Effectiveness of a valgus knee brace on biomechanical and clinical outcomes during walking and stair climbing in individuals with knee osteoarthritis.

Yousef Al-Zahrani

PhD Thesis   **2014**

Effectiveness of a valgus knee brace on biomechanical and clinical outcomes during walking and stair climbing in individuals with knee osteoarthritis.

Yousef Al-Zahrani

School of Health Sciences

College of Health and Social Care

University of Salford, Salford, UK

Submitted in Partial Fulfilment of the Requirements of the Degree of Doctor of Philosophy, September 2014

TABLE OF CONTENTS

LIST OF FIGURES

CHAPTER TWO

CHAPTER THREE

CHAPTER FIVE

LIST OF TABLES

CHAPTER FIVE

ACKNOWLEDGMENTS

ABSTRACT

The knee is the joint which is most affected by osteoarthritis (OA). Knee OA is more common in older individuals and occurs more in the medial than the lateral compartment. When we stand, walk or climb stairs, our weight is transmitted through our knee joints and this is known as load which is higher in individuals with medial knee OA than healthy counterparts. Additionally, muscle weakness is a factor in medial knee OA and previous work has demonstrated increased muscle co-contraction in these patients. In this thesis we assessed the loading on the knee joint and muscle co-contraction after wearing an assistive device (a valgus knee brace) which is a common treatment in this disease. Whilst previous literature has demonstrated changes in loading with valgus knee braces during over-ground walking, no studies (to date) have assessed the effect of valgus knee braces on knee loading and muscle co-contraction during ascending and descending stairs immediately, and after a period of use. In addition, it is an un-documented opinion that knee bracing affects muscle strength and control around the knee and weakens the joint so this research also aimed to confirm or refute this theory. To accomplish the research, we performed three separate trials; a) a repeatability trial in seven patients to determine the reliability of the outcome measures for the future study; b) a clinical trial of fifteen individuals with medial knee OA would wore a valgus knee brace for a period of three months with an interim assessment at six weeks for pain and muscle strength/function; c) finally, a small pilot study of seven patients investigating combined orthotic treatments on biomechanical outcome measures. In summary the results of this thesis have demonstrated positive biomechanical and clinical outcomes when wearing a valgus knee brace for a sustained period. This was further improved biomechanically with the combination treatment with a lateral wedge insole which reduced knee loading more during stair ascent and descent, in comparison to the orthotic devices alone in the same session. Future studies to find out the effect of a combination of an off-the-shelf valgus knee brace and off-the-shelf lateral wedge insole on knee loading, clinical and radiological outcomes after a period of longer wear were indicated.

CHAPTER ONE

INTRODUCTION

Osteoarthritis (OA) is the most common degenerative joint disease and a leading cause of musculoskeletal disability in most developed countries (Jones et al., 2004). In the United Kingdom (UK), approximately 8.5 million people have been affected (www.nhs.uk/Conditions/Arthritis/Pages/Introduction.aspx). Traditionally, OA has been only associated with the elderly, but up to third of the population over the age of 45 years complain of symptoms related to OA.

The knee joint is the most common joint affected by OA, and is perhaps the most important site with regards to pain and disability affecting some 30 – 40 % of the population by the age of 60 (Felson. 1990, Lawrence et al., 1998). Symptomatic knee OA occurs in approximately 6% of adults, 30 years of age and older, and in 11% of adults, 65 years of age and older (Guccione et al., 1990). In the UK, 20-28% of the population aged 40 years and above has knee pain of which 50% will develop knee OA (Peat et al., 2001). OA of the knee and of the hip probably have a greater social cost and more associated disability than osteoarthritis of other joints, with the knee being the greater of the two. Knee OA is one of the leading health burdens, given that in the UK; around 25% of the populations aged over 65 years have knee osteoarthritic changes resulting in major economic costs (Jinks et al., 2004; Bijlsma and Knahr, 2007).

Knee OA is a widespread disease that contributes significantly to functional limitations and disability in older people. Pain, loss of motion, and decreased quadriceps femoris muscle strength are physical impairments that accompanying with knee OA (Kelley et al, 2002).

The etiology of knee OA is multifactorial and includes both systemic (age, sex, racial characteristics, genetics, etc) and local factors (degree of joint loading, joint injury, increased WB on account of obesity, joint deformity, etc) affecting the likelihood of OA development in a joint. For instance, obesity is very common and widespread in Saudi population and this problem may have contributed to the Kingdom of Saudi Arabia

(KSA) having one of the highest prevalences of Knee OA in the world (Al-Arfaj, 2002). The radiological and clinical changes which are related to OA are more commonly observed in the medial compartment than in the lateral compartment of the knee (Thomas et al., 1975) with a ratio of up to 4 (Ledingham et al., 1993), five (Felson et al., 2002) and ten (Ahlback, 1968) times. Varus alignment increased the risk of medial compartment OA progression in knee OA, which suggests that the degree of the external knee adduction moment (EKAM) correlates with radiographic joint space narrowing of the medial compartment (Sharma et al., 2001).

One of the reasons for this greater incidence of medial compartment OA is that the loads transferred through the medial compartment during walking are substantially higher than loads transferred through the lateral compartment. The distribution of loads transferred through the medial and lateral compartments during walking can be estimated by EKAM; a higher EKAM indicates greater loads in the medial than in the lateral compartment (Mündermann et al. 2005).

During walking, the peak external knee adduction moment (EKAM) is a strong predictor of presence (Baliunas et al., 2002), severity (Henriksen et al., 2010;, Mündermann et al., 2004; Mündermann et al., 2005), and the rate of progression (Miyazaki et al., 2002) of medial knee OA, and can be reliably assessed during walking (Birmingham et al., 2007). EKAM was found to be higher in all severities of knee OA when compared to healthy participants during early-stance (Kaufman et al., 2001; Hurwitz et al., 2002; Mündermann et al., 2005; Thorp et al., 2006; Rudolph et al., 2007; Huang et al., 2008).

Stair climbing is a common and frequent activity in daily living and demanding locomotor task, compared to walking on level ground, a greater range of motion in the lower limbs joints (hip, knee and ankle), increased lower limb muscular activities, and around six times more load on the knee joint (Andriacchi et al., 1980).

Whilst the EKAM represents a single point in time, the knee adduction angular impulse (KAAI) is a frequent outcome measure used in that it assesses the load on the medial compartment during the whole of stance phase (Thorp et al., 2006). The KAAI has been found to be a sensitive method in detecting the load on the knee between mild and

moderate knee OA, and it significantly higher in moderate knee OA compared to mild OA, while the peak of EKAM did not change significantly between mild and moderate knee OA during early-stance (Thorp et al., 2006; Kean et al., 2012).

Another factor which has been attributed to increased loading on the medial compartment is the presence of muscle co-activation or co-contraction (as referred to hereafter) which is the synchronized activity of synergistic muscles (agonist and antagonist) (Sirin and Patla, 1987), which take part in creating moments of force around a joint during dynamic tasks (Nigg et al., 2003). Muscle co-contraction has been found to be increased, when utilizing electromyography (EMG) in gait studies of knee OA when compared to asymptomatic subjects (Childs et al., 2004; Lewek et al., 2004; Hubley-Kozey et al., 2006). Both medial (Lewek et al., 2004; Lewek et al., 2006) and lateral muscle co-contraction indices (Schmitt and Rudolph, 2007) have been documented to increase in OA patients compared with control subjects.

Good muscle strength is needed in order to support these excessive loads, Patients with knee OA have shown decreases in quadriceps strength and activation (Wessel, 1996; Fisher and Pendergast 1997; Hurley et al., 1997; O'Reilly et al., 1998) and impairments in knee joint proprioception. However, there is no association between quadriceps strength and EKAM even when an increase in strength was seen (Thorp et al. 2010). However, these deficits in strength and coordination (Fisher and Pendergast, 1997; Pai et al., 1997; Sharma et.al., 1997) are associated with the ageing process and might lead to larger impairments in balance compared with age matched healthy group (Hassan et al., 2001; Hinman et al., 2002). Therefore, assessment of dynamic balance using a method such as the Star Excursion Balance Test (SEBT), which is an inexpensive and quick method of assessing dynamic balance, with good reliability (Hertel et al., 2000; Kinzey and Armstrong, 1998, Al-Khlaifat, 2012), would determine the influence of increases in muscle strength.

Given that mechanical loads (EKAM, muscle co-contraction and muscle strength) play a role in the development and progression of medial knee OA, it is important to investigate ways of decreasing these loads or redistributing these to relieve stress on the underlying articular cartilage.

In the management of knee OA, surgical intervention of the condition has a good success but is of great expense to the NHS and has a large impact on the individual in terms of recovery time and functional independence. There are other surgical options such as High Tibial Osteotomy (HTO) and Unicompartmental Knee Replacement (UKR) which other than the expense, there are some individuals who may not be suitable for surgery (too young) or do not want surgery. Therefore, conservative management should be at a forefront of the treatment for individuals with medial knee OA.

There are different conservative management techniques for medial knee OA ranging from pharmacological to exercise based treatments to biomechanical orthotic treatments. Non-Steroidal Anti-Inflammatory Drug (NSAID) treatment in patients with knee OA results in a reduction in symptomatic pain but there is a paradoxical increase in loading of the knee in patients with medial knee OA; therefore, care should be taken in the use of pharmaceuticals directed at reducing pain (Hurwitz et al., 2000, Sum et al., 1997).

The exercise studies have shown good changes clinically but no changes in EKAM (Gaudreault et al., 2001). However, muscle co-contraction between vastus lateralis and biceps femoris was significantly reduced in early and mid-stance on the affected side (Al-Khlaifat. 2012).

There are other conservative management strategies which could potentially be used by individuals with medial knee OA in order to directly influence the EKAM and the load distribution in the knee joint by altering gait patterns.

One such treatment is a lateral wedge insole which in theory everts the foot to provide a valgus moment at the ankle. This resulting valgus moment causes the centre of pressure in the foot to shift laterally, thereby reducing the EKAM during walking (Sasaki and Yasuda, 1987, Pazit et al., 2010). Whilst biomechanical studies have shown consistent reductions (Jones et al., 2013, Hinman et al., 2008), there is controversy in whether the treatments offers significant pain reductions over flat non-wedged insoles (Baker et al., 2007, Parkes et al., 2013).

Valgus unloader braces are another option and are classed as a direct orthotic management strategy in that they apply a three-point-pressure directly to arthritic knees

(Reeves, & Bowling, 2011) and theoretically give pain reduction by decreasing the load on the medial compartment through the application of an opposing external valgus moment about the knee. A total of 33 studies from 1996 to 2014 have investigated the efficacy of valgus unloader braces in individuals with knee osteoarthritis patients for different periods varying from one day to 12 months duration. These studies have found improvements in pain, physical function, decreasing muscle co-contraction, improvement in hamstrings strength and improvements in kinematic and kinetic data. However, these outcome measures are from different studies utilising different valgus unloader braces studies and therefore a study needs to assess all of these outcome measures in one complete study.

Additionally, the majority of the previous studies have looked at the immediate effect of valgus knee braces on knee loading (Lindenfeld et al., 1997; Draganich et al., 2006; Gaasbeek et al., 2007; Fantini Pagani et al., 2010; Toriyama et al., 2010; Karimi et al., 2012), muscle co-contraction (Ramsey et al., 2007; Fantini Pagani et al., 2012), muscle strength (Hurley et al., 2012) and balance (Birmingh et al., 2001; Chuang et al., 2007) rather than after a period of time wearing the device. There have been no studies which have investigated the effect of a period of wearing the valgus knee brace on knee loading (EKAM) which has a strong relationship with improvement in pain(Otis et al., 1996; Lindenfeld et al., 1997; Matsuno et al., 1997; Hewett et al., 1998; Kirkley et al., 1999; Komistek, et al., 1999; Draper et al., 2000; Pollo et al., 2002; Nicholas J. Giori 2004; Richards et al., 2005; Draganich et al., 2006; Brouwer et al., 2006; Gaasbeek et al., 2007; Ramsey et al., 2007; Ramsey and Russell 2009; Schmalz et al., 2010; Müller-Rath et al., 2011; Wilson et al., 2011; Hurley et al., 2012; Deie et al., 2013), function, balance, proprioception and muscle strength. However, all studies have reported that a valgus knee brace can potentially decelerate disease progression in patient with knee OA. It is also not known whether any carry-over effects are seen after using the brace for a period of time when not wearing the brace. This is important in terms of practical treatment applications as it would allow the individual to not use the valgus knee brace for a short time and still feel the benefits of the valgus knee brace.

All of the studies aforementioned have assessed walking and in terms of daily activities, individual's with medial knee OA rate stair climbing as a more difficult task biomechanically and physiologically, when compared to walking on level ground (Yu et al., 1997a, Protopapadaki et al., 2007, Riener et al., 2002). To the author's knowledge, there are no studies that assess the effect of a valgus knee brace on EKAM and muscle co-contraction whilst ascending and descending stairs immediately and after a period of time.

The objectives of this thesis were therefore to determine three aspects in individuals with medial knee OA; firstly whether a valgus knee brace reduces the EKAM over a period of 3 months both with the brace on and with the brace off; secondly, to determine whether a valgus knee brace reduces pain and alters muscle strength/function over a period of 3 months with an interim assessment at six weeks; and thirdly to determine whether a valgus knee brace alters muscle co-contraction over a period of 3 months wear.

The structure of the thesis will firstly review the existing literature linked to knee OA, the external knee adduction moment, and valgus knee braces to demonstrate the novelty and aim to fill the gap from previous literature. Following this the reliability study will be presented including the gait analysis methods, followed by the main UNLOAD (the effectiveness of valgus knee bracing in subjects with medial knee osteoarthritis) study with a final future studies and conclusion chapter.

CHAPTER TWO

LITERATURE REVIEW

2.1   Definition of osteoarthritis

Osteoarthritis (OA) is the most common degenerative joint disease and a leading cause of musculoskeletal disability in most developed countries (Jones et al., 2004). The term osteoarthritis defines a common, age-related, heterogeneous group of disorders characterised pathologically by progressive loss of articular cartilage in synovial joints, associated with varying degrees of new bone (osteophyte formation), increased subchondral plate thickness, and synovitis (Dieppe et al., 2005). Additionally, OA characterised pathologically by joint space narrowing of joint space width which contributes to muscles weakness around the affected joint, capsular and ligamentous laxity and following joint deformity and instability (Cooke et al., 1994). The clinical symptoms of OA include inflammation, pain, swelling, joint stiffness and joint dysfunction (Kean et al., 2004).

2.2 Incidence of osteoarthritis

In the United Kingdom (UK), approximately 8.5 million people are affected (www.nhs.uk/Conditions/Arthritis/Pages/Introduction.aspx) by osteoarthritis. In the United States of America (USA) approximately 27 million adults have clinical osteoarthritis (up from the estimate of 21 million for 1995) (Lawrence et al., 2007). Ttraditionally, OA was only associated with the elderly, but up to a third of the population over the age of 45 years complain of symptoms related to osteoarthritis. The incidence of osteoarthritis increases with age (Buckwalter et al, 2004). The sex differences play a role in the prevalence of OA (Felson et al., 1995).

Although hip and knee OA are common in OA, the knee is the most common joint affected, and is perhaps the most important site with regards to pain and disability affecting 30 – 40 % of the population by the age of 60 (Felson. 1990, Lawrence et al.,

1998). The ankle OA developed secondary to trauma, (ankle ligament injury, tibial plafond fractures, and mostly malleolar fractures) but Primary OA in the ankle joint is rare (Valderrabano et al., 2009)

Incidence of knee OA

The World Health Organization (WHO) has reported that knee OA is the fourth most common cause of disability in women and the eighth in men (Vad et al., 2002). Males have a significantly reduced risk for prevalent OA in the knee compared to females (Felson et al., 1995), particularly those females ≥55 years, are more likely to have more severe OA in the knee particularly after menopausal age (Srikanth et al., 2005).

Symptomatic knee OA occurs in approximately 6% of adults 30 years of age and older and in 11% of adults 65 years of age and older (Guccione et al., 1990). The prevalence of knee OA radiographically in adults aged ≥45 was 19.2% in Framingham and 27.8% in Johnston County, and the prevalence among adults age ≥60 was 37.4% in the NHANES III study (Dillon et al., 1991-1994). The prevalence of symptomatic knee OA was 4.9% among adults age ≥26 years in the Framingham study (Felson et al., 1987), 16.7% among adults age ≥45 in the Johnston County study (Jordan et al., 2007), and 12.1% among adults aged ≥60 in the NHANES III study (Dillon et al., 1991-199).

Joint damage is caused by a mixture of systemic factors that predispose to the disease, and local mechanical factors that dictate its distribution and severity. Osteoarthritic joint damage might be accompanied with clinical problem however the radiographic severity of joint damage is weakly related to that clinical problem. Therefore, the associations and pathogenesis of pain need further investigation. Subchondral bone and synovium may be responsible for nociceptive stimuli, and peripheral neuronal sensitisation is an important feature, and can result in normal activities (such as walking) producing pain. Central pain sensitisation can also happen, and psychosocial factors are important causes of pain severity (Dieppe et al., 2005).

In the UK, 20-28% of the population aged 40 years and above has knee pain of which 50% will develop knee OA (Peat et al., 2001). Prevalence rates for knee OA, based on population studies in the USA, are comparable to those in Europe. These studies report

that severe radiographic changes affect 1% of people aged 25–34 and this figure increases to nearly 50% in those 75 years and above (Litwic et al., 2013). Studies from China, which used similar methods and definitions to the Framingham Study, found that the prevalence of bilateral knee OA and lateral compartment disease were two to three times higher in Chinese cohorts compared with estimates from the Framingham OA study (Kang et al., 2009). Data on clinically diagnosed knee OA in the Community Oriented Program for Control of Rheumatic Disorders (COPCORD) studies in the Asian region showed that the prevalence within this area ranged from 1.4% in urban Filipinos to 19.3% in rural communities in Iran (Haq et al., 2001). One of the major reasons for this difference might have been the physical and socioeconomic environment. The COPCORD studies were conducted in India, Bangladesh and Pakistan investigating differences between rural and urban populations. In India the crude prevalence of clinically diagnosed knee OA was greater in the urban (5.5%) than those in the rural community (3.3%). The prevalence was higher in rural communities after adjusting for age and sex distribution (Haq et al., 2001). Also, in China, men aged 60 and above from a rural community demonstrated approximately double the prevalence of symptomatic knee OA when compared with their urban counterparts (Kang et al., 2009).

From a personal perspective, being a Kingdom of Saudi Arabia (KSA) citizen, KSA has one of the highest prevalences of knee OA in the world. 300 patients randomly were chosen from 14 primary health cares for different medical conditions. Radiographic OA was seen in 81 out of 133 females (60.9%) and in 89 out of 167 males (53.3%). The patella was involved with radiographic osteoarthritic changes in 80.7% and 87.8% of female and male OA patients, respectively (Al-Arfaj & Al-Boukai, 2002).

2.3. Burden and cost of knee OA

OA of the knee and of the hip probably have a greater social cost and more associated disability than osteoarthritis of other joints, with the knee being the greater of the two. Knee OA is one of the leading health burdens, given that in the UK; around 25% of the population aged over 65 years have knee osteoarthritic changes resulting in major economic costs (Jinks et al., 2004; Bijlsma and Knahr, 2007). Recent reports conducted by Arthritis Care found approximately 8.5 million of the UK population have OA, which

is estimated to cost 1% of the annual Gross National Product (Arthritis Care, 2012) of the UK. The costs included physician and allied health professionals' visits and hospital as direct costs, whereas inabilities to work are classed as direct costs (March and Bachmeier, 1997). In UK, the rate of knee replacements tripled during the period of 1991 and 2006 (Culliford et al., 2010). In 2004 alone, the cost for knee replacement in the US was $14.6 billion (Kim, 2008). This cost does not including pain management, loss of work due to disability, and various treatment options such as physiotherapy and revision surgery. The economic burden of OA is increasing; 54% more knee replacements were performed in 2004 compared with 4 years earlier, and this number is estimated to increase to 1.4 million by 2015 (Kim, 2008). In view of the increasing health burden and prevalence of OA developing, there is an urgent need to understand the natural cause of knee OA in order to find preventative and effective therapies and reduce risk factors for both the incidence and progression of knee OA.

2.4. Diagnosis of knee OA

OA has been classified by the joint involved (hip, knee, hand, spine and others) and by whether it is primary (idiopathic) or secondary (caused by metabolic, anatomical, traumatic or inflammatory conditions). Primary generalised OA includes involvement of the distal and proximal inter-phalangeal joints of the hand, the first carpo-metacarpal joint, knees, hips, and the metatarsophalangeal joints.

Radiological findings showed that in approximately 5% of the population aged between 35 and 55 years knee OA has been indicated (Thorstensson et al., 2004). These changes range from the presence of only osteophytes in the early stages up to joint space obliteration. The Kellgren and Lawrence (KL) grading system (Kellgren and Lawrence, 1963) is widely used to classify radiographic osteoarthritis into five grades (KL Radiographic score: grade 0: no features (normal); grade 1: doubtful narrowing of joint space and possible osteophytic lipping; grade 2: mild: definite osteophytes and possible narrowing of joint space; Grade 3: moderate: multiple osteophytes, definite narrowing of joint space, some sclerosis and possible deformity of bone contour. Grade 4: severe: large osteophytes, marked narrowing of joint space, severe sclerosis and definite deformity of

bone contour). It might be argued that KL grade 1 should not really be considered as osteoarthritis, because it is of limited clinical importance and the relevance of osteophytes in the osteoarthritic process is not clear (Thorstensson et al., 2004). However, KL grade 1 is clearly associated with progression of radiographic features five years later and therefore should be treated as an early phase of the disease (Hart and Spector, 2003) (Figure 2-1).

Knee OA is classified as Primary OA or secondary OA. Knee OA is a degenerative disease that characterized by softening, ulceration of the articular cartilage, osteophytes formation, and subchondral sclerosis (Huch et al., 1997) which leads to narrowing of knee joint space width. A clinical diagnosis of knee OA is depend on radiographic evidence joined with the incidence of pain in the knee joint (Felson et al., 2000a, Miyazaki et al., 2002).

The first clinical symptoms stated by patients with knee OA are pain, quadriceps weakness, joint instability and functional limitation (Hurley et al., 1997, Felson et al., 1997).

Knee OA can be described depending on the side of the knee joint affected, in to three sides, inside (medial tibiofemoral compartment), outside (lateral tibiofemoral compartment) and anterior (the patellofemoral compartment).

The changes which are related to OA are more commonly observed in the medial compartment than in the lateral compartment of the knee (Thomas et al., 1975) with a ratio of up to 4 (Ledingham et al., 1993), five (Felson et al., 2002) and ten (Ahlback, 1968) times. These can be related to structural and dynamic factors which will be discussed later.

Figure 2-1: Knee OA, Left - grade II, Right - grade III (Photos source: synoviscone.com)

2.5. Risk factors for knee OA

The etiology of knee OA is multifactorial and includes both systemic and local factors affecting the likelihood of OA development in a joint. The systemic factors (age, sex, racial characteristics, genetics, etc) establish the foundation for cartilage properties but that the local biomechanical factors (degree of joint loading, joint injury, increased body weight on account of obesity, joint deformity, etc) have a crucial influence on the final qualities of articular cartilage, its wellbeing, or breakdown. Thus, local biomechanical factors determine the site and severity of OA (Haara et al. 2003; Cooper et al 2000; Felson et al. 2000). The systemic and local biomechanical factors will be discussed briefly.

2.5.1. Systemic Factors

a-   Age:
The prevalence of knee OA increases with age throughout the elderly years (Felson et al., 1987; Buckwalter et al., 2004). Up 50 % of people aged 50 and over denote having knee pain during a year, and 25 % of people have severe and disabling knee pain (Jinks et al., 2004).

b-   Sex:

Knee OA is more common in women over the age of 50 (Kohatsu and Schurman, 1990; Felson 1993) and in men before 50 (Felson et al., 2000). In addition, knee OA is more frequent in men below 45 years and women over 55 years (Silman and Hochberg, 2001).

c-   Hormone effect:

Oestrogen regulates bone metabolism, and OA increases in women dramatically in the years after menopause due to deficiency of Oestrogen hormone (Nevitt and Felson, 1998). Pre-menopausal women have greater risk of OA development as the hormone rises bone mass, which increases the load on the cartilage (Nevitt and Felson, 1996).

d-   Racial characteristics:

Risk of OA is greater among African American (Black) as compared with non-Hispanic White women (Kington & Smith, 1997; Felson & Zhang, 1998). Chinese and black women have a great incidence of knee OA compared to white women (Anderson and Felson, 1988; Zhang et al., 2001).

e-   Vitamin deficiency:

Subclinical deficiency of vitamin K was related with higher risk of progressing radiographic knee osteoarthritis and Magnetic resonance imaging (MRI)-based cartilage lesions (Misra et al., 2013). Studies have shown that low serum levels or low dietary intake of vitamin D may have important effects on knee OA development in patients with low body mass index (BMI) (Mcalindon et al., 1996).

f-   Biochemical markers:

Bone turnover markers (serum Osteocalcin (OC) and C-telopeptide of type I collagen (CTX-I)) were decreased and cartilage and synovial tissue turnover increased in patients with knee OA compared with controls and these markers are good for identifying progression and assessing therapeutic response in OA due their faster response (Garnero, 2001). The presence of cartilage oligomeric matrix protein in the synovial fluid and urine would detect those at higher risk of progression knee OA (Felson et al., 2000).

g-   Bone density:

OA and Osteoporosis (low bone density) are inversely related (Hart et al., 1994). Osteoporosis reduces the risk of knee OA, but having osteoporosis in already arthritic joints might be increase the development of the disease (Bettica et al., 2002). Bone mineral distribution of the proximal tibia is affected by the local mechanical stress around the knee with medial compartment OA (Wada et al. 2001).

2.5.2. Biomechanical factors

a-   Obesity:

Obese people are obviously at increased risk of progression knee OA (Cooper et al., 2000, Gelber et al., 2000, Felson, 2004); for each 2 pounds increment in body weight the risk of having knee OA increases by 9-13% (Cicuttini et al., 1996). Obese people are more likely to progress to bilateral Knee OA (Spector, 1994). But, being overweight increases the loading on the knee joint; in single-limb stance phase, if the weight increases by 1 pound, the force through the knee will be enlarged by 2-3 pounds, which may leading to cartilage breakdown, ligamentous malfunction and knee instability (Felson et al., 2000a). This association may clarify the reason of pain decrease and physical improvement in patients with knee OA after they lose weight (Zhang et al., 2009). Obesity is very common and widespread in Saudi population and this problem may have contributed to the Kingdom of Saudi Arabia (KSA) having one of the highest prevalence of Knee OA in the world (Al-Arfaj., 2002).

b-   Muscle weakness:

Quadriceps and gluteus medius muscle weakness, clinically, are consistently found in patients with knee OA (Slemenda et al., 1998; Chang et al., 2005).   Increases of quadriceps muscles strength is linked with a reduced risk for incident symptomatic knee OA (Segal and Glass, 2011).

c-   Previous lower limb injury:

A greater incidence of radiographic knee OA was detected in young women who had an ACL tear through playing soccer 12 years earlier (Lohmander et al., 2004). Most of the

individuals who have an acute ACL tears are less than 30 years old, which leads to early onset knee OA between ages 30 and 50 during work and life (Friel and Chu, 2013).

d-   Repetitive joint stresses:

Activities which involve repetitive squatting and bending positions during work are a risk factor of incident knee OA (Cooper et al., 1994, Coggon et al., 2000; Gaudreault et al., 2012). Knee OA had the highest incidence in men whom participated in sport and had physically demanding jobs showing the increased loading that was being transmitted through the knee joint (Sandmark and Vingard, 1999)

e-   Malalignment:

From plain radiographs a strong association between Varus and valgus malalignment of knee joint and increased risk of developing and progression of medial and lateral knee OA was seen (Sharma et al., 2001). Varus knee alignment has been stated as one of the greatest predictors of a high knee adduction moment (Barrios et al., 2011) which has been proposed to be a risk factor in progression of medial knee OA and will be discussed later in the chapter. However, healthy knees have displayed a varus alignment ($1.5 \pm 2°$) in their lower extremities (Moreland et al., 1987) but individuals with larger varus alignments ($7.2 \pm 4.8°$) are considered to have a varus malalignment (Cooke et al., 2003); which in turn can contribute to increased risk of medial knee OA (Sharma et al., 2001).

2.6. Biomechanical changes in knee OA

The definition of biomechanics includes the prefix 'bio', which means life, and the suffix 'mechanics' and it is the science of movement of a living body, involving how muscles, bones, tendons and ligaments work together to produce movement (Rau et al., 2000). Biomechanics of movement is the application of Newtonian mechanics to the neuromuscular skeletal system which involves the forces that cause the movement, and the internal forces that act within the body (Rau et al., 2000; Rose and Gamble, 2006). Before discussing the changes that occur when osteoarthritis is diagnosed, the next section will briefly discuss typical gait.

2.6.1 Typical Gait cycle

The gait cycle is the period of time for two steps and is started and measured from heel strike of one foot to the next heel strike of the same foot. The gait cycle comprises of two phases: 1) stance (when the foot is in contact with the supporting surface) and 2) swing (when the limb is swinging forward, out of contact with the supporting surface). The gait cycle is divided into four parts: early-stance, mid-stance, late-stance, and swing phases representing 0%-20%, 21%-40%, 41%-60%, and 61%-100% of the gait cycle, respectively (Mündermann et al., 2004).

Along with providing forward momentum of the leg, the swing phase also prepares and aligns the foot for heel strike and ensures that the swinging foot clears the floor and comprises about 40% of the total gait cycle. Stance comprises about 60% of the total gait cycle at freely chosen speeds and functions to allow weight-bearing and provide body stability. Five distinct events occur during the stance phase: heel-strike (HS), foot flat (FF), mid-stance (MS), heel rise (HR), and toe-off (TO) (Mary, 1988).

The ground contact starts with the heel strike, continuing to foot-flat during the single limb support and forefoot contact. The support finishes with a toe-off. The stance phase and swing phase can be divided into eight functional phases. Initial contact and loading response happen during the weight acceptance. Mid and terminal stance occur during the single support. The last phase of the stance is pre-swing, in which the limb begins the forward movement (Perry, 1992, Perttunen, 2002). The forward motion continues during three swing phases. At the initial swing, the leg is accelerated forward by knee, and hip flexion; the ankle is dorsiflexed. At the mid swing, the swinging leg is aligned with the stance limb, which is the mid stance. The foot is prepared for smooth ground touch in terminal swing with the support of eccentric activity of hamstring (Perry, 1992, Perttunen, 2002).

It has been proposed that during early-stance, knee flexion supports shock absorption, where an increased walking speed would result in additional forces on the knee thus needing more shock absorption through moving the knee into greater flexion (Winter, 1991).

2.6.2 Typical stair gait

Stair gait is defined as a style of walking, and this task is achieved through a very complicated combination of neuro-musculo-skeletal system activity in order to move the lower limbs and Head, Arms and Trunk safely (Perry, 1992).

Stair climbing is a common and frequent activity in daily living and demanding locomotor task, compared to walking on level ground, a greater range of motion in the lower limbs joints (hip, knee and ankle), increased lower limb muscular activities, and around six times more load on the knee joint (Andriacchi et al., 1980). The mean maximum net flexion and extensions moments were increased at the knee joint during ascending and descending stairs and were largest during descending stairs, with both moments higher than compared with walking on the level ground (Andriacchi et al. 1980). In stair ascent the forces and powers of both knee extensors and knee flexor are higher than in level walking (Costigan et al. 2002). Stair climbing is more difficult task biomechanically and physiologically when compared to walking on level ground where the body is lifted with each ascending step and continuously decelerated with each descending step (Yu et al., 1997a, Protopapadaki et al., 2007, Riener et al., 2002). Both ascending and descending stairs are challenging tasks for the elderly, with descending stairs the most challenging (Startzell et al., 2000). In addition, the risk of falling during descending is three times more frequent than during ascending (Svanstrom, 1974). This may be due to the demands on the body were greater ranges of motion at the hip, knee and ankle joints are needed to descend (Andriacchi et al., 1980, Mcfadyen and Winter, 1988, Riener et al., 2002) which create greater knee moments in the sagittal plane (Nadeau et al., 2003) and vertical ground reaction force (Christina and Cavanagh, 2002, Hamel et al., 2005), or more demands in a less stable activity; less time is spent in double limb support (when both feet are in contact with the stair surface) (Mcfadyen and Winter, 1988, Zachazewski et al., 1993).

During stair climbing, several strategies have been used to maintain stability and balance. Adapting the stair climbing patterns by using a step-by step pattern (placing both feet on the same stair prior before moving to the next stair) rather than the traditional step-over-step pattern (placement of one foot on the stair and immediately ascending or descending

the next stair by the another foot) is used (Shiomi, 1994) (Figure 2-2). Using step-by step pattern allows for shorter and slower strides that may increase the feeling of stability and compensate for weaknesses in the lower-limb. Using a handrail is also another strategy used (if available), to provide physical and psychological support (Studenski et al., 1994) and to reduce loads (Startzell et al., 2000), by redistributing joint moments between the ankle and knee; decreasing ankle joint moments and increasing knee joint moment while ascending (and vice versa when descending) (Reeves et al., 2008). During descending, elderly people go down backwards to maintain the centre of pressure further from the stair edge than forward descending, making a slip or fall less likely (Beaulieu et al., 2008).
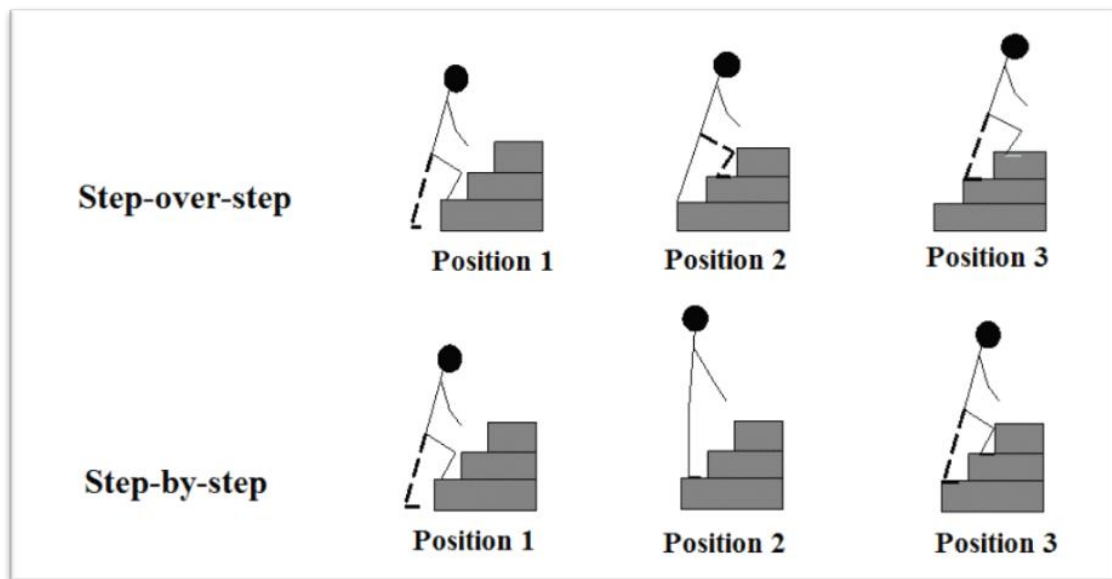
Figure 2-2: The stair climbing patterns (Reid et al., 2007).

Stair climbing is an important measure to assess mechanics of patients with knee osteoarthritis (Kaufman et al., 2001) due to the large moments, forces, lower limb muscle activity and ranges of motion required (Morrison, 1970; Mcfadyen and Winter, 1988) which make the difference from normal more noticeable and to assess knee function (Andriacchi et al., 1980; McFadyen and Winter, 1988; Nadeau et al., 2003; Reeves et al., 2008). Understanding stair gait could significantly enhance the quality of life of a person with physical impairments through improving rehabilitation and treatment planning, as well as improving the design of public environments (Archea, 1985).

Stair gait cycle

The stair gait cycle is similar to the gait cycle, both of them involving two phases, stance and swing phase (McFadyen and Winter, 1988). Both phases are divided into sub-phases which are represented in terms of a percentage through the gait cycle. The stance (support) phase is the time where the foot is in contact with the ground/stair, and it comprises about (ascending: 65% ±4%, descending: 68% ± 4 %) of the stair gait cycle. The swing phase of the stair gait cycle, where the foot is not in contact with the ground/stair, occupies the remaining time (ascending: 35% ±4%, descending: 32% ± 4 %). The sub-phases in the stair gait cycle are not the same as walking gait cycle (McFadyen and Winter, 1988; Zachazewski et al., 1993).

a)   Ascending stairs

The lower limb functions during stair ascent to support and balance body weight and also raise the weight onto the supporting step (Wu et al., 2005). The first sub phase of stair stance phase is called 'Weight acceptance' which occupies (0-17%) of the stair gait cycle (McFadyen and Winter, 1988; Nadeau et al., 2003; Zachazewski et al., 1993; Andriacchi et al., 1980; Riener et al., 2002). The weight is naturally placed on the forefoot, not on the heel like normal walking, before it gets transferred throughout the whole foot, When the foot contacts the stair, (Mcfadyen and Winter, 1988; Novak et al., 2010), the ankle becomes more dorsiflexed (reaches approximately 15 degrees of dorsiflexion) when the foot accepts the weight, and the hip and knee joints remained flexed.

The second sub-phase of stance phase is called; the 'Pull-up' sub-phase which occupies (17-37% of the stair gait cycle). Concentric contraction of hip extensors (gluteus maximus muscle), knee extensors (quadriceps femoris muscles), and the ankle plantar flexors (soleus and gastrocnemius muscles) pull the body's centre of gravity superiorly and lift the opposite foot off the ground (McFadyen and Winter, 1988; Zachazewski et al., 1993). The hip abductor muscles, mainly gluteus medius, are active to stabilise and prevent the pelvis from dropping to the unsupported side when the limb begins in single support phase (McFadyen and Winter, 1988; Zachazewski et al., 1993).

The last sub-phase of stance phase is called 'Forward continuance' which occupies (37-65%) of the stair gait cycle and single limb support interval continues to 48% of the stair gait cycle (McFadyen and Winter, 1988; Zachazewski et al., 1993). The hip and knee extensor muscles are active to maintain the lower limb when the forward movement occurs. The second double support interval begins (48-65%) of the stair gait cycle when the opposite foot hits the stair above and the body's centre of gravity moves further forward, while the ankle plantarflexes to push the foot forcefully up off the stair and the swing phase begins (Riener et al., 2002).

The first sub-phase of swing phase is called 'Foot clearance' which occupies (65-82%) of the stair gait cycle, the foot is kept clear from the stair by ankle dorsiflexion (concentric contraction of the tibialis anterior muscle) and knee flexion (concentric contraction of the hamstrings muscles) to pull the leg back, followed by hip flexion (concentric contraction of the iliopsoas muscle) to move the lower limb up and forward onto the next stair (McFadyen and Winter, 1988; Andriacchi et al., 1980).

Afterward, 'Foot placement' sub-phase of swing phase 'which occupies (82-100%) of the stair gait cycle' occurs. During this sub-phase, the foot is prepared for positioning on the next stair through eccentric contraction of the quadriceps femoris and hip flexors muscles to control any unwanted knee flexion and to allow hip extension, respectively, lowering the limb to make contact with the next stair (Zachazewski et al., 1993). Furthermore, tibialis anterior contracts eccentrically before foot placement to control ankle plantarflexion to meet the stair in preparation for weight bearing (McFadyen and Winter, 1988) (Figure 2-3).
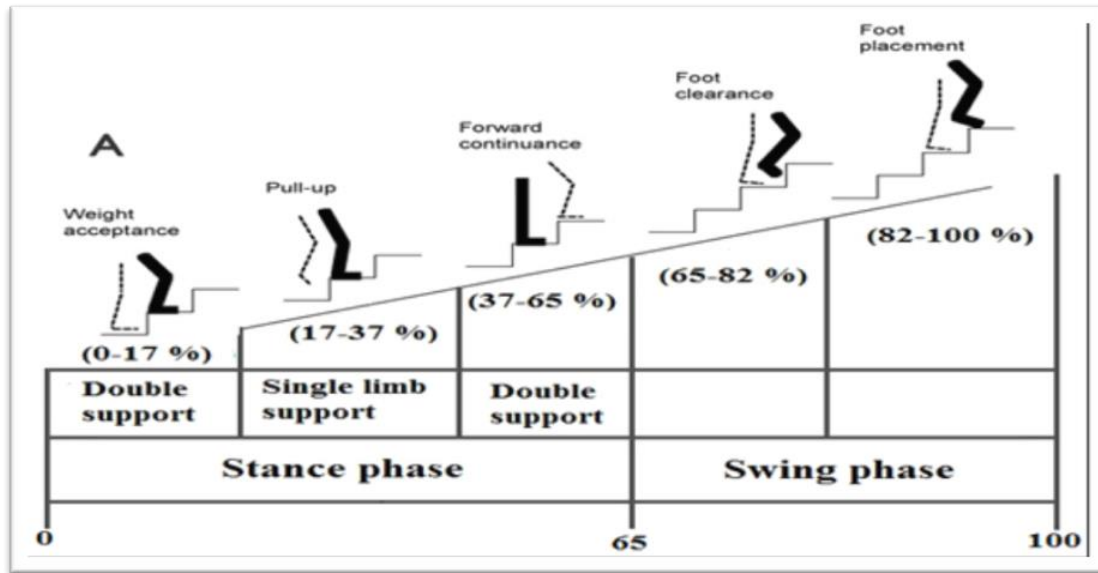
Figure 2-3. Phases of ascending stairs gait cycle (Adapted from (Novak et al., 2010).

During ascent, the knee extensor muscles have a major role in the progression from one step to the next step, helped by the ankle plantar flexors and the hip extensors (McFadyen and Winter, 1988; Moffet et al., 1993). A high increase of energy generation at the knee is provided by the plantar flexors and the hip flexors and extensors (Winter, 1983; Winter, 1991). A higher significant activation in both knee extensor muscles (vastus lateralis and medialis) and medial hamstring muscles have been occurred during walking up stairs than level walking occurred (Richards et al., 1989).

b)   Descending stairs

The stance phase of stair gait cycle during descending is considered to be three sub-phases. 'Weight acceptance' is the first sub-phase occurring when the foot touches the stair in a higher plantar flexed position, a position that lasts until the heel make contact with the stair (0-14%) (McFadyen and Winter, 1988), and the foot starts to accept the weight of the body and this weight is transferred to the leg as the opposite foot comes off the ground (McFadyen and Winter, 1988; Zachazewski et al., 1993).

The second sub-phases of stance phase is called 'Forward continuance' and during this sub-phase, the leg comes forward so that the ankle continues to increase its dorsiflexion, this sub-phase occupies (14-34%) of stair gait cycle. (McFadyen and Winter, 1988).

The third sub-phase is called 'Controlled lowering' and during this sub-phase, most of the progression occurs (34-68%) (Zachazewski et al., 1993; Riener et al., 2002). It begins when the body moves from a higher position. In this sub-phase, the knee begins to flex and reaching the maximum degree of flexion before this flexion reduces prior to early swing (Zachazewski et al., 1993; Novak et al., 2010), with the foot beginning to dorsiflex and reaching maximum dorsiflexion position when the opposite foot strikes the next stair (Andriacchi et al., 1980).

The stance phase consists of two support phases, Single limb support accounts for 39% of the stance phase (14-53 %), while double support occurs at the beginning and end of stance phase, 0-14% and 53-68%, respectively (Riener et al., 2002; Zachazewski et al., 1993).

The second phase of stair gait cycle during descending is called swing phase which comprises the last 32% of the stair gait cycle and is divided into two sub-phases 'Leg pull-through' (68-84%) and 'Foot placement' (84-100%) (McFadyen and Winter, 1988; Zachazewski et al., 1993). In the beginning of swing, the hip and knee flexion decreases and the ankle moves into plantar flexion to pull the leg through. The hip starts to flex slightly, the knee is near full extension, and the ankle is plantar flexed preparing for weight acceptance before foot placement (McFadyen and Winter, 1988; Andriacchi et al., 1980) (Figure 2-4).

The muscles (mainly from quadriceps femoris, gastrocnemius and soleus muscles) during descending stairs contract eccentrically to control the body's descent (McFadyen and Winter, 1988; Nadeau et al., 2003).
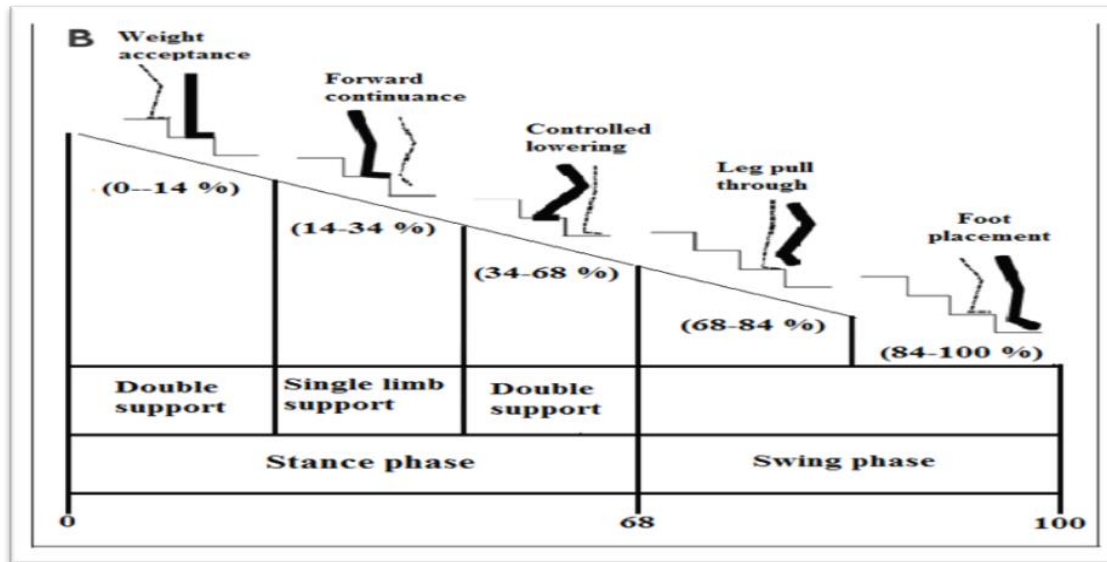
Figure 2-4. Phases of descending stairs gait cycle (Adapted from (Novak et al., 2010))

2.6.3 Knee OA kinematics and kinetics

2.6.3.1 Walking gait

Individuals with medial compartment osteoarthritis of the knee have slower walking speeds, shortened step lengths, larger double support times, decreased hip range of motion and knee range of motion angles (Al- Zahrani & Bakheit, 2002; Andriacchi et al., 1977; Baliunas et al., 2002; Brinkmann & Perry, 1985; Kaufman et al., 2001; Messier et al., 2005a; Messier et al., 1992), reduced cadence and stride length (Al-Zahrani and Bakheit, 2002)and increased stance time (Al-Zahrani and Bakheit, 2002; Landry et al., 2007; Astephen et al., 2008a) as compared to a non-arthritic population. Walking speed is likely decreased in knee OA to help reduce the load on the knee joint (Mündermann et al., 2004). Individuals also have greater mid-stance knee adduction moments, decreased peak knee flexion moments, decreased peak hip adduction moments, and decreased peak hip extension moments than age matched individuals and are summarised below (Table 2-1,2-2) (Astephen et al., 2008).

Table2-1: Asymptomatic and moderate OA discriminant analysis summary (Astephen et al., 2008).

No	kinetic measurements	Interpretation
1	Knee internal rotation moment	Moderate OA had higher knee internal rotation moments in late stance (peak internal rotation moment occurs later in stance with OA)
2	Quadriceps (rectus femoris)	Moderate OA had higher rectus femoris EMG activity throughout most of the gait cycle
3	Hip internal rotation moment	Moderate OA had smaller hip external rotation moment in early stance and smaller hip internal rotation moment in late stance (difference operator—OA had less change in moment throughout stance)
4	Hip adduction moment	Moderate OA had higher mid-stance hip adduction moment and lower adduction moment in late stance (difference operator)
5	Knee flexion moment	Moderate OA had smaller knee flexion moment in early stance

Table 2-2: Moderate OA and severe OA discriminant analysis summary (Astephen et al., 2008)

No	Measure	Interpretation
1	Hip flexion moment	Severe OA had lower early stance and lower early swing hip flexion moment than moderate OA, and higher mid-stance hip flexion moments than moderate OA
2	Ankle internal rotation moment	Severe OA had lower ankle internal rotation moment in early stance and higher internal rotation moment in late stance (difference operator) than moderate OA
3	Knee flexion angle	Severe OA had lower overall magnitude of knee flexion angle in stance and swing than moderate OA
4	Gastrocnemius (medial)	Severe OA had higher medial gastroc EMG activity in early stance and in swing phase, and lower activity in late stance than moderate OA
5	Hip internal rotation moment	Severe OA had lower magnitude of hip internal rotation moment in stance than moderate OA

The secondary gait changes observed among patients with knee OA reflect a potential strategy to shift the body's weight more rapidly from the contralateral limb to the support limb, which has been shown to be successful in decreasing the load at the knee in only patients with less severe knee OA. This over loading in the lower extremity joints may

lead to more rapid progression of presented OA and to the start of OA at joints adjacent to the knee. Interventions for knee OA should therefore be assessed for their effects on the mechanics of all joints of the lower extremity (Mündermann et al., 2005).

During early-stance phase (initial contact of the limb with the supporting surface), one important biomechanical task of the knee is to work as a shock absorber during approximately 15° of flexion, where an increased walking speed would result in more forces on the knee thus requiring extra shock absorption through moving the knee into higher flexion (Winter, 1991). This increased knee flexion requires more eccentric contraction of the knee extensors (Winter, 1983b), but quadriceps muscle weakness is present with knee OA (Slemenda et al., 1997). Muscle co-contraction is also increased in knee OA, which has been proposed to increase the compressive forces on the knee joint (Lewek et al., 2004). Furthermore, increasing walking speed resulted in higher muscle co-contractions in knee OA (Zeni et al., 2010). Consequently, people with knee OA might walk at slower speeds as an adaptive mechanism to decrease the load on the joint. During early-stance, the peak knee and hip flexion angles on the affected side were significantly less than the angles on the contralateral side in unilateral knee OA (Briem and Snyder-Mackler, 2009).

In knee OA, maximum knee flexion is decreased (Childs et al., 2004; Lewek et al., 2004; Rudolph et al., 2007; Schmitt and Rudolph, 2007; Astephen et al., 2008a) and the external rotation moment is also decreased (Landry et al., 2007) during early stance. Many reasons were suggested for the decrease in knee flexion including: quadriceps weakness (Fisher et al., 1997), pain (Kaufman et al., 2001), extra flexed position at initial contact (Childs et al., 2004), and a stiffening strategy adopted in the presence of knee instability (Schmitt and Rudolph, 2007). Peak knee flexion moments were also decreased during early and late-stance (Kaufman et al., 2001; Baliunas et al., 2002; Rudolph et al., 2007; Astephen et al., 2008b). During knee extension a strategy adopted by participants with knee OA to reduce the forces on the joint and consequently diminish pain, as reducing knee flexion moments requires less eccentric contractions. In mid-stance, knee extension moments have shown different results in knee OA given that it decreased (Huang et al., 2008), increased (Al-Zahrani and Bakheit, 2002), or did not change

(Messier et al., 2005; Mündermann et al., 2005) compared to healthy participants. Differences in walking speed, pain levels and, muscle strength are possible causes for these results. In addition, the increased and prolonged mid-stance knee extension moment accompanied by increased and prolonged biceps femoris activity might be attempted to increase stability during gait (Al-Zahrani and Bakheit, 2002).

2.6.3.2 Ascending and descending stairs gait

During ascending and descending stairs there was no differences in the maximum knee flexion angle during stance phase between healthy subjects and knee OA patients and (Kaufman et al., 2001, Asay et al., 2009), however there was a decreases in the sagittal plane knee ROM during stance and swing phase (Whatling, 2007, Hicks-Little et al., 2011), and a delay in peak knee flexion in stance phase (to 10% of gait cycle during ascending and 63% of stair gait cycle during descending compared to 5% and 59% of the stair gait cycle in healthy subjects (Hicks-Little et al., 2011).

Females with knee OA have shown a lower external knee flexion moment than males with knee OA during ascending and descending stairs (Hughes et al., 2000). Patients with medial knee OA have shown a greater peak of EKAM during ascending and descending stairs (Guo et al., 2007).

2.6.4. Biomechanical consequences of Knee OA

In medial compartment OA, there are several biomechanical consequences of the disease which have been directly related to either progression of the disease or increasing medial compartment forces. The next section will briefly explain the relevance of each of these.

2.6.4.1. The external knee adduction moment (EKAM)

The medial compartment of the knee is four times (Ledingham et al., 1993), five times (Felson et al., 2002) and ten times (Ahlback, 1968) more frequently affected by OA than the lateral compartment and this may happen due to the reduced thickness of the articular cartilage on the medial compartment compared to the lateral (Cicuttini et al., 2002) and by the passing the line of gravity medially to the knee joint during walking (Schipplein and Andriacchi, 1991). Knee OA is a mechanical disease affected by the amount of load

on the knee joint (Brandt et al., 2008). Dynamic knee joint loading is the central biomechanical factor, and is associated with the pathogenesis of medial knee OA (Andriacchi et al., 2004; Andriacchi & Mündermann., 2006; Miyazaki et al., 2002; Mündermann et al., 2005; Sharma et al., 1998). Evaluating dynamic loading of the knee joint is important for the monitoring and treatment of OA knee (Hurwitz et al., 2002). However, in vivo knee joint loading is difficult to measure the knee forces without an instrumented knee implant. Additionally, you would not be assessing the treatment for medial knee OA but the consequence of a surgical treatment which has likely realigned the knee. Therefore, non-invasive gait measures are used and the external knee adduction moment has been found to be 1) a valid surrogate measure of medial load distributions and 2) progression of osteoarthritis, lowering the EKAM has become a major goal of biomechanical treatments of medial knee OA.

The EKAM is the turning effect due to the resultant ground reaction force acting on the foot as it passes medial to the centre of the knee joint (Figure. 2-5). The perpendicular distance from the line of action of the ground reaction force is the lever arm for this force. The product of this force with this lever arm produces a moment tending to adduct the knee joint (Kim et al., 2004). The EKAM and other external forces and kinematic changes acting on the knee may be measured using a motion analysis system and a force platform to measure the ground reaction forces. The net internal moment is primarily generated by muscle forces, soft tissue forces and contact forces. The EKAM's are equal and opposite the net internal moment to attain equilibrium and stability during walking (Shelburne et al., 2006). Larger contact forces are associated with larger EKAM's in the absence of decreased antagonist muscle activity. Increased EKAM's are indicative of increased loads on the medial compartment relative to the lateral compartment (Baliunas et al., 2002) and are the main determinant of medial to lateral load distribution in the knee (Kim et al., 2004).
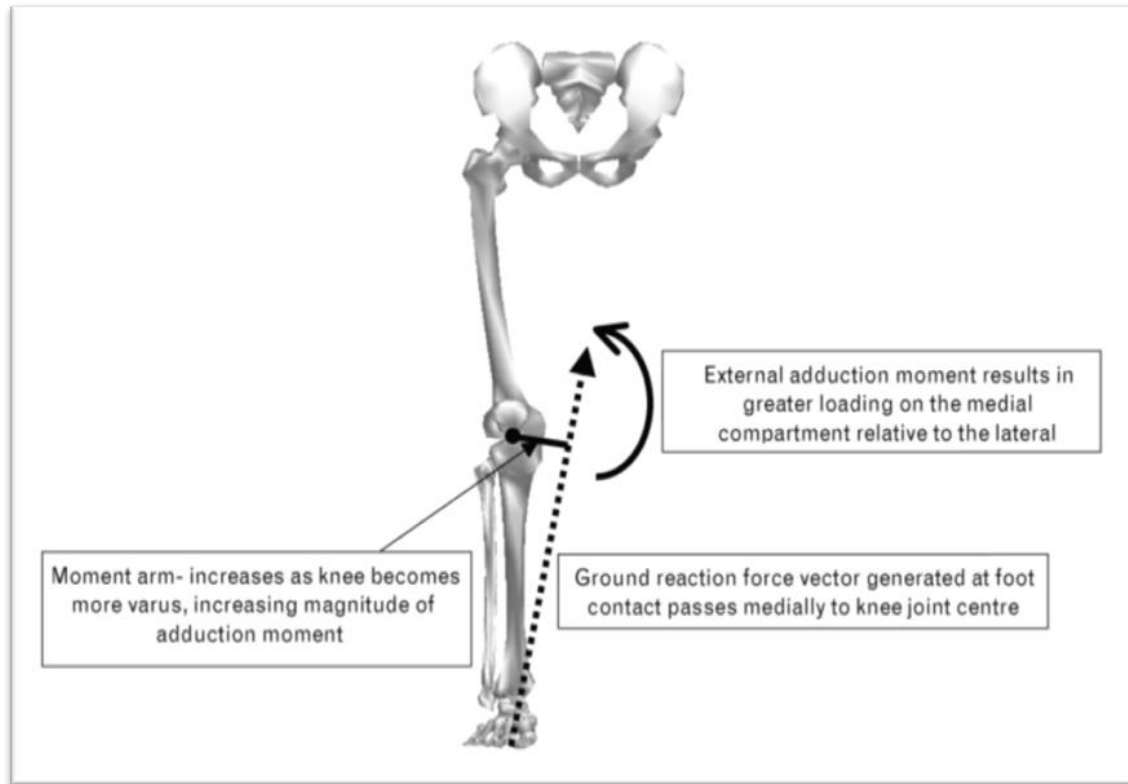
Figure 2-5. The external knee adduction moment (Hinman & Bennell, 2009).

The EKAM contains two peaks and one trough (Figure 2-6); the first peak occurs in early stance (0-20%) and the second peak in late stance (41-60%) of the gait cycle, however, the trough happens in mid-stance (21-40%) (Hurwitz et al., 2002, Newell, 2008).
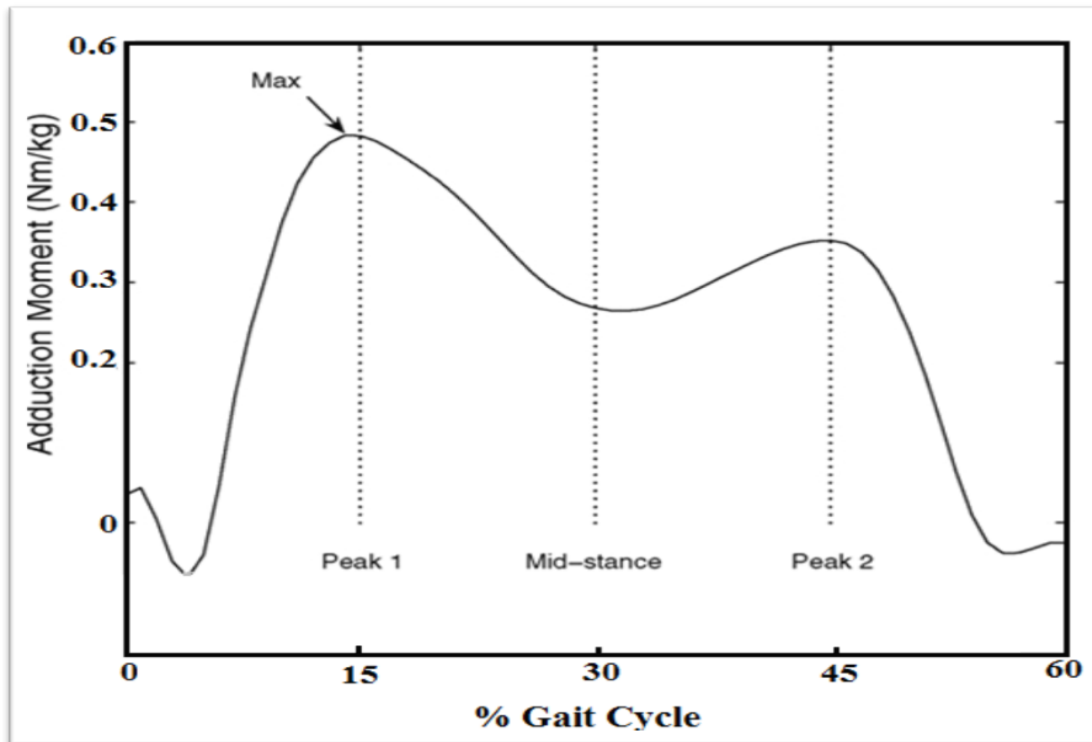
Figure 2-6. Representative knee adduction moment waveform. Peak 1 occurs at 15% gait cycle, mid-stance occurs at 30% gait cycle and peak 2 occurs at 45% gait cycle. Max is the maximum value over the whole adduction moment waveform. (Note: in the figure the max value coincides with peak 1, but this is not always the case.) (Newell et al., 2008).

In medial knee OA patients, both cartilage defects and subchondral bone area are associated with peak EKAM and knee adduction moment impulse (KAMI) suggesting that increased mechanical loading may play a role in the pathological changes in articular cartilage and subchondral bone that happen with medial knee OA (Creaby et al., 2010). EKAM have been found in patients with knee OA with medial joint space narrowing than normal (Prodromos et al., 1985, Baliunas et al., 2000). During walking, the peak external knee adduction moment (EKAM) is a strong predictor of presence (Baliunas et al., 2002), severity (Henriksen et al., 2010;, Mündermann et al., 2004; Mündermann et al., 2005), and the rate of progression (Miyazaki et al., 2002) of medial knee OA, and can be reliably assessed during walking (Birmingham et al., 2007). Different relationships between knee pain intensity and dynamic loading of the knee have been shown by patients with different radiographic disease severities during walking (Henriksen et al., 2012).

EKAM's have also been associated with greater bone mineral content on the proximal medial aspect of the tibia relative to the lateral aspect in both normal subjects and subjects with knee OA (Baliunas et al., 2002). There was a relationship between the EKAM and disease severity in medial knee OA (Sharma et al., 1998). The value of the EKAM at baseline can predict radiographic disease progression in medial compartment knee OA (Miyazaki et al., 2002). Varus alignment increased the risk of medial compartment OA progression in knee OA, which suggests that the degree of EKAM correlates with radiographic joint space narrowing of the medial compartment (Sharma et al., 2001). The peak knee adduction torque was the best single predictor of the medial to lateral ratio of proximal tibial bone density (Hurwitz et al., 1998). The external knee adduction torque is highly correlated with internal medial compartment contact force as well as medial to total contact force ratio during gait (Zhao et al., 2007).

EKAM has also been shown to be higher in all severities of knee OA when compared to healthy participants during early-stance (Kaufman et al., 2001; Hurwitz et al., 2002; Mündermann et al., 2005; Thorp et al., 2006; Rudolph et al., 2007; Huang et al., 2008). But, EKAM was similar during early stance in patients with knee OA of varied severities compared to age- and gender-matched healthy participants (Landry et al., 2007; Huang et al, 2008).

