pm 5\%$  for each participant when walking at a natural self-selected speed.

The test-retest reliability of most kinetic and kinematic knee parameters in all three planes were from good to excellent (ICC > 0.82), except the moderate (ICC = 0.75) reliable testing in peak knee abduction angle in stance phase which is in consistent with the previous test-retest reliability study that the ICC in sagittal plane was greater than 0.8 and the frontal plane was greater than 0.7 during level walking (McGinley et al., 2009). The slightly lower test-retest reliability in frontal plane angles may be influenced by kinematic cross-talk between knee flexion and adduction angles (Kadaba et al., 1990). The between-session reliability of peak external ankle moments in frontal plane were from good to excellent when both in shod (ICC: 0.87-0.94) and LWI (ICC: 0.91-0.93) conditions, and the reliability of peak ankle angles in frontal plane (ICC: 0.85-0.87 in shod; 0.87-0.89 in LWI) were similar to the external ankle moment in frontal plane, which is consistent with the study (Fernandes et al., 2016). The testretest reliability of GRFs in sagittal, frontal and transverse planes were excellent in shod walking (ICC: 0.92-0.95) and LWI walking (ICC: 0.91-0.97) in level walking, except the good reliability (ICC =0.89) in peak medial GRF in shod walking, and the excellent reliability of GRFs may come from the walking speed and stand phase time controlled well in this study.

The biomechanical outcomes are highly sensitive to the marker placement, marker signal quality (Tsushima et al., 2003, Robbins and Maly, 2009) and GRF which is directly proportional to the walking speed that inevitably bears a kind of variation even for the same participant walking in self-selected walking speed (Stansfield et al., 2006). In this study, the test-retest reliability for the walking speed and GRF were very high (ICC  $\geq 0.89$ ) and the other characteristic discrete parameters of the angle and moment of knee and ankle joint had moderate to excellent reliability (ICC  $\geq 0.75$ ) in both shod and LWI conditions. Thus, the

repeatability of marker placement must be excellent. In this study, the reliability of the testretest during the shod (ICC: 0.82-0.98) and LWI (ICC: 0.83-0.97) conditions is similar, except the moderate (ICC =0.75) reliable testing in peak knee abduction angle in stance phase during LWI condition. This indicates that the high reliability of test-retest measurement of pre-intervention and post-intervention relies on marker placement and the intervention of LWI did not affect the data quality in healthy participants. Therefore, we can investigate the different types of shoes on medial knee loading with more confidence in marker placement in the following primary study.

In addition to assessing ICC in discrete parameters between two separate sessions, this study extended previous investigations by reporting the SEM. The SEM of test-retest knee kinematics ranged from 0.86 to 1.59 in both conditions in all three planes. This also implies the kinematic knee results attained in this study were acceptable since the SEM is less than 2° according to the suggestion proposed by McGinley et al. (2009). Additionally, if a participant's score changes exceeded its value of MDC, we could be certain that a true change occurred and that it was not caused by measurement variability.

#### **3.3.7** The conclusion of the test-retest reliability study

The results of ICC and SEM values for between-session test showed high test-retest reliability in knee, ankle kinetics and kinematics and GRFs in healthy participants, and proved that the model and marker system which we used in this study were reliable to examine the kinematics and kinetics for healthy participants in gait laboratory during different time intervals with good to excellent reliability. Therefore, there is a level of consistency in the individual placing the markers demonstrating that both the model and marker system are reliable. With the study being a one-visit randomized assessment, each individual will act as their own control but confidence in the marker placement has been demonstrated.

# Chapter 4: The biomechanical effect of different types of footwear on medial compartment knee loading during stair ascent and descent

# **4.1. Introduction**

Knee OA is the most common site of OA in aging people and the lifetime risk of developing knee OA is about 46% (Murphy et al., 2008). Knee OA is a degenerative joint disease accompanied by progressive hyaline cartilage losing (Felson et al., 2000, Bijlsma et al., 2011) and its progression is characterised by pain, stiffness and reduced knee ROM, and thus leading to weight bearing activities difficult, such as level walking and stair walking (Kaufman et al., 2001). Given this background, the non-invasive biomechanical interventions to knee OA, especially the specially designed footwear and LWIs, are commonly investigated and used during level walking, such as Melbourne OA shoe (Kean et al., 2013, Bennell et al., 2013), variable stiffness shoe (Jenkyn et al., 2011, Erhart et al., 2008, Erhart et al., 2010b), mobility shoe (Shakoor et al., 2013, Shakoor et al., 2008) and LWIs (Alshawabka et al., 2014, Chapman et al., 2015) were primarily investigated during level walking.

However, it is more physical challenging for individuals with early to moderate knee OA during stair walking when compared with level walking which could be explained by the differences of the knee kinetics and kinematics between the stair walking and level walking (Costigan et al., 2002). Therefore, extensive studies have investigated the kinematics and kinetics of lower limb during stair walking (Vallabhajosula et al., 2012, Hicks-Little et al., 2011, Protopapadaki et al., 2007, Amirudin et al., 2014). The compressive TF forces averaged approximately three times BW during level walking and five times BW during stair walking (Taylor et al., 2004). Compared with level walking, the medial compartment knee loading is approximately six times greater during stair descent and the maximum EKFM is approximately three times greater during stair ascent, and a larger knee ROM is required during stair walking (Andriacchi et al., 1980). Additionally, unlike level walking where a traditional GC begins with heel strike in healthy people, stair walking partially begins with the initial contact with the middle to front part of the foot (Au et al., 2008, Riener et al., 2002, McFadyen and Winter, 1988).

Whilst the investigation of biomechanical load-reduction footwear and LWIs on individuals with medial knee OA during stair walking is limited (Alshawabka et al., 2014, Sacco et al., 2012, Moyer et al., 2017, Al-Zahrani et al., 2013). Alshawabka et al. (2014) reported that LWIs could reduce the EKAM during ascending and descending stairs in medial knee OA patients and Sacco et al. (2012) compared the Moleca shoe (a type of flexible, non-heeled footwear) with heeled shoe and barefoot and found that the Moleca shoe could decrease knee loading during stair descent in knee OA patients. Al-Zahrani et al. (2013) and Moyer et al. (2017) found that a valgus knee brace and LWI (orthotic) combined could significantly reduce knee loading during stair walking. However, there has not been a direct comparison of the different shoe based treatments available in the literature with the most commonly used LWI during stair walking.

Therefore, the main purpose of this thesis was to investigate the effect of different types of footwear (including insoles within footwear) on medial knee joint loading during stair ascent and descent and the primary null hypothesis was that there would be no significant difference in the first and second peaks of the EKAM and KAAI between the different conditions.

#### 4.2. Methods

#### 4.2.1 Research design

This study was a single session of stair ascent and descent test. The purpose of the study was to identify the immediate biomechanical effect of the chosen footwear to the knee joint during stair walking. Each participant was randomized to a computer-generated random sequence of five conditions (standard shoe, LWI, Melbourne OA shoe, variable stiffness shoe and mobility shoe) during stair ascent and stair descent (www.randomization.com, Appendix B). Totally sixteen healthy adult participants, who did not have any joint injuries or illness in the last six months and had no deformities in their feet and lower limbs, were recruited locally from the University of Salford staff and student population by posters. Before the start of each test session, the inclusion criteria for the study were confirmed. Individuals were excluded if they sustained an injury within the previous six months or had any neurological or musculoskeletal impairment which would affect their movement. Each participant signed an informed consent form as per the ethical approval (HSCR16-65, Appendix A) from the University of Salford Ethics Committee.

#### 4.2.2 Staircase system set up

A three-step interlaced handrail stairway (AMTI, USA) (18 cm in step height; 26 cm in tread length and 60 cm width, Figure 4-1(A)), which is the same type used in previous studies (Alshawabka et al., 2014, Della Croce and Bonato, 2007), was firmly fixed to the force plate 2 and 3. The mechanism of collecting kinetic data during stair walking is that the floor and second step are attached to the force plate 2, and the first and third steps are attached to the force plate 3. In addition, a custom-built four-step wooden stair set (the height of each step is the same as the interlaced stairway, Figure 4-1(B)) was placed at the opposite side and used as stair ascent and descent transitional platform, which was neither connected with any force plate nor interacted with the AMTI stair and no force data would be collected when the participant was on top of this added custom-built stair. Therefore, walking trials can be reduced due to numbers of successful steps added and more complete GCs could be obtained at the step 2 during stair ascent and stair descent.





Figure 4-1: (A) Interlaced handrail stairway (AMTI, USA), (B) Custom-built four-step wooden stair set, and (C) Combined stair set.

#### 4.2.3 Test conditions and procedure

The participant recruitment, system calibration, marker placement and general data processing were described in Chapter 3 and specific data processing during stair walking will be described later.

Before data collection, all participants had opportunity to practice stair walking and choose the suitable size of different footwear until they felt comfortable during stair walking. During stair walking, all participants were instructed to stand in front of the interlaced handrail stair (Figure 4-1(A)), and then were asked to ascend the stair until they reached the top step of the custom-built stair (Figure 4-1(B)), then turn around at the top of the custom-built stair (Figure 4-1(B)), and continue to descend at their naturally self-selected pace using a step over step pattern. All participants were asked not to touch the handrails unless they felt lost balance and started to fall.

# 4.2.3.1 Test conditions

# (i) Condition 1: standard shoe

The standard shoe (Ecco Zen, Figure 4-2) is an ordinary flat casual walking shoe which in this study as a baseline condition. This type of shoe has only one solid outsole with a uniformed stiffness.



Figure 4-2: Standard shoe (Ecco Zen).

# (ii) Condition 2: standard shoe + LWI

This condition was the combination of the standard shoe and off-the-shelf LWI (SureStep-Control<sup>™</sup>, with a medium density Shore A 70, SalfordInsole, Nuneaton, UK, Figure 4-3), which had a full-length insole featured with the inclination of five degrees (from lateral to medial) and medial arch support.

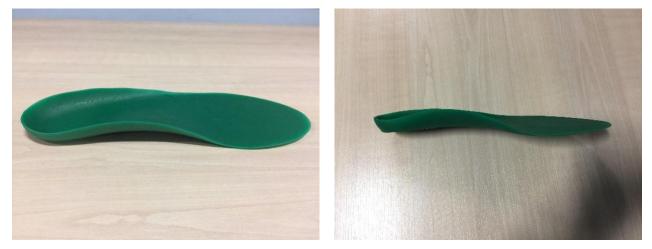


Figure 4-3: Lateral wedge insole (SalfordInsole<sup>TM</sup>, Nuneaton, UK).

# (iii) Condition 3: Melbourne OA shoe

The Melbourne OA shoe (Figure 4-4), which combined the advantages of both full-length LWI ( $5\pm1^{\circ}$  inclination) and a variable-stiffness midsole, was used in previous study (Kean et al., 2013) and its stiffness of the insole (lateral side:  $62\pm4$  and medial side:  $44\pm4$ ) was tested by Shore A durometer in her study.



Figure 4-4: Melbourne OA shoe (Gel Melbourne OA, ASICS Oceania Pty. Ltd.).

# (iv) Condition 4: variable stiffness shoe

The variable stiffness shoe (Figure 4-5) was designed and tested by Stanford University and the entire midsole was dual-density which is still in patent pending status. However, to our knowledge, the stiffness of this shoe could be found in neither the literature nor the company's website.



Figure 4-5: Variable stiffness shoe (ABEO SMART system® 3940).

# (v) Condition 5: mobility shoe

The mobility shoe (a type of lightweight flexible shoe, Figure 4-6) had a series of grooves on the sole at crucial flexion points, which mimicked natural barefoot walking (Shakoor et al., 2008). The shoes were designed with several specially designed grooves to make the bending of the shoes much easier. This type of shoe had only one solid outsole with a uniformed stiffness.



Figure 4-6: Mobility shoe (Dr Comfort).