This similarity of EKAM was suggested to be due to increased lateral trunk lean or lean of pelvic towards the stance leg as compensatory mechanism to reduce the moment lever arm and subsequently the EKAM.

In mid-stance, EKAM has been shown to be significantly greater in knee OA compared to healthy participants (Weidenhielm et al., 1994; Landry et al., 2007; Astephen et al., 2008a). So, both early-stance peak and mid-stance (trough) EKAM should be considered when investigating the load in knee OA. In Late-stance, peak EKAM has been found to be significantly greater in patients with mild, moderate, and severe knee OA compared to healthy participants (Hurwitz et al., 2002; Thorp et al., 2006; Huang et al., 2008). However, in mild knee OA patients, disagreeing results of peak EKAM have been found at late-stance with Mündermann et al. (2005) reporting that EKAM was significantly lower compared to gender- and age-matched healthy subjects and to patients with severe

knee OA (Mündermann et al., 2005), but it was not significantly changed compared to healthy individuals (Huang et al., 2008).

There is significantly less literature during ascending and descending stairs with previous studies report medial knee OA patients have a lower external knee flexion moment than healthy subjects (Whatling, 2007, Kaufman et al., 2001, Asay et al., 2009). In contrast, other research studies have found that patients with medial knee OA have a higher external knee flexion moment than healthy subjects (Schipplein and Andriacchi, 1991, Al-Zahrani and Bakheit, 2002, Gok et al., 2002) or no difference between medial knee OA patients and healthy subjects groups (Messier et al., 2005, Mündermann et al., 2005). In addition, females with knee OA have a lower external knee flexion moment than males with knee OA and healthy females and males during ascending and descending stairs (Hughes et al., 2000).

Patients with medial knee OA have showed a higher peak of EKAM during ascending and descending stairs (Guo et al., 2007). The highest peak of EKAM in subjects with knee OA was during descending stairs followed by ascending stairs and then level walking (Guo et al., 2007).

The researcher reported that patients with medial knee OA have a higher knee adduction angular impulse (KAAI) and EKAM than those without knee OA (Thorp et al., 2006; Kean et al., 2012).

2.6.4.2. The knee adduction angular impulse (KAAI)

The knee adduction angular impulse (KAAI) is another assessment used to measure the load on the medial compartment during the whole of the stance phase (Thorp et al., 2006) (the area under the adduction curve) (Figure 2-7). The KAAI was related to the cartilage volume with greater KAAI magnitudes at baseline resulting in more medial tibial cartilage damage after 12 months in comparison to the cartilage damage in individuals with greater early-stance peak EKAM at baseline (Bennell et al., 2011). Additionally, the KAAI has been found to be a sensitive method in detecting the load on the knee between mild and moderate knee OA, and it significantly higher in moderate knee OA compared to mild OA, while the peak of EKAM did not change significantly between mild and

moderate knee OA during early-stance (Thorp et al., 2006; Kean et al., 2012). Additionally, the KAAI was positively linked with pain in mild knee OA; particularly, it was significantly higher in symptomatic individuals with mild knee OA compared to asymptomatic individuals with mild knee OA and in healthy individuals (Thorp et al., 2007).
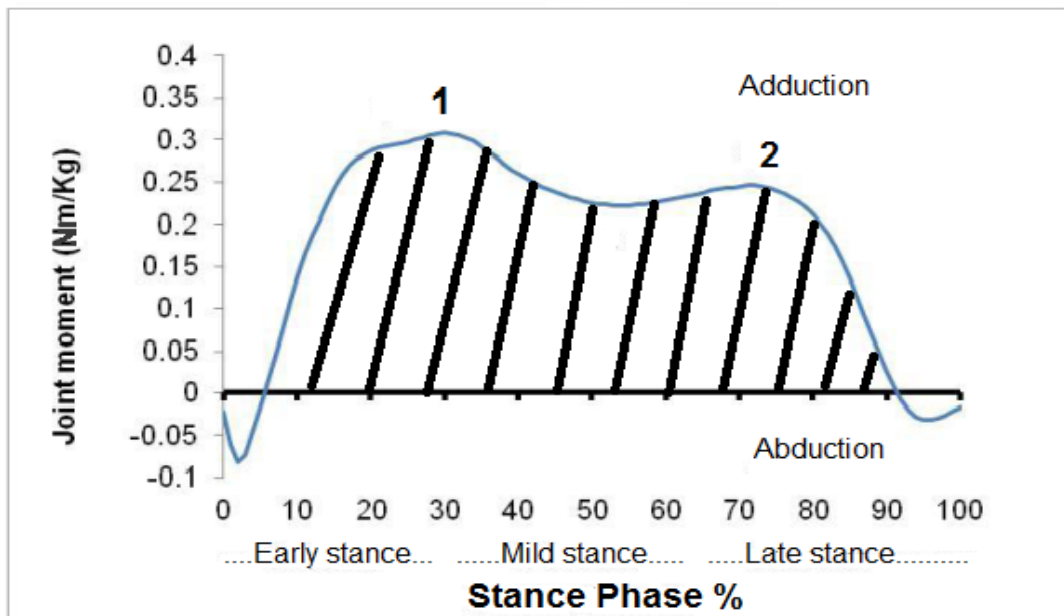
Figure 2-7: The area under the curve represents the knee adduction angular impulse (KAAI) (Thorp et al., 2006)

Given that the EKAM and its impulse (KAAI) have been found to be 1) valid surrogate measures of medial load distributions and 2) indicators into the progression of osteoarthritis, lowering the EKAM has become a major goal of biomechanical treatments of medial knee OA. However, previous literature has also identified that the EKAM may not reflect medial compartment forces in the joint (Trepczynski et al. 2014) and this is primarily because the internal forces (primarily muscles) have not been taken into account. Therefore, an understanding of the contribution of muscles is needed.

2.7 Muscle co-contraction

Muscle co-contraction is the synchronized activity of synergistic muscles (agonist and antagonist) (Sirin and Patla, 1987), which take part in creating moments of force around a joint during dynamic tasks (Nigg et al., 2003). The muscle co-contraction is increased in electromyography (EMG) gait studies of knee OA when compared to asymptomatic subjects (Childs et al., 2004; Lewek et al., 2004; Hubley-Kozey et al., 2006). Muscle co-contraction in those with knee OA is believed to lead to increase medial joint loading (Andriacchi, 1994) joint stiffness in response to pain (Fisher et al., 1997), and instability (Lewek et al., 2004).

There are two types of knee muscle co-contraction: directed co-contraction and generalised co-contraction (Lloyd and Buchanan, 2001). In generalised co-contraction all synergist (agonists and antagonists) of the knee co-contract equally, but in directed co-contraction both medial and lateral synergist (agonists and antagonists) muscles are activated to support abduction moments and adduction moments respectively. Directed co-contraction supports the external moment to inhibit condylar lift-off and decrease the concentration of articular loading in the medial knee compartment (Schipplein and Andriacchi, 1991). Generalised co-contraction can also have the same effect but due to the non-directionality it is less effective in inhibiting condylar lift-off, and might increase all articular loading (Lloyd and Buchanan, 2001; Zhang et al., 2001). Generalised co-contraction has been recognized when people support the isometric adduction/abductions knee moments, (Lloyd and Buchanan, 2001; Zhang et al., 2001). In addition, generalised co-contraction can be identified during sidestepping and crossover cutting (Besier et al., 2003a; Besier et al., 2003b). Directed co-contraction has been found in ligamento-muscular reflexes to resist adduction/abduction perturbations at the knee joint (Buchanan et al., 1996). Additionally, voluntary directed co-contraction has been revealed to the support static knee abduction–adduction moments (Andriacchi et al., 1984; Zhang et al., 2001), and abduction moments at the knee during side stepping (Besier et al., 2003a, 2003b).

Both medial (Lewek et al., 2004; Lewek et al., 2006) and lateral muscle (quadriceps to hamstring) co-contraction (Schmitt and Rudolph, 2007) have been shown to be increased

in the OA patients compared with control subjects. The muscle co-contractions occur between: Vastus lateralis (VL) and lateral hamstring (LH) (Ramsey et al., 2007; Hubley-Kozey et al., 2009), VL and medial hamstring (MH) (Childs et al., 2004), VL and semimembranosus (SM) (Zeni et al., 2010), VL and biceps femoris (BF) (Hortobágyi et al., 2005), Vastus medialis (VM) and MH (Ramsey et al., 2007; Hubley-Kozey et al., 2009), Medial quadriceps – MH (Schmitt and Rudolph, 2007).

The internal moments are very important on the lateral side to provide a valgus resistance against a varus position in the knee joint that happens due to an attempt of the EKAM to move the knee joint in to this position. So, the co-contraction between agonist and antagonist muscles stabilized the joint (Schipplein and Andriacchi, 1991), while the activity of agonist muscles alone was not sufficient to resist the EKAM. In early-stance co-contraction between VL-LH gradually increased in asymptomatic to moderate to severe knee OA groups (Hubley-Kozey et al., 2009), lateral quadriceps-lateral gastrocnemius (LG) was considerably greater in participants with mild to severe knee OA compared to healthy participants (Schmitt and Rudolph, 2007). Moreover, co-contraction of the muscles on the medial side of the knee joint in mild, moderate, and severe knee OA increase in comparison to healthy subjects during early stance (Lewek et al., 2004; Schmitt and Rudolph, 2007; Hubley-Kozey et al., 2009). This involved significantly greater co-contraction between VM-MG in participants with severe knee OA (Lewek et al., 2004), MQ-MH in individuals with knee OA compared to healthy individuals (Schmitt and Rudolph, 2007), and VM-MH was investigated only in severe knee OA compared to moderate knee OA during stance phase (Hubley-Kozey et al., 2009). Even though increased co-contraction was suggested to be a protective mechanism to reduce the load on the medial compartment knee OA, it has also been suggested that at the same time it exposes the joint to extra compressive forces (Lewek et al., 2004). One of the reasons for the increased muscle co-contraction around the knee joint could be due to instability as medial knee joint laxity was significantly greater in the OA participants groups compared to healthy participants (Lewek et al., 2004; Schmitt and Rudolph, 2007). The co-contractions between quadriceps and gastrocnemius muscles were associated with medial knee joint laxity, quadriceps weakness, and decreased knee flexion ROM in the OA patients group compared to healthy group. But, the older adult's

healthy group showed normal muscle co-contraction in addition to weak quadriceps, absence of reduced knee motion, and normal knee joint laxity. This suggests that knee laxity is the primary reason for the increased co-contraction in knee OA patients (Rudolph et al., 2007).

A primary way to reduce knee laxity is to increase muscle strength around the knee joint to provide stability and is important to discuss this in regards to the rehabilitation of the individual.

In the presence of quadriceps weakness, The ground reaction force(GRF) rate of loading is increased during gait (Mikesky et al., 2000) because muscle weakness might altering the load distribution, change the mechanical axis of the knee joint, and facilitating the development of knee OA (Andriacchi et al., 2004). However, enlarged quadriceps muscle strength might produce an abduction moment that counteracts and reduces the EKAM (Shelburne et al., 2006).

2.8 Muscle strength

Quadriceps muscle weakness is present with knee OA (Slemenda et al., 1997). However, the relationship between muscle strength and EKAM is not as clear with Thorp et al. (2010) not finding a significant variation in the EKAM even though knee muscle strength significantly increased. This was supported by previous research in a study by Lim et al. (2009), also not finding a relationship between quadriceps strength and the EKAM, even when it was tested in neural and varus lower leg alignment. In regards to progression of the disease, Mikesky et al. (2006) examined the effect of strengthening exercises on knee OA progression compared to ROM exercises. Strengthening exercises did not increase the degree of knee OA progression after 30 months, measured by joint space width. But, these results should be considered carefully as the effect of alignment, laxity, or alteration in body weight on progression was not measured.

Stronger muscles at baseline have been related with increased knee OA progression after 18 months in malaligned knees and laxity knees (Sharma et al., 2003). However, muscle strength was not measured at eighteen months therefore its effect on progression is unknown. Sharma et al. (2003) recommended considering pathophysiological factors

around the knee, such as laxity, when planning strengthening exercise programmes. This might affect results since the positive association between strength and function decreased in the presence of coronal plane knee laxity, suggesting a reduced effect of strengthening exercises with laxity (Sharma et al., 1999a). Thus, knee joint laxity should be measured when planning a strengthening exercise programme in knee OA.

Previous studies have shown an association between knee pain and quadriceps strength (O'Reilly et al., 1998) and as well as reported that decreasing of temporary pain might improve maximum voluntary muscle contraction (Hassan et al., 2002) and decrease abnormal involuntary muscular activation (Brucini et al., 1981). Pain might be a mediating factor in the assessment of both muscle strength and proprioception in these subjects (Shakoor et al., 2008). Strengthening exercises have positive effects on improving pain, strength, and functional assessment in patient with OA (Pelland et al., 2004; Lange and Vanwanseele, 2008).

One of the areas that muscle strength and indeed knee laxity would affect would be the dynamic balance of the individual with previous research identifying that individuals with medial knee OA have instability or a buckling event (Felson et al., 2007). Therefore, the role of balance in the individual with medial knee OA will be discussed.

Patients with knee OA have shown decreased in quadriceps strength and muscle activation (Wessel, 1996; Fisher and Pendergast 1997; Hurley et al., 1997; O'Reilly et al., 1998) and impairments in knee joint proprioception. These deficits (Fisher and Pendergast, 1997; Pai et al., 1997; Sharma et.al., 1997) are associated with the ageing process and might leading to larger impairments in balance compared with age matched healthy group (Hassan et al., 2001; Hinman et al., 2002).

2.9 Balance

Balance is the ability to maintain the centre of gravity of a body within the base of support (Shumway-Cook et al., 1988). Balance control is a complex function of motor skill that involves the integration of several types of sensory information and the planning and execution of flexible movement forms in order to accomplish several potential postural aims (Horak et al., 1989; Hork, 1997; Jones et al., 2000; Hinman et al., 2002).

36

Some subcomponents involve both sensory organization and motor coordination for postural control and some of them involve both motor coordination and biomechanical aspects such as joint flexibility and muscle tone (Hork, 1997). Balance can be assessed either statically or dynamically (Patla et al., 1990; Winter et al., 1990).

Dynamic balance is the ability to preserve a stable base of support during the performance of a movement or leaning task (Guskiewicz and Perrin, 1996). Both static and dynamic balance deficits were found in knee OA patient but the dynamic balance was more affected (Wegener et al., 1997; Hinman et al., 2002). These deficits have been found in individual with knee OA and could be related to muscle weakness, the aging process, and/or proprioception impairments (Slemenda et al., 1997; Koceja et al., 1999; Lin et al., 2009). Even though no relationship was found between radiographic severity and dynamic balance in knee OA (Jadelis et al., 2001), impairments in balance increases the risk of falling and poor mobility in the elderly (Shumway Cook et al., 1997).

In knee OA research, dynamic balance has been routinely assessed by using expensive (force platform) (Hurley et al., 1997; Wegener et al., 1997; Hassan et al., 2001), and non-expensive measures (step test) (Hinman et al., 2002; Hinman et al., 2007; Lim et al., 2008). A new measure which has previously been used in deficient ligament studies, namely the Star Excursion Balance Test (SEBT) is another inexpensive and quick method of assessing dynamic balance, with good reliability shown (Hertel et al., 2000; Kinzey and Armstrong, 1998, Al-Khlaifat, 2012). In this test, the participants balance on maintaining single-leg stance, while reaching with the free limb in eight different directions (the anterior, anterior-lateral, anterior-medial, medial, lateral, posterior, posterior-lateral, and posterior-medial) (Hertel et al., 2000) or in three different directions (the anterior, posteromedial, and posterolateral directions) (Plisky et al., 2006) in relation to the stance foot as far as they can, then return to double support without losing balance. Although used to assess dynamic balance in knee joint injuries, such as ACL deficiency (Herrington et al., 2009), the SEBT has been shown to be significantly improved in exercise intervention studies (Al-Khlaifat et al. 2012) but has not been assessed in other conservative management studies with medial knee OA subjects.

Given the role of biomechanical factors in the progression of osteoarthritis, many treatment methods exist to manage/ reduce these factors and these will be introduced and appraised in the next section.

2.10 Management of osteoarthritis

The management of medial knee osteoarthritis falls into three main categories, surgical, pharmacological and conservative management.

2.10.1 Surgical intervention

Surgery for medial knee OA is available. Two forms of realignment surgery for just medial compartment osteoarthritis of the knee joint are High Tibial Osteotomy (HTO) and Unicompartmental Knee Replacement (UKR). High tibial osteotomy (HTO) is used to redirect the mechanical axis from the degenerated area of the joint to the relatively well-preserved compartment.

HTO is a well-established and effective treatment modality for medial compartment osteoarthritis of the knee with varus deformity. It has shown significant improvement in symptoms, and function (El-Azab et al., 2011, Briem et al. 2007, Wada et al.1998, Ramsey et al., 2007) Medial laxity (Ramsey et al., 2007), instability (Ramsey et al., 2007) and the adduction moment of the knee decreased at 6 months after surgery (Wada et al.1998; Ramsey et al., 2007) but increased after that period (Wada et al.1998).

There were statistical reductions in the adduction moment resulted in lower levels of vastus medialismedial gastrocnemius muscle co-contractions post opening-wedge high tibial osteotomy (OW-HTO) (Ramsey et al., 2007). Under correction was associated with a significantly lower clinical outcome in comparison to accurate correction and overcorrection. Ligamentous laxity or soft tissue slackness of the knee can influence the overall correction after high tibial osteotomy and must be considered in preoperative planning. Patients with a high body mass index (BMI) had lower clinical results after open wedge high tibial osteotomy (El-Azab et al., 2011). Additionally, under- or over-correction may eventually lead to an accelerated rate of progression of arthritic changes in the knee (Briem et al., 2007). The peak adduction moment of the knee significantly

correlated with alignment and foot angle before and 6 years post-surgery but did not correlate with stride length and walking velocity (Wada et al., 1998).

Quadriceps strength deficits and knee flexion impairments persisted after realignment even though there were improvements in global rating of knee function which suggest that the movement strategy may perpetuate joint destruction and impede the long-term success of realignment. Rehabilitation should focus on quadriceps strength and improving joint mobility to improve the long-term function of individuals with medial knee OA. Preoperative high-intensity resistance training of the quadriceps and hamstrings before HTO will improves postoperative in self-reported out-comes, dynamic knee-joint loading (reduction in the external knee adduction moment) and functioning in sport, recreation, and activities of daily living (Kean et al., 2011).

Unicompartmental knee arthroplasty (UKA) is being more universally embraced as a clear and definable treatment option for unicompartmental arthritis. UKA preserves the articular cartilage, bone, and menisci in the unaffected compartments, as well as the cruciate ligaments, thus preserving proprioception and more normal kinematics in the knee than a total knee arthroplasty (TKA) does. Knees treated with UKA have a normal function compared to those treated with TKA. For some patients, UKA is a step before TKA becomes necessary; for others, it is the definitive procedure that will last their lifetimes (Lonner et al., 2009). Patients with medial Knee OA treated with UKA showed improvement in walking speed, step frequency, step length (Weidenhielm et al., 1993; Kate et al., 2003) and also single support stance phase ratio increased which indicating a more symmetrical gait. In addition, double support stance phase of both legs decreased which indicating a faster transfer of weight during walking (Weidenhielm et al., 1993).

A systematic review was published which compared the safety and efficacy of unicompartmental knee arthroplasty (UKA) in patients with knee OA, with HTO and total knee arthroplasty (TKA). Three randomised controlled trials (RCTs), two controlled trials and three cohort studies were reviewed for function (primary efficacy outcome), postoperative pain, complications and revision rate. Similar percentages of patients had improvement in function following UKA and TKA and HTO, but fewer patients

experienced complications such as deep vein thrombosis following UKA and the revision rate was lower following UKA than HTO (Griffin et al., 2007).

Surgical intervention of medial knee OA is of great expense to the NHS and has a large impact on the individual in terms of recovery time and functional independence. However, it is obviously in the interests of patients that conservative treatments are tried first in an attempt to arrest the disease process (progression and pain).

2.10.2 Conservative management of medial knee OA

Even though surgery for medial knee OA is available, there are some individuals who may not be suitable for surgery (too young) or do not want surgery. Therefore other options are desperately needed. Conservative management techniques are options that have not yet been fully justified in the scientific literature. It is therefore important to understand which technique will have the greater impact, for a particular patient type, both in terms of functional independence and reduction in pain, two primary complaints by sufferers. In addition, should individuals feel that their pain relief and functional independence increases with the conservative techniques it may delay the need for surgery.

There are different conservative management techniques for medial knee OA ranging from pharmacological to exercise based treatments. A brief overview of each of these treatments will be discussed below.

Pharmacological

Pharmacological therapy available for early OA has been studied thoroughly for the treatment of moderate to severe knee OA, showing that most of the pharmacological modalities provide only symptom relief, sometimes even at the expense of harmful effects on the articular structure (Zhang et al., 2008). Widely used anti-inflammatory or analgesic therapy may also be associated with an increase in joint forces (Schnitzer et al., 1993). NSAID treatment in patients with knee OA resulted in a reduction in symptomatic pain and an increase in loading of the knee in patients with medial compartment osteoarthritis; therefore, care should be taken in the use of' pharmaceuticals directed at

reducing pain (Hurwitz et al., 2000, Sum et al., 1997) at the consequence of increased loading.

Exercise

All clinical guidelines for the management of OA recommend exercise and Meta analyses support these exercise recommendations. Aerobic (Ettinger Jr et al., 1997), strengthening (Schilke et al., 1996) , and Tai chi exercise (Song et al., 2003; Lee et al., 2009) are helpful for improving pain and function in people with OA with benefits seen across the range of disease severities. The optimal exercise dosage has not being determined and an individualised approach to exercise prescription is required depending on the assessment of impairments, patient preference, co-morbidities and accessibility. Maximising adherence is a key element dictating success of exercise therapy. This can be improved by the use of supervised exercise sessions (possibly in class format) in the initial exercise period followed by home exercises (Bennell et al., 2011). Additionally, range of motion (ROM) exercises and stretching have been proposed because of their benefits in modulating pain, increasing ROM, reducing soft tissue inflammation, inducing relaxation, improving repair, extensibility, or stability of contractile and noncontractile tissues, facilitating movement, and improving function (Deyle et al., 2000). Both strength training and self-management are suitable treatments for the early onset of knee osteoarthritis in middle-aged adults and also, self-management alone may offer the least burdensome treatment for early osteoarthritis have been founded (Mcknight et al., 2010).

A supervised and individualised exercise program of moderate intensity may reduce peak knee adduction moment in patients with mild to moderate knee osteoarthritis. In addition, knee adduction moment during one-leg rise may be more sensitive to change than knee adduction moment during gait (Thorstensson et al., 2007). Home based exercises by patients with osteoarthritis of the knee(s), in a program of intervention through appropriate guidance, can produce considerable improvements in pain (Baker et al., 2001;Mccarthy et al. 2004; Carvalho et al., 2010; Ravaud et al., 2004; Aoki et al., 2009; O'reilly et al. 1999; Sled et al., 2010; Thomas et al., 2004; Chaipinyo & Karoonsupcharoen, 2009; Deyle et al., 2005), strength (Baker et al., 2001; Sled et al.,

2010; Deyle et al., 2005), physical function (Baker et al., 2001; Mccarthy et al. 2004; Ravaud et al., O'reilly et al. 1999; Chaipinyo & Karoonsupcharoen, 2009; Deyle et al., 2005), range of motion (Aoki et al., 2009), and gait speed (Aoki et al., 2009), but did not reduce knee joint loading (Sled et al., 2010) in patients with knee OA. If the kinematic data are not separated into more homogeneous groups when performing pre- and post-treatment comparisons, the physiotherapy treatment had no significant effect on gait kinematic and kinetic parameters (Gaudreault et al., 2001). This is important as the EKAM has been linked with increased progression of knee osteoarthritis (Miyazaki et al., 2002; Jennifer et al 2011), and therefore load modifying interventions are needed. Greater attention is needed due to the important role of mechanical factors in OA etiopathogenesis, and their modification is required if we are to find ways of reducing the public health impact of this condition (Kim et al., 2004, Sled et al., 2010, Al-Khlaifat, 2012)

Gait strategies

Different strategies might be used by individuals with knee OA to decrease the EKAM and the load distribution in the knee joint by altering gait patterns. These strategies which include:

 a)   The foot progression (toe-out) angle

The toe-out angle of the foot increases during walking in patient with knee OA (Hurwitz et al., 2002, Chang et al., 2007). Toeing-out occurs in lateral placement of the Centre of Pressure (COP); which changes the GRF nearer to the knee joint centre leading to decreased GRF moment arm length at the knee, which consequently decreases the amount of EKAM (Hurwitz et al., 2002). Toe-out has been investigated during walking to reduce the EKAM (Jenkyn et al., 2008). Toe-out angle has been found to be increased in subjects with medial knee OA to reduce the overall magnitude of EKAM (Mundermann et al., 2008). In individuals with medial knee OA who have a greater toe-out angle during walking a lower second peak EKAM was seen (Andrews et al., 1996).

During ascending stairs, the first peak of the EKAM was significantly increased with increased toe-out angle (Guo et al., 2007) unlike descending stairs, and the second peak

EKAM was significantly reduced by 11% with increased toe-out angle, while no significant decrease in the second peak EKAM was found during descending stairs when toe-out angle was increased (Guo et al., 2007).

b)   Walking speed and stride length

Positive relationship has been found between walking speed and the EKAM in individuals with medial knee OA, which means that the higher the walking speed the higher the EKAM; therefore, walking at slower speed or with reduced stride length have also been recommended as adaptive strategies to decrease the EKAM, and leading to reduce medial knee compartment loads (Mundermann et al., 2004). This strategy was also observed in patients with knee OA; they have shown reduced walking speed and stride length during stair climbing (Kaufman et al., 2001) and walking on level ground (Deluzio and Astephen, 2005).

c)   Lateral trunk sway towards the affected stance limb

The EKAM can be decreased about 65% during walking on level ground in healthy subjects by increasing lateral trunk lean toward the side of the weight bearing limb (stance limb) which can move the body's Centre of Mass (COM) laterally. This leads to a change of the GRF nearer to the knee joint centre, decreasing the length of GRF moment arm at the knee joint (Mundermann et al., 2004, 2005, 2008). Thus, lateral trunk sway has been recommended as a compensatory gait style to decrease the EKAM in knee OA patients (Hurwitz et al., 2002; Simic et al., 2011). In patients with mild to moderate knee OA, the lateral trunk sway has reduced the peak EKAM (Mundermann et al., 2008). Furthermore, a higher degree of lateral trunk sway has been detected in patients with severe knee OA when compared to patients with mild knee OA (Hunt et al., 2008).

c)   Altering foot and ankle position

Any deviation in foot position would lead to a modification in the GRF, and alteration in the static and dynamic alignment of the lower limb (Guichet et al., 2003). Strong association between the alteration of centre of pressure (COP) and knee OA have been found (Reilly et al., 2009; Lidtke et al., 2010). Knee OA patients with pronated feet have

shown a reduction in the EKAM during walking on level ground (Pazit et al., 2010; Lidtke et al., 2010) in comparison to healthy control group.

e)   Barefoot gait

A significant reduction in joint loads has found in patients with medial knee OA when walking barefoot compared with when walking in their normal shoes (Shakoor and Block, 2006). However, this is a relatively impractical solution given the risk of plantar surface foot damage,

f)   Medial thrust gait

 Medial thrust gait is beneficial since it keeps a patient's normal walking speed, and does not need special shoes. Medial thrust gait is one of a variety of gait modification have been examined based on their potential to decrease the EKAM (Fregly et al., 2007, 2009; Fregly, 2008; Barrios and Davis, 2007).
In summary, in addition to these strategies which individuals with knee OA adopt, there are other interventions options which can reduce the EKAM such as lateral wedge insoles and knee valgus braces.

Lateral wedge insoles

Lateral wedge insoles are an orthotic with a higher lateral border on the insole. Lateral wedge insoles can be used as a conservative treatment of medial knee OA, and modify the kinematics and kinetics of subtalar ankle joint. Some researchers have stated that a lateral wedge insole increases foot pronation (which is a combination movement of eversion (calcaneus goes in a lateral position in the frontal plane), dorsiflexion and abduction) which aligns the femur and tibia into a more upright position which consequently results in less medial knee loading (Sasaki and Yasuda, 1987, Yasuda and Sasaki, 1987, Kakihana et al., 2005, Pazit et al., 2010). Other investigators have studied the relationship between a lateral wedge insole and the EKAM, and they found that the lateral wedge insole aligns the foot into pronation to produce valgus moment at the ankle, which makes the centre of pressure of the ground reaction force in the foot to shift laterally (Crenshaw et al., 2000, Kerrigan et al., 2002, Maly et al., 2002, Jones et al.,

2006, Jones, 2011). Lateral wedge insoles can laterally move the centre of pressure by up to 5 mm (Shelburne et al., 2008), displacing the centre of pressure laterally decreasing the moment arm at the knee, thereby, it was found that EKAM and medial compartment loading reduced linearly with lateral displacement of the centre of pressure (for each 1 mm lateral displacement of the centre of the pressure, the peak of EKAM and medial compartment load decreased by 2% and the 1%, respectively) (Shelburne et al., 2008). Therefore, lateral wedge insoles alter the valgus moment causing the centre of pressure in the foot to shift laterally, thereby reducing the external knee adduction moment during walking (Kerrigan et al., 2002; Draganich et al. 2006; Hinman et al. 2009; Jones et al. 2013) and more recently during stair ascent and descent (Alshawabka et al. 2014; Wallace et al. 2007). The use of a full length lateral wedge insole resulted in an increased ankle joint valgus moment, which was claimed as a way of further decreasing knee adduction moment (Kakihana et al., 2005). However, lateral wedge insoles have not shown promising results in clinical based studies with randomized clinical trials showing no significant benefit over neutral non-wedged insoles (Baker et al., 2007; Bennell et al., 2011; Parkes et al., 2013). Therefore, further research is needed in order to understand this relationship between decreased loading and non-significant clinical symptom relief. Further, other management techniques which alter the mechanical loads and also clinical symptoms are needed

2.10.3 Valgus knee brace

One such load modifying intervention is valgus knee brace that aim to realign the knee and reduce transarticular loading on the medial compartment. In theory, valgus knee braces apply three-point-pressure to arthritic knees (figure 2-8) (Reeves, & Bowling, 2011) and give pain release by decreasing the load on the medial compartment through the application of an opposing external valgus moment about the knee. An achievement of pain reduction was found via the use of an external corrective force to the knee by the adjustable straps or condylar pads while opposing counter forces (arising from the upper and lower brace supports) act proximal and distal to the knee joint. The small improvement in alignment is thought to shorten the moment arm (the perpendicular distance between the ground reaction force and the knee joint center), which should in

turn lower the external knee adduction moment. At the same time, compressive load is shifted away from the medial compartment, thereby improving the distribution of compressive load over the joint surfaces (Ramsey et al., 2009). Both changes help to alleviate mechanical stress on the medial compartment.
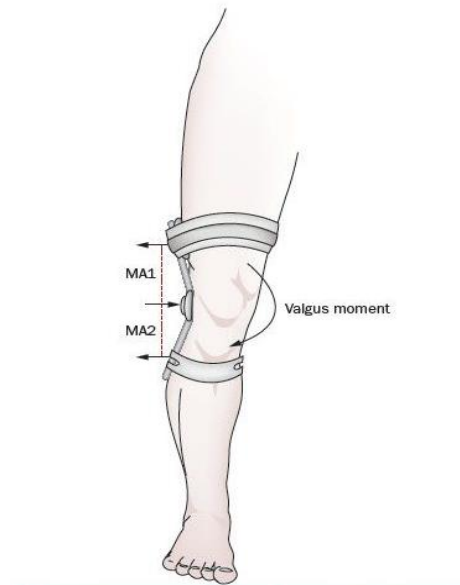
Figure 2-8. Schematic diagram illustrating how valgus bracing counteracts the external adduction moment acting about the knee during walking (Reeves, & Bowling 2011).

The brace applies points of force at three locations (indicated by arrows), which create MA1 and MA2, and result in a valgus moment about the knee. The red dotted line indicates the length of the two separate moment arms: MA1 and MA2 (distance from outer arrow to center arrow). Abbreviation: MA, moment arm (Reeves, & Bowling 2011).

Several studies from 1996 to 2014 investigated the efficacy of valgus knee braces , Bledsoe Thruster (Otis et al, 1996; Komistek, et al., 1999; Nadaud et al., 2005; Dennis et al., 2006), Custom fit (Lindenfeld et al., 1997; Hewett et al., 1998; Larsen et al., 2013), GII Unloader (Davidson et al., 1997; Matsuno et al., 1997; Draper et al., 2000; Birmingham et al., 2001; Pollo et al., 2002; Nadaud et al., 2005; Richards et al., 2005; Dennis et al., 2006; Ramsey et al., 2007; Russell and Ramsey, 2009), neoprene sleeves (Chuang et al., 2007; Brouwer et al., 2006, Müller-Rath et al., 2011), unloader braces (Kirkley et al., 1999), Custom Monarch brace (Self et al., 2000), Load-shifting knee

brace (Nicholas J. Giori, 2004), Breg Tradition X2K (Nadaud et al., 2005; Dennis et al., 2006), DJ Adjuster (Nadaud et al., 2005; Dennis et al., 2006, Jones et al., 2013), OAsys (Nadaud et al., 2005; Brouwer et al., 2006), Off-the-shelf bilateral Uniaxial hinge (Richards et al., 2005; Draganich et al., 2006), Custom (OA Defiance) (Draganich et al., 2006), ACL Brace (Dennis et al ., 2006), The SofTec OA valgus brace (Gaasbeek et al., 2007, Müller-Rath et al., 2011), The Genu Arthro knee brace (Fantini Pagani et al., 2010; Schmalz et al. 2010; Pagani et al., 2012), Ossure (Toriyama et al., 2010; Deie et al., 2013), Counter Force brace(Wilson et al., 2011), a polycentric type knee orthosis (Karimi et al., 2012) and Breg Fusiona valgus unloader braces (Hurley et al., 2012) on knee osteoarthritis patients for different periods of time varying from one day to 12 months duration.

Several studies that have investigated the efficacy of valgus unloader braces and have found improvements in pain (Otis et al., 1996; Lindenfeld et al., 1997; Matsuno et al., 1997; Hewett et al., 1998; Kirkley et al., 1999; Komistek, et al., 1999; Draper et al., 2000; Pollo et al., 2002; Nicholas J. Giori 2004; Richards et al., 2005; Draganich et al., 2006; Brouwer et al., 2006; Gaasbeek et al., 2007; Ramsey et al., 2007; Ramsey and Russell 2009; Schmalz et al., 2010; Müller-Rath et al., 2011; Wilson et al., 2011; Hurley et al., 2012; Deie et al., 2013), physical function (Lindenfeld et al., 1997; Matsuno et al., 1997; Hewett et al., 1998; Kirkley et al., 1999; Draper et al., 2000; Pollo et al., 2002; Giori, 2004; Richards et al., 2005; Draganich et al., 2006; Brouwer et al., 2006; Gaasbeek et al., 2007; Ramsey et al., 2007; Ramsey and Russell 2009; Wilson et al., 2011; Müller-Rath et al., 2011; Hurley et al., 2012; Larsen et al., 2013), knee proprioception (Birmingham et al., 2001; Chuang et al., 2007), decreasing muscle co-contraction (Ramsey et al., 2007; Fantini Pagani et al., 2012), improvement in hamstrings strength (Hurley et al., 2012), the peak isokinetic knee extensor torque has also significantly increased (Matsuno et al., 1997), and kinematic and kinetic data (The mean varus moment (Otis et al., 1996; Self et al., 2000; Pollo et al., 2002; Gaasbeek et al., 2007) the mean knee adduction moment (Lindenfeld et al., 1997; Draganich et al., 2006; Gaasbeek et al., 2007; Fantini Pagani et al., 2010; Toriyama et al., 2010; Karimi et al., 2012; Deie et al., 2013), flexion angle, coronal angle and axial angle (Davidson et al., 1997), improvement in the extension and flexion angles (sagittal plane) and the knee

rotation angles (horizontal plane) (Müller-Rath et al., 2011), condylar separation angle and condylar separation (Komistek, et al., 1999; Nadaud et al., 2005; Dennis et al., 2006), the valgus force (Self et al., 2000), the compressive Load (Pollo et al., 2002; Richards et al., 2005; Schmalz et al., 2010), varus angulation (Draganich et al., 2006) and knee adduction excursions (Ramsey et al., 2007).

A study was carried out by Birmingham et al., (2001) to investigate the effects of a functional knee brace specifically designed for patients with varus gonarthrosis on measures of proprioception and postural control on testing day. Proprioception was measured in the sitting position using an isokinetic dynamometer and was quantified as the ability to replicate target knee-joint angles. Postural control was measured with a force platform using tests of single-limb standing balance performed, during the patient was standing on a stable surface and on foam, and was quantified as the total length of the path of the centre of pressure. All tests were done with and without GII Unloader valgus brace. Proprioception was significantly improved following application of the brace [mean difference=0.7°, 95% confidence interval (CI) =0.2 to 1.1°). Postural control was not significantly changed by the use of the brace during the stable surface test (mean difference=2.6 cm, 95% CI=−4.3 to 9.5 cm) or the foam surface test (mean difference=0.9 cm, 95% CI=−7.5 to 9.4 cm). The observed improvement in proprioception may be partially responsible for stated improvements in function and quality of life with the use of a brace.

Birmingham et al., (2001) investigated the effects of a functional knee brace on static balance on testing day; in our study I will investigate the effects of a valgus knee brace on dynamic balance by a modified star excursion balance test (SEBT) over a period of 6 weeks and 3 months rather than only static balance on the day test.

A study was undertaken by Chuang et al., (2007) to evaluate the effects of knee sleeves on static and dynamic balance in knee OA patients on the same day of the test. The tests were carried out on barefoot patient and were asked to stand with their body central line perpendicular to the floor and slightly widen their legs so that their feet were aligned with their shoulders. They could slightly alter their posture until they felt comfortable with the

proper position. Subjects were examined with knee flexed at about 10° and with their arms across their chests. Each patient was given at least a 5-minute practice period to become familiar with the balance device for both static and dynamic balance test. All patients completed three consecutive balance trials in both static and dynamic conditions on the platform. The results of this study showed that medial compartment knee OA patients wearing knee sleeves might increase balance ability in both static and dynamic conditions. This improvement could lead to prevent/help knee OA patients from falling down and enhance their sense of safety during daily living activities.

Chuang et al., (2007) investigated the effects of a functional knee brace on static balance on testing day; in our study I will investigate the effects of a valgus knee brace on dynamic balance by a modified star excursion balance test (SEBT) over a period of six weeks and three months rather than on the day test.

Ramsey et al., (2007), studied the degree to which valgus-producing (apply an external valgus (abduction) moment to the knee) unloader braces (fitted with a custom Generation II Unloader for two weeks) control knee instability and influence muscle co-contractions during gait. Co-contraction indices (simultaneous antagonist muscle activation) were derived for the following muscle pairs: vastus lateralis - lateral hamstring, vastus medialis - medial hamstring, vastus lateralis-lateral hamstring, vastus medialis-medial gastrocnemius, and vastus lateralis-lateral gastrocnemius muscles. Muscle responses were calculated from 100 msec prior to initial contact (to account for an electromechanical delay) to the first peak knee adduction moment. This interval was normalized to 100 data points. The co-contraction of the vastus lateralis-lateral hamstrings was significantly reduced from baseline in both without ($p = 0.014$) and with valgus setting ($p = 0.023$), and the co-contraction of the vastus medialis-medial hamstrings was significantly reduced with the valgus setting ($p = 0.068$), as a result of bracing. Patients with higher varus alignment had higher reduction in vastus lateralis-lateral hamstring muscle co-contraction.

Ramsey et al., (2007) investigated the effect of a custom Generation II Unloader for two weeks on muscle co-contraction during walking only. However, our study will

investigate the effect of a valgus knee brace on muscle co-contraction over a period of three months during walking, ascending and descending stairs rather than short period and during walking only.

Furthermore, Fantini Pagani et al., (2012) analysed the effect of a valgus knee orthosis (Genu Arthro 28K20/21) on the electromyographic activity (EMG) of seven muscles (rectus femoris (RF), vastus lateralis (VL), vastus medialis (VM), medial hamstring (MH), lateral hamstring (LH), gastrocnemius lateralis (GL) and gastrocnemius medialis (GM)) of the lower limb during gait in patients with knee osteoarthritis. Co -contraction ratios (CCRs) were calculated for different muscle pairs and muscle groups. The muscle groups works as agonist and antagonist in the frontal and sagittal planes: medial (VM, MH, GM)/ lateral (VL, LH, GL) muscles and knee flexors (MH, LH, GM, GL) /extensors (VM, RF, VL). The muscle pairs are characterized by two muscles which work as agonist and antagonist: MH/ LH, VL/GL, VL/LH, VM/MG, VM/MH. Twelve subjects with medial knee osteoarthritis walked on a treadmill in three different conditions: without orthosis, with a knee orthosis in 4° valgus adjustment and with an orthosis in a neutral flexible adjustment. Significant reduction in muscle activity and CCRs were detected with the use of the knee orthosis in both adjustments compared to the condition with un-orthosis. Medial/lateral CCR reduced significantly during the late stance and the flexor/extensor CCR reduced significantly during the loading phase and late stance with using the valgus brace. With the neutral flexible adjustment, decreases of muscle pairs CCRs were detected. The results of this study support the theory of a probable useful effect of knee braces in decreasing knee loading by reducing muscle activation and co-contraction levels, which could leading to slow progression of the disease in patients with knee osteoarthritis.

Fantini Pagani et al., (2012) investigated the effect of Genu Arthro Knee Orthosis on the day test on muscle co-contraction during walking only. However, our study will investigate the effect of a valgus knee brace on muscle co-contraction over a period of three months during walking, ascending and descending stairs rather than day test and during walking only.

A study was undertaken by Toriyama et al., (2011) to evaluate the effects of bracing on the kinematics and kinetics of involved and contralateral joints during gait on testing day. They used the Unloader® One (Össur, Reykjavik, Iceland) valgus knee brace which combines a streamlined flexible upright with a medial hinge to account for two leverage points with an opposing force from the dynamic dual force straps that cross over the knee to disperse a counter force across two lateral-aspect points of the knee. With bracing, the ipsilateral hip showed a lesser adduction angle during 1%–49% of the stance phase, and a lesser abduction moment at the second peak during the stance phase than the hip, compared to no bracing. In bracing, the contralateral hip demonstrated a more noticeable peak extension moment and the abduction moment decreased at the first peak, and the contralateral knee adduction angle enlarged during 46%–55% of the stance phase, when compared to no bracing.

Toriyama et al., (2011) used the same valgus knee braces we will use in our study; they investigated the effect of valgus knee brace on the kinematics and kinetics of involved and contralateral joints during gait on testing day. However, our study will investigate the effect of a valgus knee brace on the kinematics and kinetics of involved and contralateral joints over a period of three months during walking, ascending and descending stairs rather than day test and during walking only, to find out if the contralateral joints (hip, knee, ankle) affecting after wearing the brace over a period of three months during walking, ascending and descending stairs.

2.11 Gap in literature

In reviewing the literature on valgus knee braces, it is apparent that the majority of the previous literature has investigated the immediate effect of valgus knee brace on knee loading (Lindenfeld et al., 1997; Draganich et al., 2006; Gaasbeek et al., 2007; Fantini Pagani et al., 2010; Toriyama et al., 2010; Karimi et al., 2012), muscle co-contraction (Ramsey et al., 2007; Fantini Pagani et al., 2012), muscle strength (Hurley et al., 2012) and balance (Birmingham et al., 2001; Chuang et al., 2007) rather than after a period of time during wear. None of these studies have investigated the effect of a period of

wearing valgus knee braces on knee loading (EKAM) which has a strong relationship with improvement in pain, function, balance, proprioception and muscle strength according to previous studies which they reported a valgus knee brace can decelerate disease progression in patient with knee OA. Therefore, a longer duration study is needed to ensure that these results remain after a period of time.

The literature on muscle co-contraction and its role in medial knee OA has demonstrated this to be an important factor in medial joint contact force (Trepczynski et al., 2014), and therefore understanding if valgus knee braces alter this co-contraction is needed. There have been no studies examining the effect of valgus knee braces on muscle co-contraction. This is linked with the un-documented opinion that knee valgus bracing would reduce the muscle strength (perceived to be that the brace takes the load and muscle atrophy would occur) and control around the knee and weakens the joint so evidence is needed to confirm or refute this theory.

As seen in the previous literature, all of the published material is on walking activities primarily even though individuals with medial knee OA find ascending and descending stairs the most challenging activity. At the start of this work, there were no literature that has assessed the effect of a valgus knee brace on kinematics and kinetics of ascending and descending stairs in individuals with medial knee OA. Whilst some studies have been performed recently they only assessment immediate outcomes (Moyer et al., 2012), therefore, the longer term assessment are needed.

The other important area to note is that whilst there have been many studies on valgus knee braces, there has not been a complete study which has included both clinical outcomes measures and biomechanical outcome measures in the same study with the same brace. This is vital in order to fully understand quantify and the mechanistic action of valgus knee braces.

In order to fulfill these gaps in the literature we plan to perform a trial whereby individuals with medial knee OA would wear a valgus knee brace for a period of three months with an interim assessment at six weeks for pain and muscle strength/function.

The aims and hypotheses of the thesis are therefore:

1. To determine whether a valgus knee brace reduces the EKAM over a period of 3 months both with the brace on and with the brace off.

Hypothesis 1a: Medial knee loading is reduced with valgus knee brace and it is reduced more after 3 months of use than immediately.

Hypothesis 1b: In brace users, medial knee loading is reduced after 3 months of use, even with the brace not worn.

2. To determine whether a valgus knee brace reduces pain over a period of 3 months

Hypothesis 2: Pain in the affected knee is reduced when using a valgus knee brace.

3. To determine whether a valgus knee brace changes muscle strength/function over a period of 3 months.

Hypothesis 3: Muscle strength is increased in the affected knee when using a valgus knee brace

4. To determine whether a valgus knee braces changes alters muscle activity profiles over a period of 3 months.

Hypothesis 4: Muscle co-contraction patterns are reduced after wearing a valgus knee brace.

CHAPTER THREE

TEST-RETEST RELIABILITY OF WEARING VALGUS KNEE BRACE ON THE EXTERNAL ADDUCTION MOMENT (EKAM) DURING WALKING AND ASCENDING, AND DESCENDING STAIRS IN SUBJECTS WITH KNEE OSTEOARTHRITIS.

3.1 Introduction

When we stand, walk or climb stairs, our weight is transmitted through our knee joints. The way this weight is transmitted and its measurement are known as load. We aim to gain a more thorough understanding of the loading on the knee joint with aging in individuals with osteoarthritis, and to assess the effect of wearing assistive devices on this loading. No study has performed repeated examinations on valgus knee brace and this information will help to determine the reliability of such measures for the study which is planned. This study will be an important addition to the current research and will enable the researchers to understand the measurement error of the approach.

3.2 Aims

This study focuses on the measuring the load transferred through the knee joint when walking and ascending, and descending stairs in subjects with osteoarthritis of the knee joint. The aim is to ensure that the knee valgus brace can be applied in the same way at two test sessions so that an understanding of the reliability of the application of the brace can be understood. Therefore, this study will determine the intra- and inter-trial reliability of walking and stair ascent and descent whilst using and not using a valgus knee brace. This was assessed over two different test sessions with two weeks between them.

3.3 Background

Clinical gait analysis is an important method in which to assess the effects of different interventions on gait kinematic and kinetic data, the outcome of a clinical analysis can be affected by several factors that cannot be totally eliminated during measurement. There are several factors which can be controlled to diminish measurement error including marker positioning, faulty equipment, walking speed, or data processing errors (Schwartz et al., 2004). Positioning of markers on bony prominences create variability and increase measurement error (Cappozzo et al., 1996), and these bony prominences were more difficult to palpate due to covering by adipose tissue and layers of muscles (Baker, 2006). Markers location is an important factor for calculating and, determining the position of joint centres and any mistake in identifying of these markers would make error in the calculation of joints kinematic and kinetic data (Della Croce et al., 1997; Stagni et al., 2000; Baker, 2006).

Encouraging results (high repeatability) were achieved after test–retest reliability of gait data study from healthy individuals (Kadaba et al., 1989; Andrews et al., 1996) and patients (Birmingham et al., 2007).

3.4 Methods

Ethical approval was obtained from the University of Salford Research and Governance committee and informed consent was obtained from each individual.

3.4.1 Participants:

Seven patients (5 female, 2 male), were radiographically confirmed with medial knee OA, participated in the study. Participants were recruited from within Salford University staff population.

In order to be eligible for the study the following inclusion and exclusion were adopted:

Inclusion criteria:

To define medial knee OA, a patient must meet all of the following:

1   Pain with walking (using Knee Osteoarthritis Outcome Score (KOOS) question, they need to have at least mild pain walking on a flat surface) – Clinical diagnosis by qualified clinician

2   On AP or PA view x-ray (weight bearing, if possible), they need to have definite medial narrowing $\geq$ lateral narrowing and evidence (osteophyte) of OA – Radiographic diagnosis. Medial tenderness either by their own indication that this is where they have pain or by examination showing tenderness at the medial TF joint line – Clinical diagnosis by qualified clinician

3   If potential participants have had a MR scan or arthroscopy as part of their usual clinical care. As well as using the K-L score of grade 2 or 3 for plain radiographs, we will use the documented evidence of at least grade 1 arthritis on arthroscopy.

4   They are able to walk for 100 metres non-stop – Participant response.

Exclusion criteria:

Participants were excluded if the pain is more localised to the patellofemoral joint on examination than medial joint line, have tricompartmental knee osteoarthritis or have grade 4 medial tibiofemoral osteoarthritis (MTOA) on the Kellgren Lawrence scale. Other exclusions include a history of high tibial osteotomy or other realignment surgery or total knee replacement on the affected side or any foot and ankle problems that will contraindicate the use of the footwear load modifying interventions. In addition, participants were excluded if they have severe coexisting medical morbidities, or currently use, or have used, orthosis of any description prescribed by a Podiatrist or Orthotist. If the participants cannot walk for 100 metres without stopping they will   also be excluded as they may be unable to complete the full testing protocol. We excluded if the brace is not likely to work because the leg is too large; or if there has been an intra-articular steroid injection into the painful knee in the last month.

3.4.2 Procedures:

3.4.2.1 System calibration

In order to collect the kinematic and kinetic data, the camera system needs to be calibrated. The reference object, an L-shaped metal frame with four markers attached to it, is placed on the corner of the first force platform parallel to its Y and X axes with a predefined distances between the markers and the origin of the force platform coordinate system (i.e. the corner of the platform) were automatically calculated and inputted into the software (Winter, 2009) (Figure 3-1). The reference object defines the origin of the laboratory (global) co-ordinate system, together with X (medial/lateral) axis, Y (anterior/posterior) axis, and Z (the vertical) axis.

Figure 3-1: L-shaped metal frame.

To perform the system calibration, a wand equipped with two markers is randomly moved around the testing space for 60 seconds while the L-shaped rigid frame still on the force platform to determine the location (position and orientation) of the 16 cameras

relative to the laboratory coordinate system (Payton and Bartlett, 2008) (Figure 3-2). After the calibration process is completed, both the calibration residual results for each camera and the standard deviation of the wand length were below 1mm.

Figure 3-2: Wand equipped with two markers.

3.4.2.2 Kinematic and kinetic data collection

Kinematic data and kinetic data were collected by an infra-red motion capture system that emits infra-red light, which is returned from the markers back to the camera to provide the two-dimensional position of each marker. The three-dimensional position of each marker is then calculated from the collected of two-dimensional positions and the relative position of the cameras to the laboratory organize system (Kaufman and Sutherland, 2006). A minimum of two cameras are needed to identify each marker at one time to determine its three-dimensional location (Cappozzo et al., 2005). For the marker set adopted in this study, at least three non-collinear markers on a body segment must be seen by the cameras to define its location and alignment. When the location and

alignment of the nearby body segment is determined in the same way, the angle between the two segments can be calculated (i.e. ROM) (Kaufman and Sutherland, 2006). The force platform data together with the kinematic data (i.e. ROM and inertial parameters of anatomy) allow inverse dynamics to be performed to calculate the hip, knee, and ankle external moments (Winter et al., 1990).

3.4.2.3 Kinematic and kinetic data devices

Kinematic data were collected by sixteen infrared cameras (Qualisys Oqus computerised motion analysis system (Qualisys, Gothenburg, Sweden) at 100Hz (Figure 3-3). that were used to measure the 3-dimensional positions of retro-reflective markers that was attached to each individual's skin over bony landmarks in both lower limbs using hypo-allergenic adhesive tape at the foot (on the 1st, 2nd, 5th metatarsal heads and Calcaneal tubercle), ankle (medial and lateral malleolus), knee (lateral and medial femoral condyle, tibial tuberosity and fibular head), thigh (greater trochanter) and pelvis (right and left anterior superior iliac spine, right and left posterior superior iliac spine, and right and left iliac crest). Fixed cluster pads made of plastic (with four markers on each) was attached to the shank, thigh and pelvis using Fabio Foam Super wrap bandages to minimize migration of these plates down the limbs (Figure 3-4).

Figure 3-3: The sixteen-camera Qualisys Oqus motion analysis system and four force platforms (AMTI BP400X600, AMTI, USA) at gait lab.

A

B

Figure 3-4: Retro-reflective markers from (A) anterior and (B) posterior view.

Kinetic data (ground reaction force and centre of pressure) was obtained using two force platforms (model BP400600, AMTI (AMTI: Advanced Mechanical Technology Incorporation), Watertown, MA, USA) at 200Hz. The individual stood on a force platform for 10 seconds and a static 3-dimensional image from the sixteen infra-red cameras was obtained. Each participant wore standard shoes (Ecco Zen) which are available to fit all sizes with and without an off-the-shelf Ossur UnloaderOne valgus knee brace (Figure 3-5) and was required to walk (at a self-selected speed) five times over a flat surface (ensuring successful contact with the force platforms) and ascend and descend three stairs for three times without using a handrail. A handrail was available if the subject needed to use this for safety. Stair trials were performed on a three stair laboratory stairway. The stairway was designed and built by AMTI (Della Croce and Bonato, 2007) (Figure 3-6) which fixes securely with bolts into the top surface of the force platform. The stairway was fixed firmly to two force platforms embedded in the walkway. It was built in three stairs (steps), the first stair (the lowest one) was attached to the second force platform, the second stair (the middle one) was attached to the first force platform, and the third stair (the highest one) was attached to the second force platform. Kinetic data for three stair climbing stairs and a transition step from level ground (where the floor immediately before the first stair is a part of the first force platform) to ascending or from descending to level ground was collected by these two force platforms. The force platforms were adapted to allow autonomous measurement of the forces over each stair separately during stair climbing. Thus, the GRF of first step on the first stair and the third step on the third stair was measured by second platform when a foot contacts the stair and the force platform measures two separate GRFs from the foot as if it contacted two different platforms.

Figure 3-5: Ossur UnloaderOne valgus knee brace
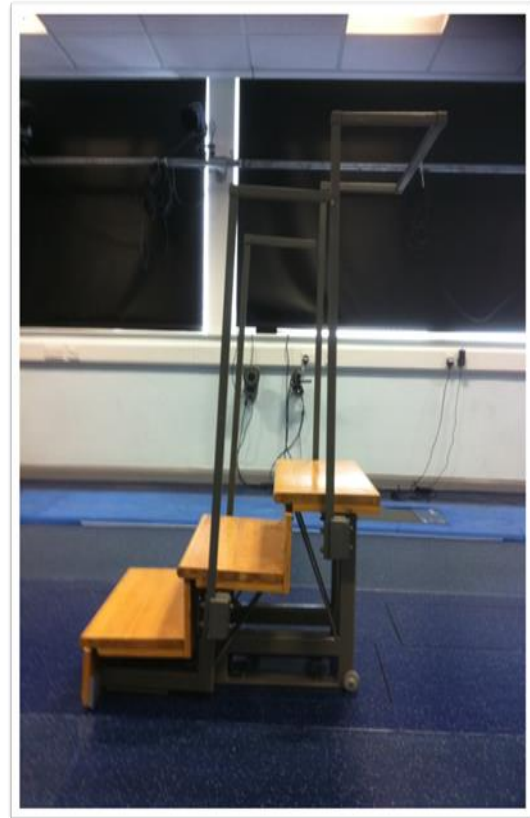
Figure 3-6: The AMTI Stairway

Two test conditions were tested:

1. Condition 1: Standard control shoe – The participant wore standard shoes which will provide a baseline dataset for the footwear conditions.

2. Condition 2: Standard control shoe with a valgus knee brace – The participant was asked to wear standard shoes and a valgus knee brace. For the brace fitting, the axis of the brace was positioned on the medial epicondyle, with the subject sitting with flexed knee about 90°. The upper strap was fitted firstly then the lower strap, after fitting the brace on the affected leg, the straps were adjusted to produce a firm tension to avoid slipping down and, without soft tissue binding.

The order of interventions was randomised according to the following website (www.randomisation.com) to ensure that carry-over effects are minimised and reduce bias. Individuals were asked to come back to the laboratory for a re-assessment two

weeks later so that repeatability data of the gait kinematics and kinetics whilst using the standard control shoe and valgus knee brace were obtained.

3.4.2.4 Biomechanical model

A variety of markers sets have been suggested but the most common one in clinical use are some variations of the Helen Hayes (HH) set (Kadaba et al., 1990). The Helen Hayes (HH) was a previous model with disadvantages as it only adopts three rotational degree of freedom (DOF) for the hip and knee and two DOF for the ankle. Part of the historical rationale for this model was that the measurement systems were less advanced (low resolution imaging systems) so a small number of markers were used with a big distance between them (Della Croce et al., 2005). Additionally, in this model the anatomical markers are used to track movement, which results in the propagation of errors to the distal segments due to inaccuracies in the movement of proximal segments. This introduces error to the measurement (Schwartz et al., 2004; Cereatti et al., 2007). Therefore, a six DOF marker set was developed in which the technical markers track the movement of each segment independently, and allowing 6DOF (3 rotational and 3 translational) at each joint (Cappozzo et al., 2005, Cereatti et al., 2007). This model has been showed to reduce some of the errors presented by previous models (Cereatti et al., 2007). In addition, 6DOF is preferable because it has showed comparable performance and overcomes an amount of HH theoretical limitations (Collins et al., 2009).

3.4.3 Data processing and statistical analysis

3.4.3.1. Data processing

Each successful walking (five trials for each participant), and ascending and descending trials (three trials for both ascending and descending for each participant) were collected on each of 2 separate days for a total of 10 trials for walking and six trials for ascending and descending for each subject. Following this, all data were processed in Qualisys Track Manager Software Version 2.8 Beta Build 835, then each marker was labeled and any abnormal movements in marker trajectories were corrected. All these trials during walking, ascending and descending were then exported as a C3D to Visual 3D (V3D) software (Version 4.91, C-Motion Inc, Rockville, MD, USA).

A six-degree of freedom model for the lower limbs were built. The model contained of rigid segments attached to the joints (Figure 3.7). Each segment/joint is considered to have six variables that describe its pose (3 variable describe the position of the origin, 3 variables describe the rotation) in 3D space, namely 3 variables describe the segment translation in three perpendicular axes (vertical, medial-lateral and anterior-posterior) and 3 variables describe the rotation about each axes of the segment (sagittal, frontal and transverse). Subject's body mass (in kilograms (kg)) and height (in metres) and were entered into the software for usage use in kinetic calculations. Each segment of Pelvis, thigh, shank, and foot was modelled to determining the proximal and distal joint/radius and the tracking markers as illustrated in table 3-1.
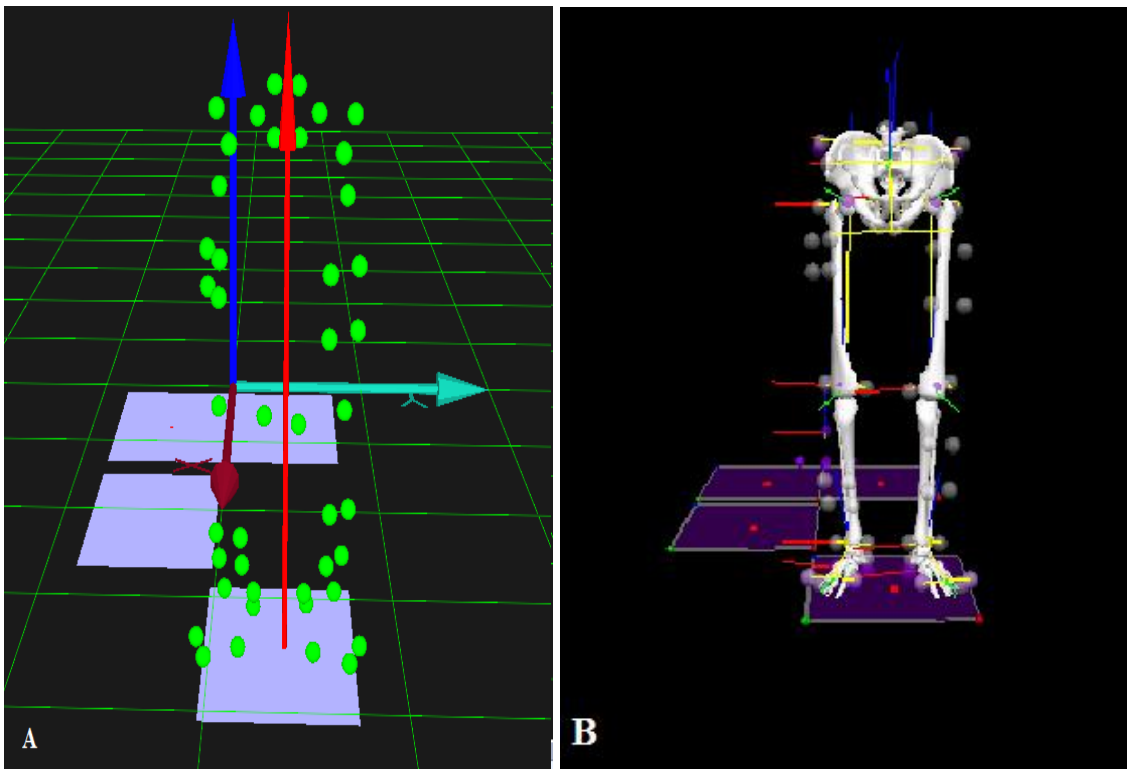
Figure 3-7: (A) Static subject model in QTM™. (B) Bone model in Visual 3D™ (Anterior view).

Table 3-1: Visual 3D™ model segments

Segment	Proximal radius/joint	Distal radius/joint	Tracking markers
Pelvis	- Right anterior superior iliac spine - Left anterior superior iliac spine	- Right posterior superior iliac spine - Left posterior superior iliac spine	Pelvis cluster pad (4 tracking markers)
Thigh	- Hip joint centre· - Greater trochanter	- Medial femoral condyle - Lateral femoral condyle	Thigh cluster pad (4 tracking markers)
Shank	- Medial femoral condyle -Lateral femoral condyle	- Medial malleolus - Lateral malleolus	Shank cluster pad (4 tracking markers)
Foot	- Medial malleolus - Lateral malleolus	- 1st metatarsal head - 5th metatarsal head	Superior/inferior calcaneus, medial/lateral calcaneus
Virtual foot	-Medial malleolus floor - Lateral malleolus floor	- 1st metatarsal head floor - 5th metatarsal head floor	
•Hip joint centre is automatically calculated by using anterior and posterior superior iliac spine markers using the regression equation by Bell and Brand (1990)			

All kinematic data were interpolated, low pass filtered, and then gait events created after building a six free dome model. Kinematic and kinetic data were filtered using a Butterworth 4th order bi-directional filter with a cutoff point of 6Hz for kinematics (Winter, 2009) and 25Hz for kinetics (Schneider and Chao, 1983).

For the stairs data and especially for the kinetic data analysis it was necessary to add two force structures in Visual 3D™. The location and dimensions between stair corners were computed in relation to the global coordinates and the two force platforms using AMTI force structure as illustrated in figure 3-8.
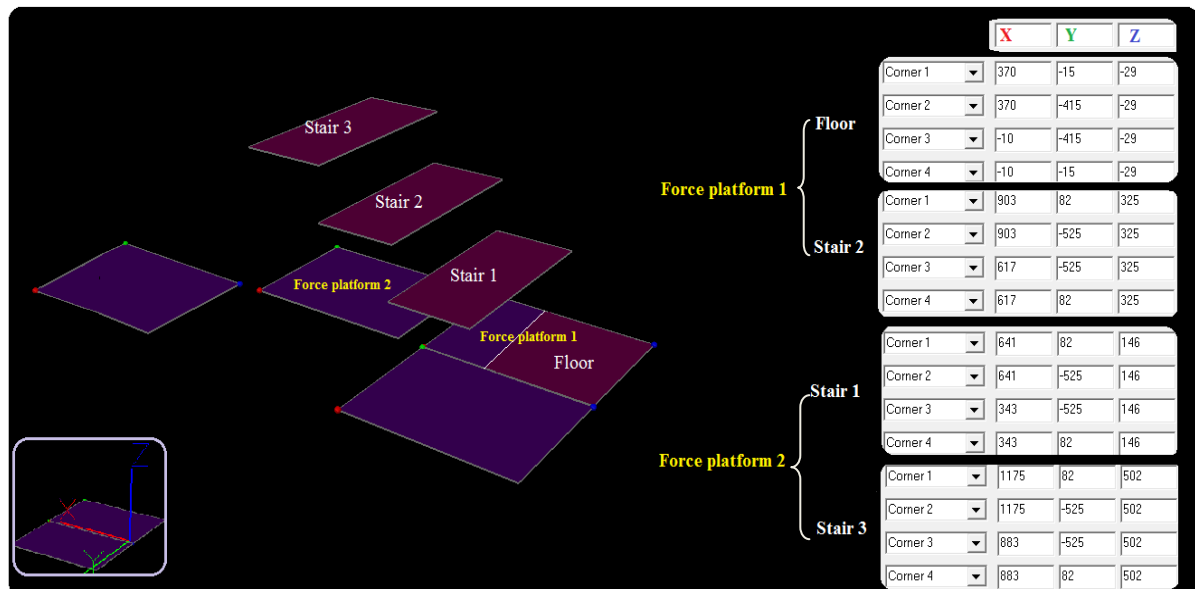
Figure 3-8: AMTI stairway force structures.

In studying the results from the two sessions, normalised stance phase was used for the kinetic data and normalised gait cycle was used for the kinematic data during walking and ascending, and descending stairs. Following this, each gait parameter of interest was exported from V3D to Microsoft Excel 2010 (Microsoft, Washington, USA).

3.4.3.2 Statistical analysis

To assess the test-retest reliability of gait data, the shapes of the waveforms demonstrating the different gait parameters were explored in detail. For between-day test-retest reliability, 10 trials were compared (i.e. five on each day) to determine these similarities. The coefficient of multiple correlations (CMC) was used in this study to assess between-day repeatability of kinematic and kinetic waveform data. The CMC was used before by Kadaba et al., 1990 and Growney et al., 1997. The nearer the result is to 1, the greater the test-retest reliability, and specifically similar waveforms with values greater than 0.8 demonstrate high test-retest reliability (Growney et al., 1997; Collins et al., 2009).

The standard error of measurement (SEM) is the amount of variation in the results. It was calculated to determine absolute reliability, with lower SEM demonstrating good reliability (Baumgartner, 1989), to enabling a clinicians and researchers an estimate of

66

the range of real change in an outcome measure rather than measurement error. The SEM was calculated by using this equation: **SEM = SD*($\sqrt{1\text{-}ICC}$)** (Harvill, 1991).

3.5. Results

3.5.1 Test participants

Seven patients with knee OA participated in the study; five women and two men (mean age 58(SD 5.88) years; age range 52-65 years; mean height 162 (SD11.04) cm; height range 164-177 cm; mean mass 81(SD 14.05) Kg; weight range 55.5- 97 Kg). They attended the two testing sessions separated by 14 (SD 5) days.

3.5.2 Test-retest reliability of gait kinematics and kinetics

Walking speed did not change significantly in the valgus knee brace (p= 0. 34, 0. 89 and 0.08) and shoe only condition (p= 0. 49, 0. 20 and 0.06) during walking, ascending and descending stairs respectively. Walking speed during the test was monitored and those trials with walking speed beyond +/- 10% of the average speed were excluded from the final results. The results demonstrated very good repeatability in the valgus knee brace (CMC 0.89, 0.74 and 0.69) and shoe only condition (CMC 0.85, 0.69 and 0.71) during walking, ascending and descending stairs respectively between sessions of different days. The lowest test-retest reliability was when the valgus knee brace was worn with standard shoe during descending stairs with a CMC of 0.69. The mean, SD and SEM between-day CMC results of joint ROM and moments for all patients are presented in table 3-2 and table 3-3. The primary outcome which is used in this thesis is the EKAM and this showed very good repeatability in the valgus knee brace (CMC 0.89, 0.74 and 0.69) and shoe only condition (CMC 0.85, 0.69 and 0.71) during walking, ascending and descending stairs respectively.

Table 3-2: Mean standard deviation (SD) and Standard error of measurement (SEM) of the coefficient of multiple correlations (CMC) of joint range of motion (ROM) and moment for all participants in Brace Condition.

BRACE	Walking			Ascending			Descending		
	Mean	SD*	SEM*	Mean	SD	SEM*	Mean	SD*	SEM*
Pelvic angles X	0.74	0.07	0.04	0.63	0.20	0.12	0.50	0.22	0.16
Pelvic angles Y	0.70	0.23	0.12	0.93	0.05	0.01	0.86	0.11	0.04
Pelvic angles Z	0.78	0.18	0.08	0.62	0.14	0.09	0.63	0.24	0.15
Hip angles X	0.96	0.03	0.01	0.90	0.08	0.03	0.73	0.15	0.08
Hip angles Y	0.90	0.04	0.01	0.81	0.14	0.06	0.70	0.17	0.09
Hip angles Z	0.68	0.21	0.12	0.52	0.12	0.08	0.55	0.16	0.11
Hip moments X	0.97	0.01	0.00	0.84	0.05	0.02	0.60	0.14	0.09
Hip moments Y	0.97	0.01	0.00	0.79	0.19	0.09	0.76	0.18	0.08
Knee angles X	0.98	0.02	0.00	0.89	0.17	0.06	0.94	0.06	0.02
Knee angles Y	0.61	0.40	0.25	0.70	0.19	0.11	0.50	0.19	0.13
Knee angles Z	0.62	0.20	0.12	0.63	0.23	0.14	0.59	0.21	0.14
Knee moments X	0.93	0.04	0.01	0.79	0.22	0.10	0.73	0.12	0.06
Knee moments Y	0.89	0.11	0.04	0.74	0.20	0.10	0.69	0.15	0.08
Virtual ankle X	0.98	0.01	0.00	0.79	0.23	0.10	0.97	0.01	0.00
Foot progression Z	0.78	0.15	0.07	0.73	0.13	0.07	0.67	0.23	0.13
Ankle moments X	0.99	0.01	0.00	0.84	0.11	0.04	0.69	0.13	0.07

SD= Standard Deviation   SEM= Standard error of measurement   X=Flexion/ Extension
Y= Abduction/Adduction   Z= Internal/ External Roation

Table 3-3: Mean standard deviation (SD) and Standard error of measurement (SEM) of the coefficient of multiple correlations (CMC) of joint range of motion (ROM) and moment for all participants in in standard shoe condition.

SHOE	Walking			Ascending			Descending		
	Mean	SD*	SEM*	Mean	SD*	SEM*	Mean	SD*	SEM*
Pelvic angles X	0.64	0.12	0.07	0.53	0.22	0.15	0.63	0.17	0.10
Pelvic angles Y	0.70	0.18	0.10	0.89	0.11	0.04	0.78	0.22	0.10
Pelvic angles Z	0.80	0.15	0.07	0.64	0.16	0.10	0.54	0.18	0.12
Hip angles X	0.96	0.03	0.01	0.90	0.06	0.02	0.72	0.16	0.09
Hip angles Y	0.89	0.04	0.01	0.78	0.15	0.07	0.72	0.25	0.13
Hip angles Z	0.68	0.17	0.09	0.50	0.22	0.16	0.61	0.16	0.10
Hip moments X	0.96	0.02	0.00	0.76	0.20	0.10	0.60	0.15	0.10
Hip moments Y	0.98	0.01	0.00	0.72	0.30	0.16	0.81	0.21	0.09
Knee angles X	0.98	0.02	0.00	0.88	0.20	0.07	0.92	0.08	0.02
Knee angles Y	0.67	0.38	0.22	0.65	0.19	0.11	0.58	0.21	0.14
Knee angles Z	0.74	0.20	0.10	0.65	0.22	0.13	0.64	0.19	0.12
Knee moments X	0.91	0.06	0.02	0.69	0.36	0.20	0.77	0.09	0.04
Knee moments Y	0.85	0.20	0.08	0.69	0.29	0.16	0.71	0.21	0.11
Virtual ankle X	0.98	0.01	0.00	0.80	0.17	0.07	0.95	0.03	0.01
Foot progression Z	0.77	0.10	0.05	0.57	0.02	0.01	0.59	0.23	0.15
Ankle moments X	0.99	0.01	0.00	0.78	0.22	0.11	0.70	0.19	0.10

SD= Standard Deviation   SEM= Standard error of measurement   X=Flexion/ Extension
Y= Abduction/Adduction   Z= Internal/ External Roation

3.6 Discussion

The high degree of repeatability for the time distance parameters confirms with previous studies founded (Kadaba et al., 1990, Growney 1997). The patients were instructed to walk at a self-selected (with in normal speed) in this study. Thus measureable time of gait and ascending and descending was very repeatable. Walking speed did not change significantly in the valgus knee brace (p= 0. 34, 0. 89 and 0.08) and shoe only condition (p= 0. 49, 0. 20 and 0.06) during walking, ascending and descending stairs respectively.

Most previous studies have investigated between-day reliability of hip, knee, ankle moment and angle in healthy subject and used a different marker set (the Helen Hays) (Kadaba et al., 1989; Andrews et al., 1996; Growney et al., 1997; Tsushima et al., 2003). Gait test-retest reliability done by Growney et al. (1997) was conducted on five subjects. Also, Gait test-retest reliability done by Tsushima et al. (2003) was conducted on six subjects.

The present between-day CMC for the EKAM of 0.89, 0.74 and 0.69 respectively during walking, upstairs and down stairs in brace condition and between-day CMC of 0.85, 0.69 and 0.71 respectively during walking, upstairs and down stairs in shod walking condition can be described as indicating good test–retest reliability of EKAM in knee OA patients. These finding conformed to the previous reliability studies reports that have evaluated healthy subjects (Kadaba et al., 1989; Andrews et al., 1996; Growney et al., 1997; Tsushima et al., 2003) and patients (Birmingham, 2007) during walking, however no studies have reported on healthy or non-healthy subjects during ascending and descending stairs. Additionally, this repeatability data on the cluster based approach used in this thesis is the first time this has been presented. Kadaba et al, 1989, examined forty healthy subjects on 3 different days and stated that the EKAM was highly repeatable (CMC 0.9). Andrews et al., 1996, examined 11 healthy subjects on different days and also reported that the knee adduction moment was highly repeatable. Birmingham et al., 2007, tested 31 patients with medial knee OA on 2 sparest days and stated that the peak of EKAM was highly repeatable (ICC 0.86). All these studies suggested that the EKAM was applicable for use when distinguishing among patient which can be done in clinical examinations of different interventions.

The present between-day CMC of 0.98, 0.89 and 0.94 respectively during walking, upstairs and down stairs in brace condition and between-day CMC of 0.98, 0.88 and 0.92 respectively during walking, upstairs and down stairs in shod condition can be described as indicating excellent test–retest reliability of sagittal knee angle in knee OA patients. Otherwise, The results showed lower value of frontal angle repeatability in the valgus knee brace (CMC 0.61, 0.70 and 0.50) and shoe only condition (bCMC 0.67, 0.65 and 0.58) during walking, ascending and descending stairs respectively. These results agree with previous reliability reports that have evaluated healthy participant (Kadaba et al., 1989; Growney et al., 1997). A study done by Growney et al., 1997, showed excellent repeatability between test days in the sagittal plane the hip, knee, and ankle angle. However, the Frontal and transverse plane angle were considerably lower in repeatability between-days. They found the variability of these data between test days was due to errors in re-application of mid-thigh and mid-calf wands. This is potentially an influence of the marker set that they adopted. Collins et al. (2009) stated high between-day hip, knee, and ankle ROM test-retest reliability in the sagittal and coronal planes in ten healthy subjects (bCMC rang 0.82-1.0)

3.7 Conclusion

This is the first study that has shown repeatability with the cluster model adopted for this thesis in individuals with medial knee OA. The data has also showed the repeatability of applying a valgus knee brace at two different test sessions which allows this to be taken forward into the main study. This ensures that any difference seen above the SEM is due to the brace effect and not due to the fitting of the valgus knee brace. Furthermore, this is the first study to demonstrate the repeatability of walking and ascending and descending stairs on EKAM and with the application of a valgus knee brace.

CHAPTER FOUR

THE EFFECTIVENESS OF VALGUS KNEE BRACING IN SUBJECTS WITH MEDIAL KNEE OSTEOARTHRITIS: UNLOAD STUDY

4.1 Synopsis:

Knee valgus braces are one conservative treatment that has been used in daily care which aims to target the EKAM. Research studies have found improvements in pain, physical function, and changes in the kinematic and kinetic. However, the majority of these studies are of increasingly short duration, look at outcome measures with the brace in situ, investigate the immediate effects rather than after a period of time, and have tended to look at the outcome measures individually rather than as a complete trial (Polo et al., 2002; Dragnich et al., 2006; Ramsey et al., 2007; Fantini Pagani et al., 2010). Therefore, to enable a complete picture of valgus knee braces, a study would need to combine clinical and biomechanical outcome measures, to be able to quantify the mechanistic action of valgus knee bracing.

As seen in the previous literature review, all of the published material for valgus knee braces is on level walking. However, the primary complaint of individuals with medial knee OA is that stair ascending and descending are the most challenging activity (reference). No study, to the author's knowledge, has assessed the effect of a valgus knee brace on the kinematics and kinetics of ascending and descending stairs in individuals with medial knee OA. Since the conception of this thesis, one study assessed this but this was an immediate assessment and not over an extended duration of wear (Moyer et al., 2012). Therefore, to understand the true effects of the valgus knee brace in question, an assessment during walking and stair climbing is needed to determine its effectiveness. Therefore, the following aims and hypotheses are directly related to this chapter:

1. To determine whether a valgus knee brace reduces the EKAM over a period of 3 months both with the brace on and with the brace off.

Hypothesis 1a: Medial knee loading is reduced with valgus knee brace and it is reduced more after 3 months of use than immediately.

Hypothesis 1b: In brace users, medial knee loading is reduced after 3 months of use, even with the brace not worn.

2. To determine whether a valgus knee brace reduces pain over a period of 3 months

Hypothesis 2: Pain in the affected knee is reduced when using a valgus knee brace.

3. To determine whether a valgus knee brace changes muscle strength/function over a period of 3 months.

Hypothesis 3: Muscle strength is increased in the affected knee when using a valgus knee brace

4. To determine whether a valgus knee braces changes alters muscle activity profiles over a period of 3 months.

Hypothesis 4: Muscle co-contraction patterns are reduced after wearing a valgus knee brace

The following sections will present the study that was undertaken.

4.2 Methods

4.2.1 Sample population

15 participants with age range of 40-85 diagnosed with unilateral symptomatic medial knee osteoarthritis grade 2 of Kellgren and Lawrence (KL) grading system and 3KL were recruited in this study.

In order to be eligible for the study the following inclusion and exclusion were adopted:

Inclusion criteria:

To define medial knee OA, a patient must meet all of the following:

1   Pain with walking (using KOOS question, they need to have at least mild pain walking on a flat surface) – Clinical diagnosis by qualified clinician.

2   On AP or PA view x-ray (weight bearing; if possible); they need to have definite medial narrowing $\geq$ lateral narrowing and evidence (osteophyte) of OA – Radiographic diagnosis. Medial tenderness either by their own indication that this is where they have pain or by examination showing tenderness at the medial TF joint line – Clinical diagnosis by qualified clinician.

3   If potential participants have had a MR scan or arthroscopy as part of their usual clinical care. As well as using the K-L score of grade 2 or 3 for plain radiographs, we will use the documented evidence of at least grade 1 arthritis on arthroscopy.

4   They are able to walk for 100 metres non-stop – Participant response.

Exclusion criteria:

Participants were excluded if the pain is more localised to the patellofemoral joint on examination than medial joint line, have tricompartmental knee osteoarthritis or have grade 4 medial tibiofemoral osteoarthritis (MTOA) on the Kellgren Lawrence scale. Other exclusions include a history of high tibial osteotomy or other realignment surgery or total knee replacement on the affected side or any foot and ankle problems that will contraindicate the use of the footwear load modifying interventions. In addition, participants were excluded if they have severe coexisting medical morbidities, or currently use, or have used, orthosis of any description prescribed by a Podiatrist or Orthotist. If the participants cannot walk for 100 metres without stopping they will also be excluded as they may be unable to complete the full testing protocol. We excluded if the brace is not likely to work because the leg is too large; or if there has been an intra-articular steroid injection into the painful knee in the last month.

4.2.2 Recruitment and consent

After getting NHS approval (Recording reference 12/NW/0419) (Appendix one), Participant Identification Centres included Salford Royal NHS Foundation Trust at Hope Hospital (Mr W Kim) (Appendix two), Stockport NHS Foundation Trust (Mr DS Johnson) (Appendix three), Central Manchester hospital (Appendix four) and after getting the ethical approval from Salford University (HSCR12/42) (Appendix five). All Individuals who have been seen in the orthopaedic clinics of the named orthopaedic surgeons, who have a clinical diagnosis of medial tibiofemoral osteoarthritis (MTFOA), were informed of the nature of the study.

An invitation letter and participation tear off slip were sent to all patients who were interested to take part in the study. When the participant was willing to enter the study, the researcher arranged a suitable date to attend the gait laboratory and an appointment letter was sent to them.

Recruitment Process

Patient who have been seen in the orthopaedic and physiotherapy clinics who have a clinical diagnosis of MTFOA

A recruitment pack consisting of the following is sent:

- Invitation Letter - Tear off slip
- Patient Information Sheet –
- Pre Paid Envelope

Has the patient returned the

NO → Further attempts to contact if > 2 weeks since received information

YES

Would they like to Participate?

NO → No further contact

YES

Researcher contacts patient to discuss study further

NO → Thank you for their time. No further contact

Do they still want to participate?

YES

Entered onto Database original Data stored Baseline appointment booked

4.2.3 Study design

The study design was a pre-post intervention repeated assessment with outcome measures recorded at baseline, six weeks and three months. Pain, muscle strength/ function (balance) measurements were taken at baseline, six weeks and three months and gait analysis and muscle co-contraction were taken at baseline, and three months. The study involved three visits to the gait laboratory to be conducted. Patients were contacted by telephone at regular intervals to ensure that they are not having problems with the valgus knee brace and pain and comfort scores were collected and documented. All outcome measures were assessed for the most affected knee

4.2.4 Procedures

Upon arrival at the gait laboratory at Salford University, patients were briefed through the study and explained the objectives of the investigations and the equipment in the gait laboratory. At this time, they were asked to sign the informed consent form after read it. Then, demographic details such as date of birth, height and mass were recorded. They were asked to complete the Knee Osteoarthritis Outcome Score (KOOS). Then, the patients were assessed to determine the correct size of shoe (Ecco Zen) and valgus knee brace that the individual required. Patients were asked to change into their shorts and a comfortable t-shirt. The patients then had the following assessments performed.

4.2.4.1 Star Excursion Balance Test (SEBT):

All patients were asked to stand on the affected leg in the centre of the grid of a modified Star Excursion Balance Test (SEBT). Depending on the direction to be tested, either facing the bar (A) or with their side to the bar (M), they were asked to reach as far as possible along the bar by pushing a small block on the bar as far as possible, and return the reaching leg back to the centre. The patients were instructed to perform the test barefoot, retain their heel of the stance leg on the platform at all times; to bend their knee of the stance leg; to push the block gradually but not suddenly, and not slide it by stepping on it. If any of these instructions were not carried out by the patients, the trial was repeated. Each patient started with four training trials in the two directions (A, and

M), followed by three test trials performed in each direction for the affected leg (Figure 4-1). The outermost distance they could reach was recorded by the location of the pushed block on the bar. The average of all of the three trials in each direction was used for the analysis.

Figure 4-1: The subject performed Star Excursion Balance Test in the A) anterior direction B) medial direction

4.2.4.2 Gait analysis

Qualisys motion analysis system (Qualisys, Gothenburg, Sweden) and two AMTI force platforms (AMTI BP400X600, AMTI, USA) were used to collect kinematic and kinetic data as per Chapter 3 section (4.2.3). Sixteen infrared cameras (Qualisys, Sweden) were used to capture the 3-dimensional positions of the retro-reflective markers that were attached to each subject's skin over bony landmarks in both lower limbs (on the 1st , 2nd, 5th metatarsal heads and Calcaneal tubercle), ankle (medial and lateral malleolus), knee (lateral and medial femoral condyle, tibial tuberosity and fibular head), thigh (greater trochanter) and pelvis(right and left anterior superior iliac spine (ASIS), right and left posterior superior iliac spine (PSIS), and right and left iliac crest). Fixed cluster pads

made of plastic (with four markers on each) were attached to the shank, thigh and pelvis to track their movements.

At the beginning of each test condition, body mass was obtained by asking the patient to stand over one of the force platforms, meanwhile a static 3D image could be obtained by the sixteen infra-red cameras. All subjects were asked to perform three tasks in two conditions in a randomised order:

Standing

The individual was asked to stand on a force platform for 10 seconds and a static 3-dimensional image from the sixteen infra-red cameras were obtained.

Walking

10 successful self-selected walks (clear foot contact with the force plates was regarded the acceptable trial) in each of the conditions performed. The participant scored the patient-perceived global change in pain and their personal rating of comfort recorded.

Stairs

Patients were asked to perform five trials of three step stairs ascent and descent at a self-selected speed starting every trial with the affected side at first step of stairs during climb up in step-over-step manner (Figure 4-2) and also starting every trial with the affected side during climb down in step-over-step manner without using the handrails. A handrail was installed to both sides of the stairs to prevent the patient from falling off at any time ascending or descending the stairs.
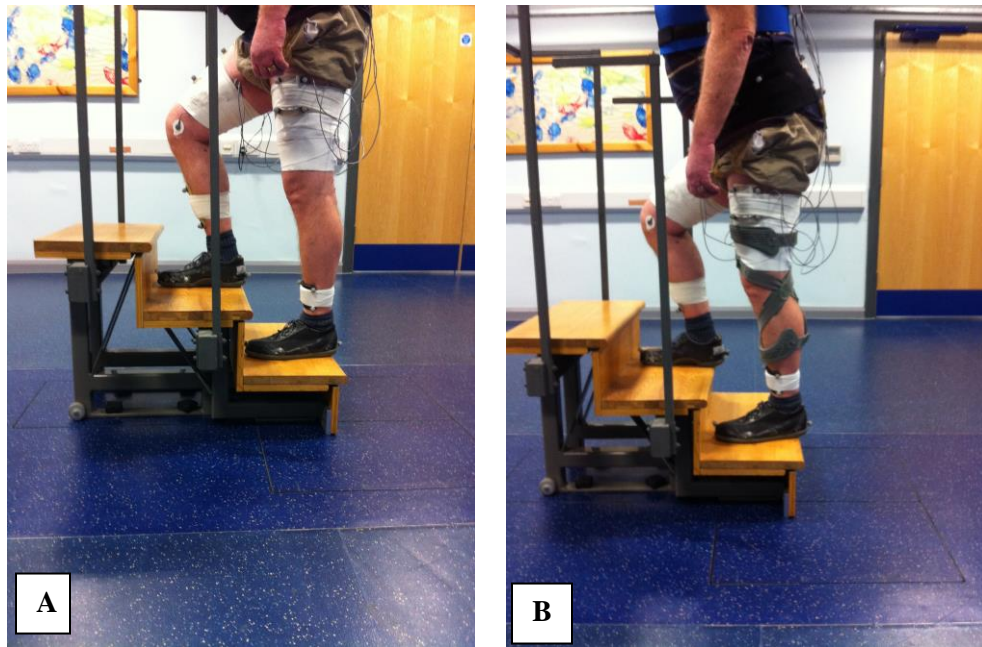
Figure 4-2: Forward step-over-step stair (A) without brace (b) with brace.

All above three tasks were performed in shod condition with and without the valgus knee brace in place. The retro reflective markers and clusters were removed when the subject came to the assessment of the muscle strength/function.

Two test conditions were tested:

1.   Standard control shoe – This provided a baseline dataset for the footwear conditions.

2.   Standard control shoe with a valgus knee brace – Standard shoes and a valgus knee brace.

4.2.4.3 EMG measurement

To measure the muscle activity with EMG (Surface electromyography (EMG) data were collected using a Noraxon Telemyo system (www.noraxon.com) at a sampling rate of 3000Hz (Figure 4-3). The ground electrode was placed on the patella and EMG electrodes were placed parallel to muscle fibres on both legs: over the muscle belly of biceps femoris (at 50% on the line between the ischial tuberosity and the lateral epicondyle of the tibia) and semitendenosis (at 50% on the line between the ischial tuberosity and the medial epicondyle of the tibia) muscles whilst the participants were lying on their front and then

over the muscle belly of vastuslateralis (at 2/3 on the line from ASIS to the lateral side of the patella) and vastusmedialis (at 80% on the line between ASIS and the joint space in front of the anterior border of the medial ligament) whilst lying on their back. The location of each electrode was determined using SENIAM (Surface Electromyography for the Non-Invasive Assessment of Muscles) Guidelines (http://www.seniam.org/). The area was shaved (2-3 cm), wiped with alcohol and rubbed with hypo-allergenic gel to decrease skin impedance and improve EMG signal quality. Then a disposable self-adhesive electrode was placed on the skin in the direction of muscle fibres.

Figure 4-3: Noraxon Telemyo system

Muscle activity profiles were used to determine any changes in the contraction of the muscles whilst using and not using the valgus knee brace. EMG data of each walking, ascending and descending trial were synchronised with the gait data. The EMG data from the muscles (Vastus lateralis, Biceps femoris, Vastus medialis and Semitendinosus) during these activities were analysed a raw signals in Visual3D. The data were filtered using a Butterworth 4th order bi-directional filter with a cutoff point of 50Hz and a moving root mean squared (RMS) algorithm was used to produce a linear envelope. The corresponding muscle activity during the MVIC was also analysed in the same manner. Each set of data from each muscle, and each activity, were exported as a text file to Microsoft Excel 2010 (Microsoft, Washington, USA).The mean average of each maximum muscle activity of five trials was taken and normalising this maximum to the corresponding MVIC. Muscle co-contraction was assessed between the antagonist and agonist muscle and assessed

using the equation from Rudolph et al. (2000) EMGS/EMGL*(EMGS+EMGL) where EMGS is the EMG activity level of the least active muscle between the two antagonists and EMGL is the EMG activity level of the more active muscle between the two antagonists (Rudolph et al., 2000).

4.2.4.4 Muscle function procedures

Maximum voluntary isometric contraction (MVIC) of the biceps femoris, semitendenosis, vastuslateralis and vastusmedialis muscles was measured using the Biodexisominetic dynamometer (Biodex Medical System, Shirley, N.Y., USA) (Figure 4-4). Muscle activity during MVIC was assessed to increase the reliability of the recorded EMG data during the walking trials by normalising it to the activity during MVIC as a reference point. The participant was sitting on the dynamometer chair with straps around his/her chest and waist to avoid any compensatory movement from other muscles. The Biodex arm was set to 45 degrees as this was the range at which the knee muscles gave their maximum force. For this assessment, the patients were asked to bend his/her knee with as much force as (s) he could against the Biodex arm (which will not move) and muscle activity of the biceps femoris and semitendenosis muscles were recorded. Three trials each lasted for 5 seconds was done with 10 seconds rest in between. Then, the participant was asked to straighten the knee with as much force as (s) he can against the Biodex arm and muscle activity of vastusmedialis and vastuslateralis were recorded. Three trials each lasting for 5 seconds were done with 20 seconds rest in between. This was done on affected side, then the EMG electrodes were removed and the participant allowed to rest. The strength of the knee flexors and extensors were assessed on the affected side using the Biodex isokinetic dynamometer. This involved assessing the strength of concentric contractions at 60°/s. Before testing, the procedure was explained followed by a practice trial. Flexion and extension strength were tested 5 times.

Figure 4-4: Biodex Medical System

This whole testing session took approximately 2.5 hours to complete. After the tests were completed at the baseline session, the individual was given the study treatment and shown how to fit this correctly.

4.2.5 Treatments:

All participants were fitted and shown how to fit with the UnloaderOne (Ossur, Iceland) valgus knee brace. This brace is very light and easy to use and cannot be easily seen when wearing loose pants. These are important aspects to ensure adherence to the brace. All participants had their thigh and calf girth measured to ensure the correct brace was given to them. The brace was worn daily for at least four hours per day for a maximum time of 3 months.

4.2.6 Outcome measurements:

4.2.6.1 Primary Outcomes measures:

External knee adduction moment:

The change in external knee adduction moment during the trials was recorded for both conditions to allow the investigators to determine the change in this measure. All sections of the knee adduction moment curve (different peaks) and also the knee adduction angular impulse (the area under the curve) were assessed for differences between conditions at

stance phase during walking and ascending and descending stairs. The EKAM and KAAI are an important data because they cover the first hypothesis of this study:

Hypothesis 1a: Medial knee loading is reduced with valgus knee brace and it is reduced more after 3 months of use than immediately.

Hypothesis 1b: In brace users, medial knee loading is reduced after 3 months of use, even with the brace not worn.

Patient-perceived global change in pain:

The KOOS questionnaire were recorded at three time points to allow different pain symptoms, activity daily living (ADL), sport/recreational and Quality of Life (QOL) scores to be collected to determine any changes in these measurements. All variables were enter in excel spread sheet from KOSS, all data were calculated in this sheet automatically. The score from 0-100 for each one of the KOSS variables, where the 100 score showed excellent result. A repeated measurement analysis of variance (ANOVA) was used to find out the effect of wearing valgus knee brace on these variables at six weeks and three months in comparing to baseline.

Dynamic balance:

A modified Star Excursion Balance Test (SEBT) was used to assess dynamic balance. Anterior (A) and medial (M) directions were assessed at base line, six weeks and three months without valgus knee brace. Descriptive data (mean, SD) were calculated for excursion distances after taking the average of three trials for each patient in the A, and M directions on the three sessions. P-value was calculated by using a repeated measurement ANOVA after taking the average of each patient in each direction (A and M) to find out the effect of wearing valgus knee brace on the balance at six weeks and three months in comparing to baseline.

Muscle function

Peak torque in the flexors and extensors muscles were measured at baseline, six weeks and 3 months without valgus knee brace to determine any changes in muscle strength during the wearing valgus knee brace. P-value was calculated by using a repeated

measurement ANOVA after taking the average of the flexors and extensors muscles in concentric contractions at 60°/s and in isometric contraction at 45°/s to find out the effect of wearing valgus knee brace on the flexors and extensors muscles at six weeks and three months in comparing to baseline.

Muscle co-contraction:

The average co-contraction between VL-BF and VM-ST was assessed unilaterally in early-stance (0-33), mid-stance (34-67), and late-stance (68-100) during walking and in single limb support during stairs ascent and descent.

4.2.6.2 Secondary Outcome measures:

Gait characteristics:

Kinematic and kinetic data (GRF, sagittal knee moment) of the knee on the affected and Kinematics and kinetics data (EKAM, KAAI, GRF, sagittal knee moment) of the knee on the contralateral leg in the coronal and sagittal planes and temporo-spatial parameters were assessed. Additionally, kinematic data of the hip and ankle on the affected and contralateral leg in sagittal planes were assessed.

Determination of gait events and outcome measures

All kinetic and kinematic parameters were based on the mean of the maximum/minimum peak values across the trials for each condition and for each subject. The contralateral leg was assessed to find out any effect of the valgus knee brace on the contralateral leg over a period of three months in comparing to base line.

In studying the results from the two sessions, normalised stance phase was divided into two sub phases, which are initial (0-33%) and late (68%-100%) which are termed first peak and second peak of EKAM the contralateral leg during walking and ascending, and descending stairs.

GRF was assessed on the affected leg and contralateral leg after normalised data in early-stance (0-33%), mid-stance (34%-67%), and late-stance (68%-100%) during walking and stairs ascent and descent.

In studying the results from the two sessions of sagittal knee angle, normalised gait cycle was divided into four sub phases, which are initial contact, loading response (2%-21%), mid stance (22%-61%) and mid swing (62-101%) during walking and ascending, and descending stairs.

All other kinetic parameters in stance phase and kinematic parameters in gait cycle were assessed based on the mean of the maximum/minimum peak values.

4.2.7 Data analysis:

Data were reviewed before analysis to determine whether the distribution was normal for all variables. The Kolmogorov-Smirnov test of normality found the speed data to be normally distributed. A normality test using the Shaprio-Wilk test exhibited that the majority of the data tested in this study were normally distributed. Other data that are non-normally distributed were not highly deviated. Because of this and the repeated measure ANOVA which is used in this study is not significantly sensitive to moderate deviations from normality (Glass et al., 1972, Harwell et al., 1992, Lix et al., 1996); parametric tests were chosen to perform statistical analysis. A repeated measures analysis of variance (ANOVA) was used to test between the four conditions in the primary outcome measures. A bonferroni correction was applied to reduce the chance of a type 1 error. This was then followed by a paired t-test to asked specific question in regards to specific time point (Shod baseline-Brace three months, Shod baseline - Shod three months) between the two testing sessions.

The first hypothesis states that the valgus knee brace intervention would reduce the medial joint loading after a period of 3 months. In order to test this hypothesis, the change in the first peak and second peak of the external knee adduction moment in stance phase and the KAAI during walking and stair ascent and descent was determined. The comparison was made between the results collected from the braced and unbraced condition at baseline, and 3 months with apaired-sample T-Test to investigate whether differences in any type of conditions were statistically significant. The second hypothesis states that the valgus knee brace intervention reduces pain after a period of six weeks and 3 months. In order to test this hypothesis, the change in pain in the KOOS was determined in compared to baseline.

This was compared at baseline, six weeks and 3 months. A repeated measurement analysis of variance statistical test was undertaken to investigate whether differences in pain scale was statistically significant in comparing to baseline. In the third hypothesis, the effect of valgus brace on quadriceps muscle strength was investigated, which has been shown to be an important correlate of locomotor function in patients with osteoarthritis of the knee (Hurley, 1999, McCarthy and Oldham, 2004). Therefore, a repeated measurement analysis of variance was performed on the knee flexors and extensors peak comparing baseline with six weeks and 3 months after the knee flexor and extensor peak were assessed in concentric at 60°/s and in isometric at 45°/s. The fourth hypothesis states that the valgus knee brace intervention will reduce muscle co-contraction after a period of 3 months. A paired-sample T Test was used to investigate whether differences in any of the muscles group were statistically significant after wearing valgus knee brace over a period of three months in comparing to base line.

All kinematics and kinetic data in the coronal and sagittal planes and temporo-spatial parameters (Secondary outcomes measurement of the affected leg and the contralateral leg) were analysed based on the mean of the maximum/minimum peak values across the trials for each condition and for each subject, so that Paired-sample T Test and repeated measures ANOVA tests were done on all other outcome measurements depending on the number of sessions the data was collected for. GRF, sagittal plane knee moment and frontal knee angle are important variables, all these variables can affect the EKAM and that an increase in sagittal plane knee moment could increase medial joint loading (Walter et al., 2010) so this is also presented for completeness.

4.3 Results

Fifteen patients with knee OA participated in the study; five women and ten men (mean age 55(SD 10.63) years; age range 44-77 years; mean height 169 (SD 0.10) cm; height range 153-182 cm; mean mass 86.73(SD 19.55) Kg; mass range 57-140 Kg; mean body mass index (BMI) 29.90 (SD 4.27) kg/m2. Nine individuals diagnosed with grade 2 KL and six individuals with grade 3 KL.

The following results will be presented in terms of the primary outcome measures first and any data that helps to explain these outcomes. These are followed by the secondary outcome measures.

4.3.1 The kinetic results of the affected leg during walking

4.3.1.1 The external knee adduction moment (EKAM)

After wearing the brace for three months, there was no significant change (mean difference 0.02 Nm/kg, p=0.29) in the first peak of the EKAM in comparison to the shoe only at baseline, even though an average decrease of 5.03 % was found. Additionally, after wearing the brace for three months, there was no significant change (mean difference 0.01 Nm/kg, p=0.60) in the first peak of the EKAM in comparison to the brace baseline, even though an average decrease of 2.67% was found. In addition, after wearing the brace for three months, there was no significant change (mean difference 0.02 Nm/kg, p=0.44) in the first peak of the EKAM between the shoe only at baseline and at three months, even though an average decrease of 4.49% was found.

After wearing the brace for three months, there was no significant change (mean difference 0.02 Nm/kg, p=0.68) in the second peak of the EKAM in comparison to the shoe only at baseline, even though an average decrease of 3.81% was found. Additionally, after wearing the brace for three months, there was no significant change (mean difference 0.02 Nm/kg, p=0.65) in the second peak of the EKAM in comparison to the brace baseline, even though an average decrease of 3.54% was found. In addition, after wearing the brace for three months, there was no significant change (mean difference 0.04 Nm/kg, p=0.32) in the second peak of the EKAM between the shoe only at baseline and three months, even though an average decrease of 9.4% was found. Descriptive data of EKAM results during walking are illustrated in figure 4-5 and table 4-1.
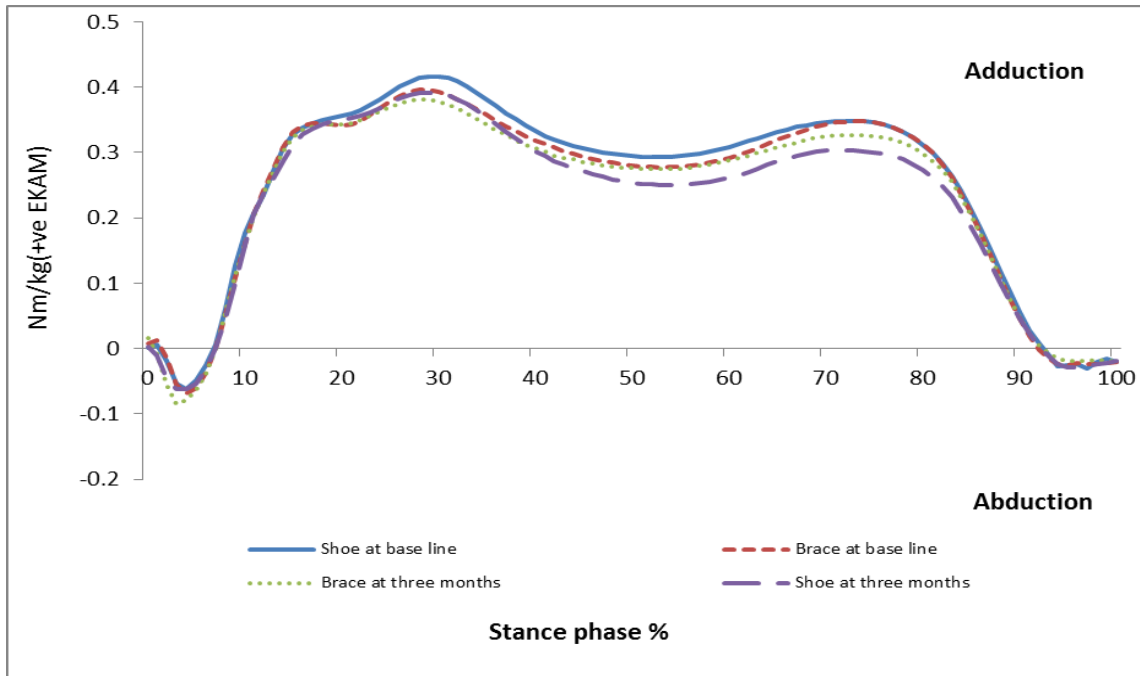
Figure 4-5: The external knee adduction moment (EKAM) of four conditions during walking.

Table 4-1: Mean (SD) first and second peak of the EKAM during walking.

Type	Shoe at Baseline	Brace Baseline	Brace at Three Months	Shoe at Three Months
EKAM 1 Mean (SD) (Nm/kg)	0. 44 (0.15)	0.43(0.15)	0.42(0.16)	0.42(0.18)
EKAM 2 Mean (SD) (Nm/kg)	0.37 (0.14)	0.37(0.12)	0.35(0.20)	0.33 (0.20)

4.3.1.2 The Knee adduction angular impulse (KAAI):

After wearing the brace for three months, there was no significant change (mean difference 0.02 Nm/kg*s, p=0.09) in the KAAI in comparison to the shoe only at baseline, even though an average decrease of 13.26 % was found. Additionally, after wearing the brace for three months, there was no significant change (mean difference 0.02 Nm/kg*s, p=0.14) in the KAAI in comparison to the brace baseline, even though an average decrease of 12.48% was found. In addition, after wearing the brace for three months, there was no significant change (mean difference 0.02Nm/kg*s, p=0.06) in the KAAI between the shoe only at baseline and three months, even though an average decrease of 13.14% was found. Descriptive data of KAAI results during walking are illustrated in figure 4-6 and table 4-2.

Table 4-2: Mean (SD) knee adduction angular impulse (KAAI) during walking.

Type	Shoe Baseline	Brace Baseline	Brace Three Months	Shoe Three Months
KAAI Mean (SD)(Nm/kg)*s	0.14(0.08)	0.14(0.09)	0.12(0.09)	0.12(0.08)
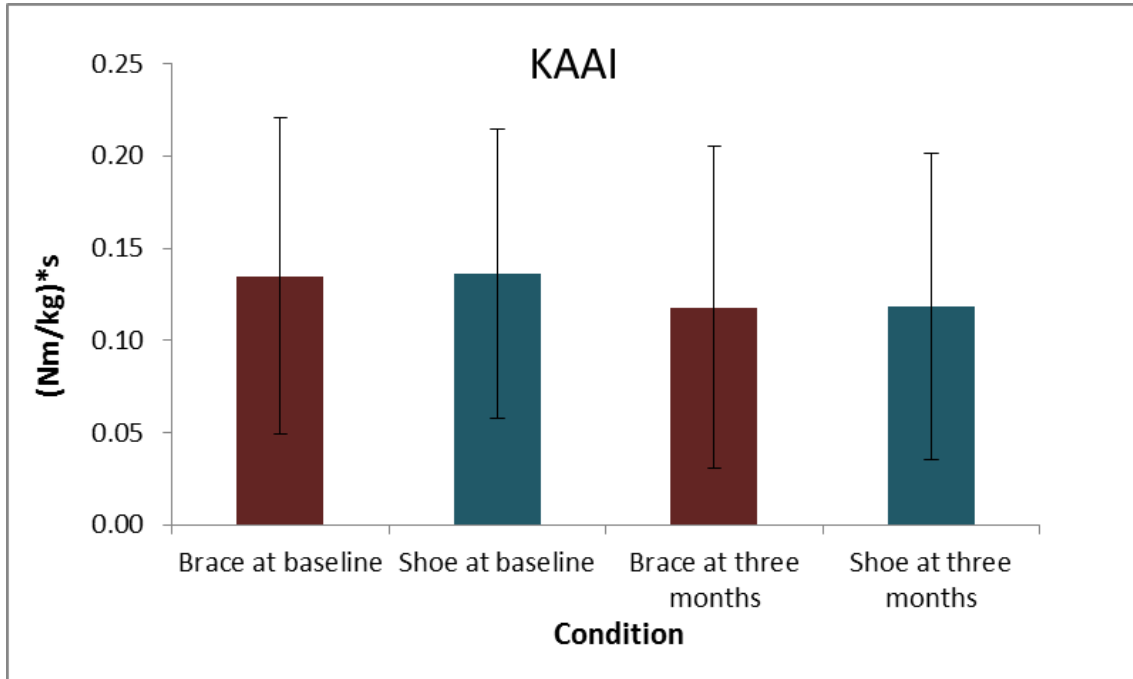
Figure 4-6: Knee adduction angular impulse (KAAI) of four conditions during walking.

4.3.1.3 The Knee moment (sagittal plane):

After wearing the brace for three months, there was no significant change (mean difference 0.09 Nm/kg, p=0.14) in the maximum knee flexor moment in comparison to the shoe only at baseline, even though an average increase of 10.8 % was found. Additionally, after wearing the brace for three months, there was no significant change (mean difference 0.06 Nm/kg, p=0.32) in the maximum knee flexor moment in comparison to the brace baseline, even though an average increase of 7.33% was found. In addition, after wearing the brace for three months, there was no significant change (mean difference 0.07 Nm/kg, p=0.25) in the maximum knee flexor moment between the shoe only at baseline and at three months, even though an average increase of 8.57% was found.

After wearing the brace for three months, there was no significant change (mean difference 0.03Nm/kg, p=0.27) in the maximum knee extensor moment in comparison to the shoe only at baseline, even though an average decrease of 10.93% was found. Additionally, after wearing the brace for three months, there was no significant change (mean difference 0.01 Nm/kg, p=0.88) in the maximum knee extensor moment in comparison to the brace baseline, even though an average increase of 1.41% was found. In addition, after wearing the brace for three months, there was no significant change (mean difference 0.04 Nm/kg, p=0.25) in the maximum knee extensor moment between the shoe only at baseline and at three months, even though an average decrease of 12.65% was found. Descriptive data of Sagittal plane knee moment results during walking are illustrated in figure 4-7 and table 4-3.
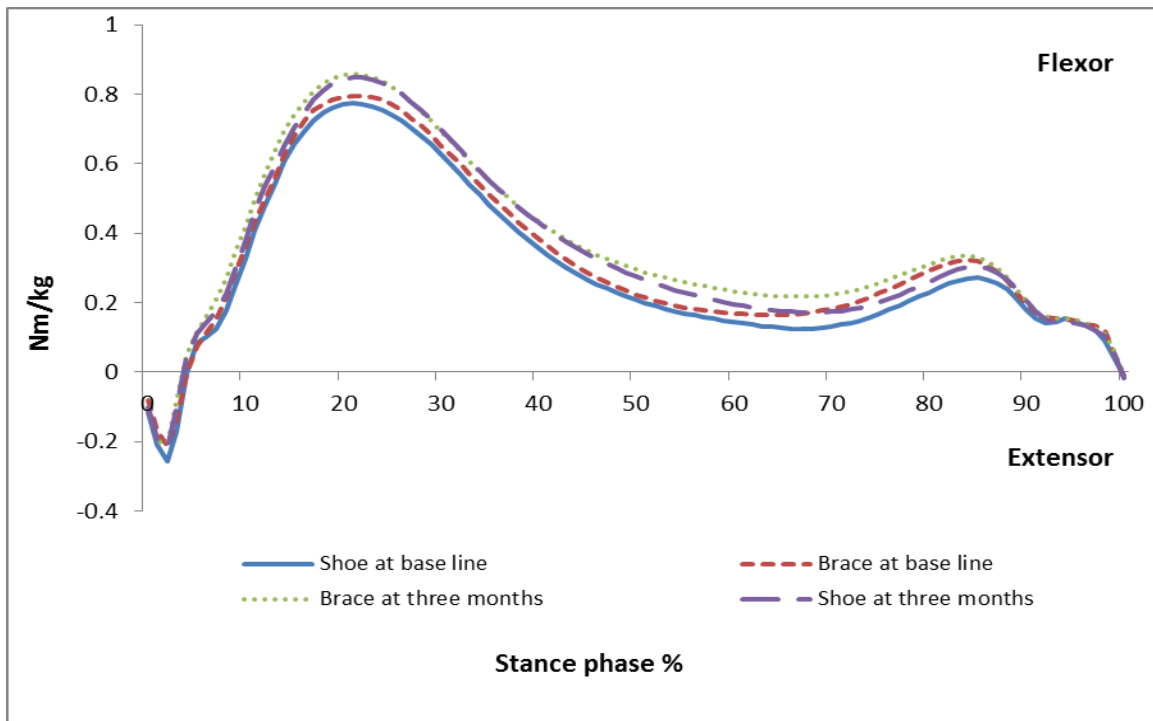
Figure 4-7: Sagittal plane knee moment of the four conditions during walking.

Table 4-3: Mean (SD) sagittal plane knee moment during walking.

Type	Shoe Baseline	Brace Baseline	Brace Three Months	Shoe Three Months
Knee flexion Mom Mean (SD) (Nm/kg)	0.80(0.2)	0.83(0.2)	0.89(0.2)	0.87(0.2)
Knee extension Mom Mean (SD) (Nm/kg)	-0.29(0.1)	-0.25(0.1)	-0.26(0.1)	-0.25(0.1)

4.3.1.4 Vertical Ground Reaction Force (GRF)

The Vertical Ground Reaction Force (GRF) did not change significantly (p>0.05) in early, mid-, and late stance phase during walking. Descriptive data of GRF results during walking are illustrated in figure 4-8 and table 4-4.
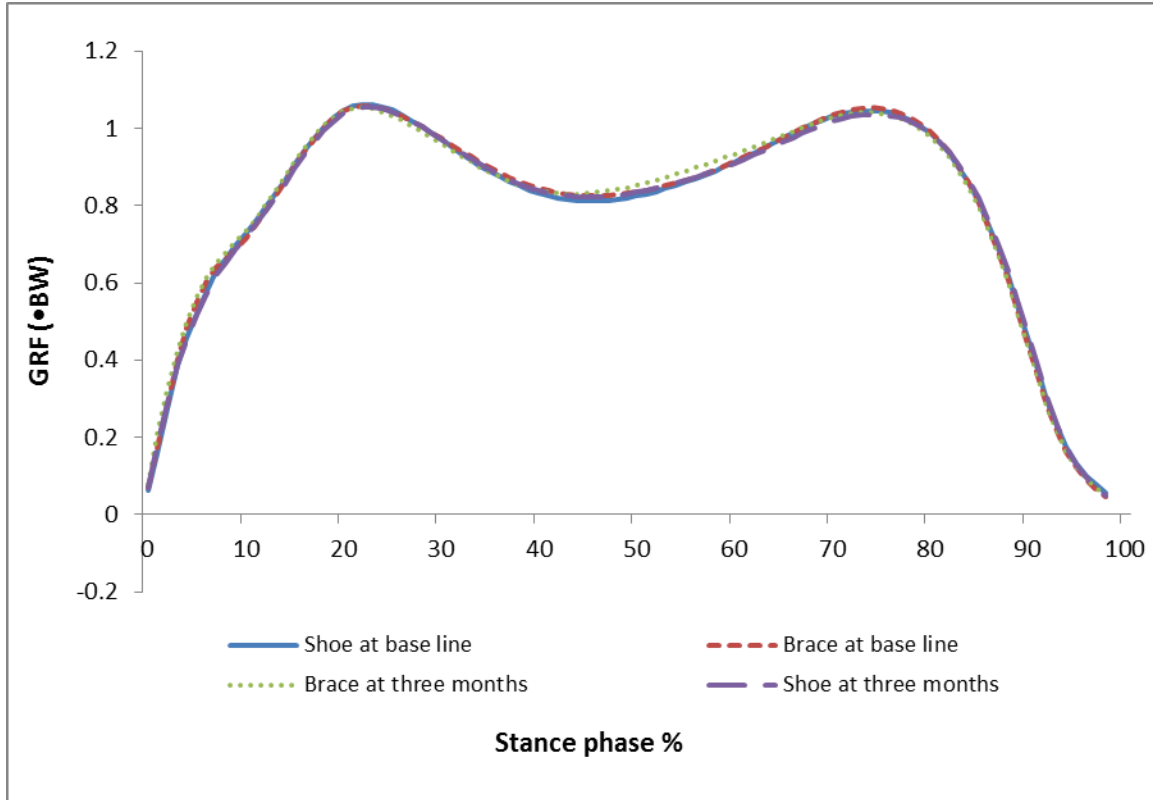
Figure 4-8: The ground reaction force (GRF) of the four conditions during walking.

Table 4-4: Mean (SD) ground reaction force (GRF) during walking.

Type	Shoe Baseline	Brace Baseline	Brace Three Months	Shoe Three Months
Early stance GRF Mean (SD)(•BW)	1.08(0.10)	1.08(0.10)	1.07(0.10)	1.07(0.10)
Mid stance GRF Mean (SD)(•BW)	0.81(0.08)	0.82(0.08)	0.82(0.07)	0.81(0.08)
Late stance GRF Mean (SD)(•BW)	1.05(0.06)	1.06(0.07)	1.04(0.06)	1.04(0.07)

4.3.2 The kinetic results of the affected leg during ascending stairs

4.3.2.1 The external knee adduction moment (EKAM)

After wearing the brace for three months, there was no significant change (mean difference 0.01 Nm/kg, p=0.90) in the first peak of the EKAM in comparison to the shoe only at baseline, even though an average decrease of 1 % was found. Additionally, after

92

wearing the brace for three months, there was no significant change (mean difference 0.01 Nm/kg, p=0.61) in the first peak of the EKAM in comparison to the brace baseline, even though an average increase of 5.40% was found. In addition, after wearing the brace for three months, there was no significant change (mean difference 0.03 Nm/kg, p=0.12) in the first peak of the EKAM between the shoe only at baseline and at three months, even though an average increase of 10.14% was found.

After wearing the brace for three months, there was no significant change (mean difference 0.01 Nm/kg, p=0.93) in the second peak of the EKAM in comparison to the shoe only at baseline, even though an average decrease of 0.67% was found. Additionally, after wearing the brace for three months, there was no significant change (mean difference 0 Nm/kg, p=1) in the second peak of the EKAM in comparison to the brace baseline, even though an average decrease of 0.03% was found. In addition, after wearing the brace for three months, there was no significant change (mean difference 0.05 Nm/kg, p=0.35) in the second peak of the EKAM between the shoe only at baseline and three months, even though an average increase of 6.96% was found. Descriptive data of EKAM results during ascending are illustrated in figure 4-9 and table 4-5.

Figure 4-9: The external knee adduction moment (EKAM) of the four conditions during Ascent.

Table 4-5: Mean (SD) first and second peak of the EKAM during ascent.

Type	Shoe Baseline	Brace Baseline	Brace Three Months	Shoe Three Months
EKAM 1 Mean (SD) (Nm/kg)	0.32(0.28)	0.30(0.26)	0.31 (0.27)	0.35(0.27)
EKAM 2 Mean (SD) (Nm/kg)	0.70(0.43)	0.69 (0.41)	0.69 (0.43)	0.75(0.45)

4.3.2.2 The Knee adduction angular impulse (KAAI):

After wearing the brace for three months, there was no significant change (mean difference 0.10 Nm/kg*s, p=0.06) in the KAAI in comparison to the shoe only at baseline, even though an average decrease of 23.68 % was found. Additionally, after wearing the brace for three months, there was no significant change (mean difference 0.04 Nm/kg*s, p=0.44) in the KAAI in comparison to the brace baseline, even though an average decrease of 9.61% was found. In addition, after wearing the brace for three months, there was no significant change (mean difference 0.02 Nm/kg*s, p=0.44) in the KAAI between the shoe only at baseline and three months, even though an average decrease of 6.05% was found. Descriptive data of KAAI results during ascending are illustrated in figure 4-10 and table 4-6.

Table 4-6: Mean, (SD±) knee adduction angular impulse (KAAI) during ascent.

Type	Shoe Baseline	Brace Baseline	Brace Three Months	Shoe Three Months
KAAI Mean (SD) (Nm/kg)*s	0.43 (0.34)	0.37(0.29)	0.33(0.23)	0.41(0.28)
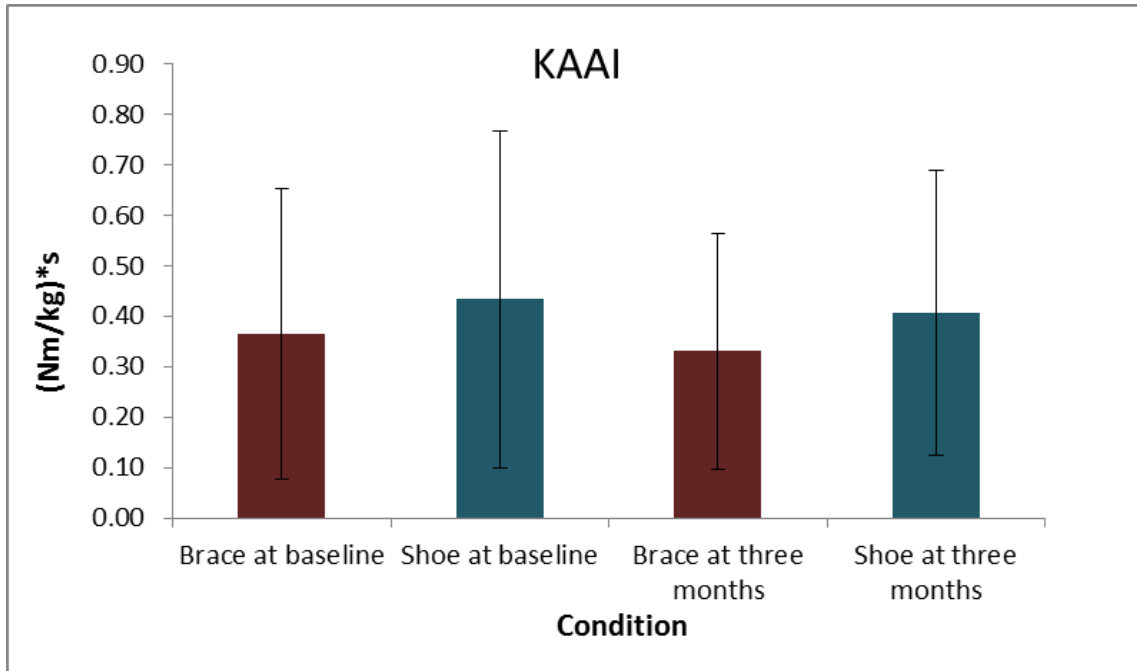
Figure 4-10: Knee adduction angular impulse (KAAI) of the four conditions during ascent.

4.3.2.3 The Knee moment (sagittal plane):

After wearing the brace for three months, there was a significant increase (mean difference 0.10 Nm/kg, p=0.01) in the maximum knee flexor moment in comparison to the shoe only at baseline, with an average increase of 12.88 % found. However, after wearing the brace for three months, there was no significant change (mean difference 0.06 Nm/kg, p=0.10) in the maximum knee flexor moment in comparison to the brace baseline, even though an average increase of 7.47% was found. Additionally, after wearing the brace for three months, there was no significant change (mean difference 0.05 Nm/kg, p=0.23) in the maximum knee flexor moment between the shoe only at baseline and at three months, even though an average increase of 5.85% was found.

After wearing the brace for three months, there was no significant change (mean difference 0.05Nm/kg, p=0.52) in the maximum knee extensor moment in comparison to

the shoe only at baseline, even though an average decrease of 10.93% was found. Additionally, after wearing the brace for three months, there was no significant change (mean difference 0.05 Nm/kg, p=0.49) in the maximum knee extensor moment in comparison to the brace baseline, even though an average decrease of 5.36% was found. In addition, after wearing the brace for three months, there was no significant change (mean difference 0 Nm/kg, p=0.99) in the maximum knee extensor moment between the shoe only at baseline and at three months, even though an average increase of 0.15% was found. Descriptive data of sagittal plane knee moment results during ascending are illustrated in figure 4-11 and table 4-7.
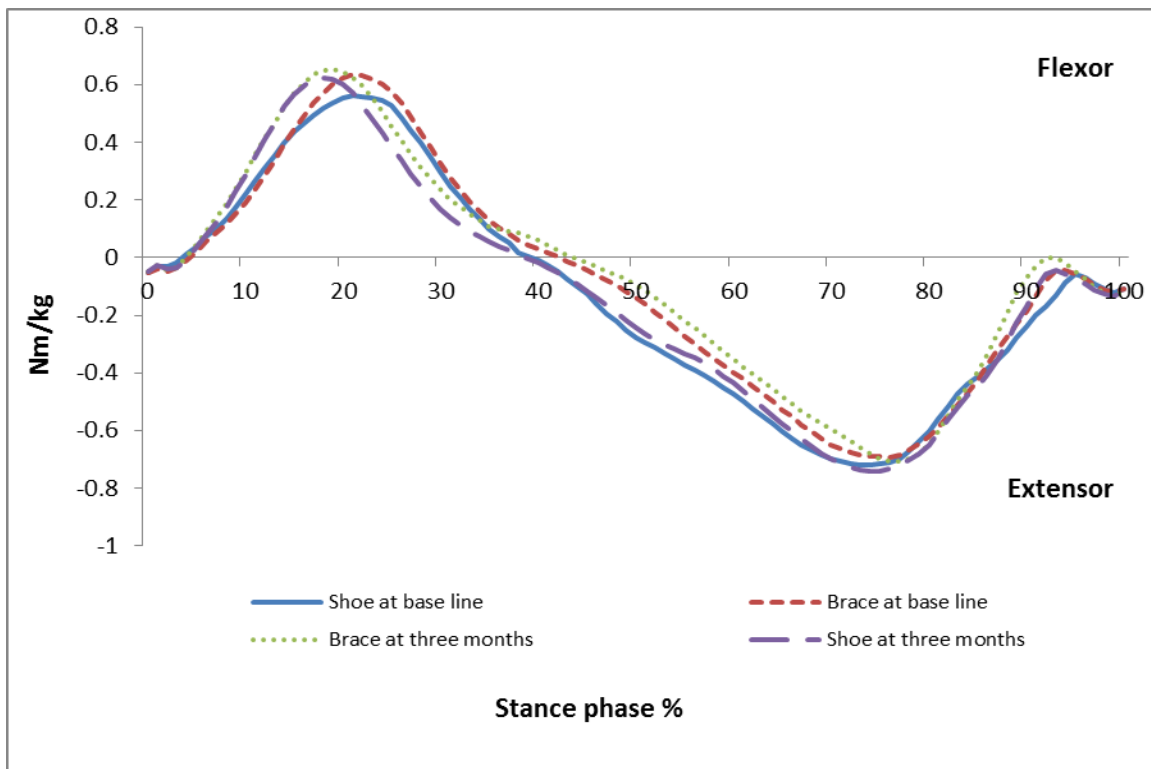
Figure 4-11: Sagittal plane knee moment of the four conditions during ascent.