#### 4.2.3.2 Stiffness of the midsole and outsole of the footwear

The stiffness of sole would affect not only the foot kinematics but also the kinetic outcomes of both knee and ankle. When the stiffness of lateral and medial part of the shoes was designed differently, the sole would deform differently that would result in the change of the dynamic foot posture and the shift of the COP medially or laterally. In order to achieve an effect similar to that of the LWI, the Melbourne OA shoes and variable stiffness shoe were developed. The material density and stiffness of the midsole or outsoles of these two types of shoes were different in the medial and lateral part. Some design features could be found in literature but many others could not be found. Due to the lack of the relative design and material property information, the hardness of the sole (midsole instead of the out layer) was measured with a type of Shore A durometer, which was performed on four parts of the sole regions, i.e. A-medial forefoot, B-lateral forefoot, C-medial rearfoot and D-lateral rearfoot (Figure 4-7). The midsole of the variable stiffness shoe and Melbourne OA shoe were divided into four parts (Figure 4-7), in such a simple way, their variations in hardness were assessed. Although both shoes were designed for medial compartment knee OA patients and

belong to variable stiffness shoes and the medial side was softer than the lateral side according to their companies' introduction, more detailed information in stiffness variation was not trackable. Therefore, the hardness of footwear and insole were measured in our study and the measurement outcomes were described below.

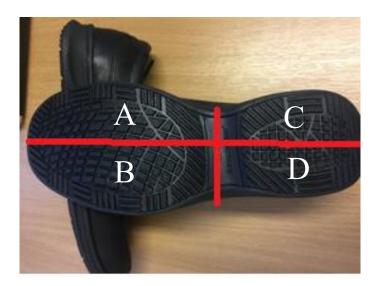


Figure 4-7: The four parts of the sole of the variable stiffness shoe

As it was hard to measure the stiffness of the shoes, their hardness in Shore A were measured and the results are presented in Table 4-1. The hardness of the variable stiffness shoe at the sole of forefoot (part A:  $51\pm2$ , part B:  $51\pm2$ , Figure 4-7) are similar and the sole of rearfoot (part C:  $46\pm2$ , part D:  $51\pm2$ , Figure 4-7) were slightly different. The hardness of Melbourne OA shoe in medial side ( $44\pm3$ ) was much smaller than that in lateral side ( $64\pm3$ ) even they have the same out layer (outsole) with a hardness of  $71\pm1$ .

Table 4-1: Hardness of the midsole and outsole

	Hardness (Shore A) Mean± SD													
		VSS					Mel			Ecco	LWI	Mob		
Α	В	С	D	Outsole	A	В	С	D	outsole	outsole	insole	outsole		
51±2	51±2	46±2	51±2	71±1	44±2	64±3	44±2	64±3	71±2	65±2	74±3	41±1		

Notes: VSS =variable stiffness shoe, Mel =Melbourne OA shoe, Ecco = Ecco shoe, LWI =lateral wedge insole, Mob =mobility shoe.

#### 4.2.3.3 The test procedure

For each shoe condition, the participants were asked to walk upstairs and downstairs several times to get used to the shoe condition as described in the test procedure. After completion of a static trial, all participants were asked to ascend (Figure 4-8) and descend (Figure 4-9) the

stairs at their self-selected pace to perform stair walking test (step over step). When all markers were captured and each foot landed on the designed step with no contacts between handrail and hand or body part, the trial was regarded as a valid trial. The stair ascent and descent were repeated five to eight times for each foot initially contacted the first step during stair ascent and the third step during stair descent to ensure at least five valid trials were achieved for both limbs.

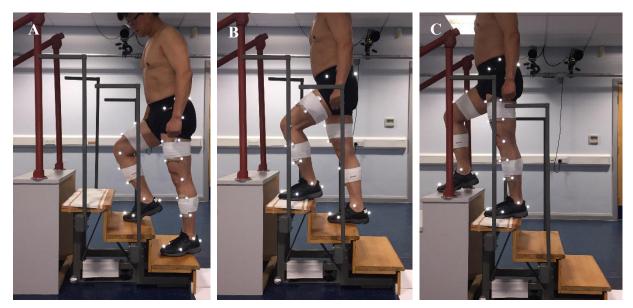


Figure 4-8: Ascending GC on step 2 (A-C), stance phase (A-B), swing phase (B-C).

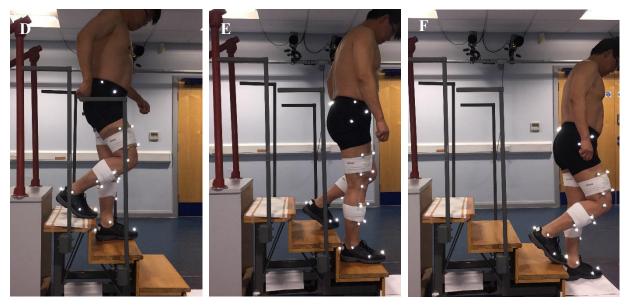


Figure 4-9: Descending GC on step 2 (D-F), stance phase (D-E), swing phase (E-F).

#### 4.2.4 AMTI stairway force structure

In the main study, two force structures were added in the Visual3D<sup>TM</sup> software to calculate and analyse kinetic data during stair ascent and descent. The location and dimensions between stair corners were computed relative to the global coordinates and the two force plates using AMTI force structure were illustrated in Figure 4-10.

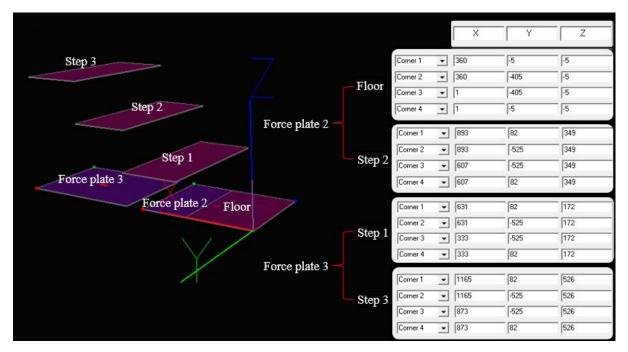


Figure 4-10: AMTI stairway structures.

#### 4.2.5 Data processing

Although the GRF on each of the three stair steps was measured alternatively with force plate 2 and force plate 3 in this study, only stance at the step 2 of the stair (ascent stance: Figure 4-11 A-B, descent stance: Figure 4-12 D-E) was used in the biomechanical analysis during both stair ascent and descent, because it kept the same step vertical distance height (2 steps height), i.e. the adjacent two initial foot contacts occurred on the steps with the same 2-step height difference, which was a stance with the highest dynamic force going through the knee joint during the stance. The chosen GC was described detailly below:

During stair ascent, each GC began with the initial foot contact with the step 2 (Figure 4-11 (A)) and ended with the same foot contact with the step 4 (Figure 4-11 (C)); for descent, the GC was initiated by the foot contact with the step 2 (Figure 4-12 (D)) and terminated with

the same foot contact with the floor (Figure 4-12 (F)). The ascending stair GC from floor to step 2 and the descending stair GC from step 4 to step 2 were excluded, as the floor of the force plate and the step 4 provided the transition from level walking to stair ascent and from stair descent to level walking, respectively. The data were excluded if handrails were used during stair walking.

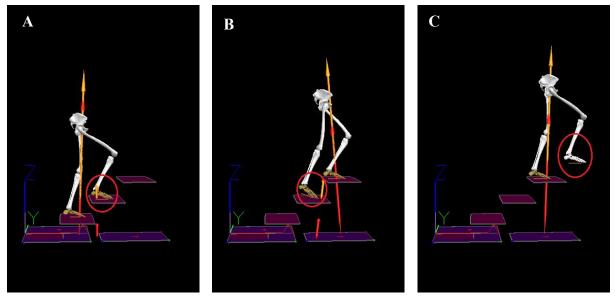


Figure 4-11: Ascending GC on step 2 (A-C), stance phase (A-B), swing phase (B-C).

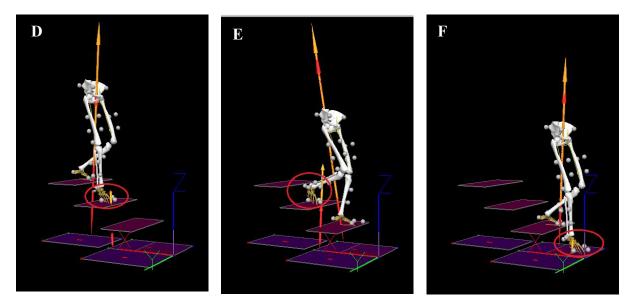


Figure 4-12: Descending GC on step 2 (D-F), stance phase (D-E), swing phase (E-F).

The raw kinematic and analogue data were processed with the methods described in Chapter 3. In this study, the main kinematic and kinetic variables relating to the biomechanical risk of knee OA progression were selected for analysis during stair ascent and descent: the first and second peaks of the EKAM, and the KAAI (Figure 2-9). The peak of the EKFM, peak knee

adduction angle, the peak knee flexion angle, the peak of the EAEM, the ankle eversion angle, and the GRF were also presented for the further understanding of the impact of different footwear. The kinematic and kinetic data were normalized to 101 (0-100) points which described in Chapter 3 and all kinetic and kinematic parameters were based on the average of the maximum/minimum peak values across the five valid trials for each condition and each participant. These were then averaged to provide the group mean maximum/minimum value and SD for moments and angles.

#### 4.2.6 Statistical analysis

All statistical analyses were conducted using IBM SPSS Statistics 23 (IBM, Armonk, NY, USA) with the statistical significance at an alpha level of 0.05 (two-sided). Prior to data analysis, Kolmogorov-Smirnov tests were performed to check the normality of kinetic and kinematic data, and most of them were normally distributed. If they are normally distributed, one-way repeated-measures analysis of variance (ANOVA) test with post hoc pairwise contrasts were used to determine the differences between two designated conditions. For the ten pairwise comparison tests, the significance tests were conducted using a Bonferroni adjustment to protect against Type I error and P-value were defined as significant when p<0.05. All the non-normally distributed data were analysed using Friedman's ANOVA (K-related samples) test. In addition, effect sizes (Cohen's d, the difference between the means divided by SD) were calculated for the parameters with statistically significant differences between the tested conditions and interpreted based on the method that the effect sizes were defined as small ( $d \ge 0.2$ ), medium ( $d \ge 0.5$ ) and large ( $d \ge 0.8$ ) (Cohen, 1992).

#### 4.3. The biomechanical results of the five footwear conditions

Sixteen healthy individuals (Table 4-2) were recruited to this study and signed an informed consent form. Five valid trials for both limbs were achieved during stair ascent and descent under each condition and used for gait analysis.

Variable	Value*
Subjects (n)	16
Gender (M/F)	8/8
Age (years)	29±5 (21-38)
Height (m)	1.65±0.09 (1.5-1.8)
Body Mass (kg)	59.22± 12.50 (43.6-87.4)
BMI (kg/m <sup>2</sup> )	21.54±2.94 (15.5-27.7)

Table 4-2: Participants characteristics

\*Value is the Mean±SD (Range) unless otherwise indicated. BMI= body mass index

#### **4.3.1** Temporal-spatial parameters and Ground reaction forces

There were no significant differences in single limb stance time among five conditions in a session during stair ascent and descent (Table 4-3 and Table 4-5). There were also no significant differences in the peak anterior-posterior, medial and vertical GRFs among these five conditions in a session during stair ascent and descent (Table 4-3 and Table 4-5). The mean data of GRFs in stance during stair ascent and descent are illustrated in Figure 4-13~18.

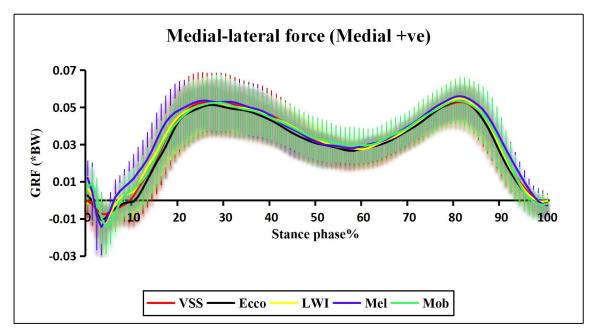


Figure 4-13: The mean (SD) profiles of the medial-lateral GRF during stair ascent.

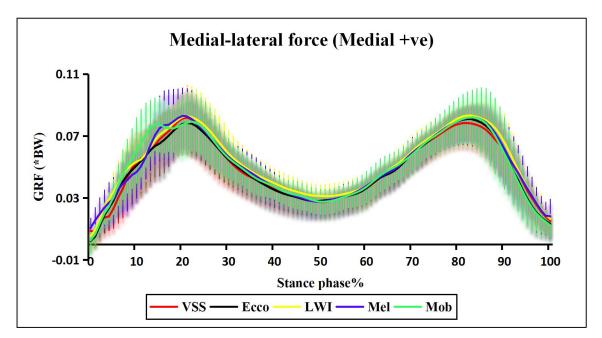


Figure 4-14: The mean (SD) profiles of the medial-lateral GRF during stair descent.