Table 4-7: Mean (SD) sagittal plane knee moment during ascent.

Type	Shoe Baseline	Brace Baseline	Brace Three Months	Shoe Three Months
Knee flexion Mom Mean (SD) (Nm/kg)	0.81(0.21)	0.85(0.22)	0.91(0.24)	0.86(0.24)
Knee extension Mom Mean (SD) (Nm/kg)	-0.88(0.71)	-0.88(0.70)	-0.83(0.65)	-0.88(0.67)

4.3.2.4 Vertical Ground Reaction Force (GRF)

At the early stage, after wearing the brace for three months there was no significant change (mean difference 0.04 •BW, p=0.05) in the peak of GRF in comparison to the shoe only at baseline, even though an average increase of 4 % was found. Additionally, after wearing the brace for three months, there was no significant change (mean difference 0.01 •BW, p=0.84) in the peak of GRF in comparison to the brace baseline, even though an average increase of 0.2% was found. In addition, after wearing the brace for three months, there was no significant change (mean difference 0.01 •BW, p=0.20) in the peak of GRF between the shoe only at baseline and at three months, even though an average increase of 1.5% was found.

At mid stage, after wearing the brace for three months, there was no significant change (mean difference 0.00 •BW, p=0.68) in the peak of GRF in comparison to the shoe only at baseline, even though an average increase of 1.00 % was found. Additionally, after wearing the brace for three months, there was no significant change (mean difference 0.00 •BW, p=0.75) in the peak of GRF in comparison to the brace baseline, even though an average decrease of 0.3% was found. In addition, after wearing the brace for three months, there was no significant change (mean difference 0.00 •BW, p=0.65) in the peak of GRF between the shoe only at baseline and at three months, even though an average increase of 0.7% was found.

At late stage, after wearing the brace for three months, there was a significant increase (mean difference 0.03 •BW, p=0.03) in the peak of GRF in comparison to the shoe only at baseline, with an average increase of 2.9 % was found. However, after wearing the brace for three months, there was no significant change (mean difference 0.01 •BW, p=0.37) in the peak of GRF in comparison to the brace baseline, even though an average increase of 1.1% was found. Additionally, after wearing the brace for three months, there was no significant change (mean difference 0.02 •BW, p=0.11) in the peak of GRF between the shoe only at baseline and at three months, even though an average increase of 2.1% was found. Descriptive data of GRF results during ascending are illustrated in figure 4-12 and table 4-8.
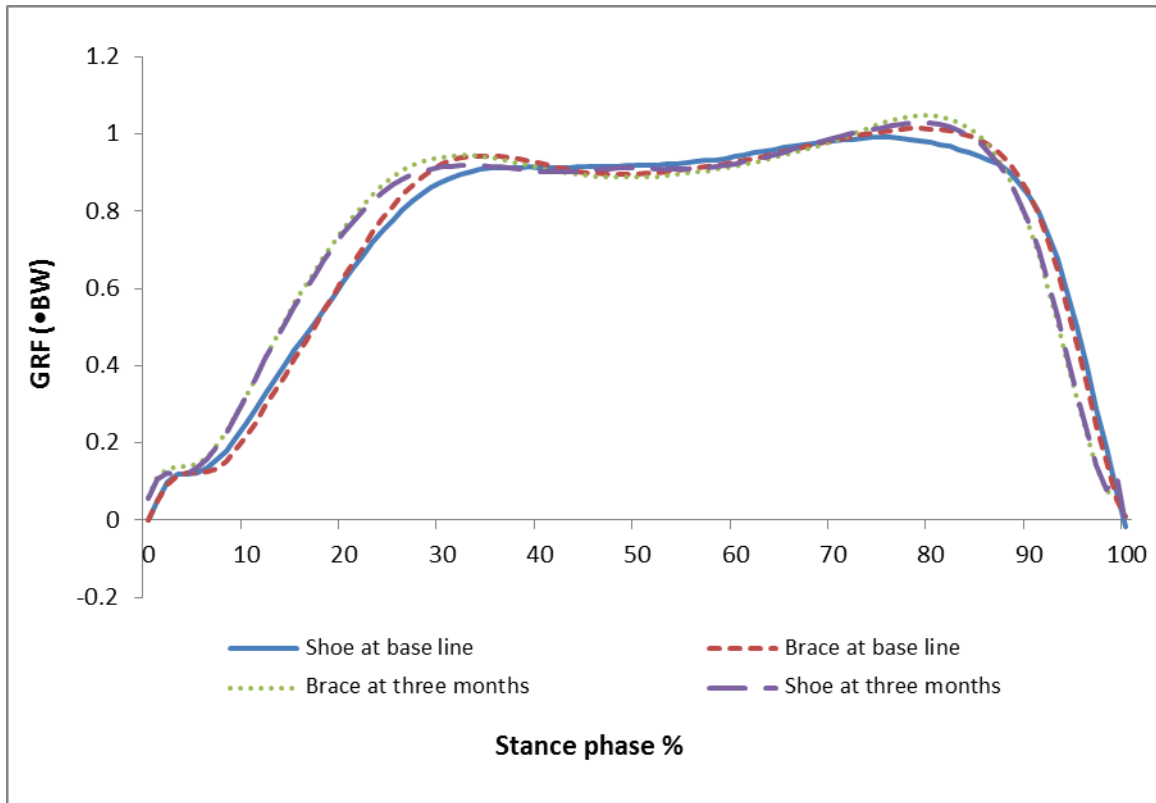
Figure 4-12: The Ground reaction force of the four conditions during Ascent.

Table 4-8: Mean (SD) Ground reaction force (GRF) during ascent.

Type	Shoe Baseline	Brace Baseline	Brace Three Months	Shoe Three Months
Early stance GRF Mean (SD)(•BW)	0.92(0.10)	0.95 (0.07)	0.96(0.07)	0.93(0.09)
Mid stance GRF Mean (SD)(•BW)	0.85(0.08)	0.85 (0.05)	0.85(0.05)	0.85(0.06)
Late stance GRF Mean (SD)(•BW)	1.04(0.03)	1.06(0.03)	1.07(0.04)	1.06(0.05)

4.3.3 The kinetic results of the affected leg during descending stairs

4.3.3.1 The external knee adduction moment (EKAM)

After wearing the brace for three months, there was no significant change (mean difference 0.14 Nm/kg, p=0.08) in the first peak of the EKAM in comparison to the shoe only at baseline, even though an average increase of 29.64% was found. Additionally, after wearing the brace for three months, there was no significant change (mean difference 0.10 Nm/kg, p=0.17) in the first peak of the EKAM in comparison to the brace baseline, even though an average increase of 18.41% was found. In addition, after wearing the brace for three months, there was no significant change (mean difference

0.16 Nm/kg, p=0.06) in the first peak of the EKAM between the shoe only at baseline and at three months, even though an average increase of 10.14% was found.

After wearing the brace for three months, there was no significant change (mean difference 0.04 Nm/kg, p=0.31) in the second peak of the EKAM in comparison to the shoe only at baseline, even though an average increase of 33.25% was found. Additionally, after wearing the brace for three months, there was no significant change (mean difference 0.04 Nm/kg, p=0.31) in the second peak of the EKAM in comparison to the brace baseline, even though an average increase of 33.31% was found. In addition, after wearing the brace for three months, there was no significant change (mean difference 0.04 Nm/kg, p=0.22) in the second peak of the EKAM between the shoe only at baseline and three months, even though an average increase of 32.92% was found. Descriptive data of EKAM results during descending are illustrated in figure 4-13 and table 4-9.
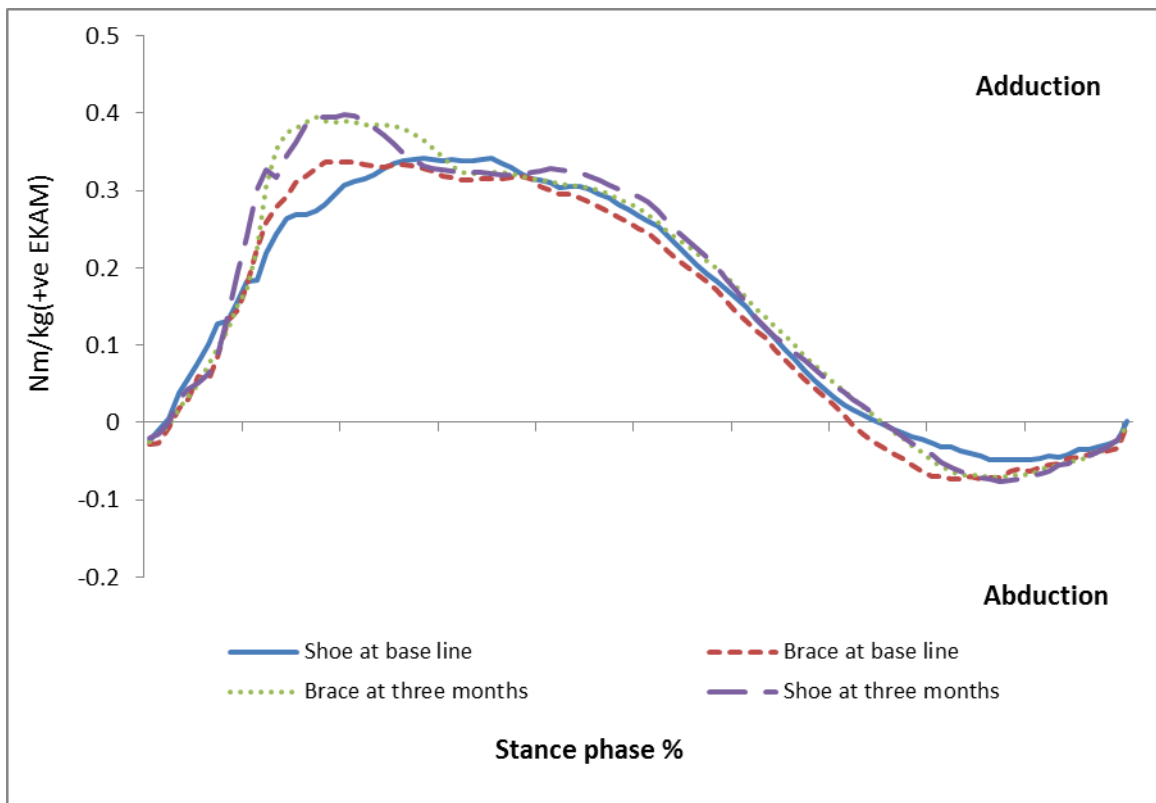
Figure 4-13: The external knee adduction moment (EKAM) of the four conditions during descent.

Table 4-9: Mean (SD) first and second peak of the EKAM during descent.

Type	Shoe Baseline	Brace Baseline	Brace Three Months	Shoe Three Months
EKAM 1 Mean (SD) (Nm/kg)	0.50 (0.22)	0.54(0.31)	0.64(0.46)	0.66(0.49)
EKAM 2 Mean (SD) (Nm/kg)	0.12 (0.12)	0.12 (0.13)	0.16 (0.21)	0.16 (0.18)

4.3.3.2 The Knee adduction angular impulse (KAAI):

After wearing the brace for three months, there was no significant change (mean difference 0.05 Nm/kg*s, p=0.15) in the KAAI in comparison to the shoe only at baseline, even though an average decrease of 17.35 % was found. Additionally, after wearing the brace for three months, there was no significant change (mean difference 0 Nm/kg*s, p=0.97) in the KAAI in comparison to the brace baseline, even though an average decrease of 0.53% was found. In addition, after wearing the brace for three months, there was no significant change (mean difference 0.02 Nm/kg*s, p=0.58) in the KAAI between the shoe only at baseline and three months, even though an average decrease of 6.34% was found. Descriptive data of KAAI results during descending are illustrated in figure 4-14 and table 4-10

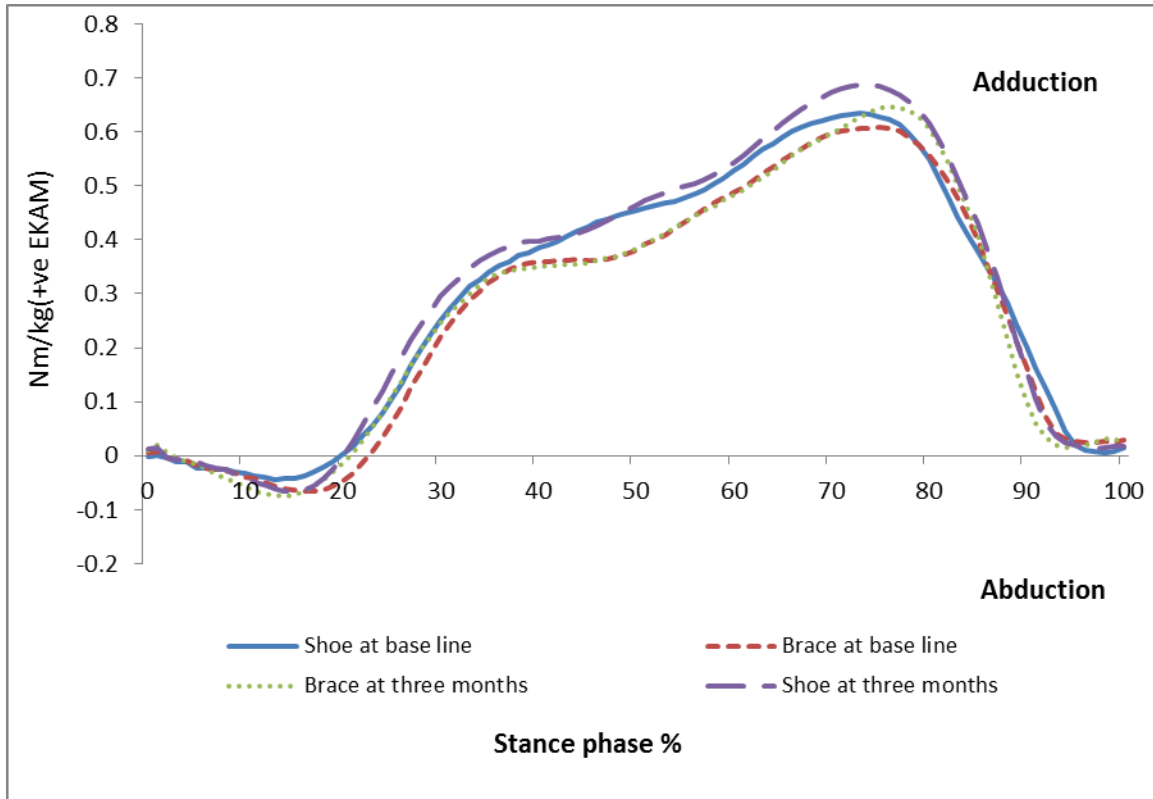Table 4-10: Mean (SD) knee adduction angular impulse (KAAI) during descent.

Type	Shoe Baseline	Brace Baseline	Brace Three Months	Shoe Three Months
KAAI Mean (SD) (Nm/kg)*s	0.26(0.16)	0.21 (0.15)	0.21 (0.19)	0.24 (0.20)
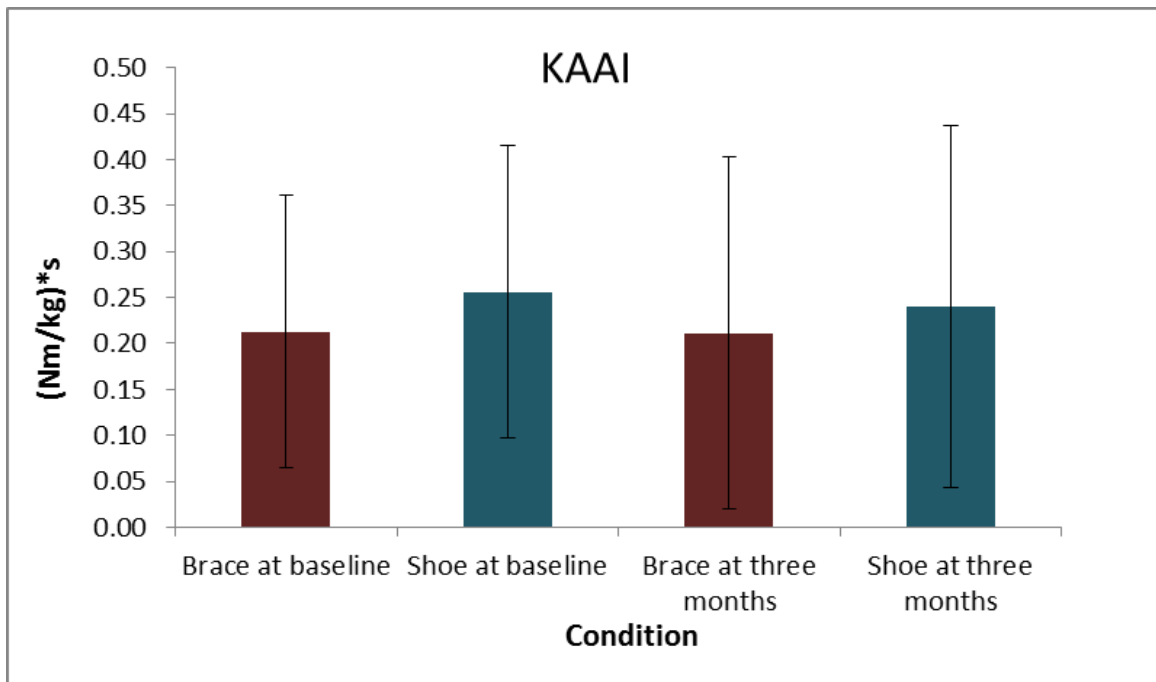
4.3.3.3 The Knee moment (sagittal plane):

After wearing the brace for three months, there was no significant change (mean difference 0.06 Nm/kg, p=0.22) in the maximum knee flexor moment in comparison to the shoe only at baseline, even though an average increase of 6.47 % was found. Additionally, after wearing the brace for three months, there was no significant change (mean difference 0.05 Nm/kg, p=0.36) in the maximum knee flexor moment in comparison to the brace baseline, even though an average increase of 4.75% was found. In addition, after wearing the brace for three months, there was no significant change (mean difference 0.07 Nm/kg, p=0.32) in the maximum knee flexor moment between the shoe only at baseline and at three months, even though an average increase of 8.24% was found.

After wearing the brace for three months, there was no significant change (mean difference 0.05Nm/kg, p=0.69) in the maximum knee extensor moment in comparison to the shoe only at baseline, even though an average increase of 19.75% was found. Additionally, after wearing the brace for three months, there was no significant change (mean difference 0.08 Nm/kg, p=0.32) in the maximum knee extensor moment in

comparison to the brace baseline, even though an average increase of 35.12% was found. In addition, after wearing the brace for three months, there was no significant change (mean difference 0.10 Nm/kg, p=0.57) in the maximum knee extensor moment between the shoe only at baseline and at three months, even though an average increase of 39.30% was found. Descriptive data of Sagittal plane knee moment results during descending are illustrated in figure 4-15 and table 4-11
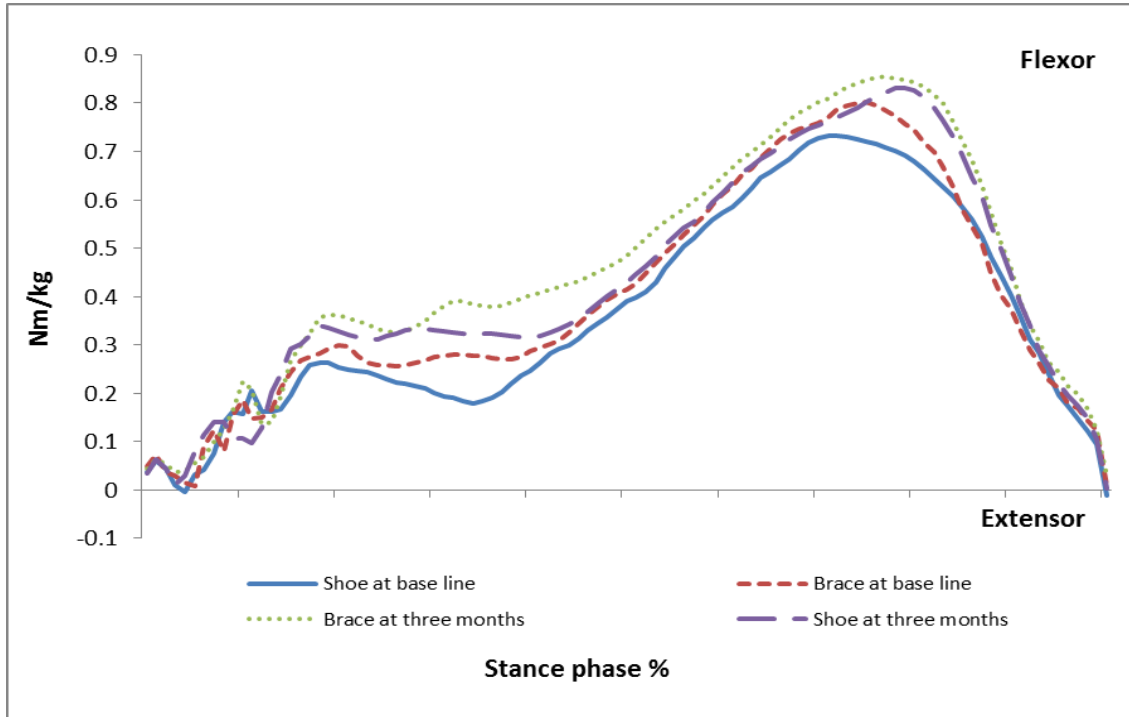
Figure 4-15: Sagittal plane knee moment of the four conditions during descent.

Table 4-11: Mean (SD) Sagittal plane knee moment during descent.

Type	Shoe Baseline	Brace Baseline	Brace Three Months	Shoe Three Months
Knee flexor mom. Mean (SD) (Nm/kg)	0.91(0.22)	0.92(0.22)	0.97(0.22)	0.98(0.26)
Knee extensor mom. Mean (SD) (Nm/kg)	-0.27(0.24)	-0.24(0.25)	-0.32(0.39)	-0.37(0.55)

4.3.3.4 Vertical Ground Reaction Force (GRF)

At the early stage of stance phase, after wearing the brace for three months, there was a significant increase (mean difference 0.12 •BW, p=0.00) in the peak of GRF in comparison to the shoe only at baseline, with an average increase of 10.7 % was found.

Additionally, after wearing the brace for three months, there was a significant increase (mean difference 0.08 •BW, p=0.00) in the peak of GRF in comparison to the brace baseline, with an average increase of 6.8% was found. In addition, after wearing the brace for three months, there was a significant increase (mean difference 0.12 •BW, p=0.00) in the peak of GRF between the shoe only at baseline and at three months, with an average increase of 11.2% was found.

At mid stage, the Vertical Ground Reaction Force (GRF) did not change significantly (p>0.05) during descent.

At late stage, after wearing the brace for three months, there was a significant increase (mean difference 0.05 •BW, p=0.03) in the peak of GRF in comparison to the shoe only at baseline, with an average increase of 5.7 % was found. However, after wearing the brace for three months, there was no significant change (mean difference 0.01 •BW, p=0.19) in the peak of GRF in comparison to the brace baseline, even though an average increase of 1.4% was found. Additionally, after wearing the brace for three months, there was no significant change (mean difference 0.03 •BW, p=0.10) in the peak of GRF between the shoe only at baseline and at three months, even though an average increase of 3% was found. Descriptive data of GRF results during descending are illustrated in figure 4-16 and table 4-12.
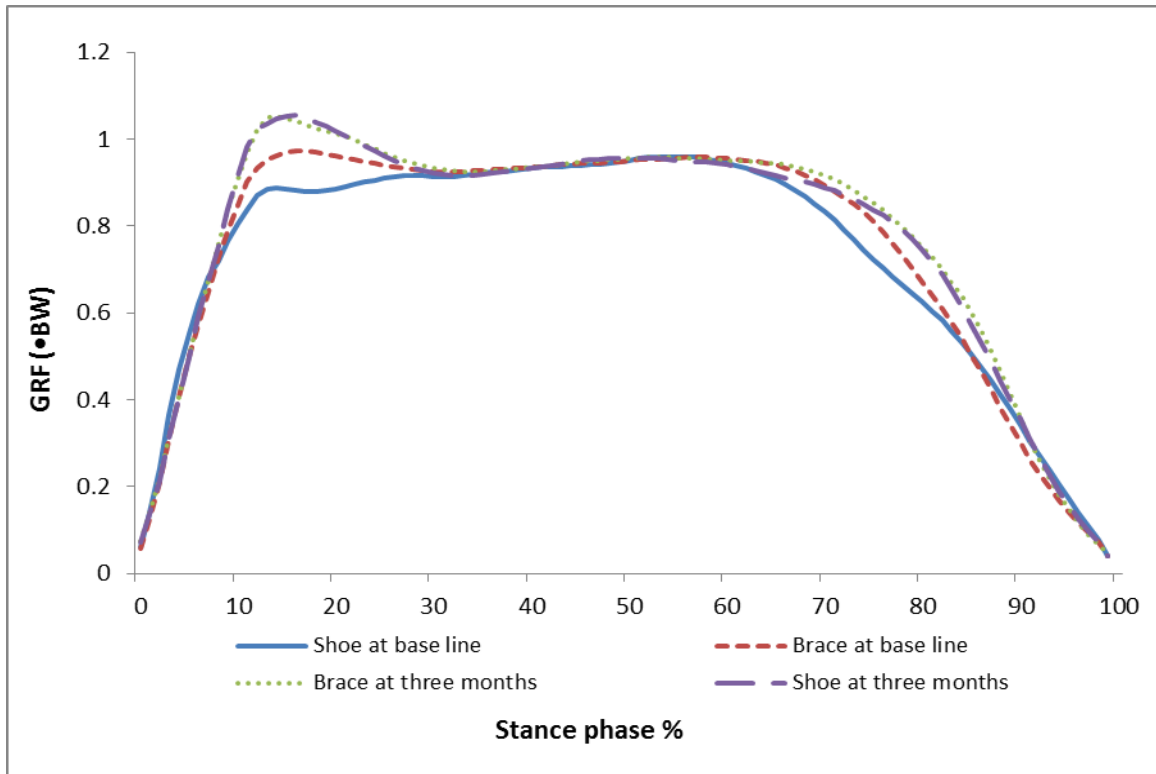
Figure 4-16: The Ground reaction force (GRF) of the four conditions during descent.

Table 4-12: Mean (SD) Ground reaction force (GRF) during descent.

Type	Shoe Baseline	Brace Baseline	Brace Three Months	Shoe Three Months
Early stance GRF Mean (SD)(•BW)	1.10(0.18)	1.14 (0.17)	1.22(0.16)	1.22(0.17)
Mid stance GRF Mean (SD)(•BW)	0.86(0.05)	0.88 (0.03)	0.88(0.04)	0.87(0.05)
Late stance GRF Mean (SD)(•BW)	0.90(0.09)	0.93(0.04)	0.95(0.05)	0.92(0.06)

4.3.4 Knee injury and Osteoarthritis Outcome Score (KOOS):

The effect of valgus knee brace on reducing the pain based on the KOOS pain subscale was clear with a 58.54% reduction at six weeks and 75.13% reduction at three months in comparison to the baseline. A significant improvement (p=0.01, p=0.00) between baseline and six weeks, and three months was achieved, respectively. Additionally, Symptoms, sport/recreational and quality of life subscales were significantly improvement (p=0.02, p=0.02, p=0.02) at six weeks and (p=0.02, p=0.00, p=0.00) at three months in comparison to the baseline, respectively. However, activity daily living subscale was the only one not significantly improves, even though an average increase of

17.88% at six weeks and 29.44% at three months were found in comparison to the baseline. All of the scores of KOOS are presented in table 4-13.

Table 4-13: Mean (SD) and P-value of pain reduction effect using the KOOS pain subscale.

Type	Baseline	Six Weeks	Three Months
Pain Mean (SD)	33.65 (17.59)	53.35 (16.74)	58.93 (21.71)
P-Value*		0.01*	0.002*
Symptoms Mean (SD)	46.68 (22.56)	57.91 (15.36)	61.48 (20.83)
P-Value*		0.02*	0.02*
Activity daily living (ADL) Mean (SD)	48.38 (18.91)	61.34 (19.27)	63.44 (20.13)
P-Value*		0.10	0.06
Sport/Rec Mean (SD)	23.21 (25.91)	37.14 (24.71)	41.43(31.83)
P-Value*		0.02*	0.00*
Quality of life (QOL) Mean (SD)	25.00 (20.80)	40.62 (21.48)	46.87 (24.85)
P-Value*		0.02*	0.00*
*Significant compared to baseline			

4.3.5 Dynamic Balance:

The results from dynamic balance tests showed a significant improvement (p= 0.00, p=0.00) at six weeks and (p= 0.00, p=0.00) at three months in Anterior and medial direction, respectively, in comparison with the baseline. The mean difference of distance increased by 7.67 cm at six weeks and 9.47 cm at three months in anterior direction and increased by 6.98 cm at six weeks and 11.66 cm at three months in medial direction. Descriptive data for Balance at baseline, six weeks and three months are presented in table 4-14.

Table 4-14: Mean (SD) and P-value of Dynamic balance in anterior and medial direction.

Type	Baseline	Six Weeks	Three Months
Anterior Mean (SD)	58.15 (6.59)	65.82 (6.35)	67.64 (6.02)
P-Value		0.00*	0.00*
Medial Mean (SD)	56.22 (5.47)	63.20 (8.67)	67.88 (6.28)
P-Value		0.00*	0.00*
*Significant compared to baseline			

4.3.6 Muscle strength

Muscle strength was assessed by conducting strength test on Biodex machine and the results indicated that the peak of muscle strength changed significantly at three months. The valgus knee brace increased the mean difference of the concentric muscle strength

peak of the knee extensor and flexors at 60˚/s by 17.88% and 38.50%, respectively, at six weeks, and by 29.44% and 52.20 at three months. Also, the valgus knee brace increased the mean difference of Isometric muscle strength peak of the knee extensor and flexors at 45˚/s by 25.61% and 23.29%, respectively, at six weeks and by 32.98% and 29.72% at three months. Descriptive data for peak torque of isometric and concentric contractions of knee flexion and extension at baseline, six weeks and three months are presented in table 4-15.

Table 4-15: Mean (SD) and P-value of peak torque (N/m) knee measurements

Type	Baseline	Six Weeks	Three Months
Knee concentric extension at 60˚/s Mean (SD)	81.11 (41.24)	95.61 (56.29)	104.99 (61.04)
P-Value		0.13	0.04*
Knee concentric flexion at 60˚/s Mean (SD)	44.18 (21.76)	61.91 (39.74)	67.24 (39.73)
P-Value		0.03*	0.01*
Knee isometric extension at 45˚ Mean (SD)	72.99 (32.48)	91.68 (52.51)	97.06(41.85)
P-Value		0.03*	0.00*
Knee isometric flexion at 45˚ Mean (SD)	58.96 (34.06)	72.69 (47.11)	76.48(41.09)
P-Value		0.11	0.02*
*Significant compared to baseline			

4.3.7 Muscle co-contraction

4.3.7.1 Walking

Muscle co-contraction between Vastus medialis and Semitendinosus decreased significantly between the shoe only at baseline (p=0.04, p=0.02) and brace and, the shoe only at three months, respectively, in early stage and (p=0.02) brace at three months in mid stage. It is also decreased significantly between Brace at baseline and three months (p=0.01, p=0.01) in early and mid-stage, respectively. In contrast, the muscle co-contraction between Vastus lateralis and Biceps femoris didn't show any significant changes between conditions in any part of stance phase. Descriptive data of Muscle co-contraction between Vastus medialis and Semitendinosus and between Vastus lateralis and Biceps femoris during walking are presented in table 4-16.

Table 4-16: Mean (SD) and P-value of Muscle co-contraction between Vastus medialis and Semitendinosus and between Vastus lateralis and Biceps femoris during walking.

Type		Shoe Baseline	Brace Baseline	Brace Three Months	Shoe Three Months
Vastus lateralis vs. Biceps femoris	Early stage Mean (SD) P-Value	0.53(0.44)	0.51(0.42)	0.34(0.17) 0.09 0.12	0.34(0.18) 0.09
	Middle stage Mean (SD) P-Value	0.22(0.18)	0.23(0.21)	0.17(0.14) 0.35 0.24	0.21(0.21) 0.91
	Late stage Mean (SD) P-Value	0.11(0.11)	0.15(0.12)	0.18(0.24) 0.32 0.63	0.17(0.29) 0.48
Vastus medialis vs. Semitendinosus	Early stage Mean (SD) P-Value	0.36(0.21)	0.41(0.24)	0.25(0.15) 0.04* 0.01ª	0.22(0.12) 0.02*
	Middle stage Mean (SD) P-Value	0.13(0.07)	0.14(0.07)	0.09(0.06) 0.02* 0.01ª	0.11(0.12) 0.46
	Late stage Mean (SD) P-Value	0.13(0.09)	0.12(0.09)	0.10(0.09) 0.35 0.05	0.08(0.02) 0.07
*Compared to Shoe baseline ªCompared to brace baseline					

4.3.7.2 Ascending stairs

The muscle co-contraction between Vastus lateralis and Biceps femoris is decreased significantly between the shoe only at baseline (p=0.02, p=0.01) and brace and, the shoe only at three months, respectively, and also it decreased significantly (p=0.02) between brace at baseline and three months.

The muscle co-contraction between Vastus medialis and Semitendinosus is reduced significantly between the shoe only at baseline (p=0.00, p=0.00) and brace and, the shoe only at three months, respectively, and also it decreased significantly (p=0.048) between brace at baseline and three months. Descriptive data of Muscle co-contraction between Vastus medialis and Semitendinosus and between Vastus lateralis and Biceps femoris during ascent are presented in table 4-17.

Table 4-17: Mean (SD) and P-value of Muscle co-contraction between Vastus medialis and Semitendinosus and between Vastus lateralis and Biceps femoris during ascent.

Type		Shoe Baseline	Brace Baseline	Brace Three Months	Shoe Three Months
Vastus lateralis vs. Biceps femoris	Single support Mean(SD) P-Value	0.62(0.40)	0.59(0.39)	0.38(0.22) 0.02* 0.02ª	0.34(0.19) 0.01*
Vastus medialis vs. Semitendinosus	Single support Mean(SD) P-Value	0.44(0.28)	0.35(0.27)	0.23(0.16) 0.00* 0.048ª	0.26(0.19) 0.00*
*Compared to Shoe baseline ªCompared to brace baseline					

4.3.7.3 Descending stairs

The muscle co-contraction between Vastus lateralis and Biceps femoris is decreased significantly between the shoe only at baseline (p=0.02, p=0.01) and brace and, the shoe only at three months, respectively, and also it decreased significantly (p=0.01) between brace at baseline and three months.

The muscle co-contraction between Vastus medialis and Semitendinosus is reduced significantly between the shoe only at baseline (p=0.01, p=0.00) and brace and, the shoe only at three months, respectively, and also it decreased significantly (p=0.01) between brace at baseline and three months. Descriptive data of Muscle co-contraction between Vastus medialis and Semitendinosus and between Vastus lateralis and Biceps femoris during descent are presented in table 4-18.

Table 4-18: Mean (SD) and P-value of Muscle co-contraction between Vastus medialis and Semitendinosus and between Vastus lateralis and Biceps femoris during descent.

Type		Shoe Baseline	Brace Baseline	Brace Three Months	Shoe Three Months
Vastus lateralis vs. Biceps femoris	Single support Mean(SD) P-Value	0.50(0.34)	0.53(0.31)	0.30(0.12) 0.02* 0.01ª	0.29(0.10) 0.01*
Vastus medialis vs. Semitendinosus	Single support Mean(SD) P-Value	0.36(0.19)	0.33(0.22)	0.22(0.18) 0.01* 0.01ª	0.19(0.20) 0.00*
*Compared to Shoe baseline ªCompared to brace baseline					

4.3.8. The kinematic results of the affected leg during walking

4.3.8.1. Gait temporo-spatial parameters:

After three months, there was no significant difference (p=0.27) between the brace three months and the shoe only baseline, and brace baseline (p=0.25). In addition, there was no significant difference (p=0.62) between the only shoe three months and baseline. Descriptive data of Gait temporo-spatial parameter results during walking are illustrated in table 4-19.

Table 4-19 Gait temporo-spatial parameter results during walking.

Type	Shoe Baseline	Brace Baseline	Brace Three Months	Shoe Three Months
Speed (m/s) Mean (SD)	1.1 (0.1)	1.2(0.1)	1.1 (0.2)	1.1 (0.2)
Stride length (m) Mean (SD)	1.2(0.1)	1.4(0.1)	1.3 (0.1)	1.3 (0.1)
Left step length (m) Mean (SD)	0.7(0.1)	0.7(0.1)	0.7(0.1)	0.7(0.1)
Right step length (m) Mean (SD)	0.7(0.1)	0.7(0.1)	0.7(0.1)	0.7(0.1)
The Left stance time (s) Mean (SD)	0.8(0.1)	0.8(0.1)	0.8(0.1)	0.8(0.1)
The right stance time (s) Mean (SD)	0.8(0.1)	0.8(0.1)	0.8(0.1)	0.8(0.1)
Cadence step per minute Mean(SD)	101.2(7.4)	101.9 (7.4)	99.4 (9.3)	100.3 (9.8)
Double limb support time (s)	0.3 (0.0)	0.3 (0.0)	0.3 (0.0)	0.3 (0.0)

4.3.8.2 Ankle angle (sagittal plane)

After wearing the brace for three months, there was no significant change (mean difference 1.94 degree, p=0.05) in the maximum of ankle dorsiflexion angle in comparison to the shoe only at baseline, even though an average increase of 7.91 % was found. Additionally, after wearing the brace for three months, there was no significant change (mean difference 1.47 degree, p=0.18) in the maximum of ankle dorsiflexion angle in comparison to the brace baseline, even though an average increase of 5.58% was found. In addition, after wearing the brace for three months, there was no significant change (mean difference 1.37 degree, p=0.10) in the maximum of ankle dorsiflexion angle between the shoe only at baseline and at three months, even though an average decrease of 5.57% was found.

After wearing the brace for three months, there was a significant decrease (mean difference 3.16 degree, p=0.04) in the maximum ankle planter flexion angle in

comparison to the shoe only at baseline, with an average decrease of 31.16 % was found. However, after wearing the brace for three months, there was no significant change (mean difference 1.05 degree, p=0.36) in the maximum of ankle planter flexion angle in comparison to the brace baseline, even though an average decrease of 13.07% was found. Additionally, after wearing the brace for three months, there was no significant change (mean difference 2.24 degree, p=0.10) in the maximum of ankle planter flexion angle between the shoe only at baseline and at three months, even though an average decrease of 22.06% was found.

After wearing the brace for three months, there was no significant change (mean difference 1.22 degree, p=0.15) in the ankle ROM in comparison to the shoe only at baseline, even though an average decrease of 3.50 % was found. Additionally, after wearing the brace for three months, there was no significant change (mean difference 0.42 degree, p=0.52) in the ankle ROM in comparison to the brace baseline, even though an average increase of 1.26% was found. In addition, after wearing the brace for three months, there was no significant change (mean difference 0.87 degree, p=0.24) in the ankle ROM between the shoe only at baseline and at three months, even though an average decrease of 2.50% was found. Descriptive data of sagittal plane ankle angle results during walking are illustrated in figure 4-17 and table 4-20.

Figure 4-17: Sagittal plane ankle angle of the four conditions during walking.

Table 4-20: Mean (SD) sagittal plane ankle angle during walking.

Type	Shoe Baseline	Brace Baseline	Brace Three Months	Shoe Three Months
Ankle Dorsiflexion Mean (SD)(°)	24.58(2.85)	25.06(2.62)	26.53(4.53)	25.95(3.96)
Ankle Planter flexion Mean (SD) (°)	-10.15(4.79)	-8.04(4)	-6.99(5.960)	-7.91(5.93)
Ankle ROM Mean (SD) (°)	34.73(3.97)	33.10(3.20)	33.51(3.79)	33.86(4.27)

4.3.8.3 Knee angle (sagittal plane)

At Initial contact after wearing the brace for three months, there was a significant increase (mean difference 3.55 degree, p=0.00) in the knee angle in comparison to the shoe only at baseline, with an average increase of 48.04 % was found. Additionally, after wearing the brace for three months, there was a significant increase (mean difference 1.99 degree, p=0.04) in the knee angle in comparison to the brace baseline, with an average increase of 22.27% was found. In addition, after wearing the brace for three months, there was significant increase (mean difference 2.59 degree, p=0.04) in the knee angle between the shoe only at baseline and at three months, with an average increase of 35% was found.

111

At loading response stage after wearing the brace for three months, there was a significant increase (mean difference 3.26 degree, p=0.01) in the maximum of knee angle in comparison to the shoe only at baseline, with an average increase of 14.95 % was found. However, after wearing the brace for three months, there was no significant change (mean difference 2.37 degree, p=0.05) in the maximum of knee angle in comparison to the brace baseline, even though an average increase of 10.42% was found. In addition, after wearing the brace for three months, there was significant increase (mean difference 2.78 degree, p=0.03) in the maximum of knee angle between the shoe only at baseline and at three months, with an average increase of 12.75% was found.

At mid stance stage after wearing the brace for three months, there was a significant increase (mean difference 3.65 degree, p=0.00) in the minimum of knee angle in comparison to the shoe only at baseline, with an average increase of 29.95 % was found. Additionally, after wearing the brace for three months, there was a significant increase (mean difference 2.44 degree, p=0.04) in the minimum of knee angle in comparison to the brace baseline, with an average increase of 18.42% was found. In addition, after wearing the brace for three months, there was significant increase (mean difference 2.44 degree, p=0.02) in the minimum of knee angle between the shoe only at baseline and at three months, with an average increase of 20.01% was found.

At mid swing stage after wearing the brace for three months, there was no significant change (mean difference 0.89 degree, p=0.59) in the maximum of knee angle in comparison to the shoe only at baseline, even though an average increase of 1.23 % was found. Additionally, after wearing the brace for three months, there was no significant change (mean difference 1.94 degree, p=0.29) in the maximum of knee angle in comparison to the brace baseline, even though an average increase of 2.70% was found. In addition, after wearing the brace for three months, there was no significant change (mean difference 1.66 degree, p=0.33) in the maximum of knee angle between the shoe only at baseline and at three months, even though an average increase of 2.28% was found.

After wearing the brace for three months, there was no significant change (mean difference 2.66 degree, p=0.09) in the sagittal knee ROM in comparison to the shoe only

at baseline, even though an average decrease of 4.06 % was found. Additionally, after wearing the brace for three months, there was no significant change (mean difference 0.05 degree, p=0.97) in the sagittal knee ROM in comparison to the brace baseline, even though an average decrease of 0.09% was found. In addition, after wearing the brace for three months, there was no significant change (mean difference 0.92 degree, p=0.54) in the sagittal knee ROM between the shoe only at baseline and at three months, even though an average decrease of 1.41% was found. Descriptive data of sagittal plane knee angle results during walking are illustrated in figure 4-18 and table 4-21.

Figure 4-18: Sagittal plane knee angle of the four conditions during walking.

Table 4-21: Mean, (SD) sagittal plane knee angle during walking.

Type	Shoe Baseline	Brace Baseline	Brace Three Months	Shoe Three Months
Initial contact Mean (SD) (°)	7.39(4.64)	8.95(5.92)	10.94(4.65)	9.98(5.02)
Loading response Mean (SD) (°)	21.80(7.24)	22.69(7.05)	25.06(5.32)	24.58(4.81)
Mid stance Mean (SD) (°)	12.20(7.52)	13.41(7.10)	15.85(6.29)	14.64(1.56)
Mid swing Mean (SD) (°)	72.80(7.17)	71.75(7.76)	73.69(3.87)	74.46(4.14)
Knee ROM X angle Mean (SD)(°)	65.41(7.31)	62.80(7.81)	62.75(6.38)	64.48(6.40)

4.3.8.4 Knee angle (frontal plane)

After wearing the brace for three months, there was no significant change (mean difference 0.40 degree, p=0.60) in the maximum of frontal knee angle in comparison to the shoe only at baseline, even though an average increase of 9.89% was found. Additionally, after wearing the brace for three months, there was no significant change (mean difference 0.98 degree, p=0.12) in the maximum of frontal knee angle in comparison to the brace baseline, even though an average increase of 32.04% was found. In addition, after wearing the brace for three months, there was no significant change (mean difference 0.48 degree, p=0.52) in the maximum of frontal knee angle between the shoe only at baseline and at three months, even though an average increase of 13.32% was found.

After wearing the brace for three months, there was no significant change (mean difference 1.72 degree, p=0.10) in the minimum of frontal knee angle in comparison to the shoe only at baseline, even though an average decrease of 30.58 % was found. Additionally, after wearing the brace for three months, there was no significant change (mean difference 0.35 degree, p=0.69) in the minimum of frontal knee angle in comparison to the brace baseline, even though an average decrease of 8.24% was found. In addition, after wearing the brace for three months, there was no significant change (mean difference 0.98 degree, p=0.23) in the minimum of frontal knee angle between the shoe only at baseline and at three months, even though an average decrease of 17.32% was found.

After wearing the brace for three months, there was no significant change (mean difference 1.30 degree, p=0.19) in the frontal knee ROM in comparison to the shoe only at baseline, even though an average decrease of 14.06 % was found. Additionally, after wearing the brace for three months, there was no significant change (mean difference 0.63 degree, p=0.48) in the frontal knee ROM in comparison to the brace baseline, even though an average increase of 8.59% was found. In addition, after wearing the brace for three months, there was no significant change (mean difference 0.47 degree, p=0.60) in the frontal knee ROM between the shoe only at baseline and at three months, even though

an average decrease of 5.07% was found. Descriptive data of frontal plane knee angle results during walking are illustrated in figure 4-19 and table 4-22.
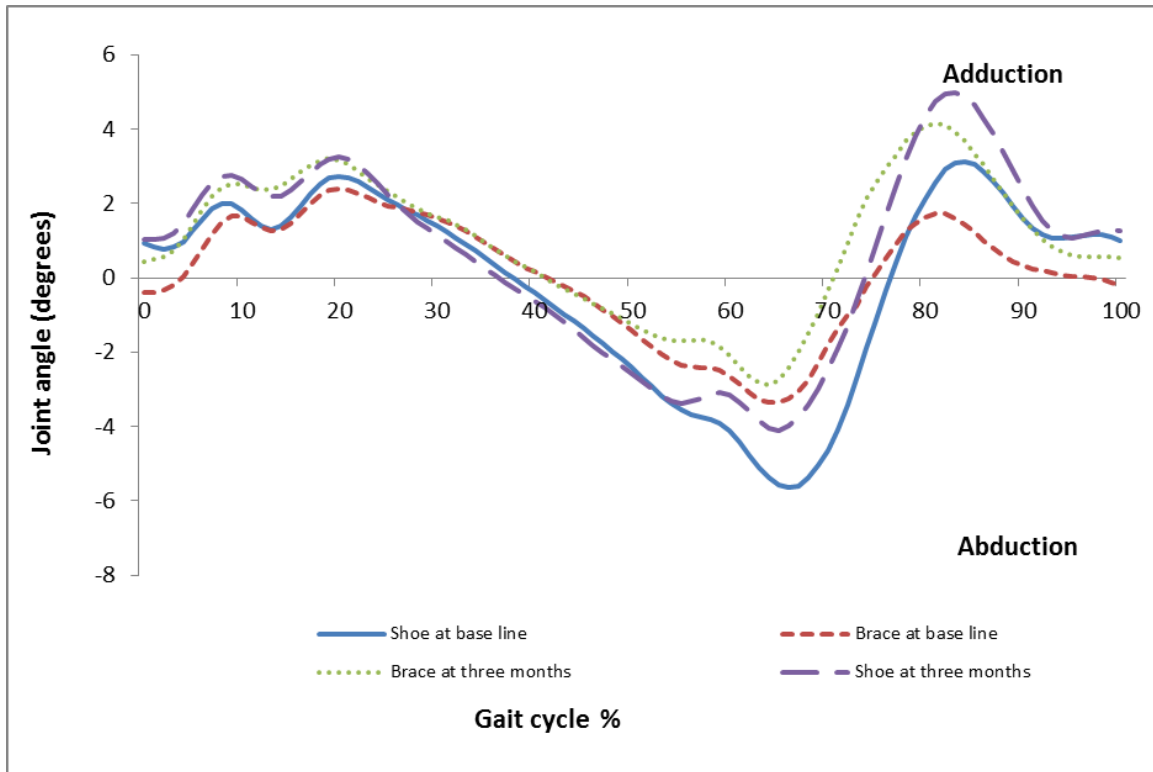
Figure 4-19: Frontal plane knee angle of the four conditions during walking.

Table 4-22: Mean, (SD) frontal plane knee angle during walking.

Type	Shoe Baseline	Brace Baseline	Brace Three Months	Shoe Three Months
Maximum knee angle Y Mean (SD)(°)	3.64(6.68)	3.06(6.38)	4.04(5.55)	4.12(5.54)
Minimum knee angle Y Mean (SD)(°)	-5.63(8.03)	-4.26(7.16)	-3.91(5.60)	-4.66(6.16)
Knee ROM Y angle Mean (SD)(°)	9.25(3.82)	7.32(3.13)	7.95(3.34)	8.78(2.85)

4.3.8.5 Hip angle (sagittal plane)

After wearing the brace for three months, there was no significant change (mean difference 3.41 degree, p=0.15) in the maximum of hip flexion angle in comparison to the shoe only at baseline, even though an average increase of 13.64 % was found. Additionally, after wearing the brace for three months, there was no significant change (mean difference 3.65 degree, p=0.17) in the maximum of hip flexion angle in comparison to the brace baseline, even though an average increase of 14.71% was found. In addition, after wearing the brace for three months, there was no significant change

(mean difference 3.40 degree, p=0.15) in the maximum of hip flexion angle between the shoe only at baseline and at three months, even though an average increase of 13.58% was found.

After wearing the brace for three months, there was a significant decrease (mean difference 5.10 degree, p=0.03) in the maximum hip extension angle in comparison to the shoe only at baseline, with an average decrease of 28.27 % was found. However, after wearing the brace for three months, there was no significant change (mean difference - 5.19 degree, p=0.05) in the maximum of hip extension angle in comparison to the brace baseline, even though decrease of 28.60% was found. However, after wearing the brace for three months, there was a significant decrease (mean difference 4.76 degree, p=0.04) in the maximum of hip extension angle between the shoe only at baseline and at three months, with an average decrease of 26.36% was found.

After wearing the brace for three months, there was a significant decrease (mean difference 1.69 degree, p=0.04) in the hip ROM in comparison to the shoe only at baseline, with an average decrease of 3.92 % was found. Additionally, after wearing the brace for three months, there was a significant decrease (mean difference 1.54 degree, p=0.03) in the hip ROM in comparison to the brace baseline, with an average decrease of 3.59% was found. However, after wearing the brace for three months, there was no significant change (mean difference 1.36 degree, p=0.10) in the hip ROM between the shoe only at baseline and at three months, even though an average decrease of 3.16% was found. Descriptive data of sagittal plane hip angle results during walking are illustrated in figure 4-20 and table 4-23.
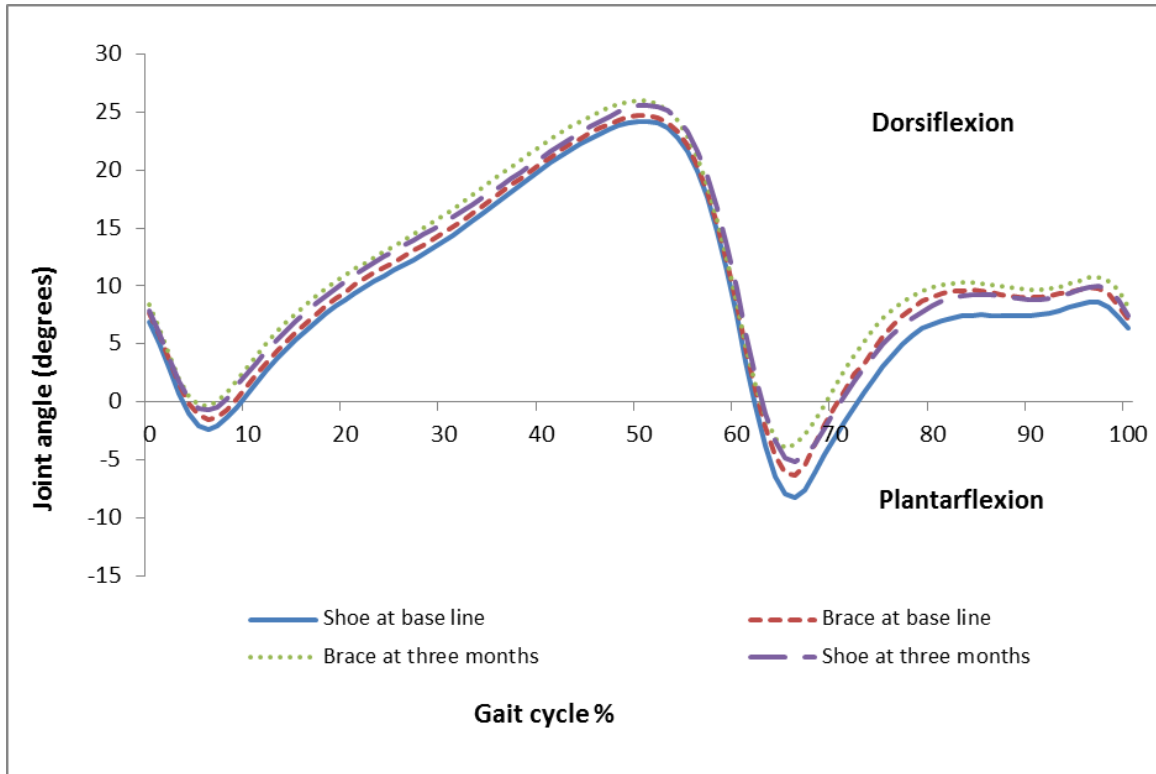
Figure 4-20: Sagittal plane hip angle of the four conditions during walking.

Table 4-23: Mean, (SD) sagittal plane hip angle during walking

Type	Shoe Baseline	Brace Baseline	Brace Three Months	Shoe Three Months
Hip Flexion Mean (SD)(°)	25.02(10.65)	24.79(11.08)	28.44(6.41)	28.42(6.65)
Hip Extension Mean (SD)(°)	-18.06(11.76)	-18.14(12.04)	-12.95(9.86)	-13.30(9.84)
Hip ROM Mean (SD)(°)	43.08(5.68)	42.93(5.01)	41.39(5.40)	41.72(5.32)

4.3.9 The kinematic results of the affected leg during ascending stairs

4.3.9.1 Gait temporo-spatial parameters

After three months, left stance time significantly decrease (p=0.01) between the brace three months and the shoe only baseline, and brace baseline (p=0.03). In addition, left stance time significantly decrease (p=0.01) between the only shoe three months and baseline.

After three months, right stance time significantly decrease (p=0.00) between the brace three months and the shoe only baseline, and brace baseline (p=0.03). In addition, left stance time significantly decrease (p=0.00) between the only shoe three months and

baseline. Descriptive data of Gait temporo-spatial parameter results during ascending are illustrated in Table 4-24.

Table 4-24 Gait temporo-spatial parameter results during ascent.

Type	Shoe Baseline	Brace Baseline	Brace Three Months	Shoe Three Months
Stride width (m) Mean (SD)	0.15(0.04)	0.15(0.03)	0.15(0.03)	0.14(0.03)
Left stance time (s) Mean (SD)	1.48(0.38)	1.34(0.24)	1.19(0.19)	1.25(0.21)
Right stance time (s) Mean (SD)	1.45(0.33)	1.30(0.19)	1.19(0.15)	1.27(0.22)

4.3.9.2 Ankle angle (sagittal plane)

After wearing the brace for three months, there was no significant change (mean difference 1.64 degree, p=0.11) in the maximum of ankle dorsiflexion angle in comparison to the shoe only at baseline, even though an average increase of 6.54 % was found. Additionally, after wearing the brace for three months, there was no significant change (mean difference 0.85 degree, p=0.38) in the maximum of ankle dorsiflexion angle in comparison to the brace baseline, even though an average increase of 3.30% was found. In addition, after wearing the brace for three months, there was no significant change (mean difference 0.0 degree, p=1) in the maximum of ankle dorsiflexion angle between the shoe only at baseline and at three months.

After wearing the brace for three months, there was a significant decrease (mean difference 3.77 degree, p=0.00) in the maximum ankle planter flexion angle in comparison to the shoe only at baseline, with an average decrease of 36.54 % was found. However, after wearing the brace for three months, there was no significant change (mean difference 1.17 degree, p=0.08) in the maximum of ankle planter flexion angle in comparison to the brace baseline, even though an average decrease of 15.13% was found. However, after wearing the brace for three months, there was a significant decrease (mean difference 2.01 degree, p=0.04) in the maximum of ankle planter flexion angle between the shoe only at baseline and at three months, with an average decrease of 19.47% was found.

After wearing the brace for three months, there was a significant decrease (mean difference 2.13 degree, p=0.00) in the ankle ROM in comparison to the shoe only at baseline, with an average decrease of 6.02 % was found. However, after wearing the brace for three months, there was no significant change (mean difference 0.31 degree, p=0.70) in the ankle ROM in comparison to the brace baseline, even though an average decrease of 0.93% was found. However, after wearing the brace for three months, there was a significant decrease (mean difference 2.01 degree, p=0.01) in the ankle ROM between the shoe only at baseline and at three months, with an average decrease of 5.69% was found. Descriptive data of sagittal plane ankle angle results during ascending are illustrated in figure 4-21 and table 4-25.
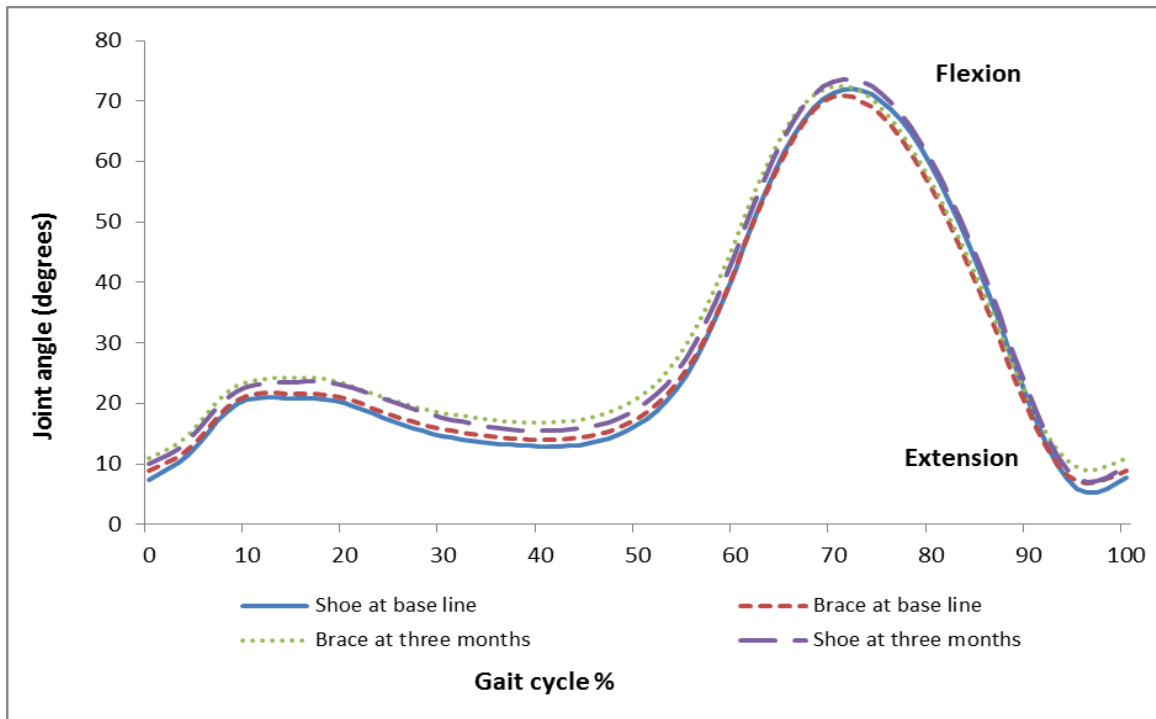

Figure 4-21: Sagittal plane ankle angle of the four conditions during ascent.

Table 4-25: Mean, (SD) sagittal plane ankle angle during ascent.

Type	Shoe Baseline	Brace Baseline	Brace Three Months	Shoe Three Months
Ankle Dorsiflexion Mean (SD)(°)	25.05(2.75)	25.83(2.66)	26.69(3.39)	25.05(3.56)
Ankle Planter flexion Mean (SD) (°)	-10.31(5.54)	-7.71(4.94)	-6.54(5.42)	-8.30(5.89)
Ankle ROM Mean (SD) (°)	35.36(6.71)	33.54(6.70)	33.23(5.83)	33.35(6.18)

4.3.9.3 Knee angle (sagittal plane)

At initial contact after wearing the brace for three months, there was a significant increase (mean difference 3.98 degree, p=0.00) in the knee angle in comparison to the shoe only at baseline, with an average increase of 6.38 % was found. Additionally, after wearing the brace for three months, there was a significant increase (mean difference 3.81 degree, p=0.02) in the knee angle in comparison to the brace baseline, with an average increase of 6.09% was found. However, after wearing the brace for three months, there was no significant change (mean difference 2.80 degree, p=0.06) in the knee angle between the shoe only at baseline and at three months, even though an average increase of 4.48% was found.

At loading response stage after wearing the brace for three months, there was a significant increase (mean difference 3.16 degree, p=0.01) in the maximum of knee angle in comparison to the shoe only at baseline, with an average increase of 14.95 % was found. However, after wearing the brace for three months, there was no significant change (mean difference 2.74 degree, p=0.07) in the maximum of knee angle in comparison to the brace baseline, even though an average increase of 10.42% was found. In addition, after wearing the brace for three months, there was no significant change (mean difference 2.33 degree, p=0.12) in the maximum of knee angle between the shoe only at baseline and at three months, even though an average increase of 3.54% was found.

At mid stance stage after wearing the brace for three months, there was a significant increase (mean difference 3.06 degree, p=0.03) in the minimum of knee angle in comparison to the shoe only at baseline, with an average increase of 20.68% was found. However, after wearing the brace for three months, there was no significant change (mean difference 2.35 degree, p=0.05) in the minimum of knee angle in comparison to the brace baseline, even though an average increase of 15.19% was found. In addition, after wearing the brace for three months, there was no significant change (mean difference 0.67 degree, p=0.58) in the minimum of knee angle between the shoe only at baseline and at three months, even though an average increase of 4.53% was found.

At mid swing stage after wearing the brace for three months, there was no significant change (mean difference 2.12 degree, p=0.59) in the maximum of knee angle in comparison to the shoe only at baseline, even though an average decrease of 2.16 % was found. Additionally, after wearing the brace for three months, there was no significant change (mean difference 1.94 degree, p=0.22) in the maximum of knee angle in comparison to the brace baseline, even though an average increase of 1.92% was found. In addition, after wearing the brace for three months, there was no significant change (mean difference 1.24 degree, p=0.49) in the maximum of knee angle between the shoe only at baseline and at three months, even though an average increase of 1.26% was found.