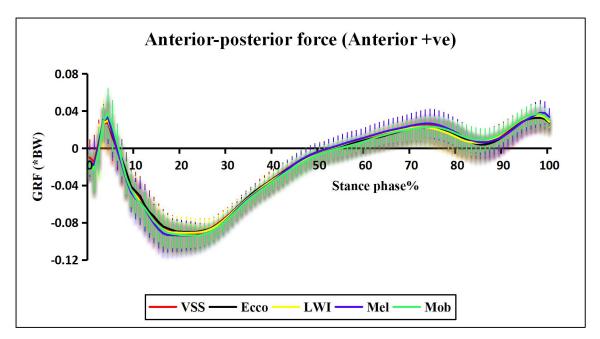


Figure 4-15: The mean (SD) profiles of the anterior-posterior GRF during stair ascent.

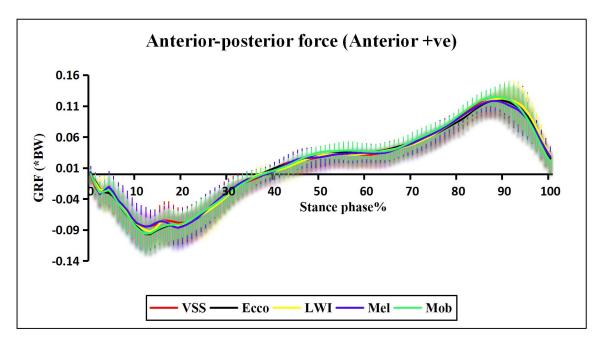


Figure 4-16: The mean (SD) profiles of the anterior-posterior GRF during stair descent.

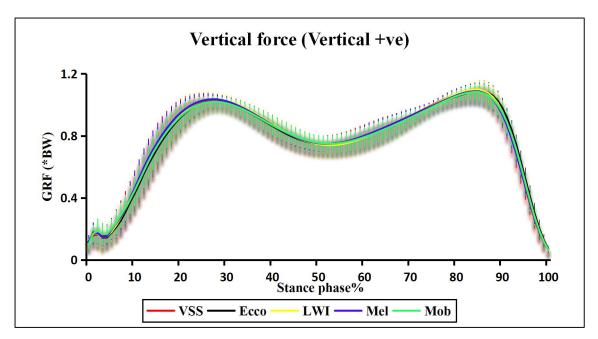


Figure 4-17: The mean (SD) profiles of the vertical GRF during stair ascent.

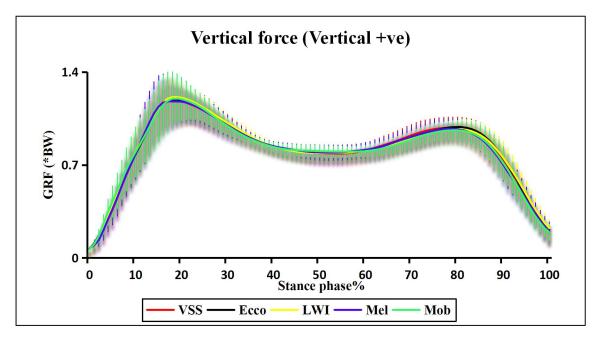


Figure 4-18: The mean (SD) profiles of the vertical GRF during stair descent.

#### 4.3.2 External knee adduction moment

Both the first and second peaks of the EKAM were significantly reduced when walking with the LWI, Melbourne OA shoe, and mobility shoe compared with walking with the standard shoe and variable stiffness shoe during stair ascent and descent. Whilst they were statistically significant, the differences between the peaks of the EKAM of specially designed footwear (LWI, Melbourne OA shoe and mobility shoe) and that of the standard shoe were smaller than MDC (Table 3-5) in the pilot study. However, there were no significant differences in both the first and second peaks of the EKAM (p>0.05) between walking with the variable stiffness shoe and standard shoe during stair walking (Table 4-3 and Table 4-4).

Compared with using the standard shoe in the early stance phase, using the LWI, Melbourne OA shoe and mobility shoe significantly reduced the first peak of the EKAM by 6.5% (p=0.003), 9.7% (p=0.005), and 9.7% (p<0.001) respectively during stair ascent, and by 6.4% (p=0.005), 8.5% (p=0.024), and 8.5% (p=0.043) respectively during stair descent. Similarly, when using the LWI, Melbourne OA shoe and mobility shoe compared with the results of the variable stiffness shoe, the first peak of the EKAM was significantly reduced by 9.4% (p=0.001), 12.5% (p=0.036), and 12.5% (p=0.003) respectively during stair ascent, and by 6.4% (p=0.019), 8.5% (p=0.002), and 8.5% (p=0.005) respectively during stair descent (Table 4-3 and Table 4-4). Additionally, there were small effect sizes (d: 0.22-0.40) when

using the LWI, Melbourne OA shoe and mobility shoe during stair walking compared with the standard shoe and variable stiffness shoe (Table 4-6).

In comparison with using standard shoe in the late stance phase, using the LWI, Melbourne OA shoe and mobility shoe significantly reduced the second peak of the EKAM by 7.4% (p=0.041), 11.1% (p=0.001), and 7.4% (p=0.039) respectively during stair ascent, and by 10.3% (p=0.013), 10.3% (p=0.016), and 13.8% (p=0.002) respectively during stair descent. Whilst they were statistically significant, the differences between the peaks of the EKAM of specially designed footwear (LWI, Melbourne OA shoe and mobility shoe) and that of the standard shoe were smaller than MDC (Table 3-5) in the pilot study. Similarly, when using the LWI, Melbourne OA shoe and mobility shoe) and that of the variable stiffness shoe, the second peak of the EKAM was significantly reduced by 10.7% (p=0.009), 14.3% (p<0.001), and 10.7% (p=0.001) respectively during stair ascent, and 10.3% (p=0.005), 10.3% (p=0.001), and 13.8% (p<0.001) respectively during stair descent (Table 4-3 and Table 4-4). The mean data of knee moments during stair ascent and descent are illustrated in Figure 4-19 and Figure 4-20. Additionally, there were small to medium effect sizes (d: 0.33-0.57) when using the LWI, Melbourne OA shoe and mobility shoe during stair ascent, and stair walking compared with the standard shoe and variable stiffness shoe.

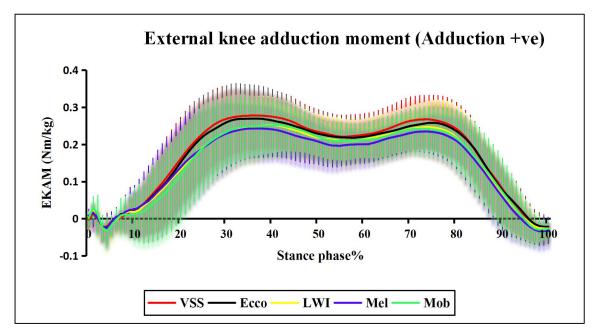


Figure 4-19: The mean (SD) profiles of the EKAM during stair ascent.

Table 4-3: Biomechanical outcomes (Mean±SD) of interest

Danamatans			Mea	n±SD		
Parameters		VSS	Ecco	LWI	Mel	Mob
	At	0.32±(0.10)	0.31±(0.09)	0.29±(0.08)	0.28±(0.08)	0.28±(0.07)
1 <sup>st</sup> peak EKAM (Nm/kg)	Dt	0.47±(0.10)	0.47±(0.12)	0.44±(0.11)	0.43±(0.09)	0.43±(0.10)
2 <sup>nd</sup> Peak EKAM (Nm/kg)	At	0.28±(0.07)	0.27±(0.06)	0.25±(0.07)	0.24±(0.07)	0.25±(0.06)
2 <sup></sup> Feak EKAIVI (INIII/Kg)	Dt	0.29±(0.07)	0.29±(0.07)	0.26±(0.05)	0.26±(0.06)	0.25±(0.06)
Peak EKFM (Nm/kg)	At	1.67±(0.22)	1.62±(0.22)	1.64±(0.20)	1.67±(0.19)	1.62±(0.17)
I Cak EKFIVI (IVIII/Kg)	Dt	1.25±(0.18)	1.21±(0.18)	1.21±(0.18)	1.23±(0.17)	1.20±(0.19)
KAAI (Nm*S/kg)	At	0.18±(0.05)	0.18±(0.05)	0.16±(0.05)	0.16±(0.04)	0.16±(0.04)
KAAI (Mii <sup>*</sup> 5/kg)	Dt	0.21±(0.05)	0.20±(0.06)	0.18±(0.05)	0.18±(0.04)	0.19±(0.05)
Peak EAEM (Nm/kg)	At	-0.14±(0.05)	-0.14±(0.05)	-0.18±(0.07)	-0.18±(0.06)	-0.16±(0.05)
I Cak EALINI (INIII/Kg)	Dt	-0.12±(0.09)	-0.13±(0.09)	-0.16±(0.10)	-0.16±(0.09)	-0.15±(0.08)
Peak knee adduction angle	At	7.51±(5.08)	8.23±(5.06)	7.41±(4.99)	7.51±(4.92)	7.51±(5.06)
(Degree)	Dt	5.28±(4.11)	5.25±(4.24)	4.78±(3.43)	4.90±(3.27)	4.97±(4.03)
Peak knee flexion angle	At	79.51±(3.47)	79.71±(3.75)	79.57±(3.52)	79.54±(3.58)	79.53±(3.32)
(Degree)	Dt	98.99±(5.81)	99.43±(5.89)	98.42±(6.13)	99.22±(6.08)	99.44±(5.53)
Minimum knee flexion	At	14.3±(3.08)	13.8±(4.02)	14.49±(2.91)	14.6±(2.42)	14.25±(3.49)
angle (Degree)	Dt	14.85±(3.35)	14.82±(3.63)	14.57±(3.51)	14.2±(3.68)	14.07±(3.09)
Peak ankle eversion angle	At	-4.29±(2.47)	-4.61±(2.46)	-4.55±(2.40)	-4.12±(2.39)	-4.67±(3.11)
(Degree)	Dt	-4.45±(2.27)	-3.72±(1.88)	-4.10±(2.13)	-4.35±(1.77)	-4.15±(2.15)
Single limb stance time (s)	At	0.91±(0.12)	0.91±(0.11)	0.9±(0.10)	0.9±(0.12)	0.89±(0.13)
Single mild stance time (3)	Dt	0.83±(0.11)	0.83±(0.11)	$0.81 \pm (0.10)$	0.83±(0.12)	0.82±(0.11)
Medial GRF (*BW)	At*	0.07±(0.02)	0.07±(0.02)	0.07±(0.02)	0.07±(0.02)	0.07±(0.02)
	Dt	0.10±(0.02)	0.10±(0.02)	0.10±(0.01)	0.10±(0.02)	0.10±(0.02)
Anterior GRF (*BW)	At*	0.06±(0.02)	0.06±(0.02)	0.06±(0.02)	0.06±(0.02)	0.06±(0.01)
	Dt*	0.13±(0.02)	0.14±(0.02)	0.13±(0.01)	0.14±(0.02)	$0.14 \pm (0.03)$
Posterior GRF (*BW)	At*	-0.10±(0.02)	-0.10±(0.02)	-0.10±(0.02)	-0.10±(0.01)	-0.10±(0.02)
	Dt	-0.12±(0.02)	-0.12±(0.02)	-0.11±(0.02)	-0.12±(0.02)	-0.11±(0.02)
Vertical GRF 1 <sup>st</sup> Peak	At	1.05±(0.04)	1.04±(0.06)	1.05±(0.05)	1.05±(0.04)	1.04±(0.04)
(*BW)	Dt	1.27±(0.15)	1.26±(0.15)	1.28±(0.14)	1.29±(0.17)	1.28±(0.16)
Vertical GRF 2 <sup>nd</sup> Peak	At	1.11±(0.05)	1.11±(0.06)	1.11±(0.06)	1.10±(0.06)	1.11±(0.05)
(*BW)	Dt	1.01±(0.08)	1.01±(0.07)	0.99±(0.07)	1.00±(0.07)	0.99±(0.07)

Notes: asterisk (\*) denotes that non-parametric tests were used, At =ascent, Dt =descent, VSS =variable stiffness shoe, Ecco =Ecco shoe, LWI =Ecco + LWI, Mel =Melbourne OA shoe, Mob =mobility shoe.

						P value					
Parameters		Ecco	Ecco	Ecco	Ecco	VSS	VSS	VSS	LWI	LWI	Mel
1 al alletter 5		VS	VS	VS	VS	VS	VS	VS	VS	VS	VS
		VSS	LWI	Mel	Mob	LWI	Mel	Mob	Mel	Mob	Mob
1 <sup>st</sup> Peak EKAM	At	1.000	0.003	0.005	0.000	0.001	0.036	0.003	1.000	1.000	1.000
(Nm/kg)	Dt	1.000	0.005	0.024	0.043	0.019	0.002	0.005	1.000	1.000	1.000
2 <sup>nd</sup> Peak EKAM	At	1.000	0.041	0.001	0.039	0.009	0.000	0.010	1.000	1.000	1.000
(Nm/kg)	Dt	1.000	0.013	0.016	0.002	0.005	0.001	0.000	1.000	1.000	1.000
Peak EKFM (Nm/kg)	At	0.058	1.000	0.017	1.000	0.341	1.000	0.382	0.047	1.000	0.071
I Car Elerin (Inii/kg)	Dt	0.673	1.000	1.000	1.000	0.165	1.000	0.109	1.000	1.000	1.000
KAAI (Nm*S/kg)	At	1.000	0.002	0.041	0.002	0.002	0.028	0.006	1.000	1.000	1.000
KAMA (I'M S/Kg)	Dt	1.000	0.045	0.031	0.026	0.003	0.001	0.000	1.000	1.000	1.000
Peak EAEM (Nm/kg)	At	1.000	0.000	0.000	0.007	0.001	0.000	0.001	1.000	0.654	0.169
	Dt	1.000	0.001	0.017	0.031	0.001	0.000	0.008	1.000	1.000	1.000
Peak knee adduction	At	0.493	0.496	0.800	0.938	1.000	1.000	1.000	1.000	1.000	1.000
angle (Degree)	Dt	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000
Peak knee flexion	At	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000	0.706
angle (Degree)	Dt	1.000	0.886	1.000	1.000	1.000	1.000	1.000	1.000	0.083	1.000
Minimum knee	At	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000
flexion angle (Degree)	Dt	1.000	1.000	0.827	0.970	1.000	1.000	0.074	1.000	1.000	1.000
Peak ankle eversion	At	1.000	1.000	1.000	0.316	1.000	1.000	1.000	0.052	1.000	1.000
angle (Degree)	Dt	0.089	0.284	0.015	1.000	1.000	1.000	1.000	1.000	1.000	1.000

Table 4-4: P-value of knee biomechanical parameters of interest between each condition

Notes: The red bold indicates significant difference.

						P valu	e				
Parameters		Ecco	Ecco	Ecco	Ecco	VSS	VSS	VSS	LWI	LWI	Mel
		VS	VS	VS	VS	VS	VS	VS	VS	VS	VS
		VSS	LWI	Mel	Mob	LWI	Mel	Mob	Mel	Mob	Mob
Single limb stance	At	1.000	0.561	1.000	1.000	1.000	1.000	0.715	1.000	1.000	0.717
time (s)	Dt	1.000	0.687	1.000	1.000	0.161	1.000	1.000	0.353	0.693	1.000
Medial GRF (*BW)	At*	0.593	0.617	0.166	0.782	1.000	0.257	0.782	0.429	0.783	0.157
Mediai GRF ( DW)	Dt	1.000	1.000	1.000	1.000	1.000	0.896	1.000	1.000	1.000	1.000
Anterior GRF	At*	0.400	0.724	0.199	0.623	0.658	0.408	0.640	0.317	1.000	0.291
(*BW)	Dt*	0.695	0.660	0.503	0.916	0.632	0.544	0.361	0.246	0.980	0.083
Posterior GRF	At*	0.806	0.662	0.142	0.231	0.674	0.109	0.207	0.554	0.543	0.903
(*BW)	Dt	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000
1 <sup>st</sup> peak vertical	At	1.000	0.610	1.000	1.000	1.000	1.000	0.665	1.000	1.000	0.612
GRF (*BW)	Dt	1.000	1.000	1.000	1.000	1.000	0.788	1.000	1.000	1.000	1.000
2 <sup>nd</sup> peak vertical	At	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000
GRF (*BW)	Dt	1.000	0.671	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000
COP for 1 <sup>st</sup> peak	At	1.000	0.001	0.000	0.000	0.001	0.000	0.002	1.000	1.000	1.000
EKAM (m)	Dt	0.509	0.011	0.013	0.009	0.000	0.001	0.000	0.415	0.576	0.634
COP for 2 <sup>nd</sup> peak	At	1.000	0.003	0.001	0.000	0.004	0.002	0.000	1.000	0.566	1.000
EKAM (m)	Dt	0.169	0.002	0.046	0.006	0.000	0.000	0.000	0.542	0.710	0.320

Table 4-5: P-value of the GRF, single limb stance time and COP between each condition

\* Denotes that non-parametric tests were used; the red bold indicates significant difference.

				E	ffect siz	æ		
Parameters		Ecco	Ecco	Ecco	VSS	VSS	VSS	LWI
		VS	vs	vs	vs	VS	VS	VS
		LWI	Mel	Mob	LWI	Mel	Mob	Mel
1 <sup>st</sup> peak EKAM	At	0.22	0.33	0.33	0.30	0.40	0.40	-
(Nm/kg)	Dt	0.25	0.33	0.33	0.30	0.40	0.40	-
2 <sup>nd</sup> peak EKAM	At	0.33	0.50	0.33	0.43	0.57	0.43	-
(Nm/kg)	Dt	0.43	0.43	0.57	0.43	0.43	0.57	-
Peak EKFM (Nm/kg)	At	-	0.23	-	-	-	-	0.15
	Dt	-	-	-	-	-	-	-
KAAI (Nm /kg*S)	At	0.40	0.40	0.40	0.40	0.40	0.40	-
	Dt	0.33	0.33	0.20	0.60	0.60	0.40	
Peak EAEM (Nm/kg)	At	0.80	0.80	0.40	0.80	0.80	0.40	-
	Dt	0.33	0.33	0.22	0.44	0.44	0.33	-
Peak ankle eversion	At	-	-	-	-	-	-	-
angle (Degree)	Dt	-	0.34	-	-	-	-	-
COP for 1 <sup>st</sup> peak	At	0.50	0.63	0.63	0.57	0.71	0.71	-
EKAM (m)	Dt	0.60	0.67	0.57	0.60	0.57	0.57	-
COP for 2 <sup>nd</sup> peak	At	0.57	0.71	0.86	0.56	0.67	0.78	-
EKAM (m)	Dt	0.86	0.63	0.86	0.88	0.75	0.88	-

Table 4-6: Effect sizes of knee biomechanical parameters of interest between each condition

Notes: The effect sizes were calculated when statistically significant differences between the tested conditions (P-value <0.05 in Table 4-4 and Table 4-5).

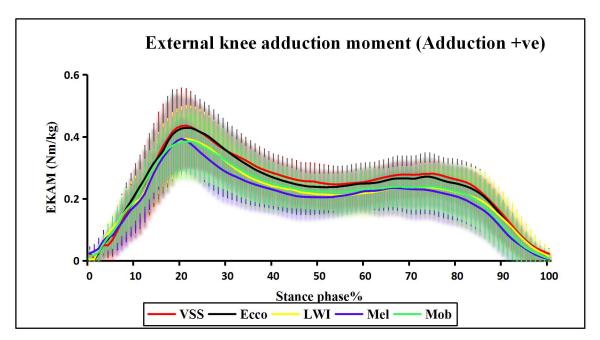


Figure 4-20: The mean (SD) profiles of the EKAM during stair descent.

#### 4.3.3 Knee adduction angular impulse

The KAAI was significantly reduced when using the LWI, Melbourne OA shoe and mobility shoe compared with the standard shoe during stair walking (Table 4-3 and Table 4-4). Whilst they were statistically significant, the differences between the peaks of the EKAM of specially designed footwear (LWI, Melbourne OA shoe and mobility shoe) and that of the standard shoe were smaller than MDC (Table 3-5) in the pilot study. However, there were no significant changes between using the variable stiffness shoe and the standard shoe, and there were also no significant differences among using the LWI, Melbourne OA shoe and mobility shoe and mobility shoe.

In comparison with the results of the standard shoe during stair walking, the KAAI was significantly reduced by 11.1% (p=0.002) during stair ascent and 10.0% (p=0.045) during stair descent when using the LWI. In comparison with the results of the standard shoe, the KAAI was significantly reduced by 11.1% (p=0.041) during stair ascent and 10.0% (p=0.031) during descent when using the Melbourne OA shoe. Similarly, the KAAI was reduced by 11.1% (p=0.002) during stair ascent and 5.0% (p=0.026) during stair descent when using the mobility shoe compared with the standard shoe. Additionally, when using the LWI, Melbourne OA shoe and mobility shoe compared with the results of variable stiffness shoe. the KAAI was reduced by 11.1%, 11.1% and 11.1% (p=0.002; 0.028; 0.006) respectively during stair ascent. Similarly, when using the LWI, Melbourne OA shoe and mobility shoe compared with the variable stiffness shoe, the KAAI was reduced by 14.3%, 14.3% and 9.5% (p=0.003; 0.001; <0.001) respectively during stair descent (Table 4-3 and Table 4-4). The mean data of the KAAI during stair ascent and descent are illustrated in Figure 4-21. Additionally, there were small to medium effect sizes (d: 0.20-0.57) when using the LWI, Melbourne OA shoe and mobility shoe during stair walking compared with the standard shoe and variable stiffness shoe (Table 4-6).

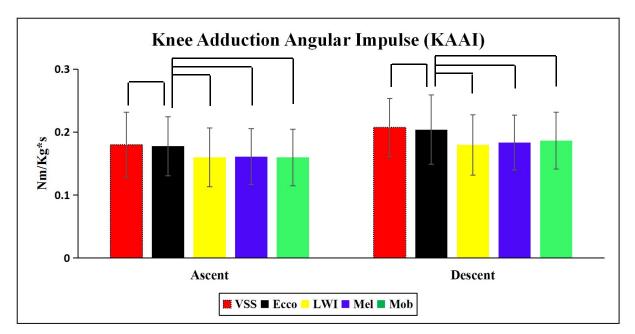


Figure 4-21: The mean (SD) profiles of the KAAI for the five conditions during stair ascent and descent (error bars denote SD and \* indicates significant between-condition differences (p<0.05)).

# 4.3.4 The response rate of the participants in terms of the reduction of the first peak of the EKAM and KAAI

The response rate of the participants in terms of the reduction of the first peak of the EKAM and KAAI varied between participants when using different types of footwear and LWI compared with the standard shoe. Based on the results of 16 participants in this study, the response rate can be summarised as follows.

The response rate in terms of the first peak of the EKAM reduction was 52%, 72%, 76%, 84% of the participants when using the variable stiffness shoe, LWI, Melbourne OA shoe and mobility shoe respectively during stair ascent; 50%, 82%, 82% and 86% of the participants when using the variable stiffness shoe, LWI, Melbourne OA shoe and mobility shoe during stair descent. The response rate in terms of the KAAI reduction was 56%, 84%, 68% and 77% of participants when using the variable stiffness shoe, LWI, Melbourne OA shoe and the mobility shoe respectively during stair ascent; 45%, 77%, 74% and 82% of the participants when using the variable stiffness shoe, LWI, Melbourne OA shoe and the mobility shoe respectively during stair ascent; 45%, 77%, 74% and 82% of the participants when using the variable stiffness shoe, LWI, Melbourne OA shoe and mobility shoe during stair ascent; 45%, 77%, 74% and 82% of the participants when using the variable stiffness shoe, LWI, Melbourne OA shoe and mobility shoe during stair ascent; 45%, 77%, 74% and 82% of the participants when using the variable stiffness shoe, LWI, Melbourne OA shoe and mobility shoe during stair descent.

The response rate of the variable stiffness shoe was the lowest in both stair ascent and descent conditions while the other specially designed footwear (LWI, Melbourne OA shoe and mobility shoe) had very good response in both stair ascent and descent.