After wearing the brace for three months, there was a significant decrease (mean difference 5.18 degree, p=0.01) in the sagittal knee ROM in comparison to the shoe only at baseline, with an average decrease of 6.19 % was found. However, after wearing the brace for three months, there was no significant change (mean difference 0.53 degree, p=0.70) in the sagittal knee ROM in comparison to the brace baseline, even though an average decrease of 0.67% was found. In addition, after wearing the brace for three months, there was no significant change (mean difference 0.57degree, p=0.69) in the sagittal knee ROM between the shoe only at baseline and at three months, even though an average increase of 0.68% was found. Descriptive data of sagittal plane knee angle results during ascending are illustrated in figure 4-22 and table 4-26.
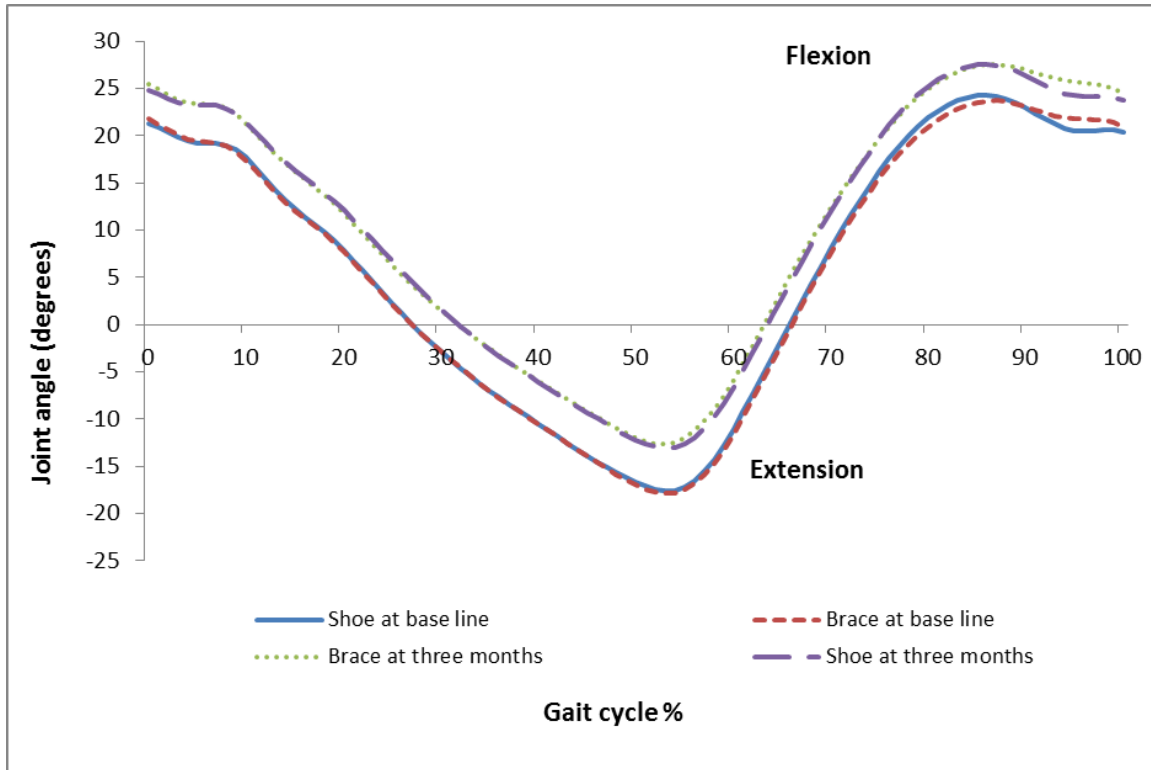
Figure 4-22: Sagittal plane knee angle of the four conditions during ascent.

Table 4-26: Mean, (SD) sagittal plane knee angle during ascent.

Type	Shoe Baseline	Brace Baseline	Brace Three Months	Shoe Three Months
Initial contact Mean (SD)(°)	62.44(4.87)	62.61(6.54)	66.42(4.56)	65.24(5.33)
Loading response Mean (SD)(°)	65.77(5.60)	66.19(7.37)	68.93(6.17)	68.10(4.41)
Mid stance Mean (SD) (°)	14.78(6.94)	15.48(6.12)	17.84(4.18)	15.45(4.55)
Mid swing Mean (SD) (°)	98.50(8.15)	94.56(8.33)	96.38(5.36)	99.74(5.05)
Knee ROM X angle Mean (SD)(°)	83.72(7.64)	79.07(7.63)	78.54(6.23)	84.29(6.45)

4.3.9.4 Knee angle (frontal plane)

After wearing the brace for three months, there was no significant change (mean difference 0.08 degree, p=0.95) in the maximum of frontal knee angle in comparison to the shoe only at baseline, even though an average decrease of 0.72 % was found. Additionally, after wearing the brace for three months, there was no significant change (mean difference 2.48 degree, p=0.12) in the maximum of frontal knee angle in comparison to the brace baseline, even though an average increase of 29.08 % was found. In addition, after wearing the brace for three months, there was no significant change (mean difference 2.14 degree, p=0.15) in the maximum of frontal knee angle between the

shoe only at baseline and at three months, even though an average increase of 19.30 % was found.

After wearing the brace for three months, there was no significant change (mean difference 0.99 degree, p=0.11) in the minimum of frontal knee angle in comparison to the shoe only at baseline. Additionally, after wearing the brace for three months, there was no significant change (mean difference 1.14 degree, p=0.09) in the minimum of frontal knee angle in comparison to the brace baseline. In addition, after wearing the brace for three months, there was no significant change (mean difference 0.96 degree, p=0.13) in the minimum of frontal knee angle between the shoe only at baseline and at three months.

After wearing the brace for three months, there was no significant change (mean difference 1.07 degree, p=0.33) in the frontal knee ROM in comparison to the shoe only at baseline, even though an average decrease of 9.19 % was found. Additionally, after wearing the brace for three months, there was no significant change (mean difference 1.34 degree, p=0.26) in the frontal knee ROM in comparison to the brace baseline, even though an average increase of 14.53% was found. In addition, after wearing the brace for three months, there was no significant change (mean difference 1.18 degree, p=0.32) in the frontal knee ROM between the shoe only at baseline and at three months, even though an average increase of 10.14% was found. Descriptive data of frontal plane knee angle results during ascending are illustrated in figure 4-23 and table 4-27.
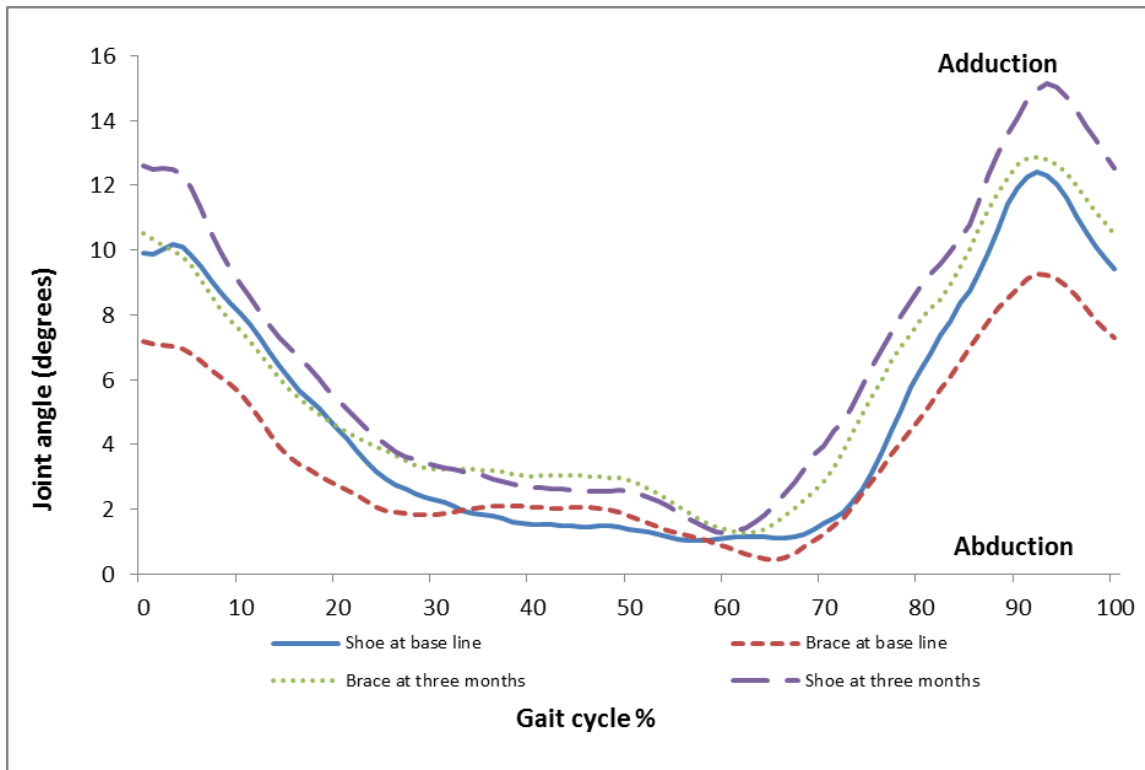
Figure 4-23: Frontal plane knee angle of the four conditions during ascent.

Table 4-27: Mean, (SD) frontal plane knee angle during ascent.

Type	Shoe Baseline	Brace Baseline	Brace Three Months	Shoe Three Months
Maximum knee angle Y Mean (SD)(°)	11.10(5.91)	8.54(7.22)	11.02(5.26)	13.24(4.87)
Minimum knee angle Y Mean (SD)(°)	-0.55(5.49)	-0.70(5.61)	0.44 (4.95)	0.41(4.57)
Knee ROM Y angle Mean (SD)(°)	11.66(6.56)	9.24(5.06)	10.58(5.73)	12.84(6.08)

4.3.9.5 Hip angle (sagittal plane)

After wearing the brace for three months, there was no significant change (mean difference 0.99 degree, p=0.71) in the maximum of hip flexion angle in comparison to the shoe only at baseline, even though an average increase of 1.71 % was found. Additionally, after wearing the brace for three months, there was no significant change (mean difference 3.0 degree, p=0.23) in the maximum of hip flexion angle in comparison to the brace baseline, even though an average increase of 5.35% was found. In addition, after wearing the brace for three months, there was no significant change (mean difference 2.38 degree, p=0.43) in the maximum of hip flexion angle between the shoe

only at baseline and at three months, even though an average increase of 4.10% was found.

After wearing the brace for three months, there was no significant change (mean difference 3.04 degree, p=0.25) in the maximum hip extension angle in comparison to the shoe only at baseline. Additionally, after wearing the brace for three months, there was a significant decrease (mean difference 4.29 degree, p=0.10) in the maximum of hip extension angle in comparison to the brace baseline. In addition, after wearing the brace for three months, there was a significant decrease (mean difference 2.87 degree, p=0.22) in the maximum of hip extension angle between the shoe only at baseline and at three months.

After wearing the brace for three months, there was no significant change (mean difference 2.05 degree, p=0.09) in the hip ROM in comparison to the shoe only at baseline, even though an average decrease of 3.60 % was found. Additionally, after wearing the brace for three months, there was no significant change (mean difference 1.29 degree, p=0.28) in the hip ROM in comparison to the brace baseline, even though an average decrease of 2.29% was found. In addition, after wearing the brace for three months, there was no significant change (mean difference 0.49 degree, p=0.72) in the hip ROM between the shoe only at baseline and at three months, even though an average decrease of 0.86% was found. Descriptive data of sagittal plane hip angle results during ascending are illustrated in figure 4-24 and table 4-28.
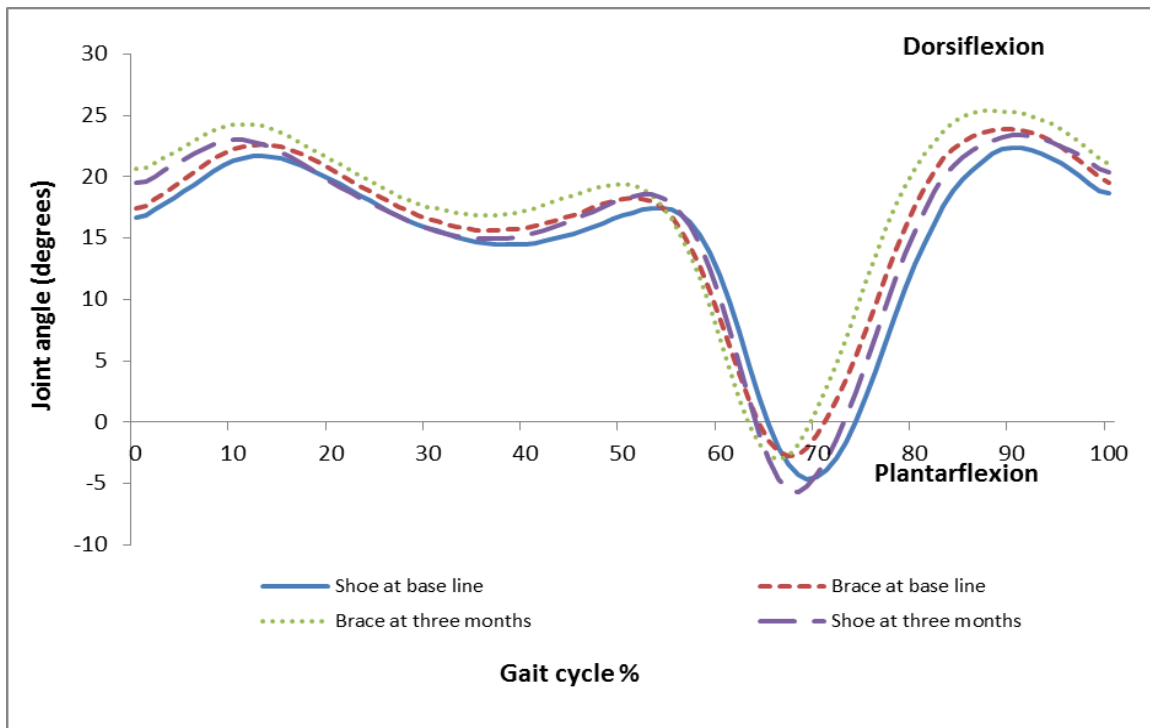
Figure 4-24: Sagittal plane hip angle of the four conditions during ascent.

Table 4-28: Mean, (SD) sagittal plane hip angle during ascent.

Type	Shoe Baseline	Brace Baseline	Brace Three Months	Shoe Three Months
Hip Flexion Mean (SD) (°)	58.07(11.77)	56.06(10.98)	59.06(6.04)	60.45(6.33)
Hip Extension Mean (SD) (°)	0.99(11.45)	-0.26(10.68)	4.03(7.92)	3.86(6.93)
Hip ROM Mean (SD) (°)	57.08(4.98)	56.32(4.88)	55.03(4.16)	56.59(4.48)

4.3.10 The kinematic results of the affected leg during descending stairs

4.3.10.1 Gait temporo-spatial parameters

After three months, left stance time significantly decrease (p=0.01) between the brace at three months and only the shoe at baseline, but did not significantly decrease (p=0.11) with brace at baseline. In addition, left stance time significantly decrease (p=0.01) between the only shoe at three months and baseline.

After three months, right stance time significantly decrease (p=0.01) between the brace at three months and only the shoe at baseline, and but did not significantly decrease (p=0.06) with brace at baseline. In addition, left stance time significantly decrease

(p=0.02) between the only shoe at three months and baseline. Descriptive data of Gait temporo-spatial parameter results during descending are illustrated in Table 4-29.

Table 4-29: Gait temporo-spatial parameter results during descent.

Type	Shoe Baseline	Brace Baseline	Brace Three Months	Shoe Three Months
Stride width (m) Mean (SD)	0.16(0.03)	0.16(0.03)	0.17(0.02)	0.16(0.02)
Left stance time (s) Mean (SD)	1.43(0.49)	1.19(0.23)	1.09(0.21)	1.16(0.23)
Right stance time (s) Mean (SD)	1.49(0.52)	1.24(0.27)	1.10(0.18)	1.20(0.30)

4.3.10.2 Ankle angle (sagittal plane)

After wearing the brace for three months, there was no significant change (mean difference 1.58 degree, p=0.14) in the maximum of ankle dorsiflexion angle in comparison to the shoe only at baseline, even though an average increase of 4.04 % was found. Additionally, after wearing the brace for three months, there was no significant change (mean difference 1.17 degree, p=0.25) in the maximum of ankle dorsiflexion angle in comparison to the brace baseline, even though an average increase of 2.95% was found. In addition, after wearing the brace for three months, there was no significant change (mean difference 1.06 degree, p=0.19) in the maximum of ankle dorsiflexion angle between the shoe only at baseline and at three months, even though an average increase of 2.71 % was found.

After wearing the brace for three months, there was a significant decrease (mean difference 2.99 degree, p=0.00) in the maximum ankle planter flexion angle in comparison to the shoe only at baseline, with an average decrease of 15.91 % was found. Additionally, after wearing the brace for three months, there was a significant decrease (mean difference 1.64 degree, p=0.01) in the maximum of ankle planter flexion angle in comparison to the brace baseline, with an average decrease of 9.40% was found. However, after wearing the brace for three months, there was no significant change (mean difference 1.48 degree, p=0.20) in the maximum of ankle planter flexion angle between the shoe only at baseline and at three months, even though an average decrease of 7.89% was found.

After wearing the brace for three months, there was no significant change (mean difference 1.41 degree, p=0.24) in the ankle ROM in comparison to the shoe only at baseline, even though an average decrease of 2.44 % was found. Additionally, after wearing the brace for three months, there was no significant change (mean difference 0.47 degree, p=0.65) in the ankle ROM in comparison to the brace baseline, even though an average decrease of 0.83% was found. In addition, after wearing the brace for three months, there was no significant change (mean difference 0.42 degree, p=0.67) in the ankle ROM between the shoe only at baseline and at three months, even though an average decrease of 0.73% was found. Descriptive data of sagittal plane ankle angle results during descending are illustrated in figure 4-25 and table 4-30.
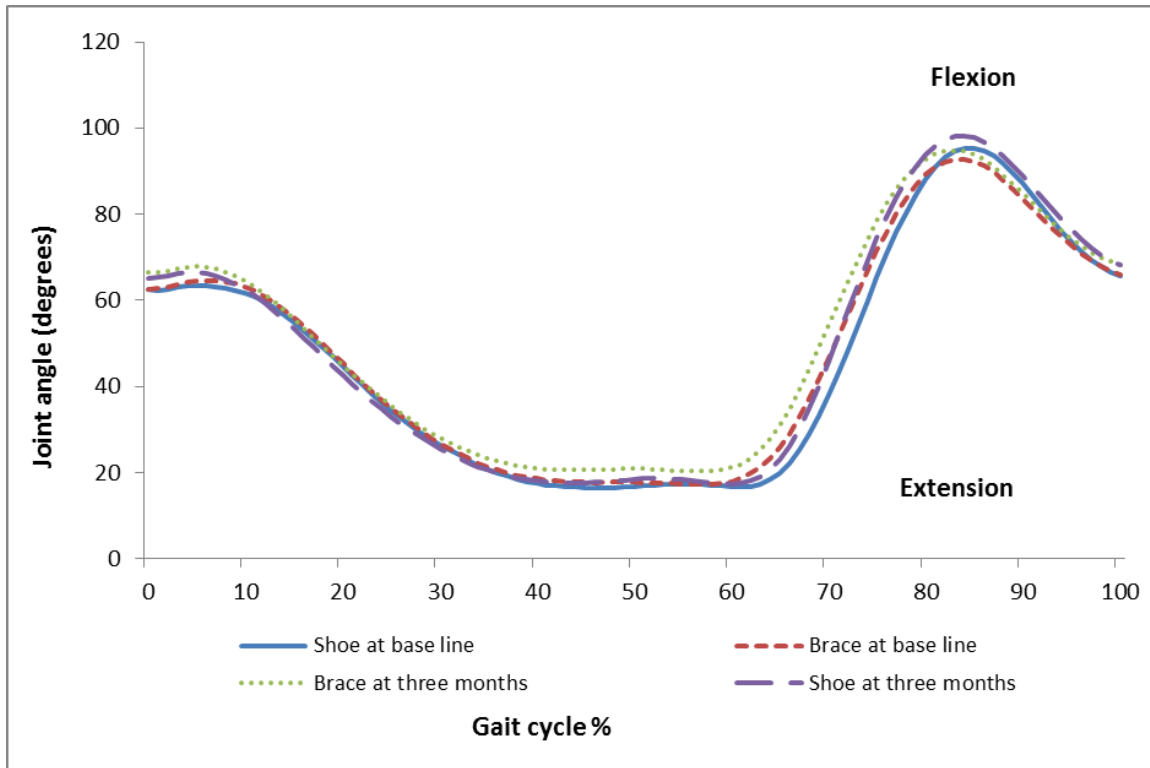

Figure 4-25: Sagittal plane ankle angle of the four conditions during descent.

Table 4-30: Mean, (SD) sagittal plane ankle angle during descent.

Type	Shoe Baseline	Brace Baseline	Brace Three Months	Shoe Three Months
Ankle Dorsiflexion Mean (SD)(°)	39.06(2.73)	39.47(3.42)	40.64(5.35)	40.12(4.65)
Ankle Planter flexion Mean (SD) (°)	-18.78(5.08)	-17.43(4.67)	-15.79(5.27)	-17.30(5.75)
Ankle ROM Mean (SD) (°)	57.84(5.91)	56.90(6.56)	56.43(7.85)	57.42(6.39)

4.3.10.3 Knee angle (sagittal plane)

At initial contact after wearing the brace for three months, there was a significant increase (mean difference 4.20 degree, p=0.00) in the knee angle in comparison to the shoe only at baseline, with an average increase of 35.72 % was found. Additionally after wearing the brace for three months, there was a significant increase (mean difference 2.97 degree, p=0.02) in the knee angle in comparison to the brace baseline, with an average increase of 22.89% was found. However after wearing the brace for three months, there was no significant change (mean difference 2.19 degree, p=0.06) in the knee angle between the shoe only at baseline and at three months, even though an average increase of 18.67% was found.

At loading response stage after wearing the brace for three months, there was a significant increase (mean difference 5.55 degree, p=0.00) in the maximum of knee angle in comparison to the shoe only at baseline, with an average increase of 23.74 % was found. Additionally, after wearing the brace for three months, there was a significant increase (mean difference 3.37 degree, p=0.02) in the maximum of knee angle in comparison to the brace baseline, with an average increase of 13.19% was found. In addition, after wearing the brace for three months, there was a significant increase (mean difference 3.90 degree, p=0.01) in the maximum of knee angle between the shoe only at baseline and at three months, with an average increase of 16.68% was found.

At mid stance stage after wearing the brace for three months, there was a significant increase (mean difference 6.31 degree, p=0.00) in the minimum of knee angle in comparison to the shoe only at baseline, with an average increase of 29.37% was found. Additionally, after wearing the brace for three months, there was a significant increase (mean difference 3.85 degree, p=0.02) in the minimum of knee angle in comparison to the brace baseline, with an average increase of 16.09% was found. In addition, after wearing the brace for three months, there was a significant increase (mean difference 4.12 degree, p=0.00) in the minimum of knee angle between the shoe only at baseline and at three months, with an average increase of 19.18% was found.

At mid swing stage after wearing the brace for three months, there was a significant increase (mean difference 3.18 degree, p=0.01) in the maximum of knee angle in comparison to the shoe only at baseline, with an average increase of 3.31 % was found. However, after wearing the brace for three months, there was no significant change (mean difference 2.12 degree, p=0.05) in the maximum of knee angle in comparison to the brace baseline, even though an average increase of 2.19% was found. However, after wearing the brace for three months, there was a significant increase (mean difference 2.76 degree, p=0.02) in the maximum of knee angle between the shoe only at baseline and at three months, with an average increase of 2.87% was found.

After wearing the brace for three months, there was no significant change (mean difference 1.02 degree, p=0.50) in the sagittal knee ROM in comparison to the shoe only at baseline, even though an average decrease of 1.20 % was found. Additionally, after wearing the brace for three months, there was no significant change (mean difference 0.85 degree, p=0.48) in the sagittal knee ROM in comparison to the brace baseline, even though an average decrease of 1.01% was found. In addition, after wearing the brace for three months, there was no significant change (mean difference 0.56 degree, p=0.53) in the sagittal knee ROM between the shoe only at baseline and at three months, even though an average increase of 0.67% was found. Descriptive data of sagittal plane knee angle results during descending are illustrated in figure 4-26 and table 4-31.
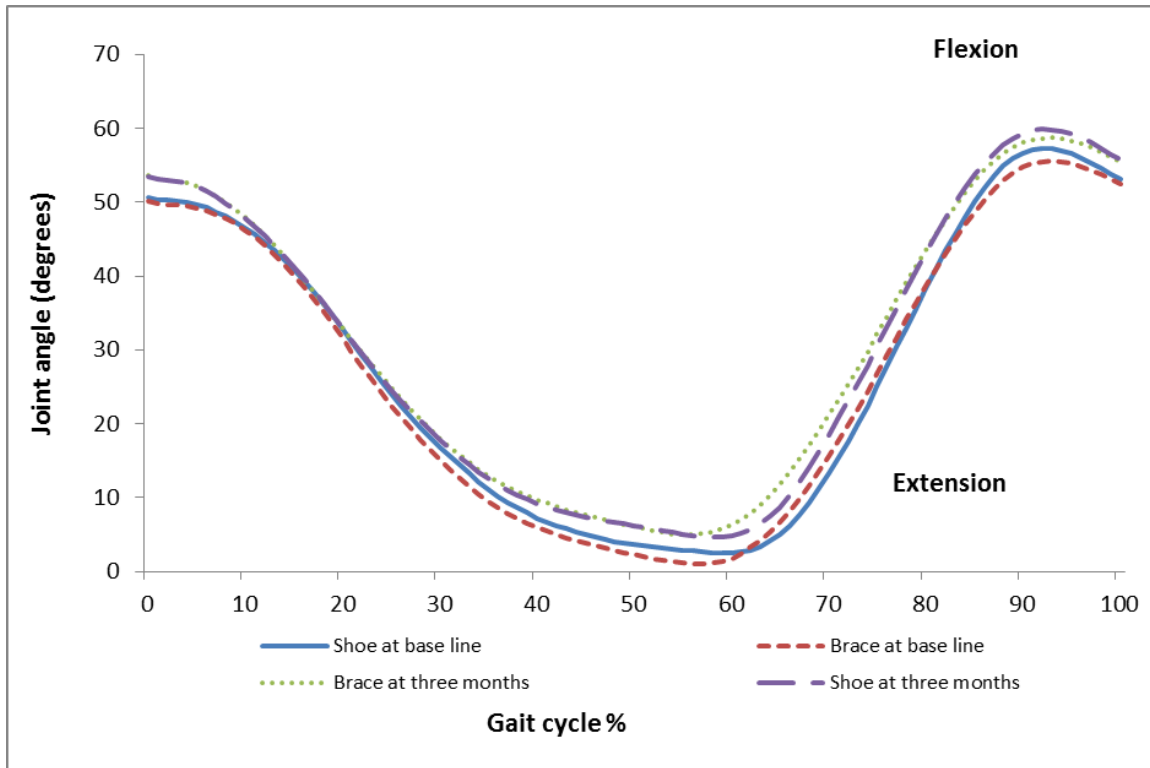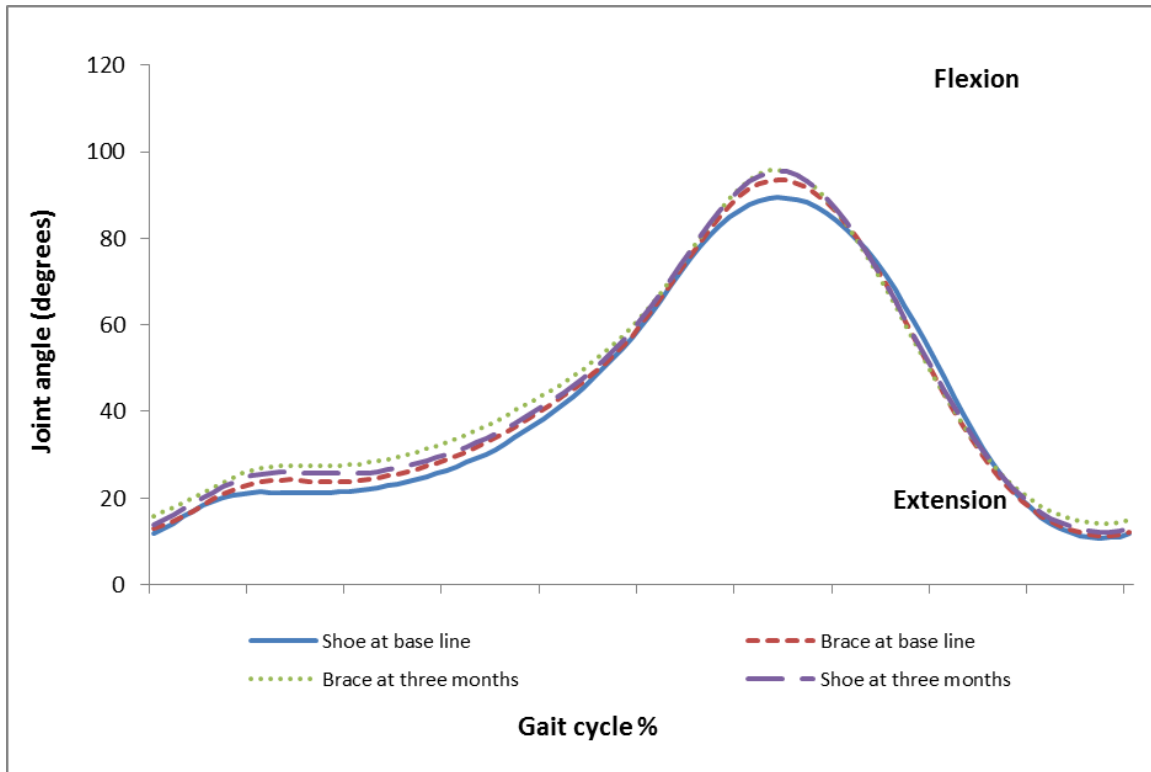
Figure 4-26: Sagittal plane knee angle of the four conditions during descent.

Table 4-31: Mean, (SD) sagittal plane knee angle during descent.

Type	Shoe Baseline	Brace Baseline	Brace Three Months	Shoe Three Months
Initial contact Mean (SD) (°)	11.75 (5.69)	12.98 (5.84)	15.95 (3.99)	13.94 (4.18)
Loading response Mean (SD) (°)	23.39 (5.37)	25.57 (6.37)	28.94 (5.25)	27.29 (4.64)
Mid stance Mean (SD) (°)	21.48(5.05)	23.94(6.59)	27.79(5.95)	25.60(5.30)
Mid swing Mean (SD) (°)	96.09 (6.62)	97.15 (6.94)	99.27(5.81)	98.85(4.68)
Knee ROM X angle Mean (SD)(°)	84.34(6.34)	84.17(6.50)	83.33(6.53)	84.91(5.57)

4.3.10.4 Knee angle (frontal plane)

After wearing the brace for three months, there was no significant change (mean difference 0.75 degree, p=0.49) in the maximum of frontal knee angle in comparison to the shoe only at baseline, even though an average increase of 9.47 % was found. Additionally, after wearing the brace for three months, there was no significant change (mean difference 1.58 degree, p=0.16) in the maximum of frontal knee angle in comparison to the brace baseline, even though an average increase of 22.42 % was found. In addition, after wearing the brace for three months, there was no significant change

131

(mean difference 1.81 degree, p=0.16) in the maximum of frontal knee angle between the shoe only at baseline and at three months, even though an average increase of 23.07 % was found.

After wearing the brace for three months, there was a significant decrease (mean difference 2.75 degree, p=0.00) in the minimum of frontal knee angle in comparison to the shoe only at baseline. Additionally, after wearing the brace for three months, there was a significant decrease (mean difference 2.54 degree, p=0.01) in the minimum of frontal knee angle in comparison to the brace baseline. In addition, after wearing the brace for three months, there was a significant decrease (mean difference 2.62 degree, p=0.00) in the minimum of frontal knee angle between the shoe only at baseline and at three months.

After wearing the brace for three months, there was a significant decrease (mean difference 2.01 degree, p=0.03) in the frontal knee ROM in comparison to the shoe only at baseline, with an average decrease of 20.92 % was found. However, after wearing the brace for three months, there was no significant change (mean difference 0.96 degree, p=0.34) in the frontal knee ROM in comparison to the brace baseline, even though an average decrease of 11.27% was found. In addition, after wearing the brace for three months, there was no significant change (mean difference 81 degree, p=0.38) in the frontal knee ROM between the shoe only at baseline and at three months, even though an average decrease of 8.42% was found. Descriptive data of frontal plane knee angle results during descending are illustrated in figure 4-27 and table 4-32.
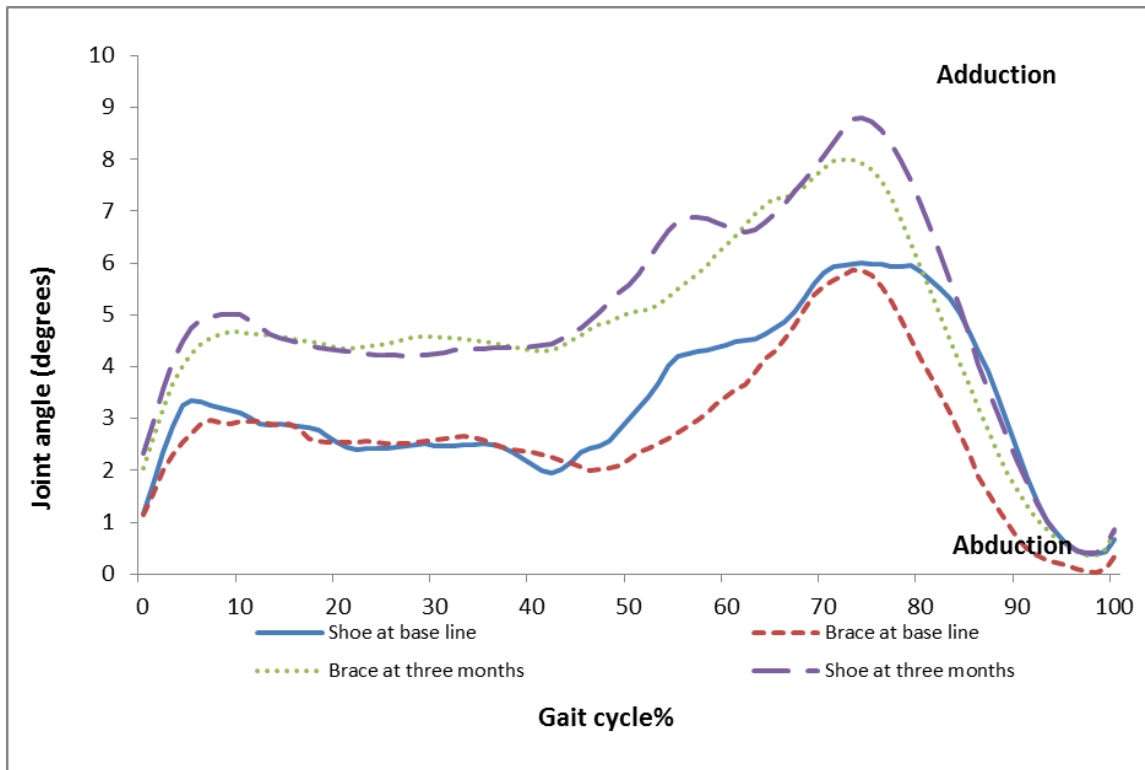
Figure 4-27: Frontal plane knee angle of the four conditions during descent.

Table 4-32: Mean, (SD) frontal plane knee angle during descent.

Type	Shoe Baseline	Brace Baseline	Brace Three Months	Shoe Three Months
Maximum knee angle Y Mean (SD)(°)	7.87(5.52)	7.03(5.60)	8.61(4.62)	9.68(4.83)
Minimum knee angle Y Mean (SD)(°)	-1.73(6.30)	-1.52(6.29)	1.02(4.78)	0.89(4.86)
Knee ROM Y angle Mean (SD)(°)	9.60(3.50)	8.55(2.96)	7.59(2.34)	8.79(3.08)

4.3.10.5 Hip angle (sagittal plane)

After wearing the brace for three months, there was no significant change (mean difference 1.09 degree, p=0.69) in the maximum of hip flexion angle in comparison to the shoe only at baseline, even though an average decrease of 3.05 % was found. Additionally, after wearing the brace for three months, there was no significant change (mean difference 1.66 degree, p=0.52) in the maximum of hip flexion angle in comparison to the brace baseline, even though an average increase of 5.07% was found. In addition, after wearing the brace for three months, there was no significant change (mean difference 1.37 degree, p=0.67) in the maximum of hip flexion angle between the

shoe only at baseline and at three months, even though an average increase of 3.85% was found.

After wearing the brace for three months, there was no significant change (mean difference 1.54 degree, p=0.59) in the maximum hip extension angle in comparison to the shoe only at baseline. Additionally, after wearing the brace for three months, there was no significant change (mean difference 3.69 degree, p=0.18) in the maximum of hip extension angle in comparison to the brace baseline. In addition, after wearing the brace for three months, there was no significant change (mean difference 2.10 degree, p=0.43) in the maximum of hip extension angle between the shoe only at baseline and at three months.

After wearing the brace for three months, there was a significant decrease (mean difference 2.63 degree, p=0.03) in the hip ROM in comparison to the shoe only at baseline, with an average decrease of 8.50 % was found. However, after wearing the brace for three months, there was no significant change (mean difference 2.03 degree, p=0.05) in the hip ROM in comparison to the brace baseline, even though an average decrease of 6.69% was found. In addition, after wearing the brace for three months, there was no significant change (mean difference 0.73 degree, p=0.55) in the hip ROM between the shoe only at baseline and at three months, even though an average decrease of 2.37% was found. Descriptive data of sagittal plane hip angle results during descending are illustrated in figure 4-28 and table 4-33.
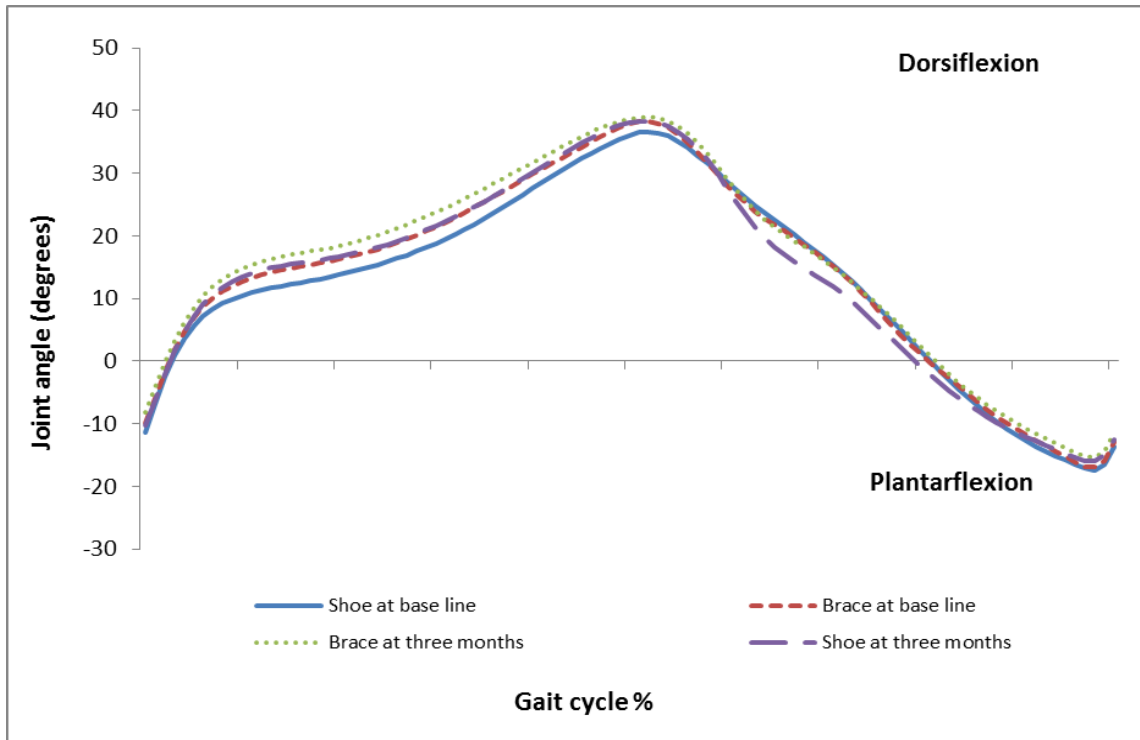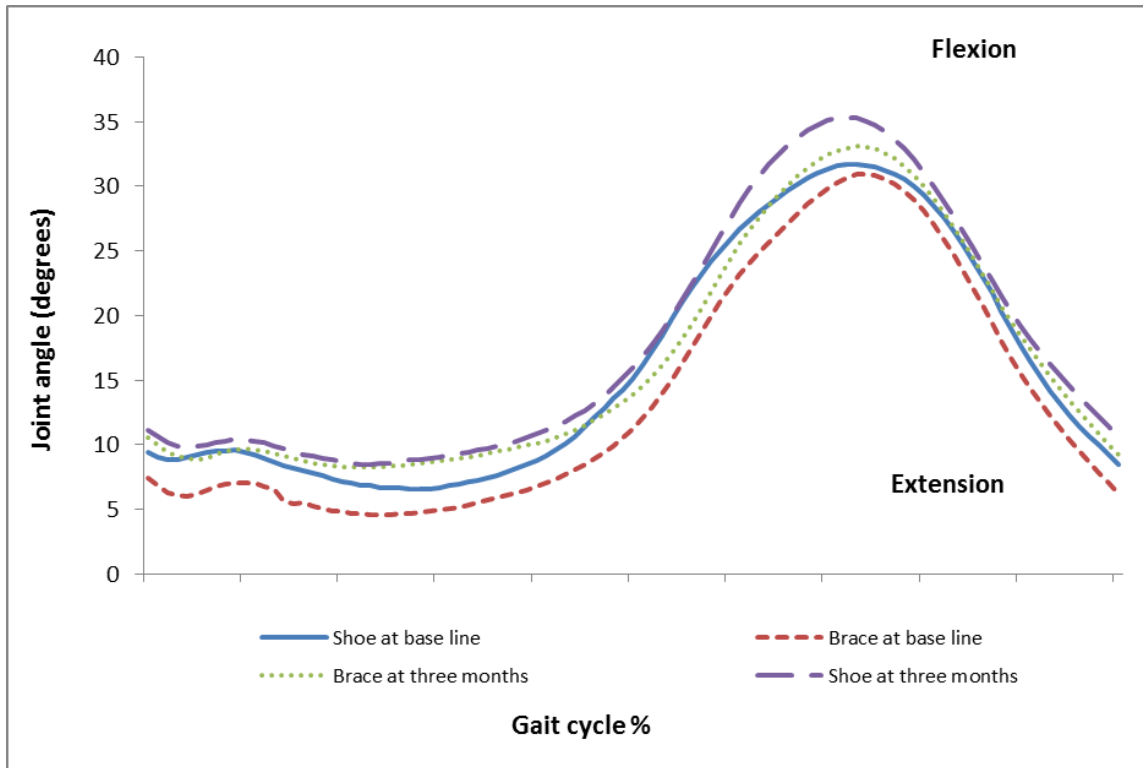
Figure 4-28: Sagittal plane hip angle of the four conditions during descent.

Table 4-33: Mean, (SD) sagittal plane hip angle during descent.

Type	Shoe Baseline	Brace Baseline	Brace Three Months	Shoe Three Months
Hip Flexion Mean (SD) (°)	35.58(11.90)	32.83(10.70)	34.49(7.24)	36.95(6.65)
Hip Extension Mean (SD) (°)	4.68(12.27)	2.53(12.03)	6.22(8.65)	6.78(8.52)
Hip ROM Mean (SD) (°)	30.90(4.27)	30.30(3.84)	28.27(3.62)	30.17(3.78)

4.3.11 The kinetic results of the contralateral leg during walking

4.3.11.1 The external knee adduction moment (EKAM)

There was no significant change (mean difference 0.07 Nm/kg, p=0.07) in the first peak of EKAM in the contralateral limb between the shoe only at baseline and after wearing the brace for three months in the brace condition. In addition, when not wearing the brace there was no significant change (mean difference 0.08 Nm/kg, p=0.07) in the first peak of EKAM in the contralateral limb between the shoe only at baseline and the shoe only condition at three months.

There was no significant change (mean difference 0.01 Nm/kg, p=0.47) in the second peak of EKAM in the contralateral limb between the shoe only at baseline and after

135

wearing the brace for three months in the brace condition. In addition, when not wearing the brace there was no significant change (mean difference 0.01 Nm/kg, p=0.65) in the second peak of EKAM in the contralateral limb between the shoe only at baseline and the shoe only condition at three months. Descriptive data of contralateral EKAM results during walking are illustrated in figure 4-29 and table 4-34.
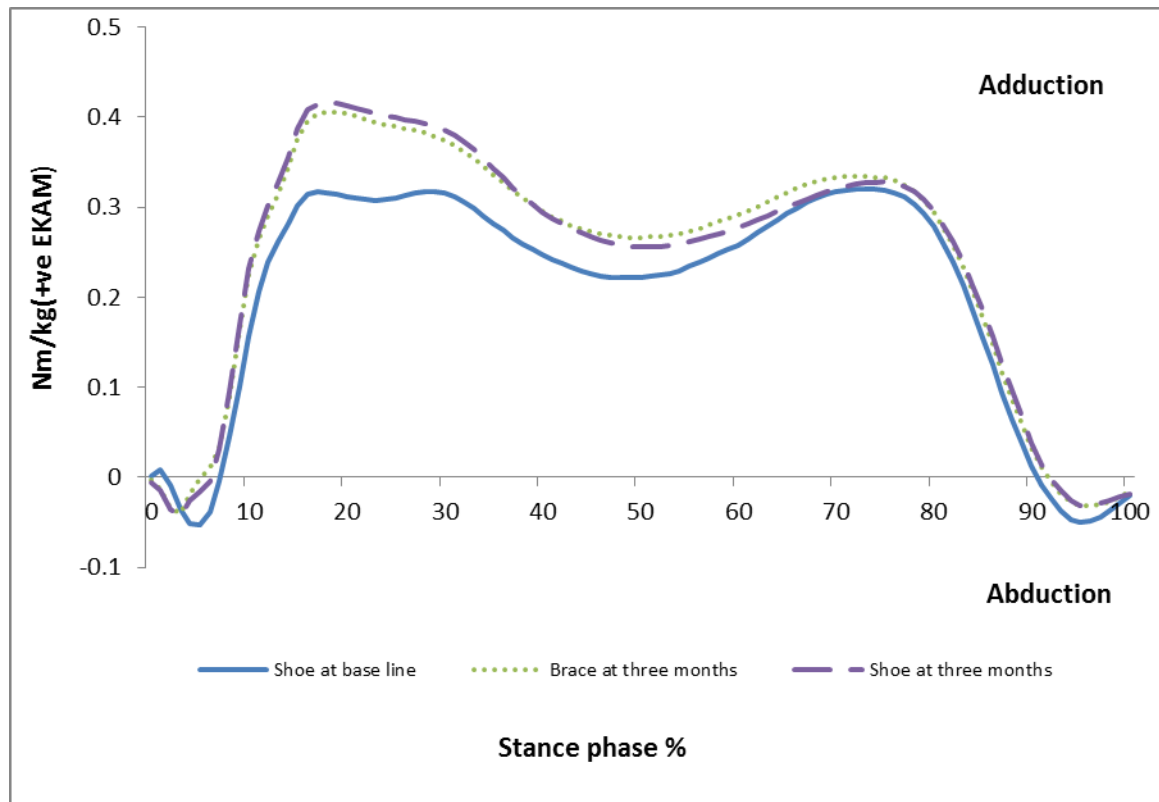
Figure 4-29: Contralateral the external knee adduction moment (EKAM) of three conditions during walking.

Table 4-34: Mean (SD) Contralateral first and second peak of the EKAM during walking.

Type	Shoe Base line	Brace Three Months	Shoe Three Months
EKAM 1 Mean (SD) (Nm/kg)	0.38(0.14)	0.45(0.21)	0.46(0.21)
EKAM 2 Mean (SD) (Nm/kg)	0.34(0.15)	0.35(0.16)	0.35(0.15)

4.3.11.2 The Knee moment (sagittal plane):

There was no significant change (mean difference 0.05 Nm/kg, p=0.33) in the maximum knee flexor moment in the contralateral limb between the shoe only at baseline and after wearing the brace for three months in the brace condition. In addition, when not wearing the brace there was no significant change (mean difference 0.07 Nm/kg, p=0.20) in the

maximum knee flexor moment in the contralateral limb between the shoe only at baseline and the shoe only condition at three months.

There was no significant change (mean difference 0.02 Nm/kg, p=0.39) in the maximum knee extensor moment in the contralateral limb between the shoe only at baseline and after wearing the brace for three months in the brace condition. In addition, when not wearing the brace there was no significant change (mean difference 0.02 Nm/kg, p=0.52) in the maximum knee extensor moment in the contralateral limb between the shoe only at baseline and the shoe only condition at three months. Descriptive data of contralateral sagittal plane knee moment results during walking are illustrated in figure 4-30 and table 4-35.
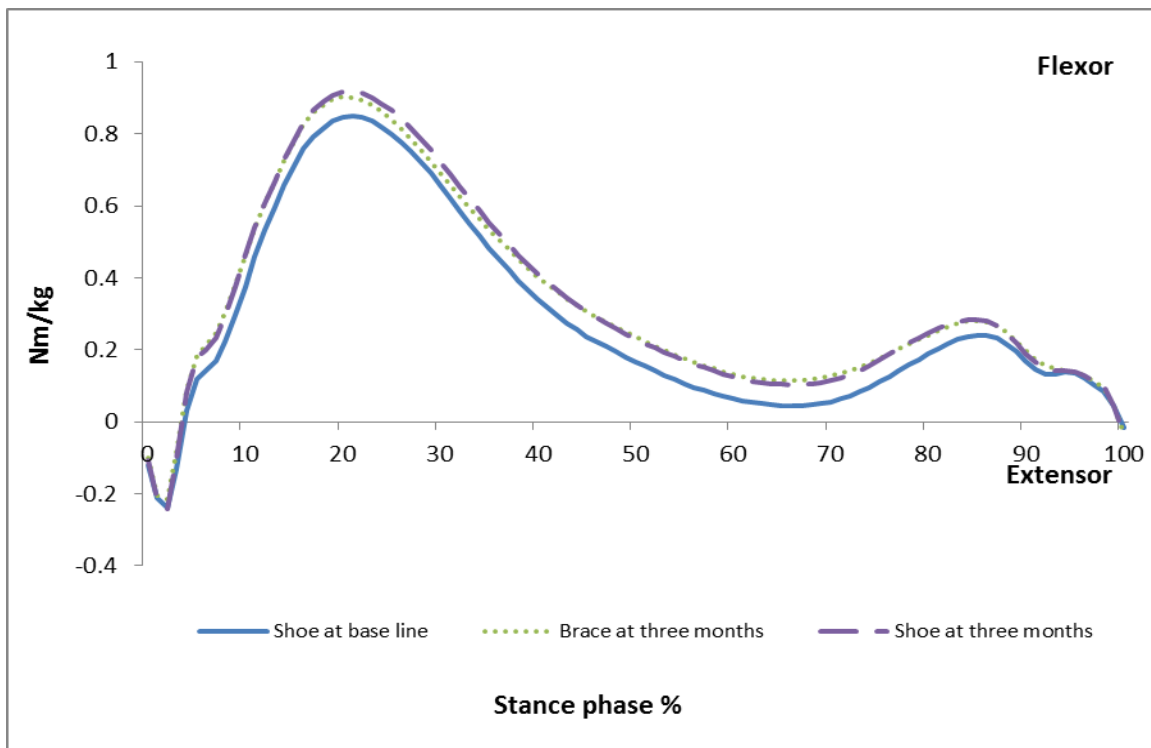
Figure 4-30: Contralateral sagittal plane knee moment of the three conditions during walking.

Table 4-35: Mean (SD) Contralateral sagittal plane knee moment during walking.

Type	Shoe Base line	Brace Three Months	Shoe Three Months
Knee flexion Mom Mean (SD) (Nm/kg)	0.87(0.22)	0.92(0.24)	0.94(0.25)
Knee extension Mom Mean (SD) (Nm/kg)	-0.29(0.11)	-0.27(0.14)	0.-28(0.14)

4.3.11.3 Vertical Ground Reaction Force (GRF)

At early stage, there was no significant change (mean difference 0.02 $^{\bullet}$BW, p=0.41) in the GRF in the contralateral limb between the shoe only at baseline and after wearing the brace for three months in the brace condition. In addition, when not wearing the brace there was no significant change (mean difference 0.03 $^{\bullet}$BW, p=0.30) in the GRF in the contralateral limb between the shoe only at baseline and the shoe only condition at three months.

At mid stage, there was no significant change (mean difference 0.02 $^{\bullet}$BW, p=0.20) in the GRF in the contralateral limb between the shoe only at baseline and after wearing the brace for three months in the brace condition. In addition, when not wearing the brace there was no significant change (mean difference 0.00 $^{\bullet}$BW, p=0.73) in the GRF in the contralateral limb between the shoe only at baseline and the shoe only condition at three months.

At late stage, there was no significant change (mean difference 0.01 $^{\bullet}$BW, p=0.31) in the GRF in the contralateral limb between the shoe only at baseline and after wearing the brace for three months in the brace condition. In addition, when not wearing the brace there was no significant change (mean difference 0.01 $^{\bullet}$BW, p=0.51) in the GRF in the contralateral limb between the shoe only at baseline and the shoe only condition at three months. Descriptive data of contralateral EKAM results during walking are illustrated in figure 4-31 and table 4-36.

Figure 4-31: Contralateral the ground reaction force (GRF) of the three conditions during walking.

Table 4-36: Mean (SD) Contralateral Ground reaction force (GRF) during walking.

Type	Shoe Base line	Brace Three Months	Shoe Three Months
Early stance GRF Mean (SD)(•BW)	1.11(0.11)	1.09(0.10)	1.08(0.13)
Mid stance GRF Mean (SD)(•BW)	0.79(0.08)	0.81(0.08)	0.79(0.08)
Late stance GRF Mean (SD)(•BW)	1.09(0.07)	1.07(0.07)	1.08(0.08)

4.3.12 The kinetic results of the contralateral leg during ascending stairs

4.3.12.1 The external knee adduction moment (EKAM)

There was no significant change (mean difference 0.10 Nm/kg, p=0.11) in the first peak of EKAM in the contralateral limb between the shoe only at baseline and after wearing the brace for three months in the brace condition. In addition, when not wearing the brace there was no significant change (mean difference 0.09Nm/kg, p=0.10) in the first peak of EKAM in the contralateral limb between the shoe only at baseline and the shoe only condition at three months.

There was no significant change (mean difference 0.03 Nm/kg, p=0.42) in the second peak of EKAM in the contralateral limb between the shoe only at baseline and after wearing the brace for three months in the brace condition. In addition, when not wearing the brace there was no significant change (mean difference 0.03 Nm/kg, p=0.46) in the second peak of EKAM in the contralateral limb between the shoe only at baseline and the shoe only condition at three months. Descriptive data of contralateral EKAM results during ascending are illustrated in figure 4-32 and table 4-37.
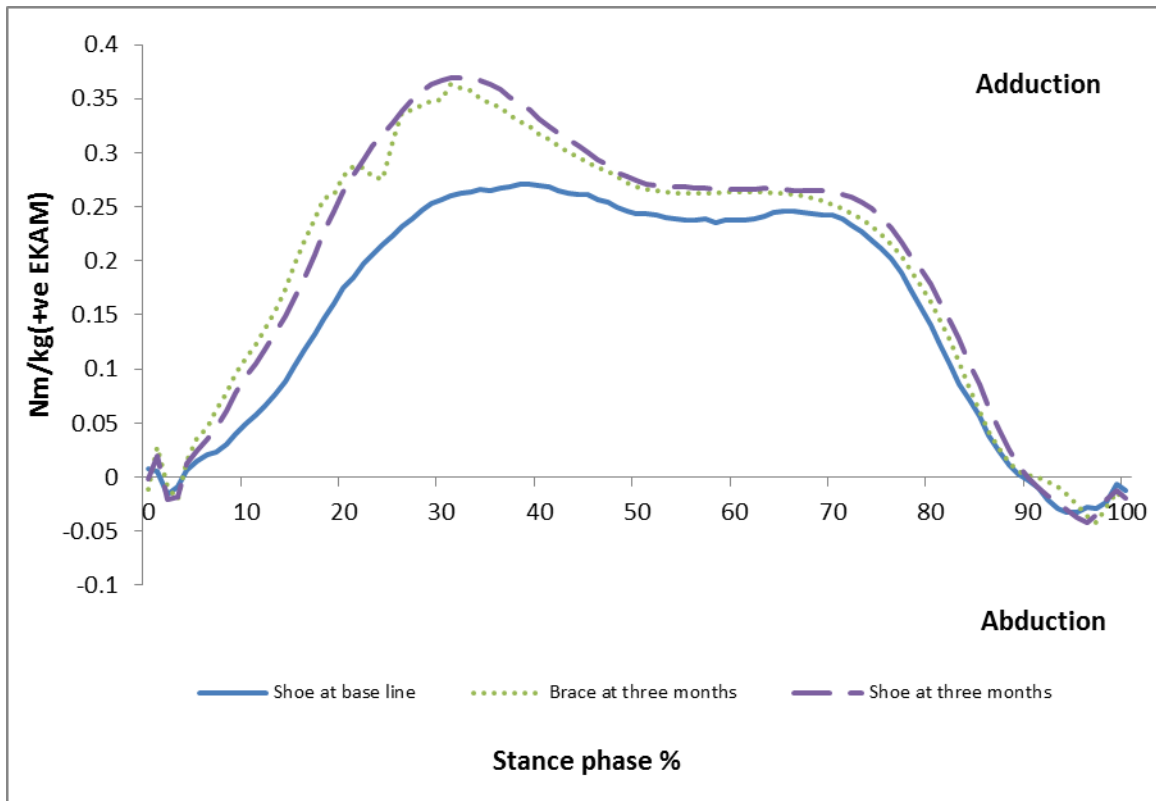
Figure 4-32: Contralateral the external knee adduction moment (EKAM) of the three conditions during Ascent.

Table 4-37: Mean (SD) Contralateral first and second peak of the EKAM during ascent.

Type	Shoe Base line	Brace Three Months	Shoe Three Months
EKAM 1 Mean (SD) (Nm/kg)	0.30(0.15)	0.40(0.27)	0.39(0.24)
EKAM 2 Mean (SD) (Nm/kg)	0.26(0.13)	0.29(0.20)	0.29(0.18)

4.3.12.2 The Knee moment (sagittal plane):

There was a significant increase (mean difference 0.15 Nm/kg, p=0.04) in the maximum knee flexor moment in the contralateral limb between the shoe only at baseline and after wearing the brace for three months in the brace condition. However, when not wearing the brace there was no significant change (mean difference 0.11 Nm/kg, p=0.14) in the maximum knee flexor moment in the contralateral limb between the shoe only at baseline and the shoe only condition at three months.

There was no significant change (mean difference 0.04 Nm/kg, p=0.06) in the maximum knee extensor moment in the contralateral limb between the shoe only at baseline and after wearing the brace for three months in the brace condition. In addition, when not wearing the brace there was no significant change (mean difference 0.00 Nm/kg, p=0.90) in the maximum knee extensor moment in the contralateral limb between the shoe only at baseline and the shoe only condition at three months. Descriptive data of contralateral sagittal plane knee moment results during ascending are illustrated in figure 4-33 and table 4-38.

Figure 4-33: Contralateral sagittal plane knee moment of the three conditions during ascent.

Table 4-38: Mean (SD) Contralateral sagittal plane knee moment during ascent.

Type	Shoe Base line	Brace Three Months	Shoe Three Months
Knee flexion Mom Mean (SD) (Nm/kg)	1.47(0.50)	1.62(0.66)	1.58(0.61)
Knee extension Mom Mean (SD) (Nm/kg)	-0.20(0.07)	-0.24(0.10)	-0.20(0.06)

4.3.12.3 Vertical Ground Reaction Force (GRF)

At early stage, there was no significant change (mean difference 0.04 ˙BW, p=0.06) in the GRF in the contralateral limb between the shoe only at baseline and after wearing the brace for three months in the brace condition. In addition, when not wearing the brace there was no significant change (mean difference 0.03 ˙BW, p=0.17) in the GRF in the contralateral limb between the shoe only at baseline and the shoe only condition at three months.

At mid stage, there was no significant change (mean difference 0.00 ˙BW, p=0.90) in the GRF in the contralateral limb between the shoe only at baseline and after wearing the brace for three months in the brace condition. In addition, when not wearing the brace there was no significant change (mean difference 0.01 ˙BW, p=0.72) in the GRF in the contralateral limb between the shoe only at baseline and the shoe only condition at three months.

At late stage, there was no significant change (mean difference 0.03 ˙BW, p=0.11) in the GRF in the contralateral limb between the shoe only at baseline and after wearing the brace for three months in the brace condition. In addition, when not wearing the brace there was no significant change (mean difference 0.03 ˙BW, p=0.10) in the GRF in the contralateral limb between the shoe only at baseline and the shoe only condition at three months. Descriptive data of contralateral GRF results during ascending are illustrated in figure 4-34 and table 4-39.
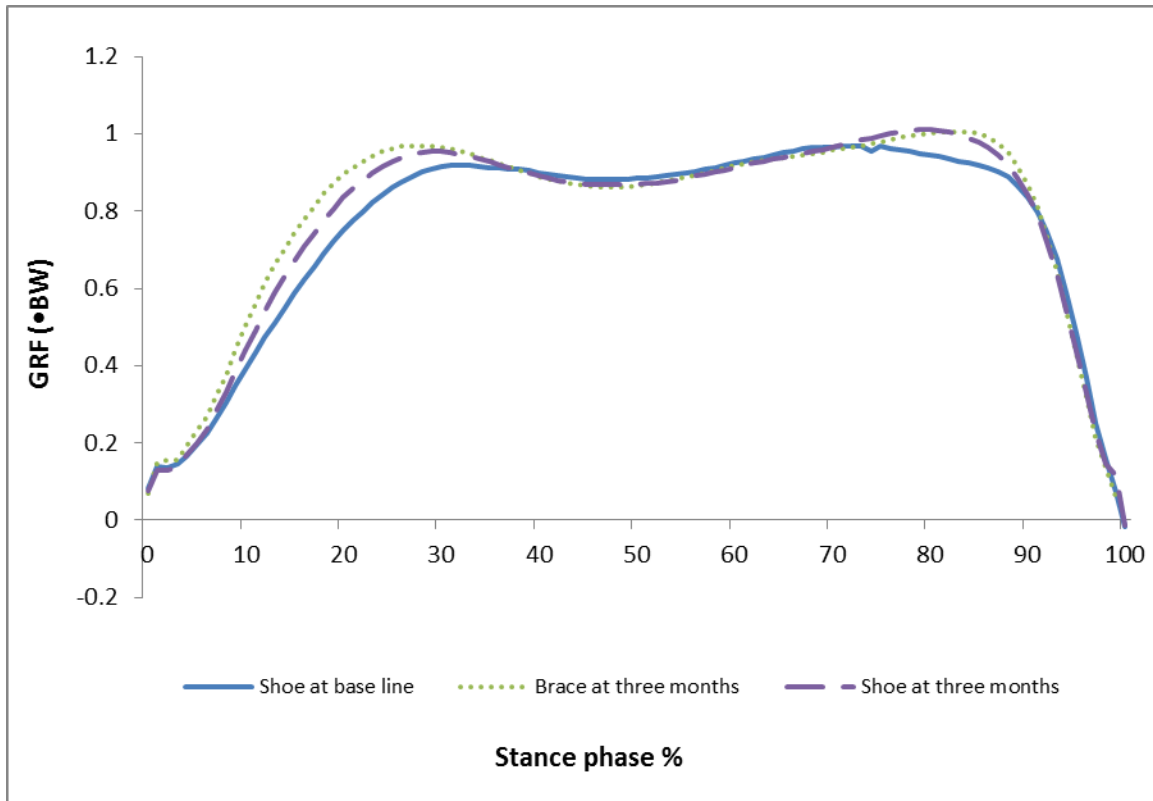
Figure 4-34: Contralateral the ground reaction force of the three conditions during Ascent.