#### 4.3.5 External knee flexion moment

In comparison with the results of the standard shoe during stair ascent, the peak of the EKFM significantly increased by 3.1% (p=0.017) with small effect size (d=0.23) when using the Melbourne OA shoe. Additionally, using the Melbourne OA shoe significantly increased the peak of the EKFM by 1.8% (p=0.047) with tiny effect size (d=0.15) when compared with LWI. During stair descent, there were no significant differences (p>0.05) in the peak of the EKFM among the variable stiffness shoe, standard shoe, LWI, Melbourne OA shoe, and mobility shoe (Table 4-3 and Table 4-4). The mean data of the EKFM during stair ascent and descent are illustrated in Figure 4-22 and Figure 4-23.

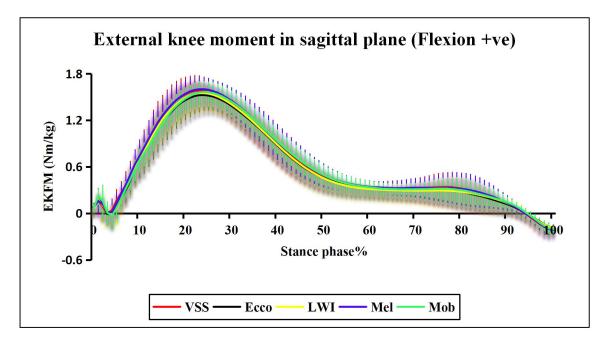


Figure 4-22: The mean (SD) profiles of the EKFM during stair ascent.

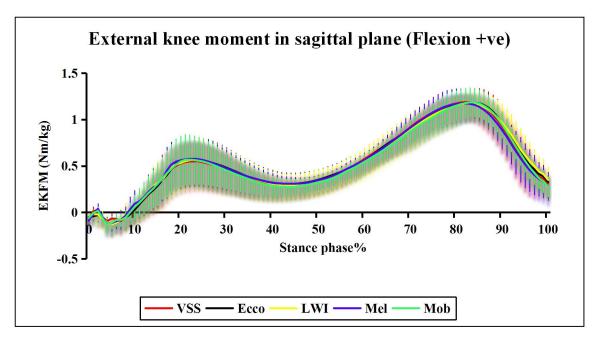


Figure 4-23: The mean (SD) profiles of the EKFM during stair descent.

#### 4.3.6 Knee joint kinematics in the sagittal plane

Compared with the results of the standard shoe, no significant differences (p>0.05) were observed in peak knee flexion angle in stance phase in the four chosen footwear conditions: variable stiffness shoe, LWI, Melbourne OA shoe, mobility shoe during stair ascent and descent (Table 4-3 and Table 4-4). Similarly, this is also true (p>0.05) in minimum knee flexion angle during stair ascent and descent (Table 4-3 and Table 4-4). The mean data of knee angles in sagittal plane results during stair ascent and descent are illustrated in Figure 4-24 and Figure 4-25.

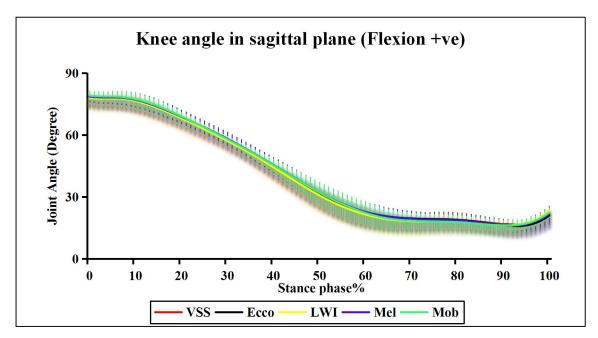


Figure 4-24: The mean (SD) profiles of the knee flexion angle during stair ascent.

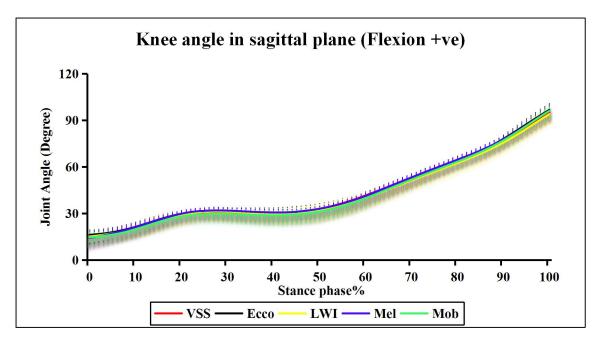


Figure 4-25: The mean (SD) profiles of the knee flexion angle during stair descent.

#### 4.3.7 Knee joint kinematics in the frontal plane

In comparison with the results of the standard shoe during stair walking, the peak knee adduction angle reduced by 10.0%, 8.7% and 8.7% during stair ascent and by 9.0%, 6.7% and 5.3% during stair descent when using the LWI, Melbourne OA shoe and mobility shoe respectively (Table 4-3), and the peak knee adduction angle reduced by 8.7% during stair ascent and slightly increased by 0.6% during stair descent when using variable stiffness shoe

(Table 4-3). However, there were no significant differences among using these five types of footwear during stair walking (p>0.05) (Table 4-4). The mean data of knee angle in frontal plane during stair ascent and descent are illustrated in Figure 4-26 and Figure 4-27.

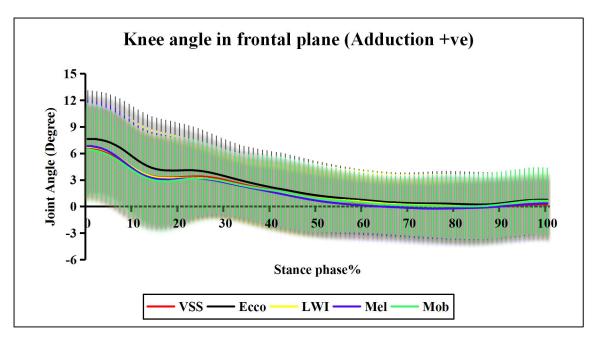


Figure 4-26: The mean (SD) profiles of the knee adduction angle during stair ascent.

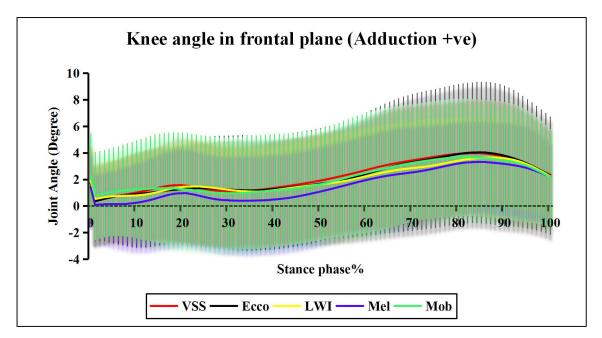


Figure 4-27: The mean (SD) profiles of the knee adduction angle during stair descent.

#### 4.3.8 External ankle eversion moment

In comparison with the results of the standard shoe during stair walking, the magnitude of peak EAEM significantly increased by 28.6%, 28.6% and 14.3% (p<0.001, p<0.001 and p=0.007, respectively) during stair ascent and by 23.1%, 23.1% and 15.4% (p=0.001, p=0.017 and p=0.031, respectively) during stair descent when using the LWI, Melbourne OA shoe and mobility shoe respectively (Table 4-3 and Table 4-4). Similarly, compared with the results of the variable stiffness shoe, the magnitude of peak EAEM significantly increased by 28.6%% and 18.2% (p=0.001, p<0.001 and p=0.001, respectively) during stair ascent and by 33.3%, 33.3% and 25.0% (p=0.001, p<0.001 and p=0.008, respectively) during stair descent when using the LWI, Melbourne OA shoe and mobility shoe during stair walking, respectively. The mean data of the EAEM during stair ascent and descent are illustrated in Figure 4-28 and Figure 4-29. Additionally, there were small to large effect sizes (d: 0.22-0.80) when using the LWI, Melbourne OA shoe and mobility shoe during stair ascent and small effect sizes (d: 0.22-0.44) during stair descent compared with the standard shoe and variable stiffness shoe (Table 4-6).

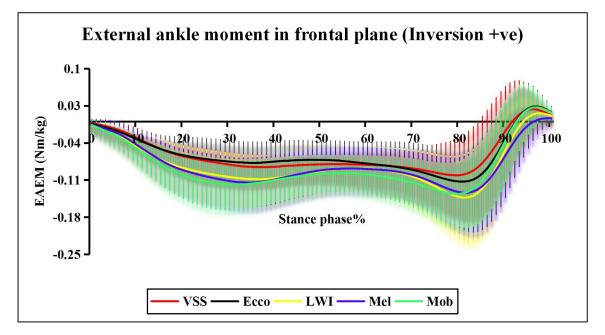


Figure 4-28: The mean (SD) profiles of the EAEM during stair ascent.

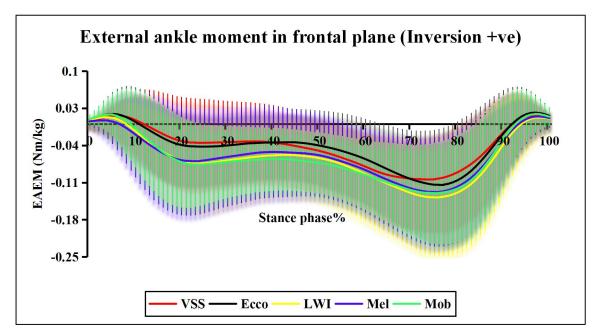


Figure 4-29: The mean (SD) profiles of the EAEM during stair descent.

#### 4.3.9 Ankle eversion angle

During stair ascent, the magnitude of peak ankle eversion angle reduced by 7.0%, 1.3%, 10.6% when using the variable stiffness shoe, LWI, Melbourne OA shoe respectively in comparison with that of the standard shoe, but the peak ankle eversion angle increased by 1.3% when using the mobility shoe (Table 4-3 and Table 4-4). In compared with using the standard shoe during stair descent, the magnitude of peak ankle eversion angle increased by 19.6%, 10.2%, 16.9% and 11.6% when using the variable stiffness shoe, LWI, Melbourne OA shoe and mobility shoe respectively (Table 4-3 and Table 4-4). However, no significant differences (p>0.05) were observed among using these five types of footwear and LWI during stair walking, except a significant difference found between using the standard shoe and Melbourne OA shoe during stair descent (p=0.015). The mean data of ankle angle in frontal plane during stair ascent and descent are illustrated in Figure 4-30 and Figure 4-31.

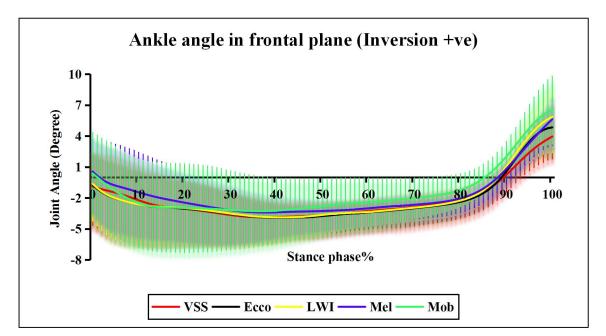


Figure 4-30: The mean (SD) profiles of the ankle eversion angle during stair ascent.

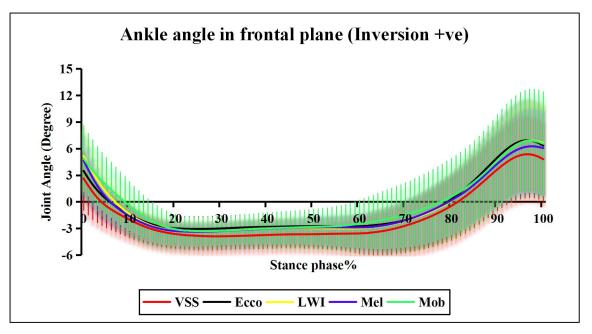


Figure 4-31: The mean (SD) profiles of the ankle eversion angle during stair descent.

# 4.3.10 Centre of pressure

The positions of the foot's COP at the corresponding point of the first and second peaks of the EKAM were significantly laterally shifted when using the LWI, Melbourne OA shoe, and mobility shoe compared with the results of the standard shoe and variable stiffness shoe, while there were no significant differences in COP position between the variable stiffness shoe and standard shoe during stair ascent and descent (Table 4-5 and Table 4-7).

Parameters				Mean±(SD)		
rarameters		VSS	Ecco	LWI	Mel	Mobility
COP for the 1 <sup>st</sup> peak	At	0.003±(0.007)	0.003±(0.008)	0.007±(0.006)	0.008±(0.006)	0.008±(0.007)
EKAM (m)	Dt	-0.001±(0.007)	-0.001±(0.006)	0.002±(0.005)	0.003±(0.006)	0.003±(0.007)
COP for the 2 <sup>nd</sup> peak	At	0.005±(0.009)	0.006±(0.007)	0.010±(0.008)	0.011±(0.007)	0.012±(0.010)
EKAM (m)	Dt	-0.004±(0.008)	-0.003±(0.007)	0.003±(0.007)	0.002±(0.008)	0.003±(0.007)

Table 4-7: The COP for the peaks of the EKAM during stair walking

In the early stance phase, when using the LWI, Melbourne OA shoe and mobility shoe compared with the results of the standard shoe, the COP trajectory at the corresponding point of the first peak of the EKAM was significantly laterally shifted by 0.004 m (p=0.001), 0.005 m (p<0.001), and 0.005 m (p<0.001) respectively during stair ascent, and by 0.003 m (p=0.011), 0.004 m (p=0.013), and 0.004 m (p=0.009) respectively during stair descent. However, there were no significant differences between the variable stiffness shoe and the standard shoe during stair ascent (p=1.000) and stair descent (p=0.509). Similarly, when using the LWI, Melbourne OA shoe and mobility shoe compared with the results of the EKAM was significantly laterally shifted by 0.004 m (p=0.001), 0.005 m (p<0.001), and 0.005 m (p=0.001) respectively during stair ascent, and by 0.003 m (p=0.001), and 0.005 m (p=0.001) respectively during stair ascent, and by 0.003 m (p=0.001), and 0.004 m (p=0.001) respectively during stair ascent (Table 4-5 and Table 4-7). Additionally, there were medium effect sizes (d: 0.50-0.71) when using the LWI, Melbourne OA shoe during stair walking compared with the standard shoe and woriable stiffness shoe (Table 4-6).

In comparison with the results of standard shoe in the late stance phase, when using the LWI, Melbourne OA shoe and mobility shoe, the COP trajectory at the corresponding point of the second peak of the EKAM was significantly laterally shifted by 0.004 m (p=0.003), 0.005 m (p=0.001), and 0.006 m (p<0.001) respectively during stair ascent, and by 0.006 m (p=0.002), 0.005 m (p=0.046), and 0.006 m (p=0.006) respectively during stair descent. However, there were no significant differences between the variable stiffness shoe and the standard shoe during stair ascent (p=1.000) and stair descent (p=0.169). Similarly, when using the LWI, Melbourne OA shoe and mobility shoe compared with the results of the variable stiffness

shoe, the COP trajectory at the corresponding point of the second peak of the EKAM was significantly laterally shifted by 0.005 m (p=0.004), 0.006 m (p=0.002), and 0.007 m (p<0.001) respectively during stair ascent, and by 0.007 m (p<0.001), 0.006 m (p<0.001), and 0.007 m (p<0.001) respectively during stair descent (Table 4-5 and Table 4-7). The mean data of the COP trajectory during stair ascent and descent are illustrated in Figure 4-32 and Figure 4-33. Additionally, there were medium to large effect sizes (d: 0.57-0.88) when using the LWI, Melbourne OA shoe and mobility shoe during stair walking compared with the standard shoe and the variable stiffness shoe (Table 4-6).

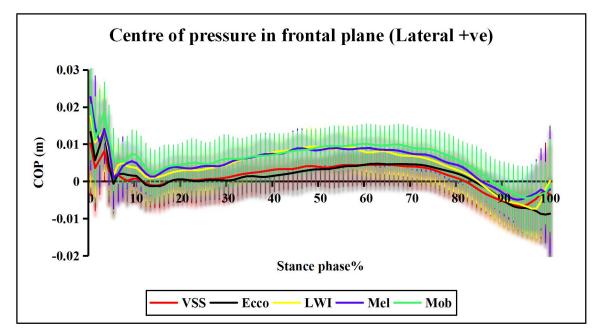


Figure 4-32: The mean (SD) profiles of the COP during stair ascent.

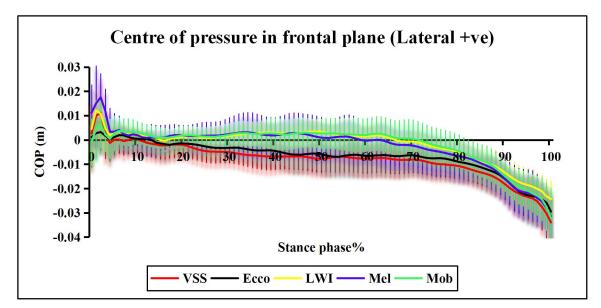


Figure 4-33: The mean (SD) profiles of the COP during stair descent.

### 4.4. Discussion

#### LWI

In accordance with the findings that LWI reduced peaks of the EKAM effectively, but there are only two similar literature available that used the LWI during stair walking (Bennell et al., 2011b, Alshawabka et al., 2014, Shimada et al., 2006, Hinman et al., 2012). In our study, the first and second peaks of the EKAM were significantly reduced by 6.5% and 7.4% respectively during stair ascent and by 6.4% and 10.3% respectively during stair descent when using the LWI compared with the standard shoe. These are consistent with the results that the first and second peaks EKAM were significantly reduced by 6.8% and 15% respectively during stair ascent, and 8.4% and 8.3% respectively during stair descent when using the LWI compared with neural flat insole (Alshawabka et al., 2014). The different reduction percentage may result from selecting different steps to collect data during stance phase. Although we all selected the continuous GC during stair walking (Alshawabka et al., 2014), the vertical distance between the adjacent two steps, on which the same foot made contact, could be different. In our study, only the stance phase on step 2 was chosen as the focused stance because the GC before and after this step was normal and the vertical height between the same foot contacting steps was the same. The other transitional stances were excluded from the analysis. A 3-step staircase was used in previous study that defined the stair ascent GC from step 1 to step 3 and stair descent from step 2 to floor (Alshawabka et al., 2014), which meant they selected the step 1 to collect stair ascent data and step 2 for stair descent data. In this way, before initial contact on the step 1 during stair ascent, the lifted vertical distance was only one step height from floor, but lifted two steps height after toe left off the step 1 to land on step 3. As to another foot, before it was landing on step 2 during stair ascent, the lifted vertical distance was a 2-step height but from step 2 to the top (step 3), the left height was only one step. While in our study we used the step 2 to collect stance phase data during both stair ascent and descent, it kept the same step vertical distance height (two steps height) lifting before and after landing the step 2 due to the utilise of the extra 4-step staircase. To the authors' knowledge, no one investigated the difference between the step 1 and step 2 in terms of kinetics since the stair steps limited the collection of the kinematic data (Alcock et al., 2014, Alcock et al., 2015, Alshawabka et al., 2014). Another reason may be due to the differences in participants. Individuals with knee OA were tested in Alshawabka's study whilst only healthy participants were tested in our study.

The previous study found that using 7° heel-length LWI in individuals with medial knee OA for 12 weeks did not decrease the peak of the EKAM during stair descent (Wallace et al., 2007), but the pain was significantly improved. However, our results identified clearly the reduction in the peak of EKAM. One of the possible reasons may be the influence of the length of the wedged part. Only the heel-length LWI was used in Wallace's study while fulllength LWI was used in our study. Hinman et al. (2008a) in her study had demonstrated that wearing full-length LWI was more effective in reducing the peak of the EKAM than heellength LWI during level walking. Another principal reason was that level walking was different from stair walking during which a stance began with forefoot or midfoot strike (Au et al., 2008, Riener et al., 2002, McFadyen and Winter, 1988). In this way, the heel of the shoe will not or partially contact the stair and thus the heel-length LWI will lose the sweet spot of the design during stair ascent and stair descent. On the stairway, the heel-length LWI did not play role on reducing the peak of the EKAM during stair descent even though the 7° heel-length LWI was used in Wallace's study, and this might be the reason why the knee pain was significantly reduced after 12 weeks' treatment since this sort of insole might function during level walking.

There were no significant differences between the LWI and standard shoe in stance time and the magnitude of GRF in sagittal, frontal and transverse planes during stair ascent and descent. The mechanisms for the EKAM reduction with the use of the LWI might result from the COP trajectory on the foot laterally shifted and the knee adduction angle reduced during stair ascent and descent. Compared with the results from the standard shoe, the peak of the EAEM was significantly increased (p<0.05) and the foot's COP trajectory was significantly laterally shifted (p<0.05) during stair ascent and descent when using the LWI. These are consistent with previous studies that the peak of the EKAM reduction was associated with the increased peak of the EAEM, via a lateral shifting of the foot's COP trajectory during level walking and stair walking (Alshawabka et al., 2014, Kakihana et al., 2004). Additionally, we also found that the peak knee adduction angle with LWI was reduced by approximately 10% during stair ascent and descent in our study, though it was not significant (p>0.05). This result is in accordance with earlier study that reducing the peak knee adduction angle may reduce the peak of the EKAM which represents dynamic medial knee loading (Schmitz and Noehren, 2014). The KAAI reduction with the use of the LWI during stair ascent and descent might be easier to be explained as both of the first and second peaks of the EKAM were significantly reduced when compared with the standard shoe in our study.

### **Melbourne OA shoe**

In our study, compared with the results of the standard shoe, the first and second peaks of the EKAM were significantly reduced when using the Melbourne OA shoe during stair ascent and descent. Bennell et al. (2013) found that the first peak of the EKAM was not significantly reduced in the healthy weight individuals with the use of Melbourne OA shoe during level walking in their study. Our study and Bennell's study involved similar healthy participants, the mean BMI of the participants in our study was 21.54 kg/m<sup>2</sup> and Bennell's healthy participants had an average BMI of 21.80 kg/m<sup>2</sup>. Our results demonstrated more inspiring benefit of this type of the shoe. However, in Bennell's study, they reported that the first peak of the EKAM was significantly reduced in both individuals with medial knee OA and overweight when using the Melbourne OA shoe. The Melbourne OA shoe has biomechanical effect on medial knee loading during level walking on individuals with medial knee OA and overweight in Bennell's study as well as during stair walking on healthy weight individuals which were identified in our study. These might result from the dynamic difference between level walking and stair walking that the compressive TF forces averaged approximately three times BW during level walking, but averaged approximately five times BW during stair walking (Taylor et al., 2004). In this way, even individuals with healthy weight may achieve the same effect with the use of Melbourne OA shoe during stair walking as individuals with overweight during level walking. Furthermore, Kean et al. (2013) found that the mechanisms of the EKAM reduction with the use of Melbourne OA shoe mainly driven by the COP laterally shifted and the reduction in the medial-lateral GRF magnitude in the individuals with medial knee OA but by changing knee adduction angle and trunk lean for individuals with overweight during level walking.

However, there was no significant difference in medial-lateral GRF magnitude change between standard shoe and Melbourne OA shoe during stair ascent and descent. Additionally, there were also no significant differences between the Melbourne OA shoe and standard shoe in stance time and the magnitude of the GRF in sagittal and transverse planes. The mechanisms for the EKAM reduction with the use of the Melbourne OA shoe during stair walking in our study could be caused by the COP trajectory laterally shifted and the peak knee adduction angle reduced. Compared with the results of the standard shoe, the peak of the EAEM was significantly increased (p<0.05) and the foot's COP trajectory for the peak of the EKAM was significantly laterally shifted (p<0.05) during stair ascent and descent when using the Melbourne OA shoe. In our study, compared with the results of standard shoe, the peak knee adduction angle was decreased by 8.7% and 6.7% during stair ascent and descent respectively when using the Melbourne OA shoe, although the differences were not statistically significant. The KAAI reduction with the use of Melbourne OA shoe during stair ascent and descent may be easier to be explained as the first and second peaks of the EKAM were significantly reduced when compared with the standard shoe in our study. No studies on the Melbourne OA shoe in stair walking to compare have been reported. The biomechanical effect of the Melbourne OA shoe on medial knee loading in individuals with medial knee OA and overweight during stair walking still need to be investigated in the future.