Table 4-39: Mean (SD) Contralateral ground reaction force (GRF) during ascent.

Type	Shoe Base line	Brace Three Months	Shoe Three Months
Early stance GRF Mean (SD)(•BW)	0.95(0.08)	0.99(0.05)	0.97(0.04)
Mid stance GRF Mean (SD)(•BW)	0.83(0.09)	0.83(0.05)	0.84(0.05)
Late stance GRF Mean (SD)(•BW)	1.03(0.04)	1.06(0.07)	1.05(0.06)

3.3.13 The kinetic results of the contralateral leg during descending stairs

4.3.13.1 The external knee adduction moment (EKAM)

There was no significant change (mean difference 0.04 Nm/kg, p=0.46) in the first peak of EKAM in the contralateral limb between the shoe only at baseline and after wearing the brace for three months in the brace condition. In addition, when not wearing the brace there was no significant change (mean difference 0.08 Nm/kg, p=0.18) in the first peak of EKAM in the contralateral limb between the shoe only at baseline and the shoe only condition at three months.

143

There was no significant change (mean difference 0.10 Nm/kg, p=0.10) in the second peak of EKAM in the contralateral limb between the shoe only at baseline and after wearing the brace for three months in the brace condition. In addition, when not wearing the brace there was no significant change (mean difference 0.10 Nm/kg, p=0.09) in the second peak of EKAM in the contralateral limb between the shoe only at baseline and the shoe only condition at three months. Descriptive data of contralateral EKAM results during descending are illustrated in figure 4-35 and table 4-40.
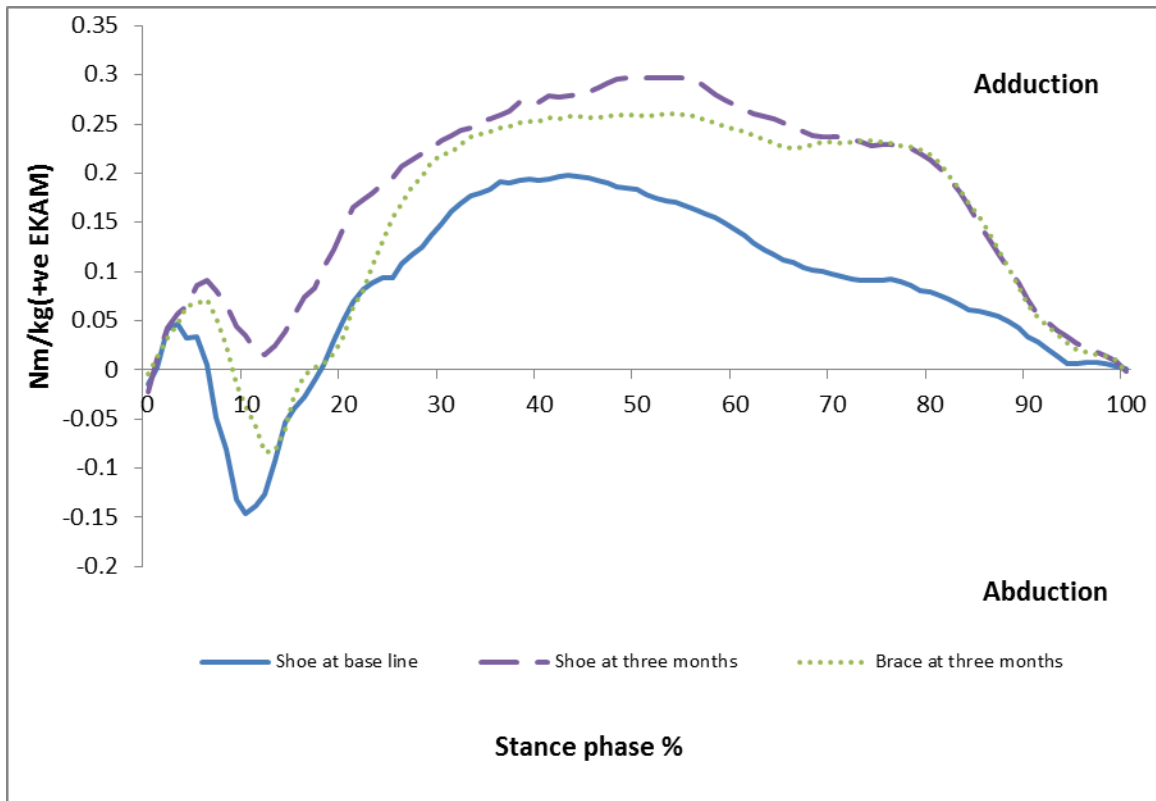
Figure 4-35: Contralateral the external knee adduction moment (EKAM) of the three conditions during descent.

Table 4-40: Mean (SD) Contralateral first and second peak of the EKAM during descent.

Type	Shoe Base line	Brace Three Months	Shoe Three Months
EKAM 1 Mean (SD) (Nm/kg)	0.26(0.16)	0.30(0.21)	0.34(0.23)
EKAM 2 Mean (SD) (Nm/kg)	0.20(0.13)	0.30(0.17)	0.30(0.18)

4.3.13.2 The Knee moment (sagittal plane):

There was no significant change (mean difference 0.48 Nm/kg, p=0.08) in the maximum knee flexor moment in the contralateral limb between the shoe only at baseline and after wearing the brace for three months in the brace condition. In addition, when not wearing the brace there was no significant change (mean difference 0.32 Nm/kg, p=0.15) in the maximum knee flexor moment in the contralateral limb between the shoe only at baseline and the shoe only condition at three months.

There was no significant change (mean difference 0.01 Nm/kg, p=0.61) in the maximum knee extensor moment in the contralateral limb between the shoe only at baseline and after wearing the brace for three months in the brace condition. In addition, when not wearing the brace there was no significant change (mean difference 0.01 Nm/kg, p=0.51) in the maximum knee extensor moment in the contralateral limb between the shoe only at baseline and the shoe only condition at three months. Descriptive data of contralateral sagittal plane knee moment results during descending are illustrated in figure 4-36 and table 4-41.

Figure 4-36: Contralateral sagittal plane knee moment of the three conditions during descent.

Table 4-41: Mean (SD) Contralateral sagittal plane knee moment during descent.

Type	Shoe Base line	Brace Three Months	Shoe Three Months
Knee flexion Mom Mean (SD) (Nm/kg)	3.16(1.01)	3.63(1.32)	3.47(1.30)
Knee extension Mom Mean (SD) (Nm/kg)	-0.10(0.06)	-0.11(0.04)	-0.12(0.07)

4.3.13.3 Vertical Ground Reaction Force (GRF)

At early stage, there was no significant change (mean difference 0.08 ˙BW, p=0.26) in the GRF in the contralateral limb between the shoe only at baseline and after wearing the brace for three months in the brace condition. In addition, when not wearing the brace there was no significant change (mean difference 0.06 ˙BW, p=0.21) in the GRF in the contralateral limb between the shoe only at baseline and the shoe only condition at three months.

At mid stage, there was no significant change (mean difference 0.01 ˙BW, p=0.58) in the GRF in the contralateral limb between the shoe only at baseline and after wearing the brace for three months in the brace condition. In addition, when not wearing the brace there was no significant change (mean difference 0.01 ˙BW, p=0.61) in the GRF in the contralateral limb between the shoe only at baseline and the shoe only condition at three months.

At late stage, there was no significant change (mean difference 0.01 ˙BW, p=0.50) in the GRF in the contralateral limb between the shoe only at baseline and after wearing the brace for three months in the brace condition. In addition, when not wearing the brace there was no significant change (mean difference 0.02 ˙BW, p=0.32) in the GRF in the contralateral limb between the shoe only at baseline and the shoe only condition at three months. Descriptive data of contralateral GRF results during descending are illustrated in figure 4-37 and table 4-42.
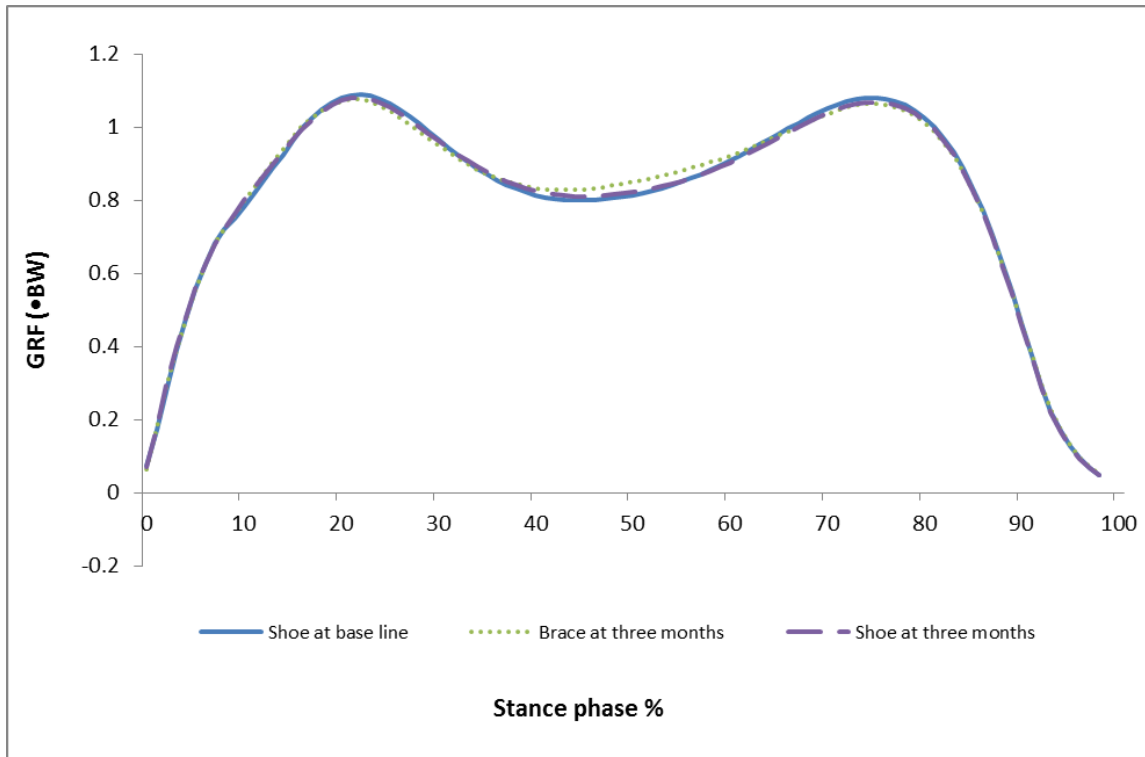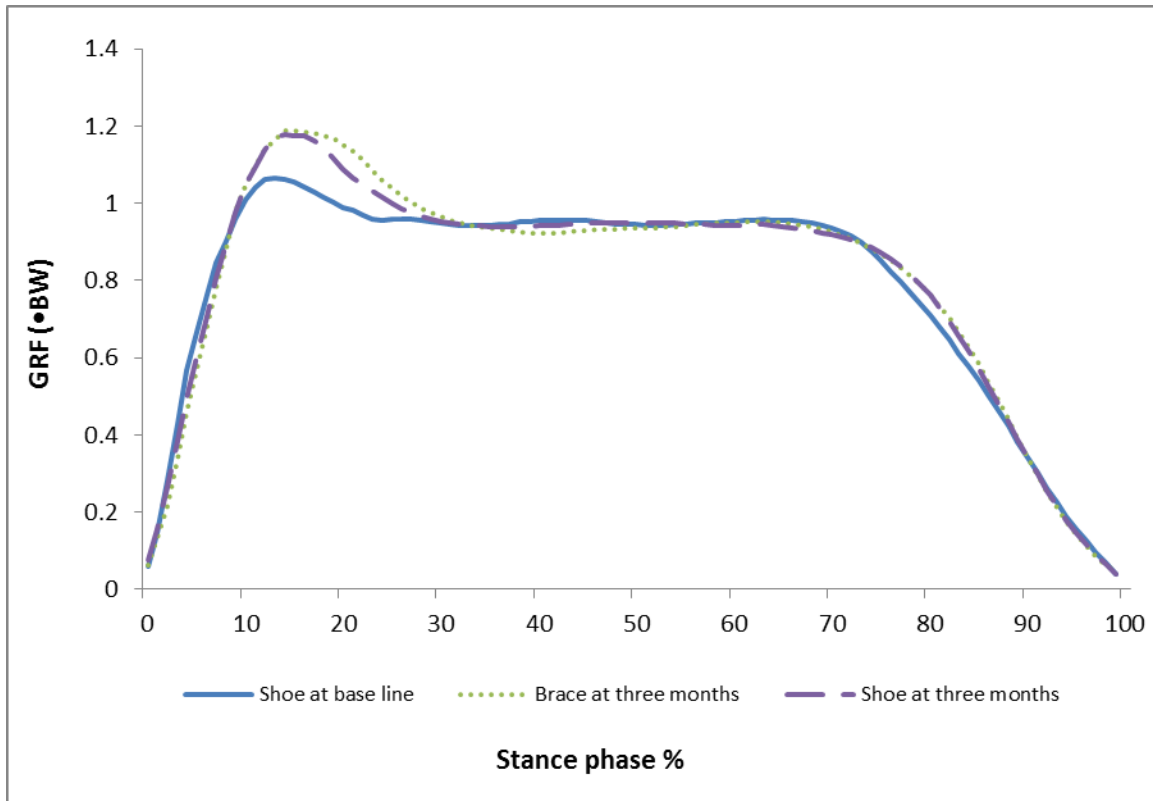
Figure 4-37: Contralateral the ground reaction force (GRF) of the three conditions during descent.

Table 4-42: Mean (SD) Contralateral ground reaction force (GRF) during descent.

Type	Shoe Base line	Brace Three Months	Shoe Three Months
Early stance GRF Mean (SD)(•BW)	1.33(0.22)	1.41(0.18)	1.39(0.19)
Mid stance GRF Mean (SD)(•BW)	0.87(0.06)	0.88 (0.04)	0.88(0.04)
Late stance GRF Mean (SD)(•BW)	0.97(0.05)	0.96(0.05)	0.95(0.05)

4.3.14 The kinematic results of the contralateral leg during walking

4.3.14.1 Ankle angle (sagittal plane)

There was no significant change (mean difference 0.91 Nm/kg, p=0.15) in the maximum of ankle dorsiflexion angle in the Contralateral limb between the shoe only at baseline and after wearing the brace for three months in the brace condition. In addition, when not wearing the brace there was no significant change (mean difference 0.97 Nm/kg, p=0.12) in the maximum of ankle dorsiflexion angle in the Contralateral limb between the shoe only at baseline and the shoe only condition at three months.

There was no significant change (mean difference 1.52 Nm/kg, p=0.08) in the maximum ankle planter flexion angle in the Contralateral limb between the shoe only at baseline and after wearing the brace for three months in the brace condition. In addition, when not wearing the brace there was no significant change (mean difference 1.48 Nm/kg, p=0.06) in the maximum ankle planter flexion angle in the Contralateral limb between the shoe only at baseline and the shoe only condition at three months.

There was no significant change (mean difference 0.61 Nm/kg, p=0.38) in the ankle ROM in the Contralateral limb between the shoe only at baseline and after wearing the brace for three months in the brace condition. In addition, when not wearing the brace there was no significant change (mean difference 0.52 Nm/kg, p=0.41) in the ankle ROM in the Contralateral limb between the shoe only at baseline and the shoe only condition at three months. Descriptive data of contralateral sagittal plane ankle angle results during walking are illustrated in figure 4-38 and table 4-43.
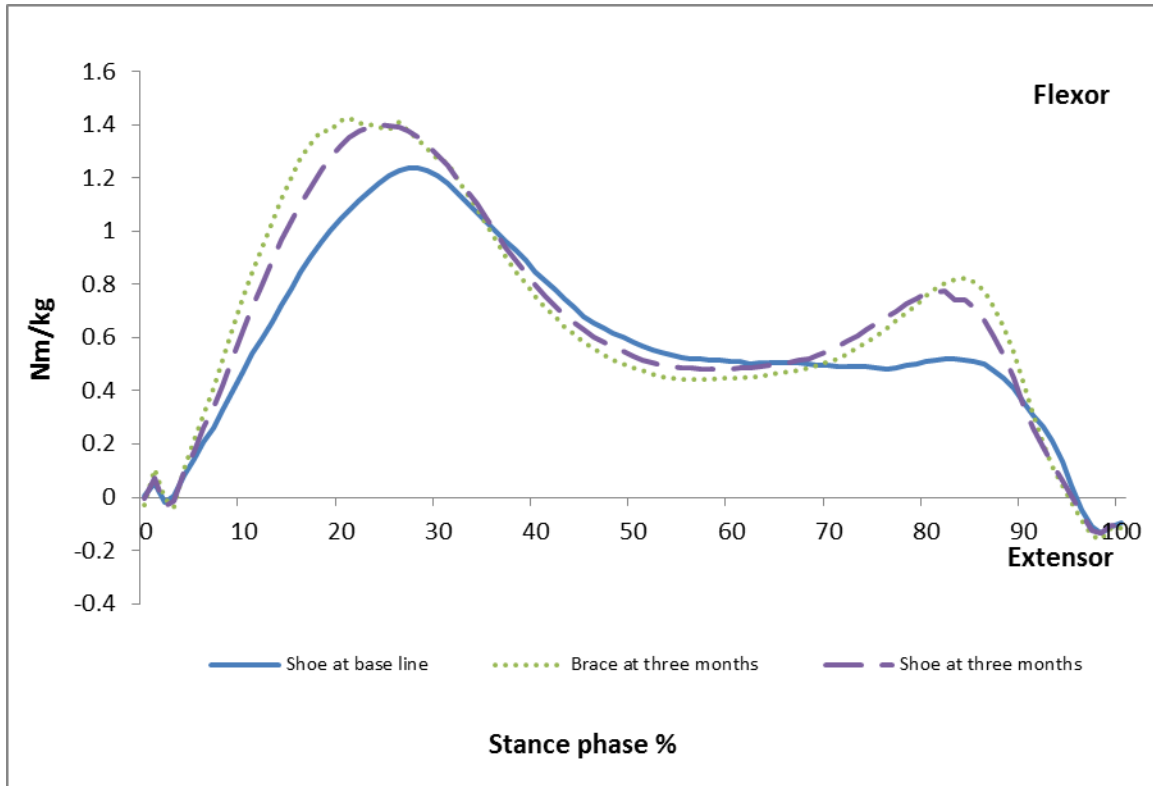

Figure 4-38: Contralateral sagittal plane ankle angle of the three conditions during walking.

Table 4-43: Mean, (SD) Contralateral sagittal plane ankle angle during walking.

Type	Shoe Base line	Brace Three Months	Shoe Three Months
Ankle Dorsiflexion Mean (SD)(°)	23.49(2.87)	24.39(3.82)	24.45(4.03)
Ankle Planter flexion Mean (SD) (°)	-9.85(4.02)	-8.33(2.97)	-8.37(3.11)
Ankle ROM Mean (SD) (°)	33.34(4.36)	32.73(4.86)	32.82(4.87)

4.3.14.2 Knee angle (sagittal plane)

At initial, there was no significant change (mean difference 2.11 Nm/kg, p=0.11) in the knee angle in the Contralateral limb between the shoe only at baseline and after wearing the brace for three months in the brace condition. In addition, when not wearing the brace there was no significant change (mean difference 2.16 Nm/kg, p=0.24) in the knee angle in the Contralateral limb between the shoe only at baseline and the shoe only condition at three months.

At loading response, there was no significant change (mean difference 2.61 Nm/kg, p=0.07) in the maximum of knee angle in the Contralateral limb between the shoe only at baseline and after wearing the brace for three months in the brace condition. In addition, when not wearing the brace there was no significant change (mean difference 3.02 Nm/kg, p=0.06) in the maximum of knee angle in the Contralateral limb between the shoe only at baseline and the shoe only condition at three months.

At mid stance stage, there was no significant change (mean difference 1.97 Nm/kg, p=0.17) in the minimum of knee angle in the Contralateral limb between the shoe only at baseline and after wearing the brace for three months in the brace condition. In addition, when not wearing the brace there was no significant change (mean difference 1.80 Nm/kg, p=0.21) in the minimum of knee angle in the Contralateral limb between the shoe only at baseline and the shoe only condition at three months.

At mid swing stage, there was no significant change (mean difference 1.83 Nm/kg, p=0.29) in the maximum of knee angle in the Contralateral limb between the shoe only at baseline and after wearing the brace for three months in the brace condition. In addition, when not wearing the brace there was no significant change (mean difference 1.88

Nm/kg, p=0.34) in the maximum of knee angle in the Contralateral limb between the shoe only at baseline and the shoe only condition at three months.

There was no significant change (mean difference 0.28 degree, p=0.75) in the sagittal knee ROM in the Contralateral limb between the shoe only at baseline and after wearing the brace for three months in the brace condition. In addition, when not wearing the brace there was no significant change (mean difference 0.28 degree, p=0.80) in the sagittal knee ROM in the Contralateral limb between the shoe only at baseline and the shoe only condition at three months. Descriptive data of contralateral sagittal plane knee angle results during walking are illustrated in figure 4-39 and table 4-44.

Figure 4-39: Contralateral sagittal plane knee angle of the three conditions during walking.

Table 4-44: Mean, (SD) Contralateral sagittal plane knee angle during walking.

Type	Shoe Base line	Brace Three Months	Shoe Three Months
Initial contact Mean (SD) (°)	7.32(5.81)	9.43(5.42)	9.48(6.51)
Loading response Mean (SD) (°)	22.56(7.09)	25.18(6.97)	25.99(7.13)
Mid stance Mean (SD) (°)	8.67(6.58)	10.64(8.04)	10.48(8.08)
Mid swing Mean (SD) (°)	74.28(7.09)	76.10(7.02)	76.16(8.53)
Knee ROM X angle Mean (SD)(°)	66.96(5.86)	66.67(5.70)	66.67(7.81)

4.3.14.3 Knee angle (frontal plane)

There was no significant change (mean difference 1.43 Nm/kg, p=0.24) in the maximum of frontal knee angle in the Contralateral limb between the shoe only at baseline and after wearing the brace for three months in the brace condition. In addition, when not wearing the brace there was no significant change (mean difference 1.56 Nm/kg, p=0.21) in the maximum of frontal knee angle in the Contralateral limb between the shoe only at baseline and the shoe only condition at three months.

There was no significant change (mean difference 2.34 Nm/kg, p=0.05) in the minimum of frontal knee angle in the Contralateral limb between the shoe only at baseline and after wearing the brace for three months in the brace condition. In addition, when not wearing the brace there was no significant change (mean difference 0.09 Nm/kg, p=2.14) in the minimum of frontal knee angle in the Contralateral limb between the shoe only at baseline and the shoe only condition at three months.

There was no significant change (mean difference 0.92Nm/kg, p=0.30) in the frontal knee ROM in the Contralateral limb between the shoe only at baseline and after wearing the brace for three months in the brace condition. In addition, when not wearing the brace there was no significant change (mean difference 0.58 Nm/kg, p=0.52) in the frontal knee ROM in the Contralateral limb between the shoe only at baseline and the shoe only condition at three months. Descriptive data of contralateral frontal plane knee angle results during walking are illustrated in figure 4-40 and table 4-45.
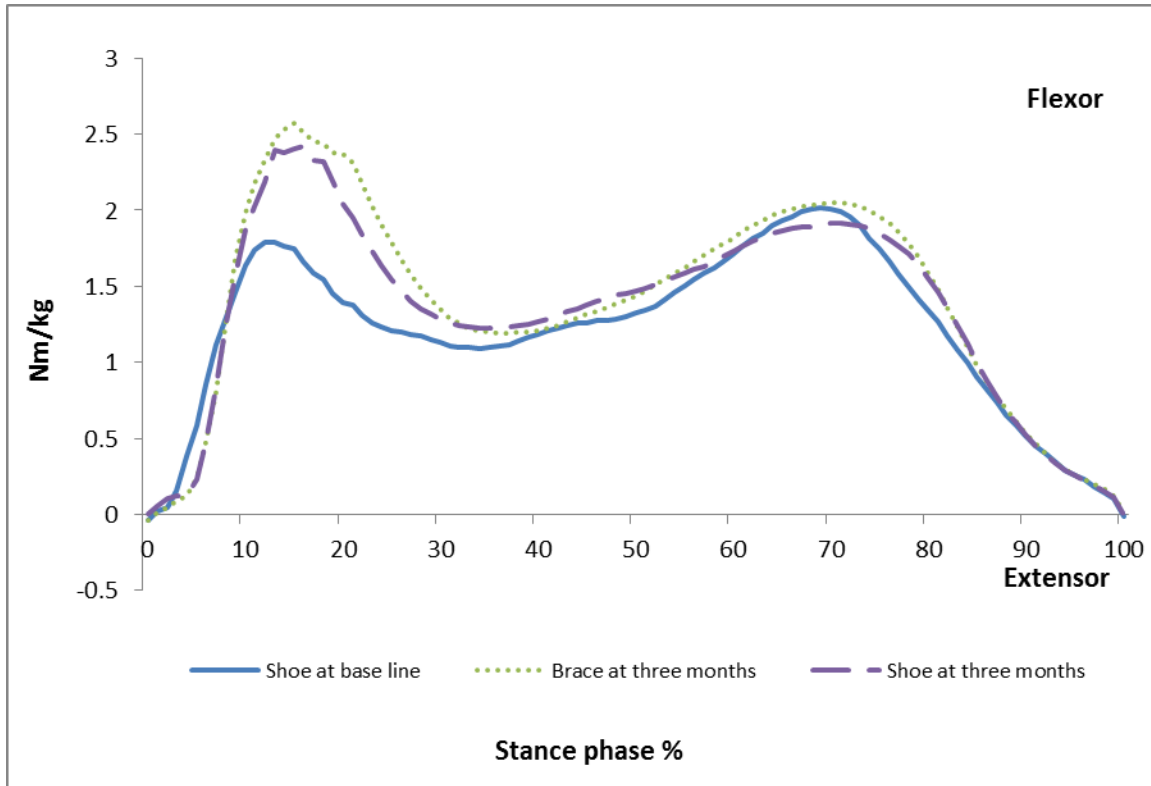
Figure 4-40: Contralateral frontal plane knee angle of the three conditions during walking.

Table 4-45: Mean, (SD) Contralateral frontal plane knee angle during walking

Type	Shoe Base line	Brace Three Months	Shoe Three Months
Maximum knee angle Y Mean (SD)(°)	-0.28(4.27)	1.16(5.13)	1.29(5.28)
Minimum knee angle Y Mean (SD)(°)	-7.77(4.54)	-5.43(4.45)	-5.63(4.69)
Knee ROM Y angle Mean (SD)(°)	7.50(2.82)	6.59 (2.21)	6.92(2.20)

4.3.14.4 Hip angle (sagittal plane)

There was no significant change (mean difference 2.93 Nm/kg, p=0.22) in the maximum of hip flexion angle in the Contralateral limb between the shoe only at baseline and after wearing the brace for three months in the brace condition. In addition, when not wearing the brace there was no significant change (mean difference 2.63 Nm/kg, p=0.31) in the maximum of hip flexion angle in the Contralateral limb between the shoe only at baseline and the shoe only condition at three months.

There was no significant change (mean difference 4.67 Nm/kg, p=0.05) in the maximum hip extension angle in the Contralateral limb between the shoe only at baseline and after wearing the brace for three months in the brace condition. In addition, when not wearing

152

the brace there was no significant change (mean difference 4.11 Nm/kg, p=0.08) in the maximum hip extension angle in the Contralateral limb between the shoe only at baseline and the shoe only condition at three months.

There was a significant decrease (mean difference 1.75 Nm/kg, p=0.03) in the hip ROM in the Contralateral limb between the shoe only at baseline and after wearing the brace for three months in the brace condition. However, when not wearing the brace there was no significant change (mean difference 1.48 Nm/kg, p=0.24) in the hip ROM in the Contralateral limb between the shoe only at baseline and the shoe only condition at three months. Descriptive data of contralateral sagittal plane hip angle results during walking are illustrated in figure 4-41 and table 4-46.

Figure 4-41: Contralateral sagittal plane hip angle of the three conditions during walking.

Table 4-46: Mean, (SD) Contralateral sagittal plane hip angle during walking

Type	Shoe Base line	Brace Three Months	Shoe Three Months
Hip Flexion Mean (SD)(°)	26.04(11.78)	28.97(8.11)	28.67(10.12)
Hip Extension Mean (SD)(°)	-21.18(12.48)	-16.51(10)	-17.07(9.97)
Hip ROM Mean (SD)(°)	47.22(4.63)	45.47(4.54)	45.74(4.62)

4.3.15 The kinematic results of the contralateral leg during ascending stairs

4.3.15.1 Ankle angle (sagittal plane)

There was no significant change (mean difference 0.65 Nm/kg, p=0.46) in the maximum of ankle dorsiflexion angle in the Contralateral limb between the shoe only at baseline and after wearing the brace for three months in the brace condition. In addition, when not wearing the brace there was no significant change (mean difference 0.39 Nm/kg, p=0.66) in the maximum of ankle dorsiflexion angle in the Contralateral limb between the shoe only at baseline and the shoe only condition at three months.

There was a significant decrease (mean difference 2.87 Nm/kg, p=0.03) in the maximum ankle planter flexion angle in the Contralateral limb between the shoe only at baseline and after wearing the brace for three months in the brace condition. However, when not wearing the brace there was no significant change (mean difference 2.44 Nm/kg, p=0.05) in the maximum ankle planter flexion angle in the Contralateral limb between the shoe only at baseline and the shoe only condition at three months.

There was no significant change (mean difference 2.22 Nm/kg, p=0.19) in the ankle ROM in the Contralateral limb between the shoe only at baseline and after wearing the brace for three months in the brace condition. In addition, when not wearing the brace there was no significant change (mean difference 2.05 Nm/kg, p=0.17) in the ankle ROM in the Contralateral limb between the shoe only at baseline and the shoe only condition at three months. Descriptive data of contralateral sagittal plane ankle angle results during ascending are illustrated in figure 4-42 and table 4-47.
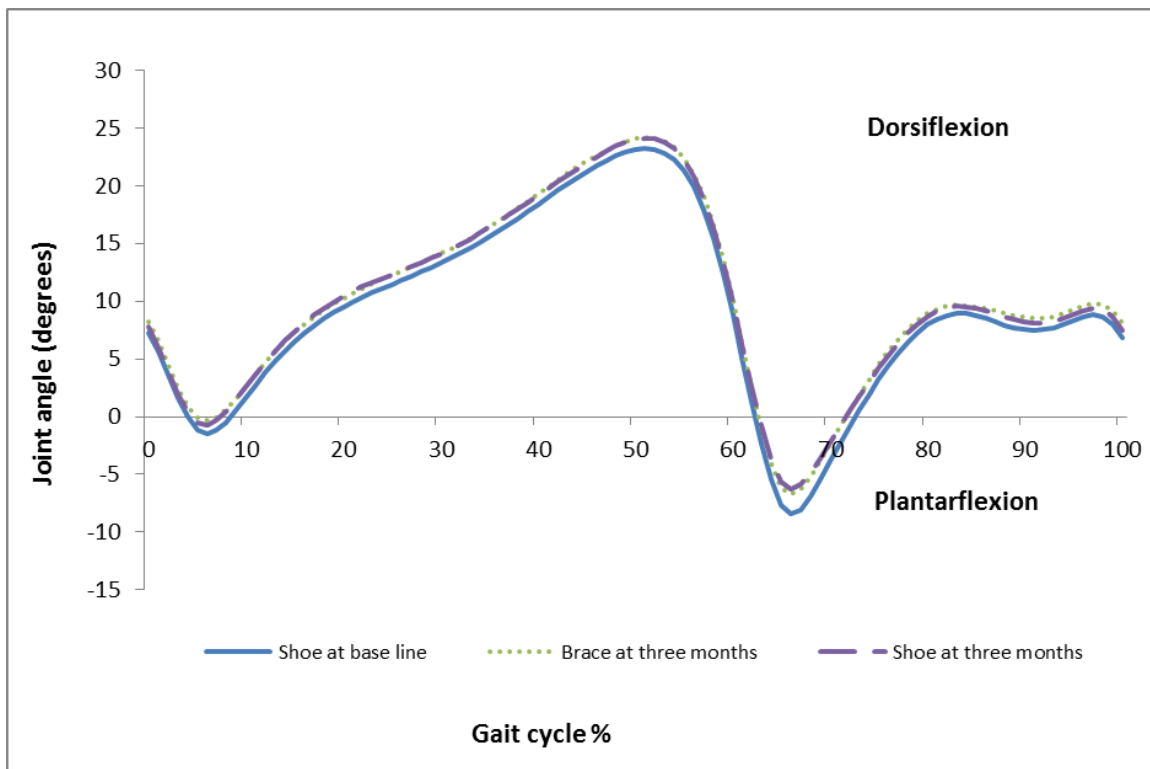
Figure 4-42: Contralateral sagittal plane ankle angle of the three conditions during ascent.

Table 4-47: Mean, (SD) Contralateral sagittal plane ankle angle during ascent.

Type	Shoe Base line	Brace Three Months	Shoe Three Months
Ankle Dorsiflexion Mean (SD)(°)	27.25(2.99)	27.90(2.36)	27.64(3.10)
Ankle Planter flexion Mean (SD) (°)	-13.44(5.37)	-10.57(5.09)	-11(5.49)
Ankle ROM Mean (SD) (°)	40.69	38.47	38.64

4.3.15.2 Knee angle (sagittal plane)

At initial, there was a significant increase (mean difference 4.52 Nm/kg, p=0.04) in the knee angle in the Contralateral limb between the shoe only at baseline and after wearing the brace for three months in the brace condition. However, when not wearing the brace there was no significant change (mean difference 3.99 Nm/kg, p=0.07) in the knee angle in the Contralateral limb between the shoe only at baseline and the shoe only condition at three months.

At loading response, there was no significant change (mean difference 0.86 Nm/kg, p=0.46) in the maximum of knee angle in the Contralateral limb between the shoe only at

baseline and after wearing the brace for three months in the brace condition. In addition, when not wearing the brace there was no significant change (mean difference 0.94 Nm/kg, p=0.42) in the maximum of knee angle in the Contralateral limb between the shoe only at baseline and the shoe only condition at three months.

At mid stance stage, there was no significant change (mean difference 0.49 Nm/kg, p=0.70) in the minimum of knee angle in the Contralateral limb between the shoe only at baseline and after wearing the brace for three months in the brace condition. In addition, when not wearing the brace there was no significant change (mean difference 0.55 Nm/kg, p=0.67) in the minimum of knee angle in the Contralateral limb between the shoe only at baseline and the shoe only condition at three months.

At mid swing stage, there was no significant change (mean difference 1.61 Nm/kg, p=0.54) in the maximum of knee angle in the Contralateral limb between the shoe only at baseline and after wearing the brace for three months in the brace condition. In addition, when not wearing the brace there was no significant change (mean difference 1.11 Nm/kg, p=0.58) in the maximum of knee angle in the Contralateral limb between the shoe only at baseline and the shoe only condition at three months.

There was no significant change (mean difference 1.12 degree, p=0.54) in the sagittal knee ROM in the Contralateral limb between the shoe only at baseline and after wearing the brace for three months in the brace condition. In addition, when not wearing the brace there was no significant change (mean difference 0.56 degree, p=0.71) in the sagittal knee ROM in the Contralateral limb between the shoe only at baseline and the shoe only condition at three months. Descriptive data of contralateral sagittal plane knee angle results during ascending are illustrated in figure 4-43 and table 4-48.
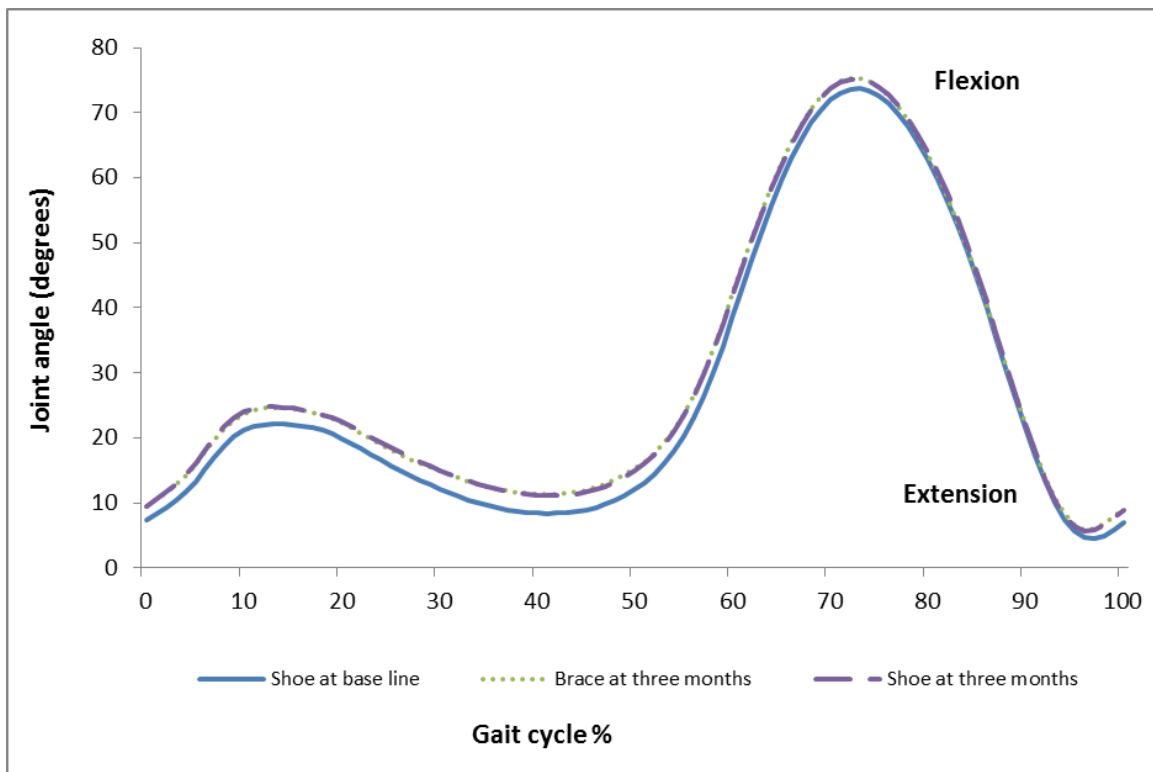
Figure 4-43: Contralateral sagittal plane knee angle of the three conditions during ascent.

Table 4-48: Mean, (SD) Contralateral sagittal plane knee angle during ascent.

Type	Shoe Base line	Brace Three Months	Shoe Three Months
Initial contact Mean (SD)(°)	68.96(17.98)	73.47(16.34)	72.95(16.19)
Loading response Mean (SD)(°)	73(15.10)	73.86(14.53)	73.94(14.34)
Mid stance Mean (SD) (°)	15.15(6.14)	15.63(7.83)	15.69(6.90)
Mid swing Mean (SD) (°)	71.41(12.05)	73.02(13.17)	72.52(12.76)
Knee ROM X angle Mean (SD)(°)	56.26(10.18)	57.39(12.03)	56.83(11.36)

4.3.15.3 Knee angle (frontal plane)

There was no significant change (mean difference 1.68 Nm/kg, p=0.45) in the maximum of frontal knee angle in the Contralateral limb between the shoe only at baseline and after wearing the brace for three months in the brace condition. In addition, when not wearing the brace there was no significant change (mean difference 2.45 Nm/kg, p=0.31) in the maximum of frontal knee angle in the Contralateral limb between the shoe only at baseline and the shoe only condition at three months.

There was no significant change (mean difference 1.57 Nm/kg, p=0.24) in the minimum of frontal knee angle in the Contralateral limb between the shoe only at baseline and after

wearing the brace for three months in the brace condition. In addition, when not wearing the brace there was no significant change (mean difference 2.14 Nm/kg, p=0.14) in the minimum of frontal knee angle in the Contralateral limb between the shoe only at baseline and the shoe only condition at three months.

There was no significant change (mean difference 0.11 Nm/kg, p=0.95) in the frontal knee ROM in the Contralateral limb between the shoe only at baseline and after wearing the brace for three months in the brace condition. In addition, when not wearing the brace there was no significant change (mean difference 0.31 Nm/kg, p=0.88) in the frontal knee ROM in the Contralateral limb between the shoe only at baseline and the shoe only condition at three months. Descriptive data of contralateral frontal plane knee angle results during ascending are illustrated in figure 4-44 and table 4-49.
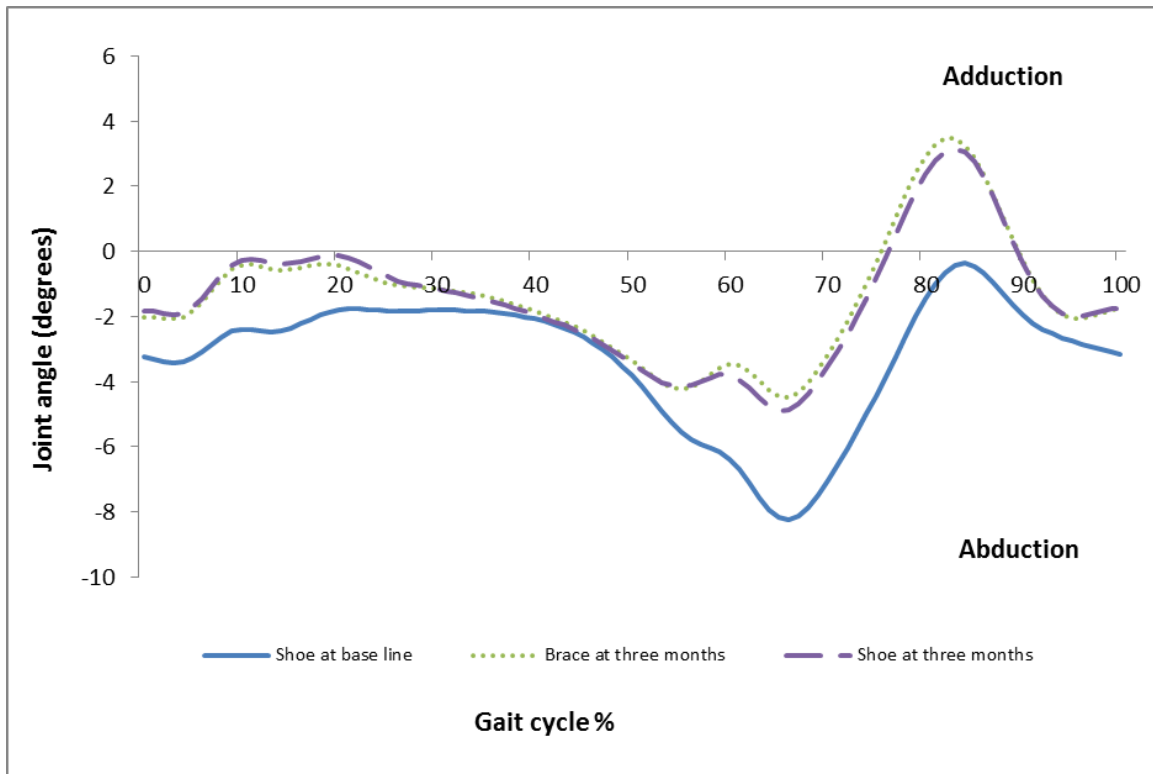

Figure 4-44: Contralateral frontal plane knee angle of the three conditions during ascent.

Table 4-49: Mean, (SD) Contralateral frontal plane knee angle during ascent.

Type	Shoe Base line	Brace Three Months	Shoe Three Months
Maximum knee angle Y Mean (SD)(°)	7.47(6.56)	9.15(8.34)	9.92(8.49)
Minimum knee angle Y Mean (SD)(°)	-4.99(5.76)	-3.43(5.03)	-2.85(5.08)
Knee ROM Y angle Mean (SD)(°)	12.47(5.28)	12.58(8.17)	12.77(8.66)

4.3.15.4 Hip angle (sagittal plane)

There was no significant change (mean difference 1.50 Nm/kg, p=0.51) in the maximum of hip flexion angle in the Contralateral limb between the shoe only at baseline and after wearing the brace for three months in the brace condition. In addition, when not wearing the brace there was no significant change (mean difference 1.60 Nm/kg, p=0.50) in the maximum of hip flexion angle in the Contralateral limb between the shoe only at baseline and the shoe only condition at three months.

There was no significant change (mean difference 1.15 Nm/kg, p=0.65) in the maximum hip extension angle in the Contralateral limb between the shoe only at baseline and after wearing the brace for three months in the brace condition. In addition, when not wearing the brace there was no significant change (mean difference 2.06 Nm/kg, p=0.41) in the maximum hip extension angle in the Contralateral limb between the shoe only at baseline and the shoe only condition at three months.

There was no significant change (mean difference 0.06 Nm/kg, p=0.95) in the hip ROM in the Contralateral limb between the shoe only at baseline and after wearing the brace for three months in the brace condition. In addition, when not wearing the brace there was no significant change (mean difference 0.31 Nm/kg, p=0.72) in the hip ROM in the Contralateral limb between the shoe only at baseline and the shoe only condition at three months. Descriptive data of contralateral sagittal plane hip angle results during ascending are illustrated in figure 4-45 and table 4-50.
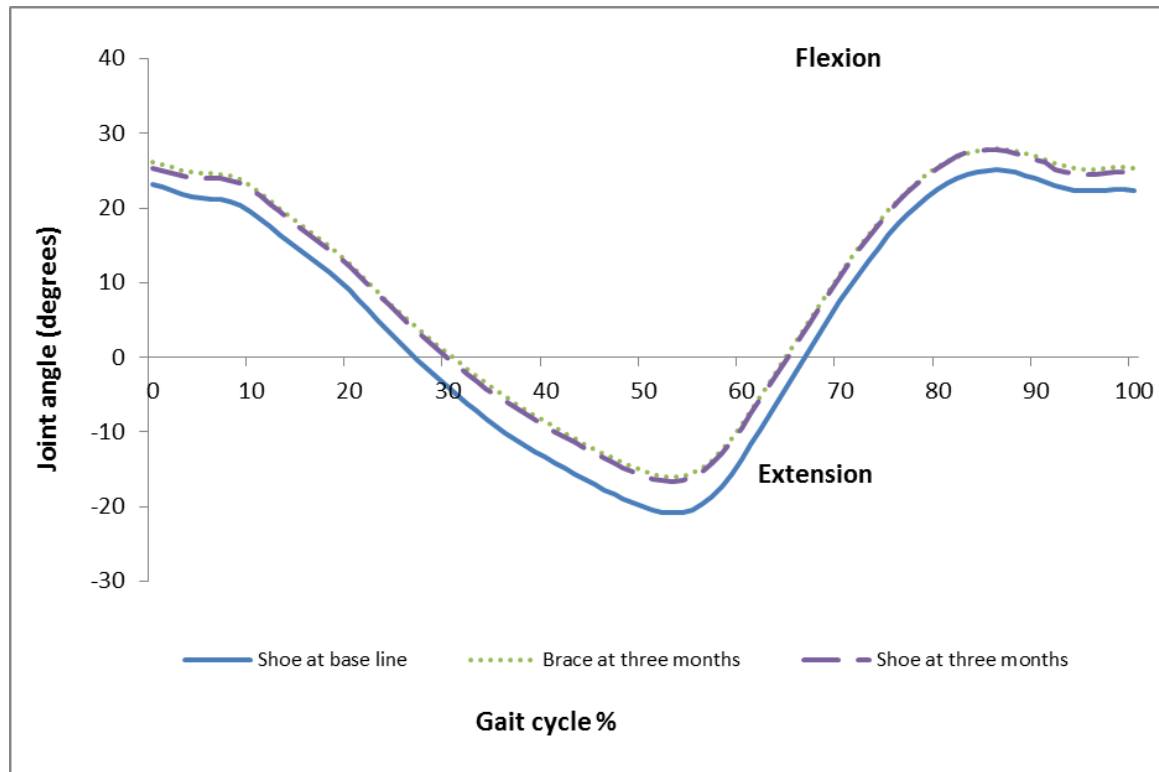
Figure 4-45: Contralateral sagittal plane hip angle of the three conditions during ascent.

Table 4-50: Mean, (SD) Contralateral sagittal plane hip angle during ascent.

Type	Shoe Base line	Brace Three Months	Shoe Three Months
Hip Flexion Mean (SD)(°)	57.34(10.35)	58.84(8.05)	58.94(7.03)
Hip Extension Mean (SD)(°)	1.08(10.20)	2.23(8.42)	3.14(7.89)
Hip ROM Mean (SD)(°)	55.49(2.43)	55.55(3.03)	55.18(2.82)

4.3.16 The kinematic results of the contralateral leg during descending stairs

4.3.16.1 Ankle angle (sagittal plane)

There was no significant change (mean difference 1.21 Nm/kg, p=0.22) in the maximum of ankle dorsiflexion angle in the Contralateral limb between the shoe only at baseline and after wearing the brace for three months in the brace condition. In addition, when not wearing the brace there was no significant change (mean difference 0.51 Nm/kg, p=0.58) in the maximum of ankle dorsiflexion angle in the Contralateral limb between the shoe only at baseline and the shoe only condition at three months.

There was no significant change (mean difference 0.60 Nm/kg, p=0.42) in the maximum ankle planter flexion angle in the Contralateral limb between the shoe only at baseline

160

and after wearing the brace for three months in the brace condition. In addition, when not wearing the brace there was no significant change (mean difference 0.82 Nm/kg, p=0.34) in the maximum ankle planter flexion angle in the Contralateral limb between the shoe only at baseline and the shoe only condition at three months.

There was no significant change (mean difference 0.61 Nm/kg, p=0.54) in the ankle ROM in the Contralateral limb between the shoe only at baseline and after wearing the brace for three months in the brace condition. In addition, when not wearing the brace there was no significant change (mean difference 0.31 Nm/kg, p=0.77) in the ankle ROM in the Contralateral limb between the shoe only at baseline and the shoe only condition at three months. Descriptive data of contralateral sagittal plane ankle angle results during descending are illustrated in figure 4-46 and table 4-51.
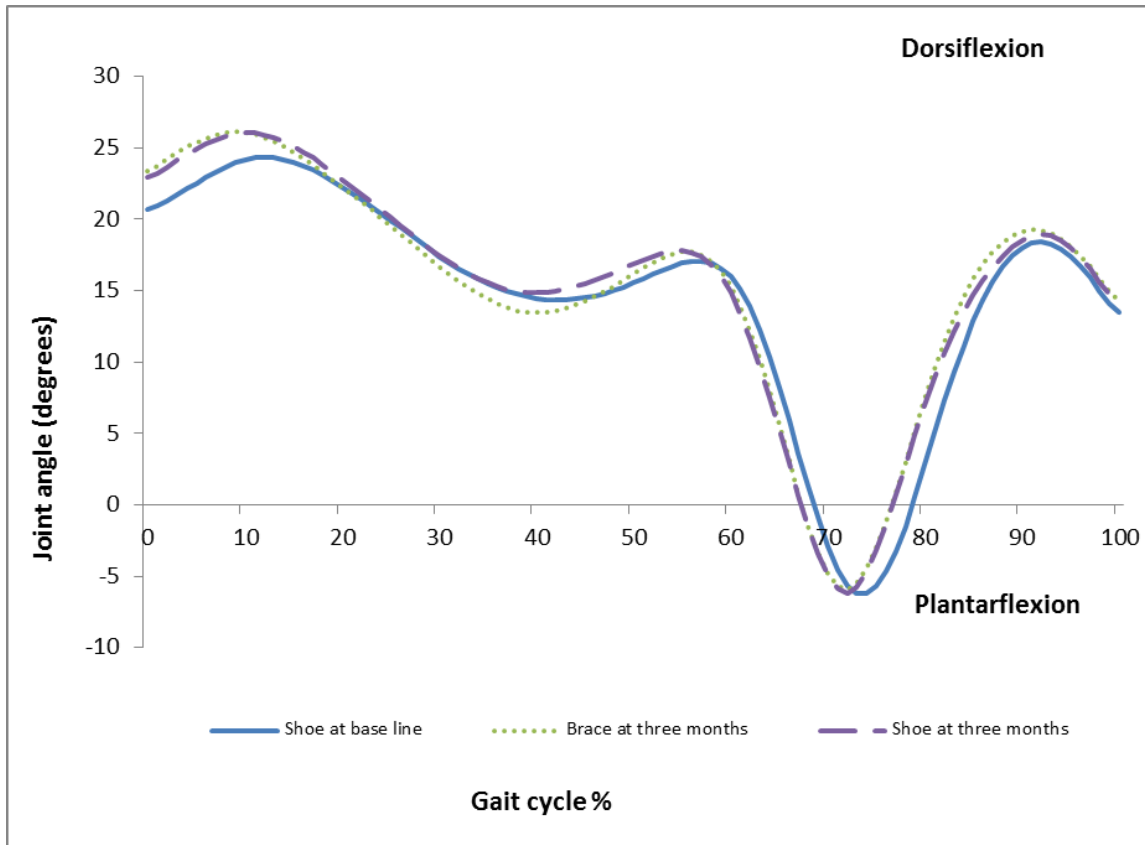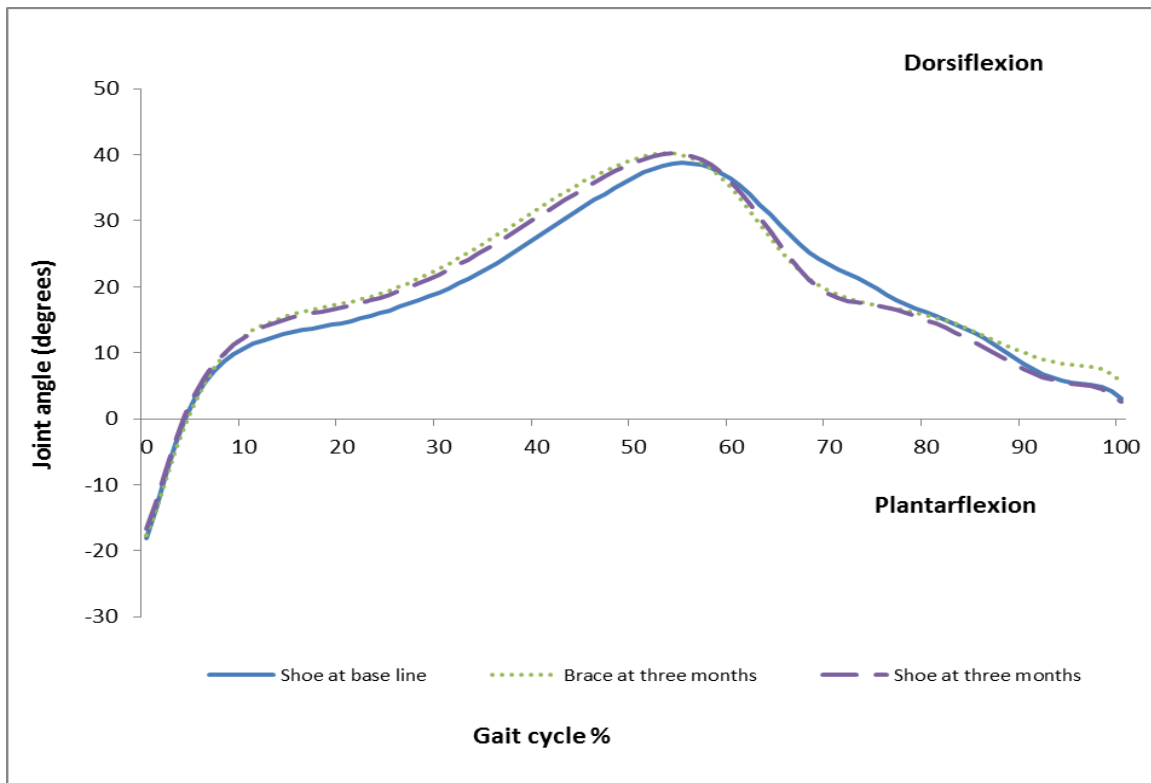

Figure 4-46: Contralateral sagittal plane ankle angle of the three conditions during descent.

Table 4-51: Mean, (SD) Contralateral sagittal plane ankle angle during descent.

Type	Shoe Base line	Brace Three Months	Shoe Three Months
Ankle Dorsiflexion Mean (SD)(°)	42.38(3.83)	43.59(4.76)	42.90(4.95)
Ankle Planter flexion Mean (SD) (°)	-18.27(4.11)	-17.67(4.31)	-17.45(4.46)
Ankle ROM Mean (SD) (°)	60.65(6.09)	61.26(5.44)	60.34(5.95)

4.3.16.2 Knee angle (sagittal plane)

At initial, there was no significant change (mean difference 2.24 Nm/kg, p=0.06) in the knee angle in the Contralateral limb between the shoe only at baseline and after wearing the brace for three months in the brace condition. In addition, when not wearing the brace there was no significant change (mean difference 2.37 Nm/kg, p=0.06) in the knee angle in the Contralateral limb between the shoe only at baseline and the shoe only condition at three months.

At loading response, there was no significant change (mean difference 2.45 Nm/kg, p=0.05) in the maximum of knee angle in the Contralateral limb between the shoe only at baseline and after wearing the brace for three months in the brace condition. However, when not wearing the brace there was a significant increase (mean difference 3.13 Nm/kg, p=0.02) in the maximum of knee angle in the Contralateral limb between the shoe only at baseline and the shoe only condition at three months.

At mid stance stage, there was a significant decrease (mean difference 3.58 Nm/kg, p=0.00) in the minimum of knee angle in the Contralateral limb between the shoe only at baseline and after wearing the brace for three months in the brace condition. In addition, when not wearing the brace there was a significant decrease (mean difference 3.87 Nm/kg, p=0.00) in the minimum of knee angle in the Contralateral limb between the shoe only at baseline and the shoe only condition at three months.

At mid swing stage, there was no significant change (mean difference 2.74 Nm/kg, p=0.13) in the maximum of knee angle in the Contralateral limb between the shoe only at baseline and after wearing the brace for three months in the brace condition. In addition, when not wearing the brace there was no significant change (mean difference 2.71 Nm/kg, p=0.06) in the maximum of knee angle in the Contralateral limb between the shoe only at baseline and the shoe only condition at three months.

There was no significant change (mean difference 0.64 degree, p=0.65) in the sagittal knee ROM in the Contralateral limb between the shoe only at baseline and after wearing the brace for three months in the brace condition. In addition, when not wearing the brace there was no significant change (mean difference 0.78 degree, p=0.52) in the sagittal knee

ROM in the Contralateral limb between the shoe only at baseline and the shoe only condition at three months. Descriptive data of contralateral sagittal plane knee angle results during descending are illustrated in figure 4-47 and table 4-52.
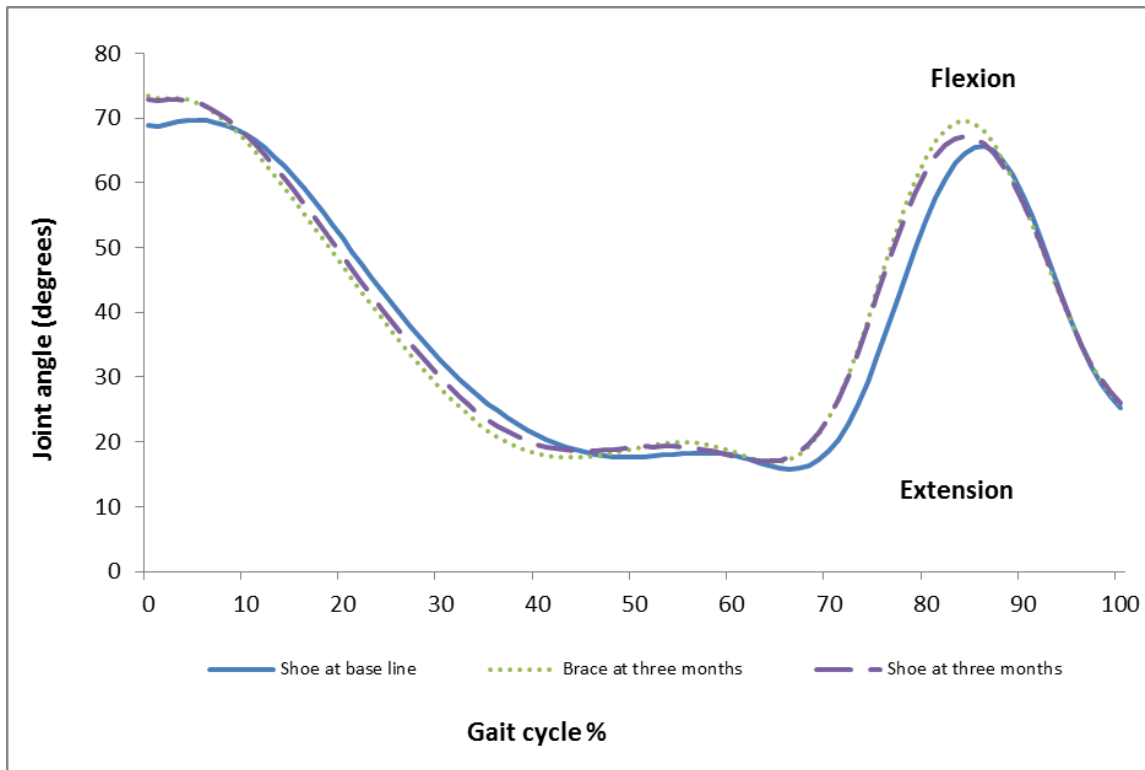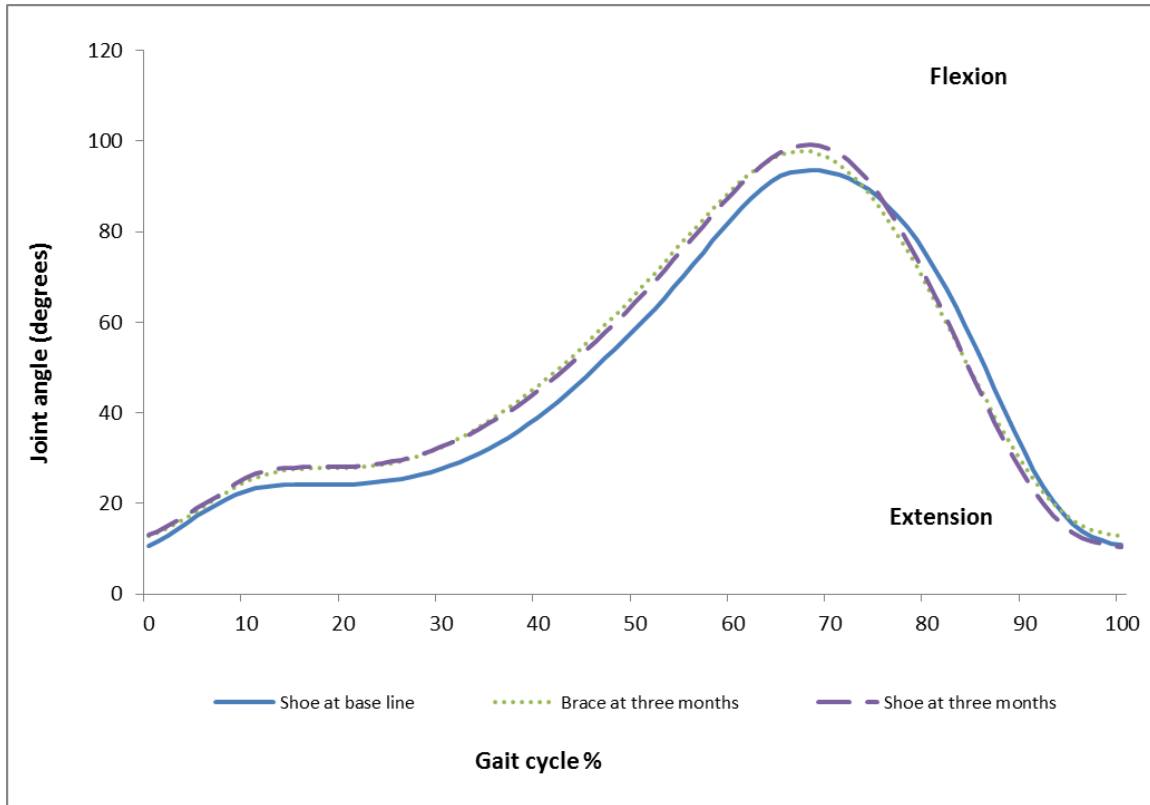

Figure 4-47: Contralateral sagittal plane knee angle of the three conditions during descent.