### **Mobility shoe**

The mobility shoe used in our study was designed to mimic barefoot walking, and the results demonstrated that it could also be an effective treatment to reduce knee loading immediately (Shakoor et al., 2008) and sustain load reduction in a long term (Shakoor et al., 2013) during level walking. In our study, the first and second peaks of the EKAM were significantly reduced (7.4~13.8%) when compared with standard shoe during stair walking, which were in accordance with the results from the previous study that reported the mobility shoe reduced the peak of the EKAM by 8% and 12% when compared with participants' conventional walking shoe and stability shoe (Brooks Addiction Walker; Brooks Sports, Bothell, WA) during level walking respectively (Shakoor et al., 2008). Similarly, in accordance with the study that the KAAI was reduced by 6% and 10% when using mobility shoe compared with conventional walking shoe and stability shoe respectively during level walking (Shakoor et al., 2008). In our study, the KAAI was significantly reduced by 11.1% during stair ascent and 5% during stair descent when using the mobility shoe compared with the standard shoe.

To our knowledge, only one similar study on stairs was reported, which used the Moleca shoe (a type of flexible, non-heeled shoe) during stair descent and showed that Moleca shoe produced similar EKAM with the barefoot and could reduce the EKAM in elderly women with and without knee OA when compared with high-heeled shoe during stair descent (Sacco et al., 2012). However, Sacco did not compare the Moleca shoe with the non-heel shoes

during stair descent and mainly compared the Moleca and the high-heeled shoe. The mechanism of the EKAM reduction for Moleca shoe during stair descent in Sacco's study was still not well understood and Sacco et al. (2012) assumed that the higher EKAM could be caused by the rigidity of sole of the high-heeled shoe and not from the high heel because the initial foot contact was forefoot and strike contact of high heel to the step was minimal during stair descent. Additionally, the ankle keeps plantarflexion during weight acceptance of stair descent when using the heel shoe and the eccentric function of the triceps surae was inhibited and the function of load absorption in the ankle joint complex was influenced, and thus the knee loading was increased.

Instead of using high-heeled footwear, standard shoes were used as the control condition in our study. The mobility shoes reduced the knee loading during stair walking when compared with standard shoes. There were no significant differences between the mobility shoe and standard shoe in stance time and the magnitude of GRF in sagittal, frontal and transverse planes during stair ascent and descent. The mechanism of the first and second peaks of the EKAM reduction for the mobility shoe in our study may be that the biomechanically mimicking barefoot walking could increase proprioceptive input and then the protective neuromuscular reflexes may be initiated to help decrease proximal joint impact and load (Nurse and Nigg, 2001, Shakoor and Moisio, 2004, Sharma and Pai, 1997). These improvements of proprioception and protective reflexes in the ankle and foot complex could be supported by the results that the foot's COP trajectory for the peak of the EKAM was significantly laterally shifted (p<0.05) and the peak of the EAEM was significantly increased by 14.3% (p=0.007) during stair ascent and 15.4% (p=0.031) during stair descent and when compared with standard shoe. The KAAI reduction with the use of mobility shoe during stair ascent and descent may be easier to be explained because both the first and second peaks of the EKAM were reduced in our study.

### Variable stiffness shoe

In our study, the variable stiffness shoe did not reduce the first and second peaks of the EKAM compared with the standard shoe, and this was not consistent with the study that the variable stiffness shoe (the midsole stiffness ratio of lateral side to medial side is 1.3-1.5) reduced the peak of the EKAM by an average of 6.2% when compared with the standard shoe (constant stiffness sole) in knee OA participants (Erhart et al., 2008). Fisher et al. (2007) also

showed that variable stiffness shoes reduced the peak of the EKAM by 4.7% (the midsole stiffness ratio of lateral side to medial side is 1.2) and 7.2% (the sole stiffness ratio of lateral side to medial side is 1.5) compared with standard shoe (personal own shoe) in healthy participants. Jenkyn et al. (2011) demonstrated that the mechanism of the EKAM reduction caused by variable stiffness shoe during level walking was the COP trajectory medially shifted and a reduction in the magnitude of medial-lateral GRF component.

However, no significant changes in medial-lateral GRF and knee adduction angle were identified in our study. Additionally, no significant changes were found in the COP track, which was normally due to the application of the lateral wedged insoles, which was formed by the different deformations of the medial and lateral parts of the sole for the specially designed variable stiffness shoe. The measured hardness of the sole (midsole) of the variable stiffness shoes indicated that there was hardly any difference between the medial and lateral part of the sole, which meant it was hard to form a wedged shape to provide the function of LWI. The reasons why there were no difference in biomechanical variables between variable stiffness shoe and the standard shoe in our study can be summarised as follows:

- The midsole hardness ratio of lateral side to medial side was not large enough. Our results of were 1.0 (the ratio of part B to A, Figure 4-7) at forefoot and 1.1 (the ratio of part D to C, Figure 4-7) at rearfoot that were much less than the figure 1.2 and 1.5 reported by Fisher et al. (2007);
- the stair walking was different from level walking, which started normally with forefoot or midfoot strike. The same hardness of the midsoles at forefoot could have resulted in the failure of forming a laterally wedged sole shape in stance, which could not produce the expected COP lateral shift so to reduce the moment arm of EKAM. In this way, the heel of the variable stiffness shoe would not or partially contact the stair and thus the midsole of the part of the heel will lose the sweet spot of the design during stair ascent and stair descent.

These may also explain why there was no significant difference in KAAI between variable stiffness shoe and standard shoe during stair ascent and stair descent.

### The difference between LWI, mobility shoe and Melbourne OA shoe

In our study, the LWI and mobility shoe have shown the similar biomechanical effect on reducing the medial knee loading during stair ascent and descent when compared with the standard shoe. These are not in consistent with the study which compared the LWI and mobility shoe with the control shoe (Ecco shoe) and reported that the LWI had better effect on the EKAM reduction than the mobility shoe when compared with the control shoe (Ecco shoe) during level walking (Jones et al., 2015). Compared with the results of the control shoe during level walking in Jones' study, the first and second peaks of the EKAM was significantly reduced by 5.63% and 5.52% respectively when using the LWI, and reduced by 1.61% and 1.59% respectively when using the mobility shoe but not significant. The potential reason could be that the stair walking begins with forefoot or midfoot contact while the level walking starts normally with heel strike (Au et al., 2008, Riener et al., 2002). In this way, the heel of the shoe will not or partially contact the stair and the full-length LWI will lose the function of the heel part and only the front and middle part of the LWI can work during stair ascent and stair descent. Therefore, the LWI would miss the typical heel strike pattern during stair walking and the function of the full-length LWI may not perform as well as during level walking.

Compared with the results of the LWI during stair ascent and descent, the magnitude of the first peak of the EKAM was slightly reduced (0.01 Nm/kg) when using the Melbourne OA shoe during both stair ascent and descent but not significant, which means there is no significant difference between Melbourne OA shoe and LWI. The reason why using the Melbourne OA shoe reduced the first peak of the EKAM larger might be explained by the Melbourne OA shoe has an additional design advantage over LWI since it has not only a  $5\pm1^{\circ}$  LWI but also a variable stiffness midsole (Shore A durometer values for the lateral sole:  $64\pm3$  and medial sole:  $44\pm2$ ). However, the LWI and Melbourne OA shoe have the similar biomechanical effect on medial knee loading when compared with the standard shoe. This is due to the wedged sole shape manufactured according to the design and formed with the deformation after subjecting the dynamic load. As far as we know, all studies in the literature related to Melbourne OA shoe were compared with standard shoe (no LWI and variable stiffness midsole) or barefoot (Bennell et al., 2013, Kean et al., 2013, Hinman et al., 2014b, Hinman et al., 2016), this is the first study that compared Melbourne OA shoe with LWI, mobility shoe, and variable stiffness shoe during stair walking. In our study, there were also

no significant differences found in the first and second peaks of the EKAM between using the Melbourne OA shoe and mobility shoe during stair ascent and descent.

In our study, the results indicated that the average peak knee flexion angle during stair ascent (approximately 80°) and stair descent (approximately 99°) were larger than that during level walking (approximately 40°) in stance phase (Perry and Burnfield, 2010), there were no significant differences between peak knee flexion angle among these five different types of footwear (p>0.05) during stair ascent and stair descent. As Walter et al. (2010) and Trepczynski et al. (2014) suggested, the peak of the EKFM needed to be taken into consideration when inferring the medial knee contact force during over-flexed knee activities. Using the Melbourne OA shoe significantly increased the peak of the EKFM when compared with the results of the standard shoe and LWI (by 3.1%, p=0.017; 1.8%, p=0.047, respectively) during stair ascent, which are not consistent with the finding that decreased first peak of the EKAM did not show increase in the peak of the EKFM during level walking (Bennell et al., 2013). The main reasons for this difference may result from Bennell compared the Melbourne OA shoe with barefoot and standard recreational walking shoe (Asics Oceania) during level walking in her study, and the knee flexion ROM is greater during stair walking than level walking. In our study, using the Melbourne OA shoe had higher first peak of the EKAM reduction during stair ascent and descent when compared with the LWI, but the peak of the EKFM was significantly increased during stair ascent. As Walter et al. (2010) stated the decreased first peak of the EKAM reduction may be accompanied by the peak of the EKFM increase. Therefore, this may be the reason why the Melbourne OA shoe did not have additional benefit over conventional walking shoes after six months' treatment in a recent study (Hinman et al., 2016).

The non-response to the first peak of the EKAM reduction varied in the participants when using different types of footwear and LWI compared with the standard shoe. In our study, about 50% of participants failed to achieve the expected reduction in their first peak of the EKAM during stair ascent and descent with the variable stiffness shoes, which was higher than that reported from the previous studies that ranged from 15% to 32% during level walking (Jenkyn et al., 2011, Erhart et al., 2010b). The reasons might be due to the dynamic differences between stair walking and level walking and the negligible difference in the hardness of the lateral and medial midsole of the variable stiffness shoes contributed to the

problem. Although the majority of the specially designed shoes (LWI, Melbourne OA shoe and mobility shoe) in our study demonstrated that they could significantly reduce knee loading during stair walking, approximately 14~28% of the participants still had no response to the specially designed feature. This was in accordance with previous studies that the non-response rate was approximately 13~23% (Hinman et al., 2012, Kakihana et al., 2007, Bennell et al., 2013). The reason for the existence of the non-response could be very complicated. It might be mediated by the anatomical, mechanical and even psychological differences, and also variations in neuromotor activity across individuals (Stacoff et al., 2000, Hinman et al., 2012, Nigg et al., 2003).

Except for the variable stiffness shoe, the specially designed shoes used in this study could reduce knee loading during stair walking by reducing the first peak of the EKAM (72-86% responders). As to which footwear can be used as a treatment depends on other factors as well, for example, the cost of the treatment. As far as we know, the price of the Melbourne OA shoe (\$180) was the highest among these shoes, followed by the mobility shoe (\$130), then the variable stiffness shoe (£84.14) and the cheapest was the LWI (£34.99). If the price of footwear and insole are taken into consideration, not all of them are equally available for the majority of the elderly people. Considering the cost of the treatment, LWI is definitely a good option because a pair of LWI could be used with different shoes. However, it is still not clear what kind of shoes would be the best for LWI to achieve the expected biomechanical effect. Further studies are still needed.

### 4.5. Conclusion

The primary aim of this work was to investigate the effects of different biomechanical footworn devices on medial knee loading during stair ascent and descent. As far as we know, no studies have been done to compare the Melbourne OA shoe with the mobility shoe and LWI before, and this is the first study that compared them during stair walking. In summary, the variable stiffness shoe did not show any change in the first and second peaks of the EKAM and KAAI when compared with the standard shoe, whereas the other specially designed shoes all showed significant reductions. This is important and it demonstrates that not all biomechanically-effective devices for walking achieve the same results when climbing stairs. In this study, along with a typical conventional footwear (standard shoe as a control group) three types of footwear (Melbourne OA shoe, mobility shoe and variability stiffness shoe) and a type of insole (LWI) specially designed for medial compartment knee OA patients were tested and assessed with healthy participants during stair walking. The primary biomechanical outcomes (EKAM and KAAI) were calculated based on the tracked marker data and GRF data. The results indicated that the Melbourne OA shoe, mobility shoe and LWI could demonstrate similar positive biomechanical effect through the reduction of EKAM and KAAI in comparison with that of the standard shoe condition during stair walking. In order to reveal the biomechanical mechanisms of the footwear and LWI, the temporal-spatial parameters, GRFs, knee adduction angle, EAEM, knee flexion angle, ankle eversion angle were investigated, and the results revealed that the value of the EAEM was significantly increased via the COP laterally shifted and knee adduction angle was reduced though it was not statistically significant which were the main reasons to achieve the similar reduction in EKAM and KAAI. The results from the healthy participants indicated specially designed footwear (Melbourne OA shoe, mobility shoe and LWI) can be used to reduce the load in the medial compartment of the knee during stair walking. They could possibly become a kind of treatment method to medial knee OA, but further studies on medial knee OA patients should be performed.

# Chapter 5: Summary of the study and future works

## 5.1. Summary

The main purpose of the study was to determine the biomechanical effect of three types of footwear (Melbourne OA shoe, mobility shoe and variability stiffness shoe) and a typical insole (LWI) specially designed for medial compartment knee OA patients during stair ascent and descent. Prior to the accomplishment of this goal, the prerequisite task was completed to ensure the accuracy and reliability of the gait measurement. The results demonstrated a high test-retest reliability of the knee and ankle joint moments and angles. Based on the 3D kinematic and GRF data, a comprehensive assessment study on the immediate biomechanical effect of the selected footwear (Melbourne OA shoe, mobility shoe and variability stiffness shoe) and LWI was conducted. To avoid any bias judgement, the data in the contrast condition that was the use of a standard shoe walking on stairs were also collected as a control group. The main study found that during stair walking the specially designed shoe (Melbourne OA shoe, mobility shoe and LWI) could achieve a similar reduction in the peak of the EKAM and the cumulative knee loading, i.e. the knee adduction angular impulse (KAAI) similarly during stance phase when compared with the standard shoe and variable stiffness shoe. One thing which needs to be taken into account is the fact that whilst the significant changes in the primary outcomes (EKAM and KAAI) detailed above, between conditions, are statistically significant, they were not greater than the MDC which was recorded during level walking. Potential reasons for this may be due to the increased variability in the walking data and also the smaller sample sizes. Such as the results from the test-retest reliability study and the main study showed the SD of the first peak of the EKAM (0.14 Nm/kg) during level walking was higher than that of stair ascent walking (0.09 Nm/kg). Future research should assess these significant changes with reference to the MDC for stair ascent and descent.

## 5.2. Limitations

Like any other studies, this study had its limitations. Firstly, only level walking was performed in the test-retest reliability pilot study and stair walking was not included. Although the data in level walking demonstrated high accuracy and reliability in the pilot

study, they might not be the direct reflection of the data quality from stair walking even the marker set and placement were exactly the same. Due to the differences between the level walking and stair walking, the variation of kinetics and kinematics of the lower limb during stair walking could be different. The primary results of the main study were assessed based on the MDC of the level walking and it may be that not knowing what this was for stair ascent and descent may have caused the non-clinically significant difference. However, the test-retest reliability pilot study was purely to ensure the marker placement was reliable. Future studies should also assess the reliability on stair ascent and descent.

Secondly, the sample size in the main study might be relatively small, even though statistically significant differences in main parameters were found between conditions.

Thirdly, only healthy individuals were recruited to investigate the effect of different types of footwear and LWI on medial knee loading during stair walking, individuals with medial knee OA were not included in the study. The knee loading reduction during stair walking in healthy individuals cannot guarantee a reduction in knee loading or the same effective reduction in individuals with medial knee OA. Further work with individuals with medial knee OA would be needed as their knee joint structure and lower limb alignment might be different in these individuals and should be taken into account. Additionally, due to the biomechanical difference between level walking and stair walking, such as the initial foot contact are different between each other, the knee loading reduction in stair walking cannot guarantee the same effect in level walking. In order to get a comprehensive understanding of these shoes used in the main study, it is necessary to compare them in level walking too.

Lastly, the effect of different types of footwear on the electromyography (EMG) signals of the leg and spine muscles (such as tibialis anterior, gastrocnemius, erector spinae, etc.) was not investigated during stair walking.

## 5.3. Future works

This study investigated the effect of specially designed footwear and LWI on medial knee loading during stair walking and confirmed the reductions in knee loading from previously reported level walking studies. This study also showed the same level of non-responder to the intervention as previously reported. The future work would be envisaged to investigate this non-response further but also to confirm the results in a population of individuals with medial knee OA. Additionally, EMG could be utilized to determine the effect of different types of footwear used in this study to the major muscle functions around the knee joint. It is hypothesised that reductions in knee loading would be shown and allow recommendations to be proposed for biomechanically foot-worn devices during not only walking but also during stair walking.

# Appendices

Appendix A: Research Governance and Ethics Committee approval letter



Research, Innovation and Academic Engagement Ethical Approval Panel

Research Centres Support Team G0.3 Joule House University of Salford M5 4WT

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7 October 2016

Dear Anmin Liu,

<u>RE: ETHICS APPLICATION</u> – HSCR16-65 - The footwear study. Reliability of biomechanical outcome measures from healthy individuals and knee osteoarthritis patients wearing control shoes with lateral wedged insoles to test the marker placement and outcome.

Based on the information you provided, I am pleased to inform you that application HSCR16-65 has been approved.

If there are any changes to the project and/ or its methodology, please inform the Panel as soon as possible by contacting <u>Health-ResearchEthics@salford.ac.uk</u>

Yours sincerely,

day, A.

Sue McAndrew Chair of the Research Ethics Panel

a. Mel       a. LWI         b. VSS       b. Mob         c. Ecco       c. Ecco         d. Mob       e. Mel         2.       7.         a. Mob       b. VSS         b. Md       b. VSS         c. Ecco       c. Ecco         d. LWI       a. LWI         b. Mel       b. VSS         c. Ecco       c. Ecco         d. LWI       d. Mob         e. VSS       e. Mel         3.       —         a. VSS       e. Mel         b. LWI       c. Ecco         d. Mel       d. VSS         e. Mob       e. Mel         3.       —         a. VSS       e. Mob         b. LWI       c. Ecco         d. Mob       e. Mob         4.       —         math distribution       g.         a. VSS       e. Mob         c. Mel       d. VSS         c. Mel       d. Mob         d. Mob       d. Mob         e. Mob       d. Mob         e. Mob       d. Mob         c. Mel       d. Mob         e. Ecco       Ecco         5.       — </th <th>1.</th> <th></th> <th>6</th>	1.		6
c. Ecco       c. Ecco         d. Mob       d. VSS         e. LWI       e. Mel         2.       7.         a. Mob       b. VSS         c. Ecco       c. Ecco         d. LWI       b. VSS         c. Ecco       c. Ecco         d. LWI       b. VSS         c. Ecco       c. Ecco         d. LWI       d. Mob         e. VSS       e. Mel         3.		a. Mel	a. LWI
d. Mob       d. VSS         e. LWI       e. Mel         2.       7.         a. Mob       b. VSS         b. Mel       b. VSS         c. Ecco       c. Ecco         d. LWI       d. Mob         e. VSS       c. Ecco         d. LWI       d. Mob         e. VSS       e. Mel         3.       8.         a. VSS       e. Mel         3.       8.         a. VSS       e. Mel         4.       9.         a. VSS       e. Mob         4.       9.         a. VSS       c. LWI         b. VSS       c. LWI         d. Mob       d. Mob         e. Ecco       e. Ecco         5.       10.         a. LWI       b. Mob         b. Mob       b. Mob         c. Ecco       c. VSS         d. Mel       d. Ecco		b. VSS	b. Mob
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b. Mel b. VSS c. Ecco c. Ecco d. LWI d. Mob e. VSS e. Mel 3	2.		_ 7
c. Ecco       c. Ecco         d. LWI       d. Mob         e. VSS       e. Mel         3.		a. Mob	a. LWI
d. LWI       d. Mob         e. VSS       e. Mel         3.		b. Mel	b. VSS
e. VSS       e. Mel         3.       8.         a. VSS       b. LWI         b. LWI       b. LWI         c. Ecco       c. Ecco         d. Mel       d. VSS         e. Mob       e. Mob         4.       9.         a. VSS       e. Mob         4.       9.         a. VSS       c. LWI         b. LWI       b. VSS         c. Mel       c. LWI         d. Mob       d. Mob         e. Ecco       e. Ecco         5.       10.         a. LWI       a. LWI         b. Mob       b. Mob         c. Ecco       c. VSS         d. Mel       d. Ecco		c. Ecco	c. Ecco
3.       8.         a. VSS       a. Mel         b. LWI       b. LWI         c. Ecco       c. Ecco         d. Mel       d. VSS         e. Mob       e. Mob         4.       9.         a. VSS       a. Mel         b. LWI       b. VSS         c. Mel       c. LWI         d. Mob       d. Mob         e. Ecco       e. Ecco         5.       10.         a. LWI       b. Mob         b. Mob       d. Mob         c. Ecco       c. VSS         d. Mel       d. Ecco		d. LWI	d. Mob
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b. LWI       b. LWI         c. Ecco       c. Ecco         d. Mel       d. VSS         e. Mob       e. Mob         4.       9.         a. VSS       a. Mel         b. LWI       b. VSS         c. Mel       c. LWI         d. Mob       d. Mob         e. Ecco       e. Ecco         5.       10.         a. LWI       b. Mob         b. Mob       d. Ecco         4.       4.         5.       10.         5.       10.         6.       10.         7.       10.         7.       10.         7.       10.         7.       10.         7.       10.         7.       10.         8.       10.         9.       10.         10.       10.         10.       10.         10.       10.         10.       10.         10.       10.         10.       10.         10.       10.         10.       10.         10.       10.         10.       10.	3.		8
c. Ecco       c. Ecco         d. Mel       d. VSS         e. Mob       e. Mob         4.       9.         a. VSS       a. Mel         b. LWI       b. VSS         c. Mel       c. LWI         d. Mob       d. Mob         e. Ecco       e. Ecco         5.       10.         a. LWI       b. Mob         b. Mob       d. Ecco         c. Ecco       c. VSS         d. Mel       d. Ecco		a. VSS	a. Mel
d. Mel       d. VSS         e. Mob       e. Mob         4.       9.         a. VSS       a. Mel         b. LWI       b. VSS         c. Mel       c. LWI         d. Mob       d. Mob         e. Ecco       e. Ecco         5.       10.         a. LWI       b. Mob         b. Mob       c. VSS         d. Mob       d. Ecco		b. LWI	b. LWI
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4.       9.         a. VSS       a. Mel         b. LWI       b. VSS         c. Mel       c. LWI         d. Mob       d. Mob         e. Ecco       e. Ecco         5.       10.         a. LWI       a. LWI         b. Mob       c. VSS         d. Mel       d. Ecco		d. Mel	d. VSS
a. VSS     a. Mel       b. LWI     b. VSS       c. Mel     c. LWI       d. Mob     d. Mob       e. Ecco     e. Ecco       5.     10.       a. LWI     a. LWI       b. Mob     b. Mob       c. Ecco     c. VSS       d. Mel     d. Ecco		e. Mob	e. Mob
b. LWI       b. VSS         c. Mel       c. LWI         d. Mob       d. Mob         e. Ecco       e. Ecco         5.       10.         a. LWI       a. LWI         b. Mob       c. VSS         d. Mel       d. Ecco	4.		_ 9
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e. Ecco       e. Ecco         5.       10.         a. LWI       a. LWI         b. Mob       b. Mob         c. Ecco       c. VSS         d. Mel       d. Ecco		c. Mel	c. LWI
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a. LWI b. Mob c. Ecco d. Mel d. Ecco		e. Ecco	e. Ecco
b. Mob c. Ecco d. Mel d. Ecco	5.		10
c. Ecco d. Mel d. Ecco		a. LWI	a. LWI
d. Mel d. Ecco		b. Mob	b. Mob
		c. Ecco	c. VSS
e. VSS e. Mel		d. Mel	d. Ecco
		e. VSS	e. Mel

Appendix B: Randomization Plan from (<u>http://www.randomization.com</u>)

11	13
a. LWI	a. Ecco
b. VSS	b. Mob
c. Ecco	c. LWI
d. Mob	d. VSS
e. Mel	e. Mel
12	14
a. VSS	a. Ecco
b. Mel	b. LWI
c. Mob	c. Mel
d. Ecco	d. Mob
e. LWI	e. VSS
15	16
a. VSS	a. LWI
b. LWI	b. Mob
c. Mel	c. Mel
d. Ecco	d. VSS
e. Mob	e. Ecco

Note: VSS =variable stiffness shoe, Ecco = standard shoe, LWI = lateral wedge insole inserted into standard shoe, Mel =Melbourne OA shoe, Mob =mobility shoe.

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