Table 4-52: Mean, (SD) Contralateral sagittal plane knee angle during descent.

Type	Shoe Base line	Brace Three Months	Shoe Three Months
Initial contact Mean (SD) (°)	10.60(4.79)	12.84(5.44)	12.97(6.01)
Loading response Mean (SD) (°)	26.45(7.92)	28.90(7.90)	29.57(8.74)
Mid stance Mean (SD) (°)	23.93(7.84)	27.51(7.72)	27.79(8.58)
Mid swing Mean (SD) (°)	99.90(8.55)	102.63(5.30)	102.61(5.86)
Knee ROM X angle Mean (SD)(°)	90.43(7.90)	89.79(4.16)	89.64(5.88)

4.3.16.3 Knee angle (frontal plane)

There was no significant change (mean difference 2.67 Nm/kg, p=0.15) in the maximum of frontal knee angle in the Contralateral limb between the shoe only at baseline and after wearing the brace for three months in the brace condition. In addition, when not wearing the brace there was no significant change (mean difference 2.95 Nm/kg, p=0.12) in the

163

maximum of frontal knee angle in the Contralateral limb between the shoe only at baseline and the shoe only condition at three months.

There was no significant change (mean difference 1.91 Nm/kg, p=0.27) in the minimum of frontal knee angle in the Contralateral limb between the shoe only at baseline and after wearing the brace for three months in the brace condition. In addition, when not wearing the brace there was no significant change (mean difference 2.03 Nm/kg, p=0.23) in the minimum of frontal knee angle in the Contralateral limb between the shoe only at baseline and the shoe only condition at three months.

There was no significant change (mean difference 0.75 Nm/kg, p=0.69) in the frontal knee ROM in the Contralateral limb between the shoe only at baseline and after wearing the brace for three months in the brace condition. In addition, when not wearing the brace there was no significant change (mean difference 0.92 Nm/kg, p=0.63) in the frontal knee ROM in the Contralateral limb between the shoe only at baseline and the shoe only condition at three months. Descriptive data of contralateral frontal plane knee angle results during descending are illustrated in figure 4-48 and table 4-53.
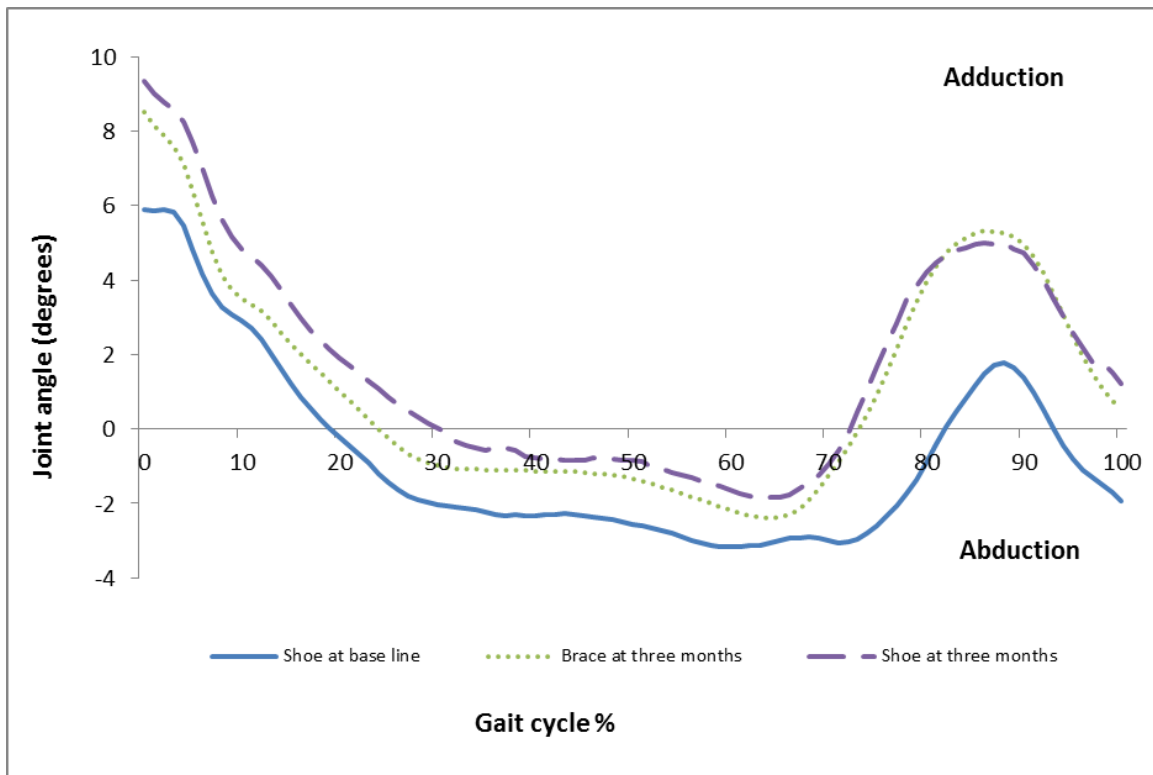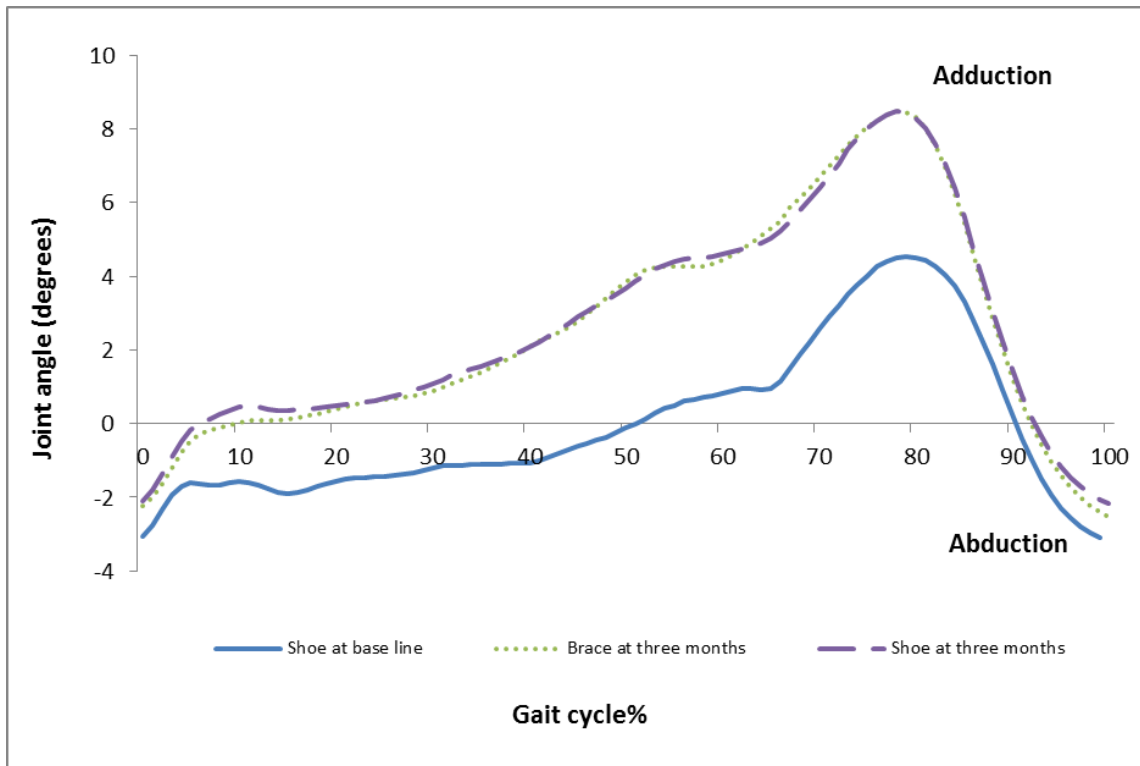
Figure 4-48: Contralateral frontal plane knee angle of the three conditions during descent.

Table 4-53: Mean, (SD) Contralateral frontal plane knee angle during descent.

Type	Shoe Base line	Brace Three Months	Shoe Three Months
Maximum knee angle Y Mean (SD)(°)	3.96(3.89)	6.63(4.81)	6.91(5.17)
Minimum knee angle Y Mean (SD)(°)	-5.24(6.46)	-3.32(4.97)	-3.21(4.97)
Knee ROM Y angle Mean (SD)(°)	9.20(4.68)	9.95(5.14)	10.12(4.89)

4.3.16.4 Hip angle (sagittal plane)

There was no significant change (mean difference 0.72 Nm/kg, p=0.81) in the maximum of hip flexion angle in the Contralateral limb between the shoe only at baseline and after wearing the brace for three months in the brace condition. In addition, when not wearing the brace there was no significant change (mean difference 2.20 Nm/kg, p=0.33) in the maximum of hip flexion angle in the Contralateral limb between the shoe only at baseline and the shoe only condition at three months.

There was no significant change (mean difference 0.73 Nm/kg, p=0.81) in the maximum hip extension angle in the Contralateral limb between the shoe only at baseline and after wearing the brace for three months in the brace condition. In addition, when not wearing

the brace there was no significant change (mean difference 2.86 Nm/kg, p=0.31) in the maximum hip extension angle in the Contralateral limb between the shoe only at baseline and the shoe only condition at three months.

There was no significant change (mean difference 0.01 Nm/kg, p=0.99) in the hip ROM in the Contralateral limb between the shoe only at baseline and after wearing the brace for three months in the brace condition. In addition, when not wearing the brace there was no significant change (mean difference 0.66 Nm/kg, p=0.50) in the hip ROM in the Contralateral limb between the shoe only at baseline and the shoe only condition at three months. Descriptive data of contralateral sagittal plane hip angle results during descending are illustrated in figure 4-49 and table 4-54.
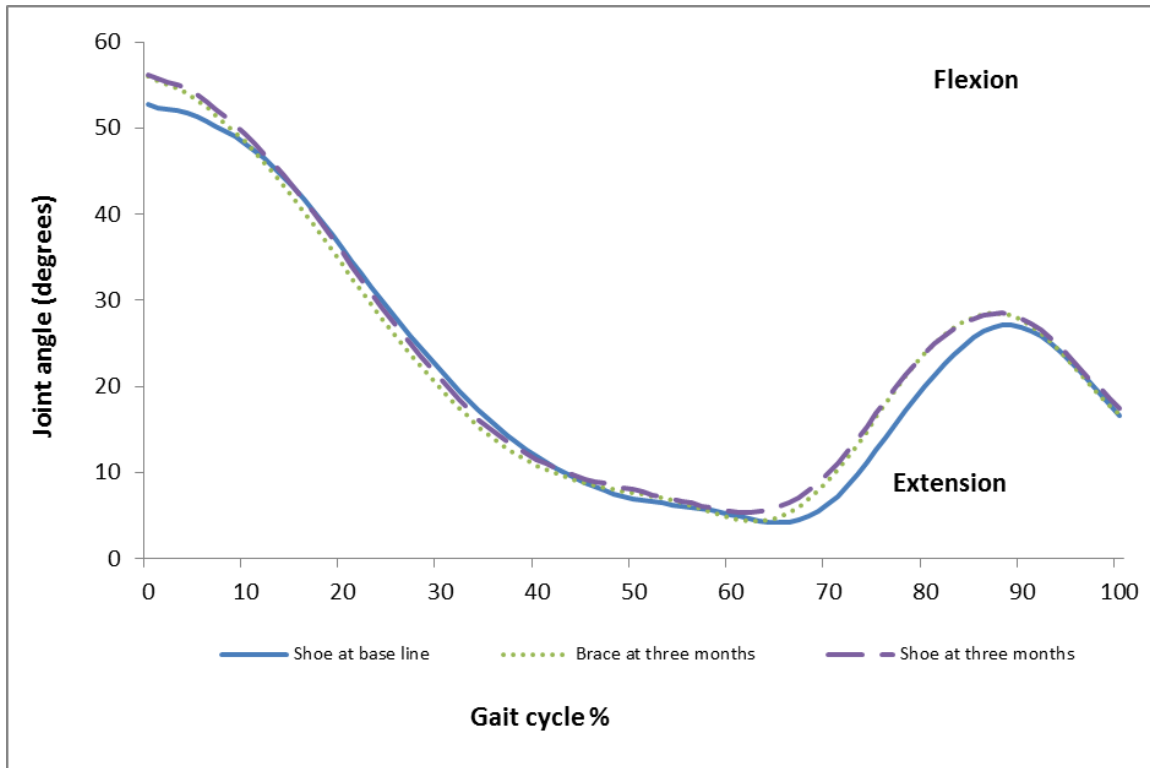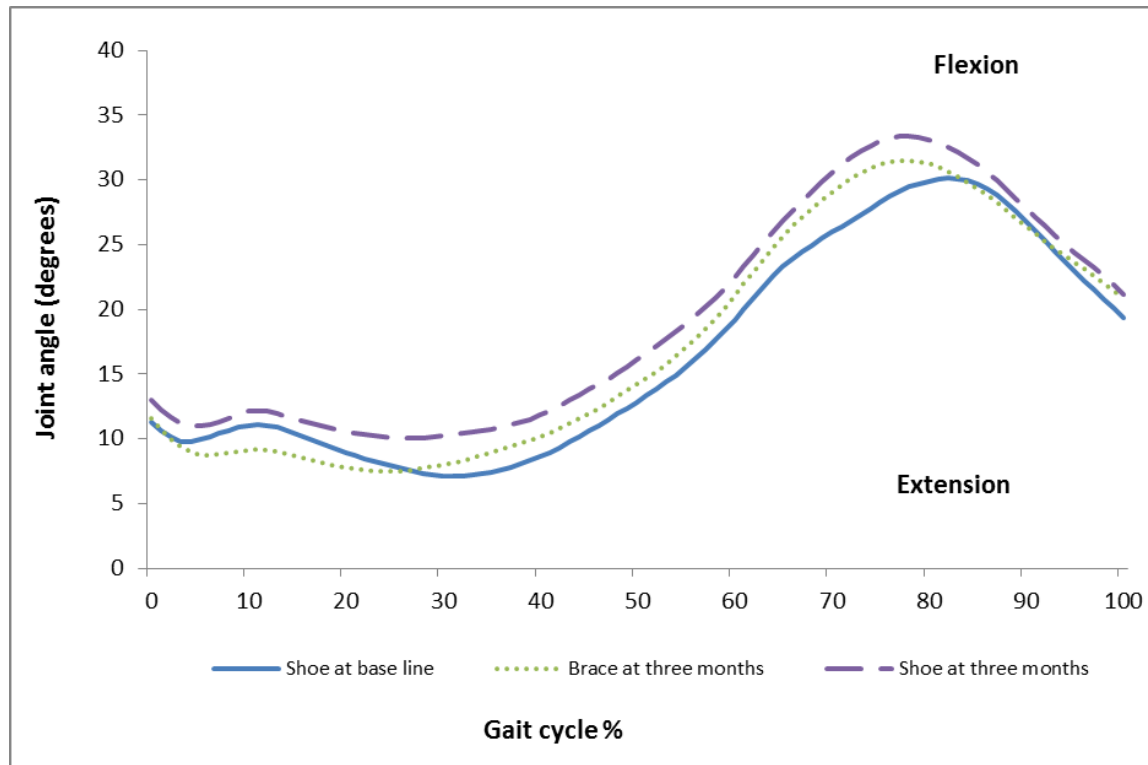

Figure 4-49: Contralateral sagittal plane hip angle of the three conditions during descent.

Table 4-54: Mean, (SD) Contralateral sagittal plane hip angle during descent.

Type	Shoe Base line	Brace Three Months	Shoe Three Months
Hip Flexion Mean (SD)(°)	32.31(12.43)	33.03(9.54)	34.51(9.17)
Hip Extension Mean (SD)(°)	5.74(11.71)	6.20(9.86)	8.32(9.14)
Hip ROM Mean (SD)(°)	26.84(4.03)	26.83(3.12)	126.18(4.02)

4.3.17 Observational outcome

Patients were contacted by telephone at regular intervals biweekly to ensure that they were not having problems with the valgus knee brace and pain and comfort scores were collected.

The mean average duration of wearing of the valgus knee brace was 6.67 (SD 1.54) hours whereby their self-reported pain was 3.2 (SD 0.56) out of five (5 no pain) and comfort was 3.4 (SD 0.51) out of five (5 very comfortable).

4.4 Discussion

4.4.1   Background of discussion

The majority of the previous studies of valgus knee bracing have concentrated on the clinical effect over a short duration rather than tracking this over a period of time, such as three months as in this study. Additionally, no study has investigated multiple outcomes such as biomechanical (EKAM, KAAI and Knee angles), clinical (pain and function), and physiological (Muscle co-contraction and balance) during walking, ascending and descending stairs in the same valgus knee brace. This study was performed to both address these limitations from previous studies and to also add new novel data to the literature.

4.4.2 Overview of the results

A short summary of the results from the six week and the three month assessment will be presented before discussing these results.

After six weeks of use

After six weeks of wearing the valgus knee brace, the clinical and function outcomes significantly improved with the pain scores from the KOOS subscale increasing by 58.54%, Symptoms scores from the KOOS subscale increasing by 24.06%, sport/rec scores from the KOOS subscale increasing by 59.33%, and quality of life scores from the KOOS subscale improving by 62.48% in comparison to the base line. However, the

activity of daily living subscale was the only one not significantly improved, even though an average increase of 17.88% at six weeks was found.

After six weeks of wearing the valgus knee brace, dynamic balance, as one of the function outcomes assessed on the affected leg, significantly improved with the mean distance increasing by 7.67 cm in anterior direction and increasing by 6.98 cm at six weeks in the medial direction in comparison to the baseline.

Muscle strength significantly improved with the knee isometric extensor muscles at 45°/S increasing by 25.61% and knee concentric flexor muscles at 60°/s by 38.50%. However, the knee isometric flexor muscles at 45°/s and knee concentric extensor muscles at 60°/s were not significantly improved, even though an average increase of 23.29% and 17.88%, respectively, in comparison to baseline.

After three months of using the valgus knee brace

After using the valgus knee brace for three months, there was no change in the external knee adduction moment or knee adduction angular impulse during walking or during ascending and descending stairs. There were however significant improvements in the clinical and function scores with the pain scores from the KOOS subscale increasing by 75.13%, symptoms scores from the KOOS subscale increasing by 31.71%, sport/rec scores from the KOOS subscale increasing by 77.73%, and quality of life scores from the KOOS subscale increasing by 87.48% in comparison to the baseline. However, activity of daily living subscale was the only one which was not significantly improved, even though an average increase of 29.44% at three months was found. Dynamic balance also improved significantly with the mean distance increasing by 9.47 cm in the anterior direction and increasing by 11.66 cm in the medial direction in comparison to the baseline.

Muscle strength outcomes significantly improved with the knee isometric extensor muscles at 45°/s increasing by 32.98%, the knee isometric flexor muscles at 45°/s by 29.72, knee concentric extensor muscles at 60°/s by 29.44% and knee concentric flexor muscles at 60°/s by 52.20% in comparison to the baseline.

After three months of wearing the valgus knee brace, there were significant changes in the muscle co-contraction in the vastus medialis and semitendinosus in the shoe only at baseline and brace at three months in the early and middle stage but not in the late stage. Significant changes in the vastus medialis and semitendinosus in the shoe only at baseline and at three months in the early stage but not in the middle and late stage; and in the vastus medialis and semitendinosus in the brace at baseline and at three months in the early and middle stage during walking. However, there were no significant changes in the muscle co-contraction in the vastus lateralis and biceps femoris during walking in shoe at baseline and brace and, shoe at three months.

There were significant changes in the muscle co-contraction in the vastus medialis and semitendinosus during ascending and descending stairs in the shoe only at baseline and brace and, shoe at three months and in the vastus lateralis and biceps femoris during ascending and descending stairs in shoe at baseline and brace and, shoe at three months.

4.4.3 Comparison to previous literature

Fifteen patients with unilateral medial knee OA participated in this study which is similar to previous studies (Gaasbeek et.al, 2002) whereby the population had a BMI of 29.90 kg/m^2 in comparison to an average of 34.1 ± 4.9 kg/m^2 (Draganich et.al.2006). This BMI is slightly less than the previous literature but does show that the sample in this study was in the overweight category which is not dissimilar to previous knee OA research. One of the primary outcome measures in this study was the external knee adduction moment as this surrogate of knee loading is one of the most important measures to identify the progression of medial knee OA (Miyazaki et al., 2002). Hypothesis one was examining whether there were any significant differences in the external knee adduction moment between the baselines and after three months use of the valgus knee brace and in order for comparisons to the literature to be made, it appears sensible to compare the baseline values of the individuals in this study. The external knee adduction moment values reported in this study (2.65 % bodyweight * height) are similar to previous studies on medial OA participants (Sharma et al., 1998; Hurwitz et al., 2000). Therefore, we can demonstrate that our sample is indicative of typical medial knee OA individuals.

The hypotheses which were presented at the end of chapter 2 will now be examined as well as the gait and user observations that were collected alongside the trial.

4.4.4   Hypotheses

4.4.4.1 Knee loading

Hypothesis 1a: Medial knee loading is reduced with a valgus knee brace and it is reduced more after 3 months of use than immediately.

Hypothesis 1b: In brace users, medial knee loading is reduced after 3 months of use, even with the brace not worn.

The results of this study showed the external knee adduction moment during walking did not significantly improve on the affected leg after wearing the brace over a period of three months in comparison to the shoe only and the brace at baseline. The first peak of the EKAM reduced by 5.03% in comparison to the shoe only at baseline as a treatment effect, and by 2.67% in comparison to the brace at baseline as functional assessment for a valgus knee brace and by 4.49% between the shoe only at baseline and at three months as residual effect during walking. Additionally, the results of this study showed that after wearing the brace for three months the second peak of EKAM reduced by 3.81% in comparison to the shoe only at baseline as treatment effect, by 3.54% in comparison to the brace at baseline as functional assessment for a valgus knee brace and by 9.4% between the shoe only at baseline and at three months as residual effect during walking. The results of this study therefore have showed that knee loading is reduced but not statistically significantly and is in agreement with Brouwer et al., (2006) who reported that a brace intended to decrease load shows small effects in patients with unicompartmental OA. Additionally, Pollo et al., (2002), did not find a reduction in the maximum external varus knee moment for the unbraced and normal mode of use conditions, even though a reduction in the load of the medial compartment of the knee (using an analytical approach) was observed in the brace condition. These results in this study agree with the study performed by Hewett et al, (1998) who reported that the peak knee adduction moments were statistically unchanged (although a small reduction was seen) by wearing a Bledsoe brace system during walking.

Different percentage of reductions of peak EKAM (up to 19%) have been reported from previous studies (Lindenfeld et al., 1997; Self et al., 2000; Pollo et al. 2002; Fantini Pagani et al., 2010; Kutzner et al., 2011) when walking with a valgus knee brace depending on the type of the brace and the degree of valgus position (4°- 8°). In our study the dynamic force strap was set to number 5 out of 10 and this setting was recommended by the company due to many people finding that this average setting of 5 will provide adequate pain relief. However, in the study by Pollo et al., (2002) they reported that increasing the strap tension did not have as great an effect as increasing the valgus angulation. Therefore, with a higher degree of valgus angulations of the brace will lead to higher load reduction in the medial compartment. Strap tension of a valgus brace different in patients who had slight or no change in adduction moment and strap could not be tightened sufficiently to provide any significant unloading effect (Lindenfeld et al., 1997). This brings into question the brace that was used in this study as whilst it was aesthetic, the amount of correction that this could apply may have been limited by both the dynamic force strap and also the rigidity of the brace.

However, our results are in contrast to the majority of previous studies who have showed an improvement in the mean varus moment (Otis et al., 1996; Self et al., 2000; Pollo et al., 2002; Gaasbeek et al., 2007) and in the mean knee adduction moment (Lindenfeld et al., 1997; Draganich et al., 2006; Gaasbeek et al., 2007; Fantini Pagani et al., 2010; Toriyama et al., 2010; Karimi et al., 2012; Deie et al., 2013) in different treatment periods of wearing the brace up to 8 weeks and in different types of the brace.

Draganich et al., (2006) compared two valgus knee braces and found the average peak adduction moment was significantly decreased with the custom brace (5.9% ± 2.0%) compared with the baseline value (6.9% ± 1.9%), but it was not significantly decreased with the off-the-shelf brace (6.6% ± 2.2%) during walking. Additionally, the average peak adduction moment was significantly decreased from baseline (6.9% ± 2.3%) with the custom brace (5.2% ± 2.5%), but it was not significantly reduced with the off-the shelf brace (6.3% ± 2.2%) during stair-stepping. The custom brace significantly decreased varus angulation of the knee by 1.3° compared with the off-the-shelf brace by 1.5° compared with baseline. The custom brace was more effective than the off-the-shelf

brace due to the custom brace fit the limb better, and this then allowed the custom brace to keep higher levels of valgus loading of the knee in the patients during walking and stepping stairs. This also gives some insight into the reasons why we did not see a reduction as the brace which we used was an off-the-shelf brace and this may not have been an exact fit for the patient to maintain the higher levels of valgus loading.

However, we did find some agreement with the previous studies if we looked in depth at the individual patient changes. After three months of wearing of the brace, the 1st peak of EKAM was decreased in eleven patients out of fifteen during walking by 11.00% compared to the shoe only and this percentage of reduction is concurrent with a study was done by Toriyama et al., (2010) found a reduction of the EKAM was 11.1% that used the same type of brace was using in our study. In this study, 19 patients were assessed so a slightly larger sample size was seen. They do not however give details on the variable response to the valgus knee braces and the baseline EKAM values were higher than in the current study. This could mean that the individuals were in a higher varus angulation than the previous study which allowed the brace valgus moment to have a desired effect.

An interesting finding was that the 1st peak of EKAM was decreased in nine patients by 16.21% out of fifteen patients between the shoe only at baseline and at three months. There are no other studies which have assessed the effect on walking (without no intervention being worn) after wearing a valgus knee brace for an intervention period. This would give some indication to the carry-over effect or residual effect that the valgus knee brace is having on the individual. It may be plausible that with longer-term studies of valgus knee braces that functional changes occur in the affected limb and may aid the limb even without wearing the valgus knee brace. However, one needs to be mindful that the assessment was conducted very shortly after wearing the valgus knee brace and it may be that these residual effects would not be maintained. If these residual effects are seen, it is likely that the increases in muscle strength and decreases in muscle co-contraction could be possible reasons. This would mean that the support given by the valgus knee brace allows the limb to be better mechanically aligned in regards to the EKAM but this would need further research to understand if this was the case.

There was no significant change in the vertical ground reaction force (GRF) at early, mid-, and late stance phase in all conditions during walking. These results of this study is the same as the results of the research undertaken by (Schmaltz et al. 2011, Karimi et al., 2012) showed no significant change in the GRF with brace during walking. However, the ground reaction forces on the affected side showed a significant increase during loading and push-off (Richards et al., 2005).

As this is the first study that has investigated ascending and descending stairs, the results showed that the external knee adduction moment also did not significantly reduce on the affected leg after wearing the brace over a period of three months. As with walking, there was a variable response with eight out of 15 patients reducing their EKAM after three months. This was similar in descending with seven out of 15 noting a significant reduction. No previous studies are available to compare with the results of this study during ascending and descending stairs by using a valgus knee brace. On a similar mechanical intervention (using a lateral wedge insole), Alshawabka et al. (2014), reported that the first peak of EKAM reduced significantly during ascending by 6.8% and, descending by 8.4% in all patients in this study. However, there were only eight patients in this study and it may be that with a larger sample size that this consistent reduction would not be seen. This non reduction during ascending and descending stairs may have been due to strap tension of the brace which may not have been enough because the moment at the knee joint is higher during ascending and descending stairs, with both moments higher than compared with walking on the level ground (Andriacchi et al. 1980). In addition, the GRF increased in both in ascending and descending after three months in compared to baseline which is likely to be due to the pain adaptations with the knee supported by the brace which potentially gave the individuals more confidence to ascend and descend stairs with less pain.

The knee adduction angular impulse (KAAI) is another assessment used to measure the load on the medial compartment during the whole of stance phase (Thorp et al., 2006). There was no significant change in the KAAI during walking. The result of this study showed after wearing the brace for three months the KAAI reduced by 13.26% in comparison to the shoe only at baseline as a treatment effect, by 12.48% in comparison to

the brace at baseline as functional assessment for a valgus knee brace and by 13.14 % between the shoe only at baseline and at three months as residual effect during walking.

There was also no significant change in the KAAI during ascending and descending stairs. During ascending, the results of this study showed after wearing the brace for three months, the KAAI reduced by 23.68% in comparison to the shoe only at baseline as a treatment effect, by 9.61% in comparison to the brace at baseline as functional assessment for a valgus knee brace and by 6.96 % between the shoe only at baseline and at three months as residual effect. In addition, during descending, the results of this study showed after wearing the brace for three months the KAAI reduced by 17.35% in comparison to the shoe only at baseline as a treatment effect, by 0.58% in comparison to the brace at baseline as functional assessment for a valgus knee brace and by 6.34 % between the shoe only at baseline and at three months as residual effect during descending.

No previous studies are available to compare with the results of this study during ascending and descending stairs by using a valgus knee brace, other than other mechanical interventions as previously discussed (Alshawabka et al., 2014) who also found a significant reduction in KAAI. This demonstrates that there is a further need to examine valgus knee braces in activities other than walking as the literature is lacking to make justified conclusions if these devices help during these activities.

As it has been there were small but non-significant reductions in EKAM during walking and ascending and KAAI during walking, ascending and descending. In understanding why there was no significant change in EKAM or KAAI with the valgus knee brace a few potential confounders may help us to explain this. These are namely the application of the valgus knee brace itself (fitting of the brace), the type of brace (custom, off the shelf, unloader valgus brace), the degree of valgus position 4°- 8° (Lindenfeld et al., 1997; Self et al., 2000; Pollo et al., 2002; Fantini Pagani et al., 2010), and the factors that influence the calculation of the EKAM, namely the ground reaction force.

The valgus knee brace which was used was an off-the-shelf version and one potential confounder is that if individuals had excessive soft tissue on the thigh and the shank it

would not allow the brace to reduce the loading as the direct applying force would be on the soft tissue rather than altering the alignment in the bony structures (Dennis et al., 2006). This could have been further improved with the use of a custom valgus knee brace but the difference in cost (350-650) is significant and cannot be ignored. As previously mentioned, the dynamic force strap was set to the same level in all patients, based on the recommendation from the company representative, and this could have affected the results as individuals may not have felt enough force was being applied. The use of the custom knee brace is also another solution for this or to allow the individuals to choose the level of force they were comfortable with and instruct them that they could change this if they felt they were not getting the benefit. However, given the clinical changes seen in the patient group, this does not appear to be the case from a pain perspective and the low changes in loading may have been beneficial for them. There is also evidence from previous literature (Trepczynski et al., 2014) that the EKAM may not represent the true loading in the knee joint and that changes in muscle co-contraction need to be understood, as these are likely to reduce medial compartmental load.

The EKAM is the turning effect due to the resultant ground reaction force acting on the foot as it passes medial to the centre of the knee joint. The product of this force with this lever arm produces a moment tending to adduct the knee joint (Kim et al., 2004). The vertical GRF would increase with the speed increase thus the EKAM will increase (Mündermann et al., 2004). So, any change in the vertical GRF consequently may result in a change in EKAM (Yu et al., 1997b). In this study, the vertical GRF increased significantly during ascending and descending stairs with stance times decreasing significantly, so this is a potential reason why EKAM showed no significant differences among the test conditions. We chose not to standardise speed ascending and descending the stairs as we wanted to understand the true effect of valgus knee braces on the individual and any changes in speed would reflect functional limitation or improvement. These increases in vertical GRF could be due to the clinical (pain reduction) and physiological changes (increased strength and reduced muscle co-contraction) that occurred during the study as these patients may have felt more confident in the brace and thus loaded the joint more in terms of vertical GRF.

There was no significant change in the vertical ground reaction force (GRF) at early, mid, and late in all condition during ascending but there was a significant increase at late stage between the shoe only at baseline and brace at three months. To our knowledge, there was no previous study before to compare our results with and this increase in GRF at the late stage could be happening due to a need to stabilise the knee, increased muscle strength, relived pain and decreased muscle co-contraction by brace, all these factor gave the patent to toe off with maximum power .

There was a significant change in the vertical ground reaction force (GRF) at early stage in all conditions and at late stage between the shoe only at baseline and brace at three months during descending. To our knowledge, there was no previous study was done before on valgus knee brace during descending to compared with our results and this increasing in GRF at late stage could be happen this happen due to stabilizing the knee, increased muscle strength, relived pain and decreased muscle co-contraction by brace, all these factor gave the patient to step down with more confidence at early stage and toe off with maximum power at late stage.

In summary, the valgus knee brace used in this study did not have the perceived reductions in knee loading that were hypothesised and whilst the reasons aforementioned may be indicators, it could have simply been that some individuals did not adhere to the valgus knee brace as well as others. The observational outcome scores do not highlight this but given that these follow-up calls were made to ensure they were not having any problems with the brace, exact wear details should be taken with caution. There is obviously the fact that only 15 individuals were used in this study and whilst the sample size can be criticised, previous research with similar and smaller numbers have found significant decreases in knee loading.

Therefore in conclusion, both hypotheses are rejected because there was no significant change in knee loading after 3 months of use, and not when assessed with the brace not worn during walking and ascending and descending stairs.

4.4.4.2 Pain

Hypothesis 2: Pain in the affected knee is reduced when using a valgus knee brace.

Valgus knee braces apply three-point-pressure to arthritic knees via the use of an external corrective force to the knee (Reeves, & Bowling, 2011) and theoretically give pain release by decreasing the load on the medial compartment through the application of an opposing external valgus moment about the knee.

The effect of the valgus knee brace on reducing the pain based on the KOOS pain subscale was obvious with a 58.54% reduction at six weeks and 75.13% reduction at three months in comparison to the baseline and is in agreement with previous studies that found improvements in pain immediately (Komistek, et al., 1999; Pollo et al., 2002; Dennis et al., 2006), after 2 weeks (Otis et al., 1996; Ramsey et al., 2007), after 4 weeks (Draganich et al., 2006; Schmalz et al., 2010), after six weeks (Lindenfeld et al., 1997; Gaasbeek et al., 2007), after nine weeks (Hewett et al., 1998), after three months (Draper et al., 2000; Finger and Paulos, 2002; Brouwer et al., 2006), after six months (Kirkley et al., 1999; Richards et al., 2005; Brouwer et al., 2006; Hurley et al., 2012), after 12 months (Matsuno et al., 1997; Hewett et al., 1998; Brouwer et al., 2006; Deie et al., 2013), after an average of 2.7 years (Wilson et al., 2011), and after an average of 3.3 years (Giori, 2004).

A significant improvement from baseline as a result of valgus knee brace was seen for symptoms, sports, and recreation and for quality of life. These results are in agreement with a study by Ramsey et al., (2007) that used the KOOS as outcome measurement over a period of two weeks. Ramsey et al., (2007) found a significant improvement from baseline for the scores for sports and recreation as a result of both bracing conditions demonstrated (neutral setting and for valgus setting), and for quality of life for the neutral and these results agree with our results where we showed sport/rec and quality of life subscales significantly improved at six weeks and at three months in comparison to the baseline, respectively.

Furthermore, Finger and Paulos, (2002), found pain was decreased by 50% by using visual analogue scale (VAS) at three months after wearing the OAdjuster brace and this

result concurs with our study after three months although our results showed the pain reduction to be higher. Matsuno et al., (1997) found that 19 patients of 20 showed pain relief at 12 months and that knee pain scores had improved during walking by 19.44% and during ascending and descending increased from by 23.43% according to the Japan Orthopaedic Association's knee scoring system (JOA) when using custom off-loader brace as treatment and the results of this study showed less of pain reduction in comparing to our results showed all 15 patients recorded pain relief

Previous studies have suggested that by stabilizing the knee mechanically, less muscle activity is necessary and is part of the pain relief mechanism (Lindenfeld et al., 1997; Richards et al., 2005; Brouwer et al., 2006; Kirkley et al., 1999, Ramsey et al., 2007). Additionally, when the brace surrounds the knee joint, it can play a role in providing the joint support, heat, and enhanced proprioception (Birmingham et al., 2001) and reducing muscle co-contraction (Ramsey et al., 2007; Fantini Pagani et al., 2013). Pain relief might result from reduced muscle co-contractions rather than from so-called medial compartment unloading (Ramsey et al., 2007). Our results of this study showed the valgus knee brace was stabilizing the knee joint as we saw an increase in muscle strength, improved dynamic balance will lead to enhanced proprioception and function, and decreased muscles co-contraction, thus giving positive results will lead to the relief of the pain the individual is reporting. However, as previously discussed, this may actually have a negative effect on joint loading in terms of EKAM as no significant reduction was seen, however, with muscle co-contraction reducing and potentially having an effect on pain; it may be that actual compartment loads are reduced.

Therefore, this hypothesis was accepted as pain is significantly reduced in the affected knee when using a valgus knee brace.

4.4.4.3 Muscle strength and function

Hypothesis 3: Muscle strength is increased in the affected knee when using a valgus knee brace.

One of the undocumented opinions that are routinely stated is that valgus knee braces reduce the muscle strength around the knee joint as they are taking the strain from the affected knee and therefore the strength is not needed. This was suggested in the study by Risberg et al., (1999) who found significant increases in thigh atrophy with functional knee bracing over a period of three months where both the quadriceps and hamstring muscle reaction times were decreased by the different knee braces on the medial and lateral aspects of the knee joint. However, the results of this study disagree with this statement and previous research as significant improvements in muscle strength were found after using the valgus knee brace for three months. An improvement of 29.44% in knee extensors and 52.20% in knee flexors at $60°/s$ and of 32.98% in extensors and 29.72% in flexors at $45°/s$ were observed over a period of three months. These results agree with the only previous literature by Matsumo et al., (1997) who also found improvements in isokinetic knee extensor torque (quadriceps muscle strength) which was increased from an average of 36.8Nm to 42.8Nm by 16.30% for all patients after wearing the Generation II (G II) over a period of 12 months. However, our results do appear to be slightly larger which may be due to the shorter duration of the current trial in that the individuals adhered to the brace whereas over 12 months adherence would have been varied.

In the study by Hurley et al., (2012) using a valgus unloader brace, they found increases in quadriceps and hamstrings muscle strength measures between baseline visit and 6-month follow-up ; however, only the hamstrings torque increased significantly for the knee flexion at 15° Maximum Voluntary Isometric Contraction exercise and these improvement in muscle strength trended toward improvements in WOMAC function.

In identifying potential reasons for the increased muscle strength found in our study in comparison to previous literature could be due to a better mechanical stabilization of the knee. This would therefore mean that the individual has decreased pain and reducing

muscle co-contraction which would improve activities of daily living and function. Overall, taking all of these into account it would allow the knee to generate more power with the antalgic pain response reduced and therefore would increase muscle strength.

Balance and strength are two components of physical function. Greater knee and ankle muscular strength is linked with improved balance. Patients with knee OA have shown decreases in quadriceps strength and activation (Wessel, 1996; Fisher and Pendergast 1997; Hurley et al., 1997; O'Reilly et al., 1998) and impairments in knee joint proprioception. These deficits (Fisher and Pendergast, 1997; Pai et al., 1997; Sharma et.al., 1997) are associated with the ageing process and/or proprioception impairments and might lead to larger impairments in balance compared with age matched healthy group (Hassan et al., 2001; Hinman et al., 2002; Slemenda et al., 1997; Koceja et al., 1999; Lin et al., 2009). Both static and dynamic balance deficits have been found in knee OA patients but dynamic balance was more affected (Wegener et al., 1997; Hinman et al., 2002).

Dynamic balance was improved significantly by 13.19% at six weeks and 16.32% in anterior direction and by 12.42% at six weeks and 20.74% in medial direction. The balance improved in both direction but at three months showed better results which infers that the hip abductor muscle coordination improved better.

These changes in dynamic balance concur with a study undertaken by Chuang et al., (2007) used a balance system machine (KAT 2000; Breg Inc., Vista, CA, USA) for quantifying motor performance of the lower extremities. The tests were carried out on barefoot patient and were asked to stand with their body central line perpendicular to the floor and slightly widen their legs so that their feet were aligned with their shoulders. Subjects were tested with knee flexed at approximately 10° and with their arms across their chest. For the static balance test, the subjects were instructed to keep the platform as level as possible for about 30 seconds. For the dynamic balance test, the subjects had to move the platform in a circular direction while chasing a moving object on a computer screen for about 30 seconds. All subjects finished three consecutive balance trials in both static and dynamic conditions on the platform. By viewing the monitor, subjects could judge their balance function. They did their best to keep their center of gravity in the

referred position. The test was done with and without wearing knee sleeves. They found the knee OA patients wearing knee sleeves could experience increased balance ability in both static and dynamic conditions. The improvement might prevent knee OA patients from falling down and increase their sense of security during physical activities. Who showed that medial compartment knee OA patients wearing knee sleeves could experience increased balance ability in both static and dynamic conditions.

In knee OA research, Dynamic balance was has routinely been assessed by using expensive (force platform) (Hurley et al., 1997; Wegener et al., 1997; Hassan et al., 2001), and non-expensive measures (step test) (Hinman et al., 2002; Hinman et al., 2007; Lim et al., 2008). A new measure which has previously been used in deficient ligament studies, namely the Star Excursion Balance Test (SEBT) is another inexpensive and quick method of assessing dynamic balance, with good reliability shown (Hertel et al., 2000; Kinzey and Armstrong, 1998, Al-Khlaifat, 2012).

No other studies have assessed dynamic balance using the SEBT so it is difficult to draw definitive comparisons. However, in a previous study on exercise interventions Al-Khlaifat (2012) also demonstrated significant improvements on dynamic balance in anterior and medial direction showing that a valgus knee brace potentially could have similar effects on balance as an exercise intervention programme. However, this would need to be further explored in comparative studies. One aspect in increasing dynamic balance is that this could benefit individuals with knee OA patients from falling down and would help to enhance their sense of safety during daily living activities.

Previous studies have assessed function with the use of qualitative questionnaires (Lindenfeld et al., 1997; Matsuno et al., 1997; Hewett et al., 1998; Kirkley et al., 1999; Draper et al., 2000; Pollo et al., 2002; Giori, 2004; Richards et al., 2005; Draganich et al., 2006; Brouwer et al., 2006; Gaasbeek et al., 2007; Ramsey et al., 2007; Ramsey and Russell 2009; Wilson et al., 2011; Hurley et al., 2012; Larsen et al., 2013) and have found improvements in physical function. For example, Draper et al., (2000) and Richards et al., (2005) both found significant improvements in functional scores after wearing a valgus knee brace and noted that this would improve the confidence on the affected side increasing the vertical ground reaction forces as was described earlier.

In our study, the KOOS sub score showed significant improved in QOL by 62.48%, and in sport/rec by 78.50% but not significantly improved in ADL even though an average increased by 31.12% at three months which could infer that the overall function of the individual is improved.

However, our results do disagree from the perspective of off-the-shelf valgus knee brace research as Draganich et al., (2006) found that the off-the-shelf brace used in their study did not alter physical function scores although a different intervention period was used and a different brace. Therefore, definitive comparisons cannot really be made.

In summary, the valgus knee brace significantly increased muscle strength and associated dynamic balance and function scores after both six weeks and 3 months which we perceive to be important aspects in the overall disease process of the individual with medial knee OA.

Therefore, this hypothesis was accepted as the muscle strength and function were significantly improved in the affected knee over a period of 3 months using a valgus knee brace.

4.4.4.4 Muscle co-contraction

Hypothesis 4: Muscle co-contraction patterns are reduced after wearing a valgus knee brace.

Muscle co-contraction has been found to be increased in individuals with medial knee OA (Childs et al., 2004; Lewek et al., 2004; Hubley-Kozey et al., 2006) and has been thought to increase medial compartment loads (Trepczynski et al., 2014), so reducing this co-contraction could be perceived as a sensible option. The results of this study showed that the muscle co-contraction between Vastus medialis and Semitendinosus decreased significantly after using the valgus knee brace for three months and this was found whilst wearing the brace and not wearing the brace. The reductions in co-contraction were most evident during the periods where knee loading and peak EKAM are at their highest during walking. This is in agreement with previous literature (Ramsey et al., 2007; Fantini Pagani et al., 2013). Fantini Pagani et al., (2013) found that vastus medialis (VM)

/ medial hamstring (MH) muscle co-contraction decreased significantly by 10.4% and 19.6% for the valgus 4° and flexible adjustments, respectively compared to baseline. In addition, our results concur with Ramsey et al., (2007) who found the co-contraction of the vastus medialis-medial hamstrings was significantly reduced with the valgus setting, as a result of bracing after two weeks. Although the significant reductions presented here are greater (30.56% at early stage, 30.76% at middle stage and 23.07% at late stage between the shoe only and the brace at three months) and are likely due to the longer duration of wear as the previous studies assessed muscle co-contraction immediately (Fantini Pagani et al., 2013) and after only two weeks (Ramsey et al., 2007). This demonstrates that the valgus knee brace is allowing better coordination of the knee muscles which with the increased strength will help to provide an increased function.

There was a reduction, but not significant, in the muscle co-contraction between Vastus lateralis and Biceps femoris in all conditions of the study at early and middle stage. However no reduction was observed in the muscle co-contraction at late stage but rather an increase of 63.63% and 54.55% between the shoe only at base line and brace and the shoe only at three months, respectively, and by 20% between the brace at baseline and at three months was observed between Vastus lateralis and Biceps femoris at late stage. At the early stage, the muscle co-contraction between Vastus lateralis and Biceps femoris was decreased by 35.85% and 32.08% between the shoe only at baseline and the brace at three months and in comparison to the brace at baseline, and by 35.58% between the shoe only condition at baseline and three months. This does show that after wearing the brace for a period of time the muscle co-contraction will reduce further and there appears to be a residual effect which is evident without the brace being worn. This is important for future designed studies whereby longer intervention periods are suggested. At the middle stage, the muscle co-contraction between Vastus lateralis and Biceps femoris was decreased by 22.72%, 27.27% and 4.55% between the shoe only at baseline and the brace at three months, the brace at baseline and three months, and the shoe only at baseline and three months respectively. These results showed a reduction in the muscle co-contraction between Vastus lateralis and Biceps femoris but not significant and these results disagree with Fantini Pagani et al., (2010) who found a significant decrease of 5.9% and 16.8% for the vastus lateralis (VL) / lateral hamstring (LH) were observed with the valgus 4° and

flexible adjustments, respectively, compared to baseline immediately. In addition, these results also disagree with Ramsey et al., (2007) who reported that the co-contraction of the vastus lateralis- / lateral hamstrings was significantly reduced from baseline in both without and with valgus setting. However, both of these studies only assessed the average co-contraction during stance and not in specific period.

The ratio of VL-BF average co-contraction was higher than that of VM-ST in early and mid-stance during walking and ascending and descending stairs. This is in agreement with previous studies reporting higher ratios of VL-BF average co-contraction than that of VM-ST in early-stance (Andriacchi, 1994; Ramsey et al., 2007; Hubley-Kozey et al., 2009) and mid-stance (Schmitt and Rudolph, 2007) during walking. The internal moments are very important on the lateral side to provide a valgus resistance against a varus position in the knee joint that occurs where the EKAM attempts to move the knee joint in this position. Therefore, the co-contraction between agonist and antagonist muscles stabilize the joint (Schipplein and Andriacchi, 1991), while the activity of the agonist muscles alone is not sufficient enough to resist the EKAM. Decreasing average co-contraction between VL-BF during ascending and descending might propose a decrease in the internal moment resisting the external moment by the EKAM, although the EKAM did not change significantly. Furthermore, the increases co-contraction corresponds to a more generalised muscle activity, whereas lower co-contraction indicated more selective activation (Rudolph et al., 2000). Decreasing average co-contraction between VL-BF during ascending and descending might be a factor in reduction in pain and increase in strength, function, and balance. Additionally, when the brace surrounds the knee joint, it can play a role in providing the support, heat, and enhanced proprioception (Birmingham et al., 2001) and reducing muscle co-contraction (Ramsey et al., 2007; Fantini Pagani et al., 2013). Average co-contraction between VL-BF showed a reduction but not statistically significant during walking after wearing the brace three months. This might be due to the fact that co-contraction between VL-BF is not significantly different in individuals with OA and healthy which means that a smaller magnitude is evident which could be harder to reduce further.

The results of this study showed the muscle co-contraction between Vastus medialis and Semitendinosus and between Vastus lateralis and Biceps femoris decreased significantly between the shoe only at baseline and brace and, shoe at three months and brace at three months in single support during ascending and descending stairs. It is also decreased significantly between brace at baseline and three months in single support during ascending and descending stairs. There are no studies that have been previously performed on muscle co-contraction during ascending and descending but as greater flexion angles are noted with this activity, this is potentially one of the reasons why co-contraction is reduced significantly in both of these muscles compared to walking.

Fantini Pagani et al., (2012) supports the theory that valgus knee braces decrease knee loading by reducing muscle activation and co-contraction levels, which could lead to slow progression of the disease in patients with knee osteoarthritis. Our results showed a small reduction of EKAM in both walking and ascending and descending stairs, with reduced muscle co-contraction and this may be beneficial on the total knee joint compartmental loads (Trepczynski et al., 2014). The combination of a reduced EKAM and reduced muscle co-contraction is proposed by Trepczynski et al., (2014) to reduce medial compartment loads so whilst we did not show a significant change in EKAM, in-vivo compartment loads may be reduced which potentially relate to the clinical findings reported. Ramsey et al., (2007), reported the changes in muscle activation with the use of valgus knee braces is based on the mechanical stabilization of the knee by the brace, reducing the perception of knee instability and thus, decreasing muscle co-contraction. In addition, this mechanism could act in combination with the mechanical mechanisms of load reduction induced by the three-point bending system of valgus braces (Fantini Pagani et al., 2013). Even though increased co-contraction has been suggested to be a protective mechanism to reduce the load on the medial compartment knee OA, it has also been suggested that at the same time it exposes the joint to extra compressive forces (Lewek et al., 2004). One of the reasons for the increased muscle co-contraction around the knee joint could be due to instability as medial knee joint laxity was significantly greater in the OA participants groups compared to healthy participants (Lewek et al., 2004; Schmitt and Rudolph, 2007) and weakness of the quadriceps (Rudolph, 2007). Our results showed an increase in quadriceps muscle strength, thus decreasing the perception

of knee instability (buckling) by stabilizing the knee joint with the valgus knee brace. This was also demonstrated with the significant changes in dynamic balance as previously reported, leading to an overall reduction in pain.

Therefore, this hypothesis was partially accepted because the muscle co-contraction significantly decreased between Vastus medialis and Semitendinosus during walking, ascending and descending stairs and between the Vastus lateralis and Biceps femoris during ascending and descending stairs. However, the muscle co-contraction between the Vastus lateralis and Biceps femoris did not decrease significantly during walking.

4.4.5   Kinetic and kinematic outcomes

Medial knee OA impacts on the whole body therefore it is important to understand the effect of the use of valgus knee braces on the kinematics of surrounding joints. With the increased importance of the sagittal plane knee moment on joint loading (Walter et al., 2010), this has also been presented for completeness. In addition, the contralateral limb has also been presented which literature for this limb whilst wearing interventions is limited.

Affected leg

Walking

A valgus knee brace should not affect motion in the sagittal plane at the knee joint given that its action should be in the coronal plane. In this study, there was no significant change in the sagittal knee range of motion (ROM) in any conditions during walking, at any time point. These results concur with Toriyama et al., (2011) who also reported no significant difference between the braced and unbraced conditions in the sagittal knee flexion angles. However, Gaasbeek et al., (2006) reported that the knee range of motion in the sagittal plane was significantly reduced in the braced condition. The knee angles at different events of the gait cycle were assessed in this study and showed that the brace prevented full extension at the end of swing phase and this happen due to the strap

tension resisting knee extension. These results concur with other studies by Davidson et al., (1996), who reported that there was a significant change in the second inflection point during stance where the brace prevented full extension. Matsuno et al., (1997), one of their interesting observations was the decrease in the knee flexion angle from 185.1° to 183.7° with Generation II knee bracing at 12 month and this reduction is possibly linked to the improvement in knee stability. In swing phase, it has been identified by two studies (Richards et al., 2005; Jones et al., 2013) that valgus knee braces reduce knee flexion during swing phase which could limit step length. However, we did not find this with the current brace and this may have been due to the lighter construction of the brace and a single hinge rather than a double hinged brace.

The action of a valgus knee brace is theoretically to improve the limb alignment with the valgus forces aiming to reduce the knee varus (Pollo et al., 2002). The results from this study disagree with this concept in that there was no significant change in the frontal plane knee angle in all conditions, at any time point during walking. These results concur with Toriyama et al., (2011) who also reported no significant change in the knee angle in the frontal plane during walking. This would suggest that the valgus knee brace is not applying a great enough valgus moment onto the proximal and distal segments surrounding the knee joint as previous research has shown significant changes (Self et al., 2000; Pollo et al., 2002; Draganich et al., 2006). Draganich et al., (2006) showed a 1.5° and 1.3° change in varus angulation after using a custom-brace and the off-the-shelf brace, respectively, for four to five weeks and this is potentially due to the more robust design of the brace. In the study conducted in this thesis, the valgus strap was kept on a consistent level and this could also be a potential reason for the non-reduction of the knee frontal plane angle. Future work should be considered whereby knee coronal plane angular changes are seen at initial fitting as this would potentially increase the biomechanical effectiveness of the valgus knee brace.

Given that there was no significant difference in the sagittal plane knee joint motion, it is not surprising to see that there was no significant change in the sagittal knee moment in any condition, at any time point during walking showing that the valgus knee brace did not affect the kinetics at the knee joint in the sagittal plane. This result concur with study

was done by Lindenfeld et al., (1997) found no significant change in the knee flexion and extension moment between braced and unbraced group after 6 weeks. However, using the same type of brace, Toriyama et al., (2011) found that the knee extension moment increased at the first peak and knee flexion moment decreased at the lowest point. This study was conducted immediately and not after a period of time and it may be that there were gait changes induced by wearing the valgus knee brace rather than seeing if these changes persisted after a period of time.

There was no significant change in the maximum ankle dorsiflexion and plantar flexion in all conditions during walking except significant decreased was observed in the maximum ankle planter flexion angle between the shoe only at baseline and brace and the shoe only at three months. The decreasing was observed in the maximum of ankle plantar flexion was due to the strap of the brace around lower leg which reduced the muscle contraction thus reducing the ankle plantar flexion angle ROM during toe off time of walking. A study was done by Jones et al., 2013, showed there was no significant change in the sagittal plane ankle motions between conditions (baseline 1, baseline 2, lateral wedged insole, Knee brace) and these results concur with our results no significant change in the in the peak of ankle ROM in all conditions.

During walking, there was a significant decrease in the hip ROM after wearing the brace immediately and after three months, but no significant change was found between the shoe only at baseline and at three months. Toriyama et al., (2011) reported no significant changes were observed between the braced and unbraced conditions in the maximum hip flexion angle and agree with this study. The decrease in ROM was observed due to a restriction in the peak of hip extension and is potentially due to the strap of the brace around upper thigh that may have restricted the full extension of the thigh during mid-swing although previous studies have not found this. However, the decrease in ROM was only 6.02 % and this would not be thought to alter functional gait motion. Whether this change has any clinical or functional meaning would need to be further examined in studies focussing primarily on these changes. . No difference was seen when not wearing the brace between baseline and three months showing no residual effect of the brace.

Ascending and Descending stairs

There was a significant decrease in the sagittal knee ROM between the shoe only and the brace at three months during ascending. Given the increased knee flexion that occurs during ascending stairs (Andriacchi et al., 1980) it could have been due to the straps surrounding the knee joint. This reduction primarily occurred at mid- stance in knee extension and may have had some impact on the way the individuals ascended the stairs. Given that there are no other studies on ascending stairs on valgus knee braces, further research is needed to understand if this is indeed a restriction caused by the valgus knee brace. However, there was no significant change in the sagittal knee ROM in all conditions during descending. Whilst not the same type of intervention for medial knee OA, Wallace et al., (2007) and Alshawabka et al., (2014), found no difference in sagittal plane knee angle whilst using lateral wedge insoles and a standard shoe during ascending and descending.

It would however be expected that similar to walking the peak frontal plane knee angle would be affected by the valgus knee brace but there was no significant change during ascending. However, there was a significant decrease in the of frontal knee ROM between the shoe only at baseline and brace at three months and this happen due to an decrease was observed in the abduction knee angle; however other conditions didn't significantly reduced during descending.

With the reduction in sagittal plane ROM, there was also a corresponding increase in the maximum knee flexor moment between the shoe only and brace at three months. This could have due to the slightly increased knee flexion angle at early stance bringing the ground reaction force vector further behind the knee joint. From the work by Walter et al., (2010) this increase in knee flexor moment may increase medial compartment loads but further work would need to confirm this. There were no other significant effects in any of the other conditions or any aspects during descending.

There was no significant change in the maximum of ankle dorsiflexion in all conditions during ascending. However, there was a significant decrease in the maximum of ankle plantar flexion between the baseline assessment and the brace and shoe only conditions at

three months. This was shown with a corresponding decrease in ankle ROM. The reasons for the decrease are not really understood but it may be due to the brace supporting the shank segment which restricts ankle motion slightly. Further work would need to confirm this however. During descending, there was no significant change in the ankle ROM in all conditions. Additionally, there was no significant change in the maximum of ankle dorsiflexion in all conditions during descending. However, there was a significant decrease in the maximum of ankle plantar flexion between the baseline assessments and the brace at three months, but no significant change was found between the shoe only at baseline and at three months. Again as previously discussed, the reasons for this are not particularly clear. At the hip joint, there was no significant change in the hip ROM in all conditions during ascending. However, there was a significant decrease in the hip ROM between the shoe only at baseline and brace at three months; however other conditions didn't significantly reduce during descending.

The contralateral limb

In previous studies on valgus knee braces, only one has reported on changes in the contralateral limb (Toriyama et al., 2011) but this was assessed immediately upon application of the valgus knee brace. Therefore, the comparison can only be made to this study but with the obvious time limitations. The contralateral limb is important given that a recent study by Jones et al., (2013) found that an individual with medial disease on one knee has a 90% risk of developing medial OA on their contralateral knee. Therefore, understanding the gait kinematics and kinetic changes in the contralateral limb is important in the OA disease process and the effectiveness of the valgus knee brace.

Walking

There was no significant difference in the first peak and second peak of the EKAM in the contralateral leg in all conditions. These results are in agreement with Toriyama et al., (2012) who used the same brace is used in this study and they reported no significant change the first peak and second peak of the EKAM was found between conditions at immediate assessment. Our results showed the first peak in the contralateral limb increased by 19.99% between the shoe only at baseline and brace at three months and by

22.44% between the shoe only at baseline and at three months. This increase, whilst not significant may increase knee loading and may be detrimental. This could have happened due to more confidence being placed in the affected leg which may have caused other changes in the contralateral limb. It could have been that the individuals did have some disease in this limb but were asymptomatic. From a kinematic standpoint, there was no significant change was found in the frontal plane knee angle in the contralateral limb in all conditions during walking which would infer that the knee joint is not being affected in this plane.

There was no significant change found in the sagittal plane knee angle in the contralateral limb in all conditions during walking. These results concur with Toriyama et al., (2011) who reported the contralateral knee flexion angle patterns showed no significant differences between conditions. This was also similar in the sagittal plane knee moment and peak of the vertical GRF which was not changed in the contralateral limb. One would expect that with more reliance on the affected limb that there would be reduced GRF on the contralateral limb but this does not seem to be the case in this study. There was no significant change in the frontal plane knee angle in the contralateral limb between conditions during walking. These results are in disagreement with Toriyama et al., (2011) who reported the knee adduction angle patterns were significantly increased in the braced condition by an average of 0.32° during 46%−55% of the stance phase.

There was no significant change found in the sagittal plane ankle angle in the contralateral limb in all conditions during walking and there was no previous study was done to compare our results with them. There was no significant change was found in the sagittal plane hip angle in the contralateral limb in all conditions during walking in agreement with the study undertaken by Toriyama et al., (2011) who reported the contralateral hip flexion angle patterns showed no significant differences between conditions.

Ascending and Descending stairs

Given that there is no other study that has been performed on stair ascending and descending with valgus knee braces, no discussion with regards to previous literature can

be done. There was no significant difference in the first peak and second peak of the EKAM in the contralateral leg in all conditions during ascending and descending stairs. No previous study was done before to compare and the results showed no changes as we expected.

There was no significant change found in the sagittal plane knee angle or knee moment in the contralateral limb in the majority of conditions during ascending. There was a significant increase in the maximum knee flexion angle at initial contact and also the maximum knee flexor moment between the shoe only at baseline and the brace after three months. This could have been due to more reliance on the affected side but as there are no previous studies, this does need confirming if this is relevant to functional knee motion. However, no change in the peak of vertical GRF was found.

At the ankle, no significant change was found in the sagittal plane ankle angle in the contralateral limb in all conditions during ascending and descending. There was also no significant change found in the sagittal plane hip angle in the contralateral limb in all conditions during ascending and descending.

4.4.6   Observational outcome

Patients were contacted by telephone at regular intervals biweekly to ensure that they were not having problems with the valgus knee brace. The mean average duration of wearing of the valgus knee brace increased from 4 hours as the beginning of treatment when asked patient to wear the brace at least 4 hours a day for three months to 6.67 (SD 1.54) hours. The increase in the amount of time wearing the brace is probably due to the brace giving more confidence to the limb helping to relieve pain and increased patient comfort to wear this brace more time than usual. In addition, the type of brace in this study was light, invisible under the clothes, could be adjusted easily by the patient and easy to fit. No patient recorded any complaints from brace.

4.4.7 Limitations of this study

As with any study, there are limitations. Firstly, the individuals or the investigator was not blinded to the brace being used in gait lab test even though all the kinetic and kinematic data was through automated measurements tools, so the assessor bias was low. The collection of biomechanical data was completed without knowledge of the results of this data and were analysed at the end of the trial. The clinical outcome data was collected independently and assessed at the end of the study without any input from the investigator to the patient's comments.

The valgus angle of this knee brace was fixed by strap tension throughout the three months period of wearing. In our study the dynamic force strap was set to number 5 out of 10 in the first session and this setting was recommended by the company due to many people finding that this average setting of 5 will provide adequate pain relief which meant that the patients were not instructed to change this. This is a limitation as it could have been this reason for some of the null effects on EKAM and coronal plane knee angle. In contrast, others studies have found with increased the valgus angulation will lead to increase reduction in the external knee adduction moment however the brace that used in this study depend of the degree tension if the dynamic force strap, so tension of this strap was not represent angulation of the brace.

The stairs that were used in this study were only three steps and are different from the typical stairs that are used in daily living activity. The typical stairs may differ from our stair that used in the study in both stair dimensions (height and depth) and environmental conditions (indoor/outdoor), and this altered feeling of stairs may contribute to different results if this was captured with a full staircase or outside. The stairs of this study would also not allow independent collection of kinetic and kinematic data on the contralateral leg during the full gait cycle because the staircase in this study only had 3 steps with only two steps were collected during the test for the gait cycle. Therefore, a larger staircase or adding an extra step would have been an improvement on this study.

The study was only conducted with 15 individuals which could be another reason for the null findings on EKAM in the study, although the variation was quite large between

subjects with some increasing their EKAM. However, other studies on valgus knee braces have been around this number, but a larger sample size in a study similar to what was conducted here should be completed to fully understand this type of valgus knee brace. A sample size was conducted on the data collected and a (standard deviation of EKAM (0.015), the mean difference of 0.02 Nm/kg, with a 90% power and the significance level at the 95% confidence interval) total number of 26 patients would be needed for statistical significance in EKAM. The primary reason for limiting the study to 15 patients was due to previous studies and also with some issues with recruitment. Therefore, there are plans to recruit more individuals but this is outside the scope of this thesis timeline. However, significant clinical and functional results were found and from a patient perspective these are of the utmost importance.

One of the major limitations of this study is that it was not a randomised clinical trial and that the effects seen with the brace could have been seen if the individual did not wear the brace. However, given that the brace surrounds the knee joint offering support and some proprioception, it would not be thought that this would be case. Nevertheless, for a complete picture a control group and a comparator group (knee sleeve only) should be assessed to determine the full effectiveness and efficacy of this valgus knee brace. A control group was not chosen in this study as we wanted to fully understand the effects of the brace during different activities and time points and a RCT was not the objective but obviously this is a limitation of the results found.

4.5 Conclusions

The aims of this thesis were to understand whether an off-the-shelf valgus knee brace altered biomechanical and clinical outcomes during walking and ascending and descending stairs. The literature review identified that whilst many studies have been undertaken on valgus knee braces, the findings have been from different designs of valgus knee brace and no study has assessed the effect of valgus knee braces on ascending and descending stairs.

It was found in this study that the valgus knee brace used in this study did not significantly reduce the knee loading during walking, ascending or descending stairs.

There were some individuals where the loading was decreased after three months when compared to the shoe only at baseline with the brace on and with the brace off. This does give some indication that there could be a residual effect of the valgus knee brace which would be beneficial in that reductions of loading could occur without the brace being worn. This however, would need to be further confirmed in a larger study.

From a clinical perspective, pain was reduced and the overall strength and function were significantly improved both from a balance perspective and motion at the knee joint. One reason for this could have been the reduced muscle co-contraction between antagonist and agonist muscles of the knee joint which has been postulated to reduce medial compartment loading. Given the small reduced loading and decreased muscle co-contraction it would be hypothesied that medial compartment joint forces would be reduced with this valgus knee brace. However, this would need to be assessed in a more complex multi-scale modelling or knee implant study.

Future work should assess whether any structural changes (bone marrow lesions for example) could be seen after an intervention period with valgus knee braces as this would give evidence that the reduced loading was seen. Other future work should assess whether a combined valgus knee brace with exercise could have effect on reducing in loading and muscle co-contraction over long period of treatment.

It is also unknown whether combining a valgus knee brace with another intervention would significantly reduce EKAM and therefore a pilot study was performed to understand if a combined orthotic management of a valgus knee brace and lateral wedged insole was better at reducing EKAM than the single treatments alone in individuals patient with knee OA during ascending and descending stairs.

CHAPTER FIVE

PILOT STUDY: Comparison of isolated and combined orthotic devices on knee loading whilst ascending and descending stairs in patients with medial knee osteoarthritis

(Presented at the Osteoarthritis and Cartilage Annual Symposium, Philadelphia, 2013)

5.1 Background:

Osteoarthritis (OA) is the most common form of arthritis and a leading cause of disability worldwide with over 8.5 million people in the UK having osteoarthritis in 2002 (Arthritis Care (2004) OA Nation) . Knee OA is estimated to be the eighth leading global cause of disability in men, and the fourth most common in women (Vad et al., 2002) and accounted for 2.8% of total years living with disability (Murray et al., 1996).

Stair climbing is a common and frequent activity in daily living and demands, compared to walking on level ground, a greater range of motion and around six times more load on the knee joint. The moment was increased at the knee joint during ascending and descending stairs and was largest during descending stairs, with both moments higher than compared with walking on the level ground (Andriacchi et al. 1980).

Even though surgery for knee OA is available, there are some individuals who may not be suitable for surgery or do not want surgery. Therefore other options are needed. Conservative management techniques are options that have not yet been fully justified in the scientific literature. It is therefore important to understand which technique will have the greater impact, for a particular patient type, both in terms of functional independence and reduction in pain, two primary complaints by sufferers.

Valgus knee braces and lateral wedged insoles are common modalities used in the treatment of medial tibiofemoral osteoarthritis (OA) of the knee joint. Both treatments have been shown to reduce the external knee adduction moment (EKAM) during walking

(Draganich et al. 2006; Jones et al. 2013; Hinman et al. 2009) and more recently during stair ascent and descent (Alshawabka et al. 2014; Wallace et al. 2007). There is evidence suggesting that combining treatments during walking tasks (by altering the position of the knee joint centre with a valgus knee brace and the orientation of the ground reaction force with a lateral wedge insole) produces a greater reduction of the EKAM. In a previous study by Moyer et al., (2012), they investigated a custom-fit valgus knee brace and custom-made lateral wedge foot orthotic and the effects that this would have during gait. They found that can produce a greater overall reduction in the knee adduction moment, through combined effects in decreasing the frontal plane lever arm during walking. Therefore, determining whether insoles, valgus knee braces or a combined approach reduces loads in patients with medial knee OA for other activities is warranted.

However, it is not known if off-the-shelf devices have the same effect or whether the reductions in knee loading are there for the more challenging activity of stair ascent and descent. Therefore, the aim of this study was to determine whether a combined orthotic management (of an off-the-shelf valgus knee brace and an off-the-shelf lateral wedge insole) reduced knee loading greater than the single treatments alone.

5.2 Methods

5.2.1 Participants:

Seven patients (5 female, 2 male) were radiographically confirmed with medial knee OA, participated in the study. Participants were recruited from within Salford University after getting the ethical approval from Salford University (HSCR12/17).

In order to be eligible for the study the following inclusion and exclusion were adopted:

Inclusion criteria:

To define medial knee OA, a patient must meet all of the following:
1   Pain with walking (using KOOS question, they need to have at least mild pain walking on a flat surface) – Clinical diagnosis by qualified clinician

2   On AP or PA view x-ray (weight bearing; if possible); they need to have definite medial narrowing ≥ lateral narrowing and evidence (osteophyte) of OA – Radiographic diagnosis. Medial tenderness either by their own indication that this is where they have pain or by examination showing tenderness at the medial TF joint line – Clinical diagnosis by qualified clinician

3   If potential participants have had a MR scan or arthroscopy as part of their usual clinical care. As well as using the K-L score of grade 2 or 3 for plain radiographs, we will use the documented evidence of at least grade 1 arthritis on arthroscopy.

4   They are able to walk for 100 metres non-stop – Participant response.

Exclusion criteria:

Participants were excluded if the pain is more localised to the patellofemoral joint on examination than medial joint line, have tricompartmental knee osteoarthritis or have grade 4 medial tibiofemoral osteoarthritis (MTOA) on the Kellgren Lawrence scale. Other exclusions include a history of high tibial osteotomy or other realignment surgery or total knee replacement on the affected side or any foot and ankle problems that will contraindicate the use of the footwear load modifying interventions. In addition, participants were excluded if they have severe coexisting medical morbidities, or currently use, or have used, orthosis of any description prescribed by a Podiatrist or Orthotist. If the participants cannot walk for 100 metres without stopping they will also be excluded as they may be unable to complete the full testing protocol. We excluded individuals if the brace is not likely to work because the leg is too large; or if there has been an intra-articular steroid injection into the painful knee in the last month.

5.2.2 Procedure

The research was conducted on osteoarthritis patients aged between 35 (it is age 35 years and upwards as this is the target age for the subsequent trials and individuals were likely to have knee osteoarthritis after this age) and 65 and if they have had a knee x-ray they asked to give consent for a radiologist to read these for radiological confirmation of the disease. All participants were recruited from within Salford University. For this purpose, an e-mail invitation was sent to all students and staff of Salford University after prior

approval from Colleges' deans. A poster that explained the study was pinned onto notice boards in buildings around Salford University to enhance recruitment.

When the volunteers decided to take part in this study, they asked to contact the chief investigator using the information that provided in the poster, the invitation e-mail, and the participant information sheet. The volunteer whom met the eligibility criteria was then asked to visit the podiatry gait laboratory in Allerton building on one occasion lasting approximately two hours.

On attendance at the gait laboratory, the study was explained in full and the subject completed a consent form and the following demographic data such as date of birth, height and mass were recorded. Then, the patients were assessed to determine the correct size of shoe (Ecco Zen), lateral wedged insole (Salford Lateral Wedge) and valgus knee brace that the individual required. Patients were asked to change into their shorts and a comfortable t-shirt. The patients then had the following assessments performed.

Qualisys motion analysis system (Qualisys, Gothenburg, Sweden) and two AMTI force platforms (AMTI BP400X600, AMTI, USA) were used to collect kinematic and kinetic data as per Chapter 3 section (4.2.3). Sixteen infrared cameras (Qualisys, Sweden) were used to capture the 3-dimensional positions of the retro-reflective markers that were attached to each subject's skin over bony landmarks in both lower limbs (on the 1st , 2nd, 5th metatarsal heads and Calcaneal tubercle), ankle (medial and lateral malleolus), knee (lateral and medial femoral condyle, tibial tuberosity and fibular head), thigh (greater trochanter) and pelvis(right and left anterior superior iliac spine, right and left posterior superior iliac spine, and right and left iliac crest). Fixed cluster pads made of plastic (with four markers on each) were attached to the shank, thigh and pelvis to track their movements.

At the beginning of each test condition, body mass was obtained by asking the patient to stand over one of the force platforms, meanwhile a static 3D image could be obtained by the sixteen infra-red cameras. All subjects were asked to perform three tasks in four conditions in a randomised order:

Standing

The individual was stand on a force platform for 10 seconds and a static 3-dimensional image from the sixteen infra-red cameras were obtained.

Walking

5 successful self-selected walks (clear foot contact with the force plates was regarded the acceptable trial) in each one of the conditions were performed.

Stairs

Patients were asked to perform three trials of three step stairs ascent and descent at a self-selected speed starting every trial with the affected side at first step of stairs during climb up in step-over-step manner and also starting every trial with the affected side during climb down in step-over-step manner without using the handrails. A handrail was installed to both sides of the stairs to prevent the patient from falling off at any time ascending or descending the stairs.

Kinetic data (ground reaction force and centre of pressure) was obtained by using two force platforms (AMTI BP400600, Boston, USA).

Each participant worn standard shoes (Ecco Zen) which was available to fit all sizes and be required to ascend and descend three stairs for three times without using a hand rail or any other device to assist climbing of the stairs. A handrail was available if the subject needed to use this for safety.

Four test conditions were been tested:

1. Condition 1: Standard control shoe – The participant wore standard shoes which will provide a baseline dataset for the footwear conditions.

2. Condition 2: Standard control shoe with a lateral wedged insole (Salford Lateral Wedge) – The participant was asked to wear standard shoes that are modified to have a lateral wedge insole inserted inside (Jones et al., 2013).

3. Condition 3: Standard control shoe with an off-the-shelf Ossur UnloaderOne valgus knee brace, – The participant was asked to wear standard shoes and a valgus knee brace.

4. Condition 4: Standard control shoe with a lateral wedged insole (Salford Lateral Wedge) and an off-the-shelf Ossur UnloaderOne valgus knee brace – The participant was asked to wear standard shoes that are modified to have a lateral wedge insole and valgus knee brace.

The order of interventions was randomised according to the following website (www.randomisation.com) to ensure that carry-over effects are minimised and reduce bias.

5.2.3 Data Analysis

For this study, only the external knee adduction moment was assessed. The EKAM was calculated and exported during single support and stance phase. Normalised stance phase was divided into two sub phases, which are initial (0-33%), and late (68%-100%) which are termed first peak and second peak along with the knee adduction angular impulse (KAAI) for stance phase. Peak early-single support (0-33%) EKAM; and peak late-single support (68-100) EKAM were extracted along with the knee adduction angular impulse (KAAI) for the support phase. SPSS (SPSS Inc., USA) was used for the statistical analysis. A repeated measures of analysis of variance was undertaken to determine any significant differences at the 95% Confidence interval ($p<0.05$) between the control shoe and the orthotic conditions. A bonferroni correction was applied due to multiple test conditions to reduce the change of a type1 error.

5.3 Results

5.3.1 Test participant

Seven patients with knee OA participated in the study; five women and two men (mean age 58(SD 5.88) years; age range 52-65 years; mean height 162 (SD11.04) cm; height range 164-177 cm; mean mass 81(SD 14.05) Kg; mass range 55.5- 97 Kg); mean body mass index (BMI) 30.82 (SD 5.33) kg/m2. Four individuals diagnosed with grade 2 KL and three individuals with grade 3 KL.

5.3.2 Kinetic results during ascending stairs

5.3.2.1 EKAM Stance phase

There was a significant decrease (mean difference 0.07 Nm/kg, p=0.047) in the first peak of EKAM with the valgus knee brace and lateral wedged insole combined in comparison to the shoe only, with an average decrease of 23.90%. However, there was no significant change in the first peak of EKAM between the lateral wedged insole, or valgus knee brace, and the shoe only (mean difference 0.02 Nm/kg, p=0.37, 0.04 Nm/kg, p=0.34), although average decreases of 8.14% and 14.63% were found respectively.

There was a significant decrease in the second peak of EKAM with the valgus knee brace and lateral wedged insole combined and the lateral wedged insole in comparison to the shoe only, (mean difference 0.12 Nm/kg, p=0.03, 0.06 Nm/kg, p=0.02), with average decreases of 29.50% and 15.05% were found respectively. However, there was no significant change in the second peak of EKAM between the valgus knee brace and the shoe only (mean difference 0.06 Nm/kg, p=0.11), although average decreases of 15.45% was found. Descriptive data of EKAM results during ascending are illustrated in figure 5-1 and table 5-1.
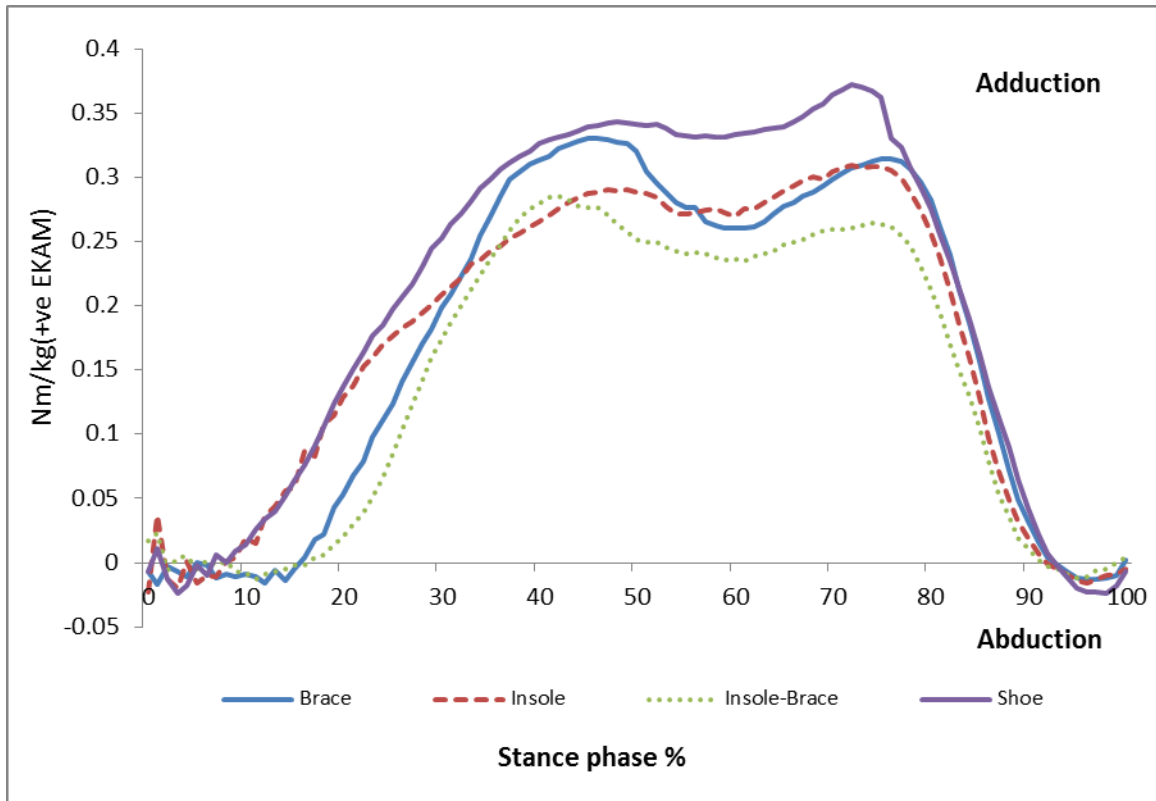
Figure 5-1: The external knee adduction moment (EKAM) in stance phase during ascending.

Table 5-1: Mean (SD±) first and second peak of the EKAM in stance phase during ascending.

Type	Brace	Insole	Insole-Brace	Shoe
EKAM 1 Mean (SD) (Nm/kg)	0.25(0.16)	0.27(0.15)	0.22(0.12)	0.29(0.16)
EKAM 2 Mean (SD) (Nm/kg)	0.34(0.23)	0.34(0.22)	0.28(0.19)	0.40(0.25)

5.3.2.2 EKAM Single limb support

There was a significant decrease (mean difference 0.06 Nm/kg, p=0.048) in the first peak of EKAM with the valgus knee brace and lateral wedged insole combined in comparison to the shoe only, with an average decrease of 15.66%. However, there was no significant change in the first peak of EKAM between the lateral wedged insole, or valgus knee brace, and the shoe only (mean difference 0.04 Nm/kg, p=0.07, 0.02 Nm/kg p=0.62), although average decreases of 12.39% and 4.91% were found respectively.

There was a significant decrease in the second peak of EKAM with the valgus knee brace and lateral wedged insole combined and the lateral wedged insole in comparison to the shoe only, (mean difference 0.12 Nm/kg, p=0.03, 0.06 Nm/kg, p=0.02), with average

decreases of 24.87% and 11.46% found respectively. However, there was no significant change in the second peak of EKAM between the valgus knee brace and the shoe only (mean difference 0.03 Nm/kg, p=0.67), although average decreases of 5% was found. Descriptive data of EKAM results during ascending are illustrated in figure 5-2 and table 5-2.

Figure 5-2: The external knee adduction moment (EKAM) in single limb support during ascending.

Table 5-2: Mean (SD±) first and second peak of the EKAM in single limb support during ascending.

Type	Brace	Insole	Insole-Brace	Shoe
EKAM 1 Mean (SD) (Nm/kg)	0.34(0.18)	0.32(0.18)	0.30(0.16)	0.36(0.18)
EKAM 2 Mean (SD) (Nm/kg)	0.42(0.23)	0.39(0.19)	0.33(0.15)	0.45(0.22)

5.3.2.3 KAAI Stance phase:

The KAAI was significantly reduced for the insole (p = 0.001) and the combined lateral wedged and valgus knee brace (p = 0.009), and the valgus knee brace (p=0.024) in comparison to the control shoe. Descriptive data of KAAI results during ascending are illustrated in figure 5-3 and table 5-3.

Table 5-3: Mean (SD±) Knee adduction angular impulse (KAAI) in stance phase during ascending.

Type	Brace	Insole	Insole-Brace	Shoe
KAAI Mean (SD±)(Nm/kg)*s	0.23(0.14)	0.23(0.13)	0.19(0.11)	0.27(0.15)

Figure 5-3: Knee adduction angular impulse (KAAI) in stance phase during ascending.

5.3.2.4 KAAI Single limb support

The KAAI was significantly reduced for the insole (p = 0.003) and the combined lateral wedged and valgus knee brace (p = 0.008), with the valgus knee brace bordering significance (p=0.054) in comparison to the control shoe. Descriptive data of KAAI results during ascending are illustrated in figure 5-4 and table 5-4.

Table 5-4: Mean (SD±) Knee adduction angular impulse (KAAI) in single limb support during ascending.

Type	Brace	Insole	Insole-Brace	Shoe
KAAI Mean (SD±)(Nm/kg)*s	0.17(0.09)	0.16(0.08)	0.14(0.07)	0.20(0.09)
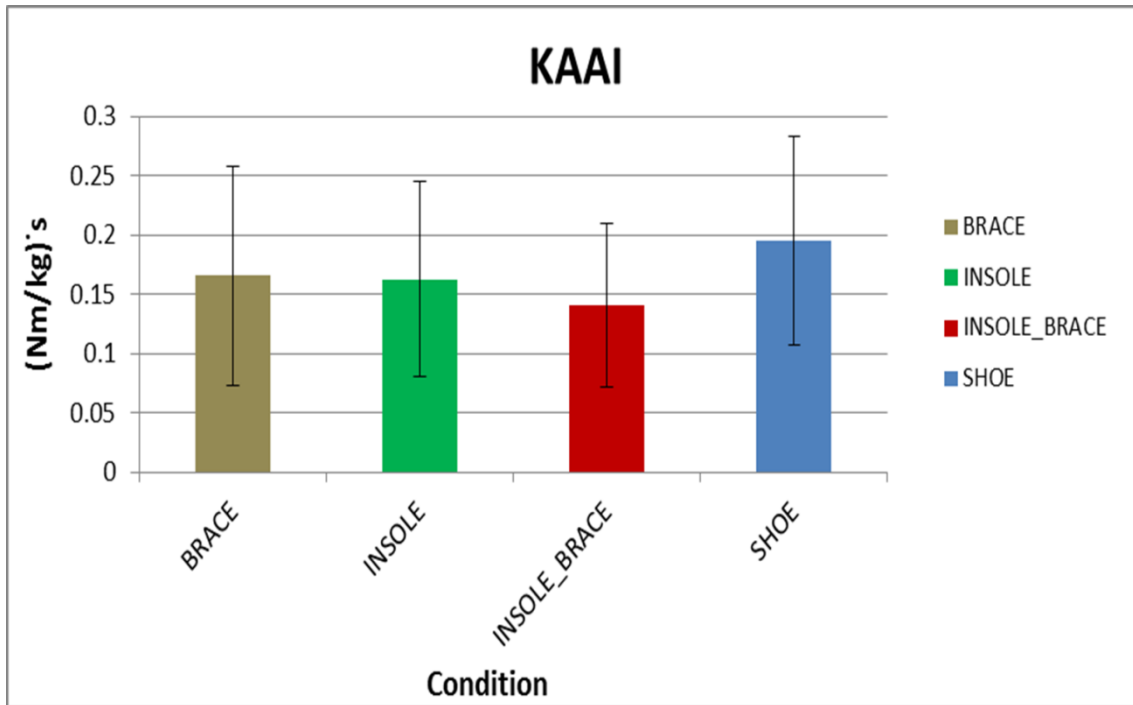
Figure 5-4: Knee adduction angular impulse (KAAI) in single limb support during ascending.

5.3.3. Kinetic results during descending stairs

5.3.3.1 EKAM Stance phase

There was no significant change (mean difference 0.07 Nm/kg, p=0.13) in the first peak of EKAM with the valgus knee brace and lateral wedged insole combined in comparison to the shoe only, although average decrease of 14.22% was found. In addition, there was no significant change in the first peak of EKAM between the lateral wedged insole, or valgus knee brace, and the shoe only (mean difference 0.00 Nm/kg, p=0.94, 0.00 Nm/kg, p=0.88), although average decreases of 0.47% and 0.91% were found respectively.

There was no significant change (mean difference 0.07 Nm/kg, p=0.09) in the second peak of EKAM with the valgus knee brace and lateral wedged insole combined in comparison to the shoe only, although an average decrease of 22.27% was found. In addition, there was no significant change in the second peak of EKAM between the lateral wedged insole, or valgus knee brace, and the shoe only (mean difference 0.04 Nm/kg, p=0.48, 0.04 Nm/kg, p=0.25), although average decreases of 11.30% and 11.72%

206

were found respectively. Descriptive data of EKAM results during descending are illustrated in figure 5-5 and table 5-5.

Figure 5-5: The external knee adduction moment (EKAM) in stance phase during descending.

Table 5-5: Mean (SD±) first and second peak of the EKAM in stance phase during descending.

Type	Brace	Insole	Insole-Brace	Shoe
EKAM 1 Mean (SD) (Nm/kg)	0.48(0.15)	0.48(0.17)	0.41(0.14)	0.48(0.20)
EKAM 2 Mean (SD) (Nm/kg)	0.28(0.19)	0.28(0.15)	0.24(0.16)	0.31(0.24)

5.3.3.2 EKAM Single limb support

There was a significant decrease (mean difference 0.08 Nm/kg, p=0.03) in the first peak of EKAM with the valgus knee brace and lateral wedged insole combined in comparison to the shoe only, with an average decrease of 15.87%. However, there was no significant change in the first peak of EKAM between the lateral wedged insole, or valgus knee brace, and the shoe only (mean difference 0.03 Nm/kg, p=0.54, 0.05 Nm/kg, p=0.15), although average decreases of 5.19% and 10.79% were found respectively.

There was no significant change (mean difference 0.07 Nm/kg, p=0.15) in the second peak of EKAM with the valgus knee brace and lateral wedged insole combined in comparison to the shoe only, although average decrease of 18.35% was found. In addition, there was no significant change in the second peak of EKAM between the lateral wedged insole, or valgus knee brace, and the shoe only (mean difference 0.05 Nm/kg, p=0.53, 0.02 Nm/kg, p=0.60), although average decreases of 5.49% and 5.23% were found respectively. Descriptive data of EKAM results during descending are illustrated in figure 5-6 and table 5-6.
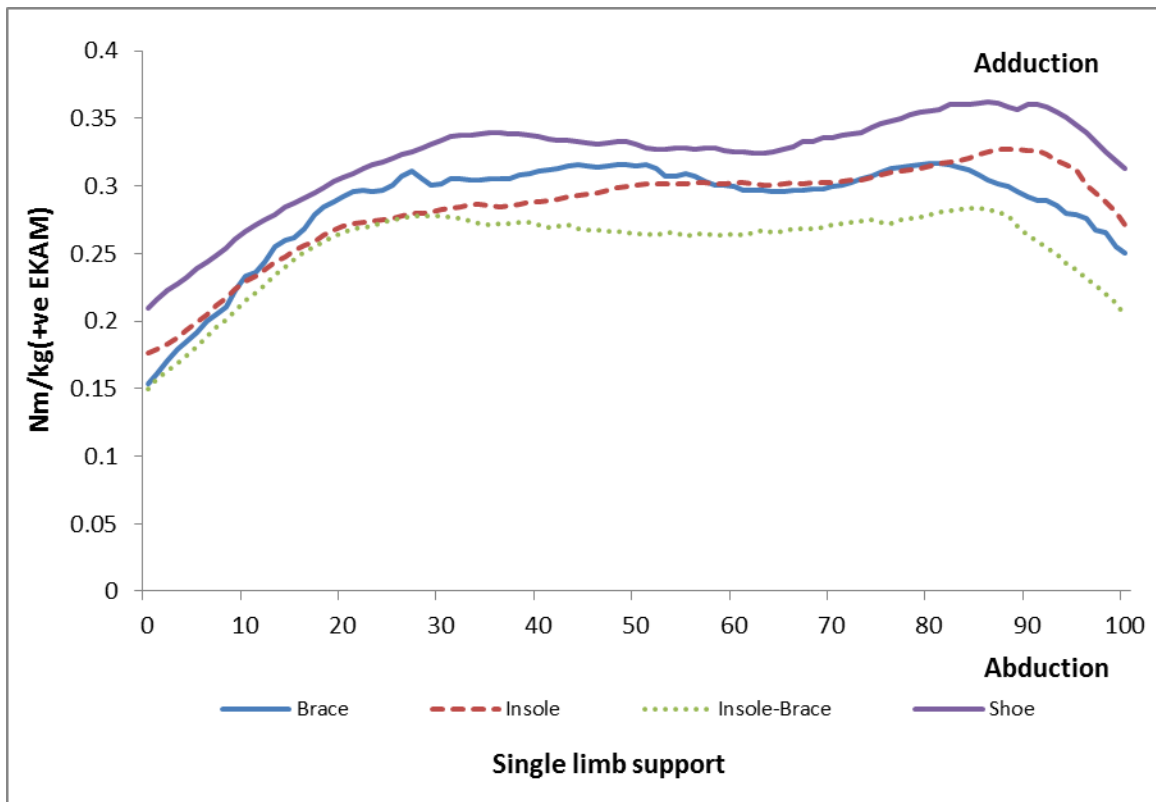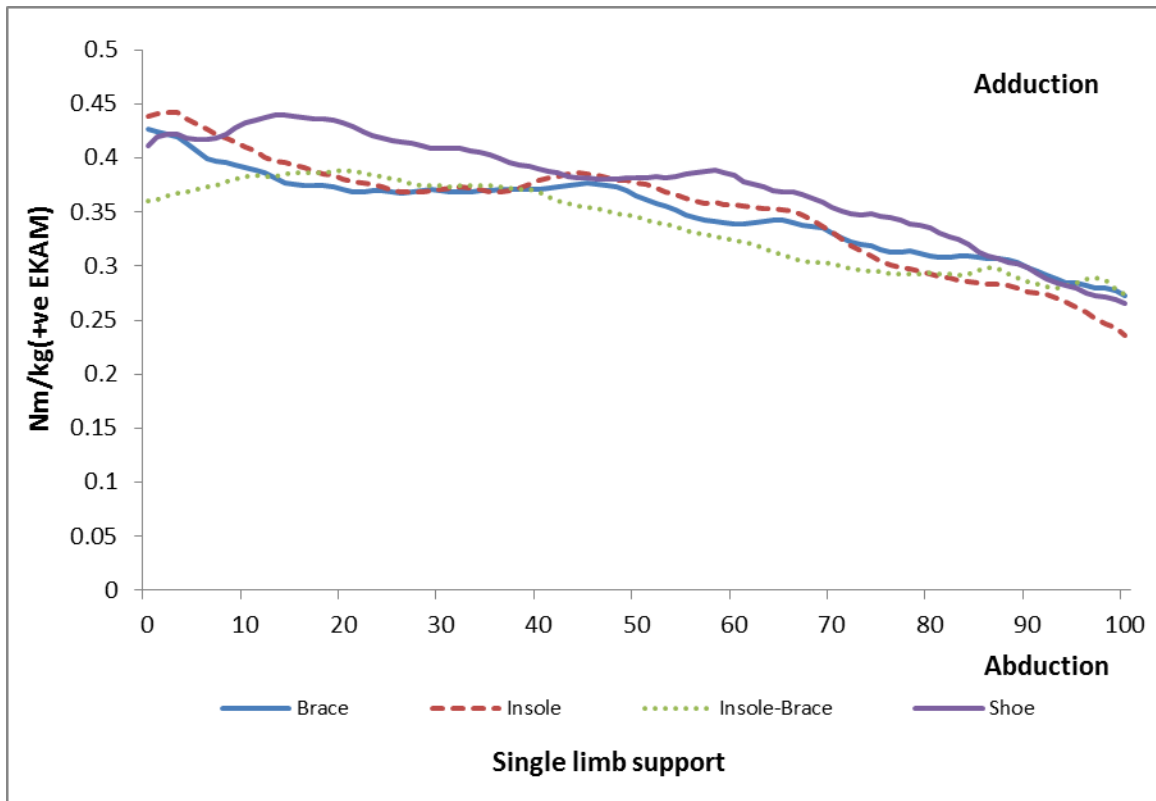

Figure 5-6: The external knee adduction moment (EKAM) in single limb support during descending.

Table 5-6: Mean (SD±) first and second peak of the EKAM in single limb support during descending.

Type	Brace	Insole	Insole-Brace	Shoe
EKAM 1 Mean (SD) (Nm/kg)	0.45(0.16)	0.48(0.17)	0.42(0.16)	0.50(0.21)
EKAM 2 Mean (SD) (Nm/kg)	0.37(0.15)	0.37(0.18)	0.32(0.14)	0.39(0.19)

5.3.3.3 KAAI Stance phase

There was no significant change (mean difference 0.05 Nm/kg, p=0.63) in the KAAI with the valgus knee brace and lateral wedged insole combined in comparison to the shoe only, although average decrease of 15.84% was found. In addition, there was no significant change in the KAAI between the lateral wedged insole, or valgus knee brace, and the shoe only (mean difference 0.05 Nm/kg, p=0.56, 0.03 Nm/kg, p=0.12), although average decreases of 14.72% and 13.35% were found respectively. Descriptive data of KAAI results during descending are illustrated in figure 5-7 and table 5-7

Table 5-7: Mean (SD±) knee adduction angular impulse (KAAI) in stance phase during descending.

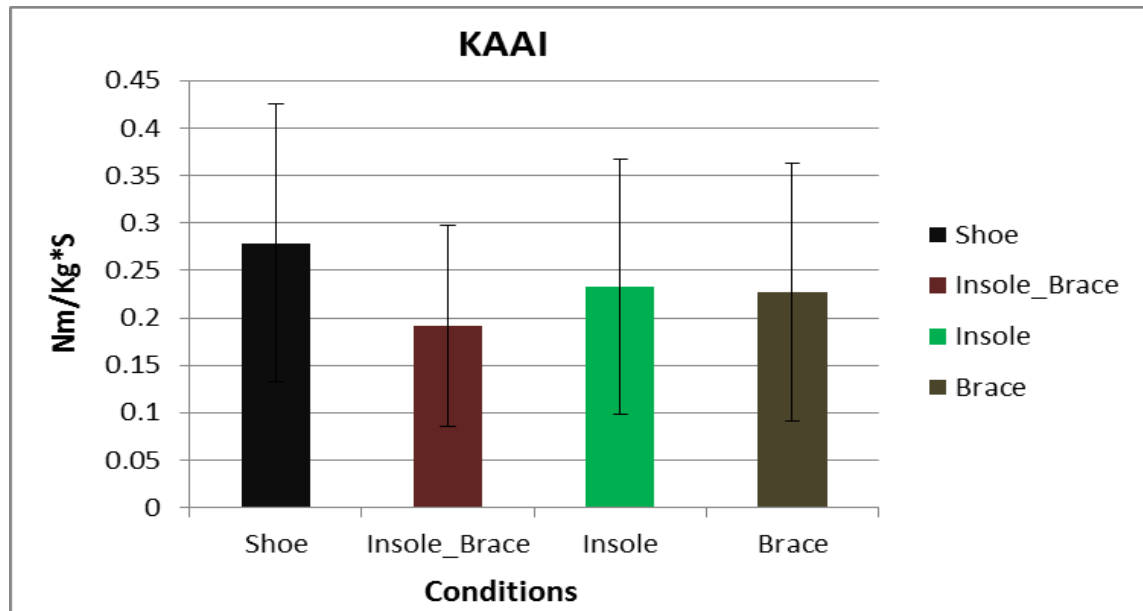| Type	Brace	Insole	Insole-Brace	Shoe
KAAI Mean (SD±)(Nm/kg)*s	0.27(0.10)	0.26(0.11)	0.26(0.11)	0.31(0.15)
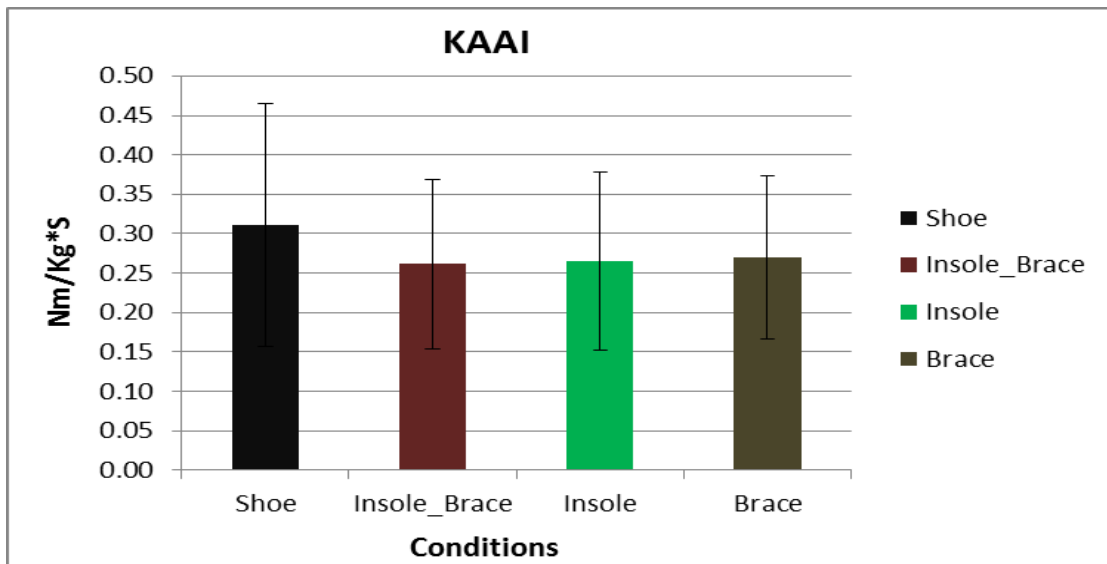
Figure 5-7: Knee adduction angular impulse (KAAI) in stance phase during descending.

5.3.3.4 KAAI Single limb support

There was a significant decrease (mean difference 0.03 Nm/kg, p=0.04) in the KAAI with the valgus knee brace and lateral wedged insole combined in comparison to the shoe only, with an average decrease of 15.76%. However, there was no significant change in the KAAI between the lateral wedged insole, or valgus knee brace, and the shoe only (mean difference 0.03 Nm/kg, p=0.07, 0.03 Nm/kg, p=0.07), although average decreases

of 14.57% and 18.04% were found respectively. Descriptive data of KAAI results during descending are illustrated in figure 5-8 and table 5-8.

Table 5-8: Mean (SD±) knee adduction angular impulse (KAAI) in single limb support during descending.

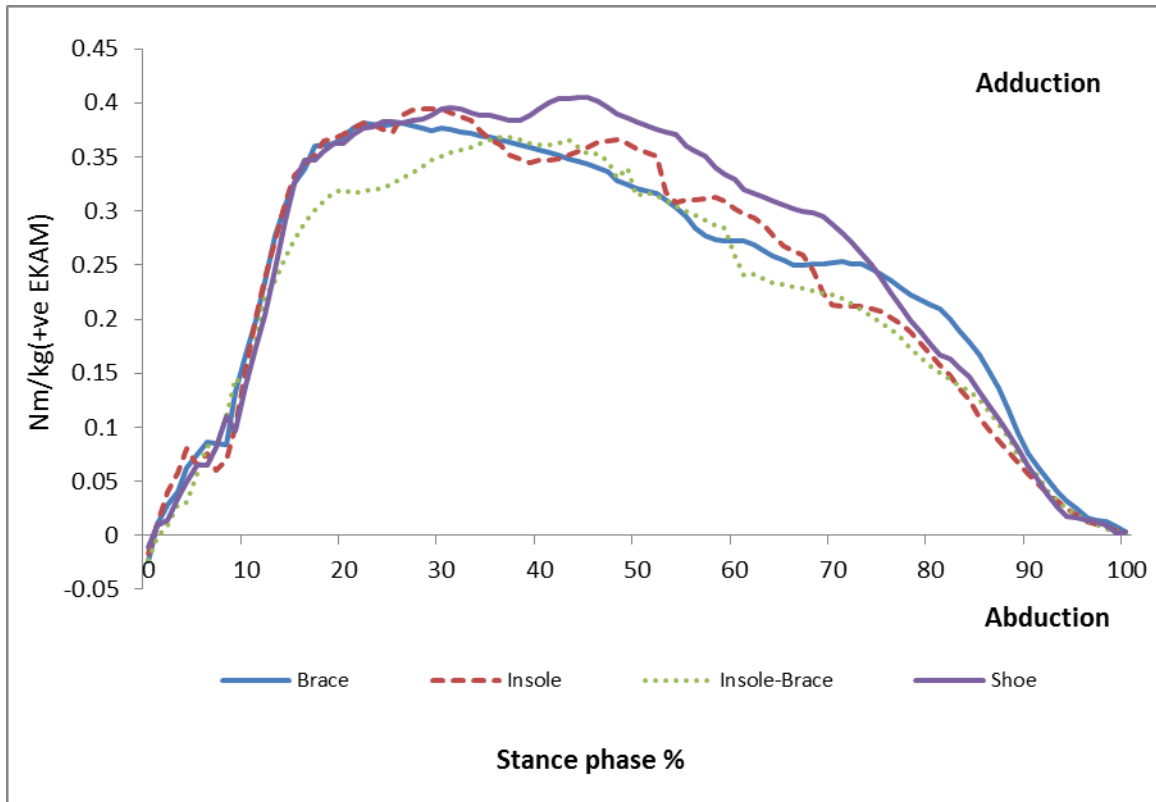| Type	Brace	Insole	Insole-Brace	Shoe
KAAI Mean (SD±)(Nm/kg)*s	0.18(0.07)	0.18(0.07)	0.18(0.08)	0.21(0.10)
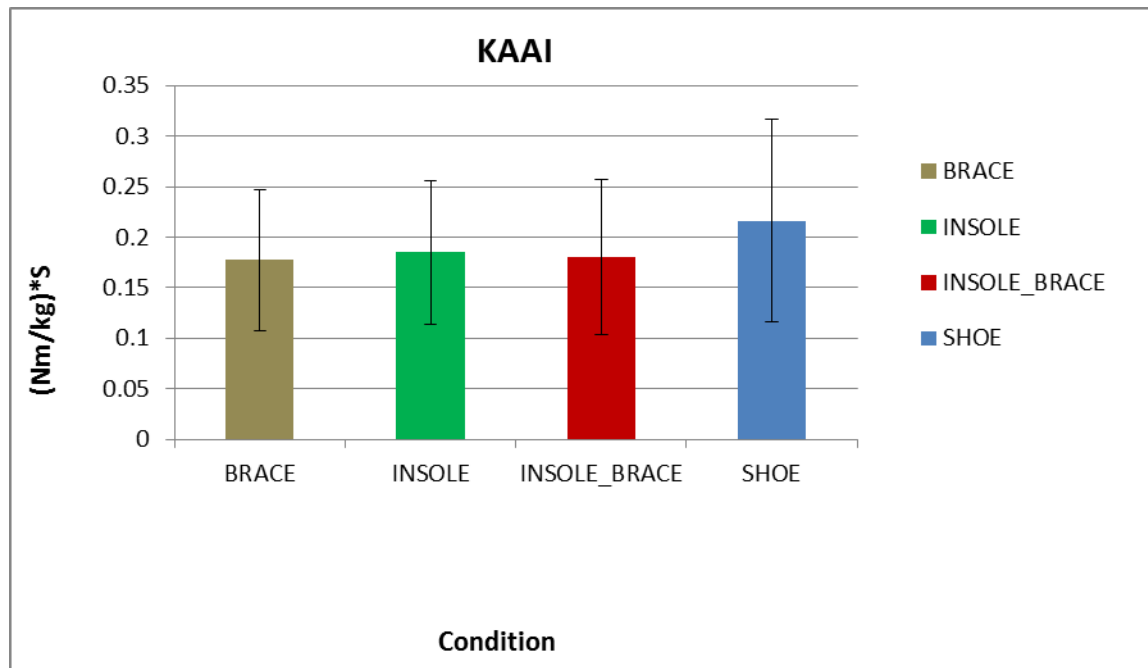
Figure 5-8: Knee adduction angular impulse (KAAI) in single limb support during descending.

5.4 Discussion

This is the first study to examine the effect of an off-the-shelf valgus knee brace and an off-the-shelf lateral wedge insole on ascending and descending stairs. The results demonstrated that that using a combination of an off-the-shelf valgus knee brace and off-the-shelf lateral wedge insole significantly reduces knee loading during stair ascent during early- and late- stance phase and single support, in comparison to a control shoe. However, it was only during late-single support where the combination was significantly different to the orthotic treatments alone. Additionally, a combination of an off-the-shelf valgus knee brace and off-the-shelf lateral wedge insole significantly reduces knee loading during stair descent during early single support, in comparison to a control shoe. There

was a significant decrease in the KAAI with the valgus knee brace and lateral wedged insole combined in comparison to the shoe only during ascending in stance phase and single support. Additionally, there was a significant decrease in the KAAI with the valgus knee brace and lateral wedged insole combined in comparison to the shoe only during descending in single support. Only one study has been undertaken previously on combined orthotic management (Moyer et al., 2012) who found that a combination of using a custom-fit valgus knee brace and custom-made lateral wedge foot orthotic concurrently produced a greater overall reduction in the knee adduction moment, through combined effects in decreasing the frontal plane lever arm during walking (Moyer et al., 2012).

The results of this study support the combination of the two therapies in that they may produce higher reductions in knee loading in patients with knee OA, not just during walking (Moyer et al., 2013) but also during stair ascent and descent. The present study shows that the EKAM and KAAI reduces during ascending and descending stairs and this concurs with Alshawabka et al. (2014) where the EKAM was reduced with lateral wedge insole during ascending stairs. Additionally, a study was performed by Kutzner et al. (2011) using instrumented, telemeterized knee implants, reported that the tibial implant medial forces were significantly reduced by 26% and 24% only observed with the MOS (MOS Genu, long version, Bauerfeind AG, Germany) during stair ascending/descending.

The results of this study showed improvement in the KAAI for the insole and the valgus knee brace in comparison to the control shoe in stance phase and single support during ascending and in single support during descending. These results concurrent with a (Alshawabka et al., 2014) reported the KAAI was significantly reduced with lateral wedge insoles as single treatment.

However, the results do not agree with previous literature on lateral wedge insoles (Alshawabka et al., 2014) who showed that lateral wedge insoles reduce EKAM and KAAI during stair ascent and descent. The valgus knee brace alone also showed no significant change when ascending or descending stairs and this is in line with the results

found in the previous chapter. There were however decreases in both EKAM and KAAI which potentially may unload the medial compartment of the knee.

The use of single support examination in this study showed a significant improvement in EKAM and KAAI which mean more activity was measured and showed the benefit of the combined of treatment on knee loading. This does infer that future studies should also examine unilateral single-support loading to determine the changes.

The results of this study have demonstrated that off-the-shelf orthotic devices in combination support previous literature on custom designed braces and insoles during walking. Given that adherence to valgus knee braces is a challenge, one potential outcome of this study would be for an individual to constantly wear a lateral wedged insole and use the valgus knee brace at times of heavy activities during the day. Future research investigating beneficial clinical effects are needed over both the short and long term.

CHAPTER SIX

OVERALL CONCLUSIONS AND FUTURE STUDIES

6.1 Summary

The aim of this thesis was to find out the effectiveness of a valgus knee brace on biomechanical and clinical outcomes during walking and stair climbing in individuals with knee osteoarthritis. In this thesis we assessed the both the loading on the knee joint and muscle co-contraction after wearing an assistive device (a valgus knee brace) which is a common treatment in this disease, and also changes in muscle strength, balance and pain.

In chapter two, the first focus of this thesis is a review of the existing literature linked to knee OA, the external knee adduction moment, and valgus knee brace to identify the gaps from previous studies. The knee is the most affected joint by arthritis. Knee osteoarthritis (OA) is more common in older individuals and occurs more in the medial than the lateral compartment. The external knee adduction moment is a measurement used in gait analysis to measure the loading in knee joint. There is a direct relationship between knee loading and progression of knee osteoarthritis. Whilst previous literature has demonstrated changes in loading with valgus knee braces during over ground walking, no studies (to date) assessed the effect of valgus knee braces on knee loading and muscle co-contraction during ascending and descending stairs immediately, and after a period of time. In addition, it is an un-documented opinion that knee bracing affects muscle strength and control around the knee and weakens the joint so this research also aimed to confirm or refute this theory. Therefore, the thesis aimed to answer whether knee loading, pain, muscle strength and muscle co-contraction was altered after wearing a brace for three months.

In chapter three, no study had been previously performed on repeated examinations on the measuring the load transferred through the knee joint when walking and ascending, and descending stairs in subjects with osteoarthritis of the knee joint and with a valgus knee brace, to ensure that brace can be applied in the same way at two test sessions so

that an understanding of the reliability of the application of the brace can be understood. This information will help to determine the reliability of such measures for short term study that is planned. This study was an important addition to the current research and will enable the researchers to ensure no measurement error will be happen in the results. The reliability study including the gait analysis methods was done before the main study. This is the first study to demonstrate the repeatability of walking and ascending and descending stairs on EKAM and with the application of a valgus knee brace. These were explored in the next chapter.

In chapter four, valgus knee braces are one conservative treatment that has been used in daily cares which aim to target the EKAM. Research studies have found improvements in pain, physical function, and changes in the kinematic and kinetic of the affected leg and contralateral leg. The majority of these studies are of increasingly short duration, look at outcome measures with the brace in situ, investigate the immediate effects rather than after a period of time. The aim of this chapter to enable a complete picture of valgus knee braces, a study would need to combine clinical and biomechanical outcome measures, to be able to quantify the mechanistic action of valgus knee bracing. The clinical and biomechanical data were collected in this chapter to find out the effect of valgus knee brace on knee loading, pain, muscle strength/function and muscle co-contraction in patient with knee OA over a period of three months. The results showed small non-significant effect on the reduction of knee loading and a significant improvement in pain, muscle strength/function, dynamic balance and decreasing of muscle co-contraction. No change on loading was found during ascending and descending stairs.

In chapter five, a pilot study was performed to find out a combined orthotic management of a valgus knee brace and lateral wedged insole was better at reducing EKAM than the single treatments alone in patient with knee OA during ascending and descending stairs. The results of this pilot study support the combination of the two therapies in that they may produce higher reductions in knee loading in patients with knee OA during stair ascent and descent.

6.2 Thesis novelty

This is the first study to explore the effect of valgus knee brace on knee adduction moment during ascending and descending and has not been previously explored. This involved investigating the effect of valgus knee brace on EKAM, KAAI, and kinematic data on the affected side and contralateral limb over a period of three months with the brace on and with the brace off during walking, and ascending and descending stairs.

Performed repeated examinations of gait on valgus knee brace during ascending and descending stairs in patient with knee OA and this information helped to determine the reliability of such measures for short term study that is planned. This first study examines the effect of valgus knee brace on knee loading during ascending and descending stairs

This is the first study which has investigated the short term effect of a valgus knee brace on muscle co-contraction of knee joint between agonist and antagonist muscles by using EMG data and its relationship with knee joint loading during ascending and descending stairs in patient with knee OA.

No studies have investigated dynamic balance and whether after wearing a valgus knee for a period of three months. The modified SEBT was used which has not been used in the assessment of dynamic balance after a mechanical intervention. This allowed indications of dynamic function to be attained which has not been previously explored.

Determining whether a combined orthotic management of a valgus knee brace and lateral wedged insole is better at reducing EKAM than the single treatments alone during in stance phase and single limb support during ascending and descending stairs. This is the first study explored the effect of a combination treatment on knee loading during ascending and descending stairs.

Overall, this is the first study investigate the effect of valgus knee brace on EKAM, kinematics, kinetics, pain, function, dynamic balance, muscle strength, and muscle co-contraction in the affected leg and the contralateral leg in one study. This thesis will therefore add much to the knowledge of both experimenters and clinicians within the knee osteoarthritis field.

6.3 Future studies

In this thesis, the unload study in chapter four was the main study and at the end of that chapter the results showed the small effect of valgus knee brace on knee loading in patient with knee OA during ascending and descending stairs, Therefore, a pilot study was done in chapter five to find out a combined orthotic management of a valgus knee brace and lateral wedged insole was better at reducing EKAM than the single treatments alone in patient with knee OA during ascending and descending stairs.

According to the positive biomechanical effect of the combined orthotic management of a valgus knee brace and lateral wedged insole on knee loading in patient with knee OA during ascending and descending stairs, future research investigating the biomechanical and clinical effects of the combined treatment over a period of time are needed. In addition, investigation the effect of combined orthotic management of a valgus knee brace and exercises on muscle co-contraction in patient with medial knee osteoarthritis. Additionally, does the addition of a valgus knee brace with home based exercises have increased effectiveness on knee loading in compared to home based exercise alone in individuals with knee osteoarthritis?. Longer term follow-ups of combined studies measuring joint loading and structural changes such as bone marrow lesion are needed to confirm efficacy. If the valgus knee brace does indeed reduce medial compartmental loading, a change in bone marrow lesions would be seen. Furthermore, this would also allow the scientific community to understand the effects of mechanical stabilization devices on structural changes at the knee joint and could be further supplemented by modelling based studies to understand compartmental loads.

References

1- Ahlback S. (1968). Osteoarthrosis of the knee. A radiographic investigation. *Acta Radiol Digan (Stockh)*, Suppl-72.

2- Al-Arfaj, A. S. (2002). Radiographic osteoarthritis and obesity. *Saudi medical journal*, *23*(8), 938-942.

3- Al-Arfaj, A. S., Alballa, S. R., Al-Saleh, S. S., Al-Dalaan, A. M., Bahabry, S. A., Mousa, M. A., & Al-Sekeit, M. A. (2003). Knee osteoarthritis in Al-Qaseem, Saudi Arabia. *Saudi medical journal*, *24*(3), 291-293.

4- Al-Arfaj, A. S., & Al-Boukai, A. A. (2002). Prevalence of radiographic knee osteoarthritis in Saudi Arabia. Clinical rheumatology, 21(2), 142-145.

5- Al-Khlaifat, L. S. (2012). Towards Improved Efficacy of Exercise Programmes in Knee Osteoarthritis. *Ph.D. thesis. University of Salford*.

6- Al-Zahrani, K. S., & Bakheit, A. M. O. (2002). A study of the gait characteristics of patients with chronic osteoarthritis of the knee. *Disability & Rehabilitation*, *24*(5), 275-280.

7- Alshawabka, A. Z., Liu, A., Tyson, S. F., & Jones, R. K. (2014). The use of a lateral wedge insole to reduce knee loading when ascending and descending stairs in medial knee osteoarthritis patients. *Clinical Biomechanics*.

8- Anderson, J. J., & Felson, D. T. (1988). Factors associated with osteoarthritis of the knee in the first national Health and Nutrition Examination Survey (HANES I) evidence for an association with overweight, race, and physical demands of work. *American journal of epidemiology*, *128*(1), 179-189.

9- Andrews, M., Noyes, F. R., Hewett, T. E., & Andriacchi, T. P. (1996). Lower limb alignment and foot angle are related to stance phase knee adduction in normal subjects: a critical analysis of the reliability of gait analysis data. *Journal of Orthopaedic Research*, *14*(2), 289-295.

10- Andriacchi, T. P. (1994). Dynamics of knee malalignment. *The Orthopedic clinics of North America*, *25*(3), 395-403.

11- Andriacchi, T. P., Andersson, G. B., Fermier, R. W., Stern, D., & Galante, J. O. (1980). A study of lower-limb mechanics during stair-climbing. *J Bone Joint Surg Am*, *62*(5), 749-57.

12- Andriacchi, T. P., Andersson, G. B. J., Örtengren, R., & Mikosz, R. P. (1983). A study of factors influencing muscle activity about the knee joint. *Journal of orthopaedic research*, *1*(3), 266-275.

13- Andriacchi, T. P., & Mündermann, A. (2006). The role of ambulatory mechanics in the initiation and progression of knee osteoarthritis. *Current opinion in rheumatology*, *18*(5), 514-518.

14- Andriacchi, T. P., Mündermann, A., Smith, R. L., Alexander, E. J., Dyrby, C. O., & Koo, S. (2004). A framework for the in vivo pathomechanics of osteoarthritis at the knee. *Annals of biomedical engineering*, *32*(3), 447-457.

15- Andriacchi, T. P., Ogle, J. A., & Galante, J. O. (1977). Walking speed as a basis for normal and abnormal gait measurements. *Journal of biomechanics*, *10*(4), 261-268.

16- Aoki, O., Tsumura, N., Kimura, A., Okuyama, S., Takikawa, S., & Hirata, S. (2009). Home stretching exercise is effective for improving knee range of motion and gait in patients with knee osteoarthritis. *Journal of Physical Therapy Science*, *21*(2), 113-119.

17- Arthritis Care (2012). OA nation. The most comprehensive UK report of people with osteoarthritis. Retrieved 24 May, 2012, from http://www.arthritiscare.org.uk/NewsRoom/Statementsandpressreleases/oanation2012

18- Arthritis Care (2004) OA Nation. www.arthritiscare.org.uk

19- Asay, J. L., Mündermann, A., & Andriacchi, T. P. (2009). Adaptive patterns of movement during stair climbing in patients with knee osteoarthritis. *Journal of Orthopaedic Research*, *27*(3), 325-329.

20- Astephen, J. L., Deluzio, K. J., Caldwell, G. E., & Dunbar, M. J. (2008). Biomechanical changes at the hip, knee, and ankle joints during gait are associated with knee osteoarthritis severity. *Journal of Orthopaedic Research*, *26*(3), 332-341.

21- Astephen, J. L., Deluzio, K. J., Caldwell, G. E., Dunbar, M. J., & Hubley-Kozey, C. L. (2008). Gait and neuromuscular pattern changes are associated with differences in knee osteoarthritis severity levels. *Journal of Biomechanics*, *41*(4), 868-876.

22- Baker, R. (2006). Gait analysis methods in rehabilitation. *Journal of Neuro Engineering and Rehabilitation, 3*(1), 4-14.

23- Baker, K. R., Nelson, M. E., Felson, D. T., Layne, J. E., Sarno, R. O. B. E. R. T., & Roubenoff, R. O. N. E. N. N. (2001). The efficacy of home based progressive strength training in older adults with knee osteoarthritis: a randomized controlled trial. *The Journal of rheumatology*, *28*(7), 1655-1665.

24- Baliunas, A. J., Hurwitz, D. E., Ryals, A. B., Karrar, A., Case, J. P., Block, J. A., & Andriacchi, T. P. (2002). Increased knee joint loads during walking are present in subjects with knee osteoarthritis. *Osteoarthritis and cartilage*, *10*(7), 573-579.

25- Baliunas, A, Ryals A.R., Hurwitz, D.E., Kerrar, A., Andriacchi, T.P. (2000). Gait adaptations associated with early radiographic tibiofemoral knee osteoarthritis. *In: 46th Annual Meeting Orthopaedic Research Society; 260.*

26- Barrios, J.A., Davis, I.S. (2007). A gait modification to reduce the external knee adduction moment at the knee: a case study. *Proceedings of the 31st Annual Meeting of the American Society of Biomechanics.; Stanford, CA. paper #219*

27- Barrios, J. A., Higginson, J. S., Royer, T. D. and Davis, I. S. V. Static and dynamic correlates of the knee adduction moment in healthy knees ranging from normal to varus-aligned. *Clin. Biomech. (Bristol, Avon) 24*, 850-854.

28- Bennell, K. L., Bowles, K. A., Wang, Y., Cicuttini, F., Davies-Tuck, M., & Hinman, R. S. (2011). Higher dynamic medial knee load predicts greater cartilage loss over 12

months in medial knee osteoarthritis. *Annals of the rheumatic diseases*, *70*(10), 1770-1774.

29- Bennell, K. L., & Hinman, R. S. (2011). A review of the clinical evidence for exercise in osteoarthritis of the hip and knee. *Journal of Science and Medicine in Sport*, *14*(1), 4-9.

30- Besier, T. F., Lloyd, D. G., & Ackland, T. R. (2003a). Muscle activation strategies at the knee during running and cutting maneuvers. *Medicine and science in sports and exercise*, *35*(1), 119-127.

31- Besier, T. F., Sturnieks, D. L., Alderson, J. A., & Lloyd, D. G. (2003b). Repeatability of gait data using a functional hip joint centre and a mean helical knee axis. *Journal of biomechanics*, *36*(8), 1159-1168.

32- Bettica, P., Cline, G., Hart, D. J., Meyer, J., & Spector, T. D. (2002). Evidence for increased bone resorption in patients with progressive knee osteoarthritis: longitudinal results from the Chingford study. *Arthritis & Rheumatism*, *46*(12), 3178-3184.

33- Bijlsma, J. W. J., & Knahr, K. (2007). Strategies for the prevention and management of osteoarthritis of the hip and knee. *Best Practice & Research Clinical Rheumatology*, *21*(1), 59-76.

34- Birmingham, T. B., Hunt, M. A., Jones, I. C., Jenkyn, T. R., & Giffin, J. R. (2007). Test–retest reliability of the peak knee adduction moment during walking in patients with medial compartment knee osteoarthritis. *Arthritis Care & Research*, *57*(6), 1012-1017.

35- Birmingham, T. B., Kramer, J. F., Kirkley, A., Inglis, J. T., Spaulding, S. J., & Vandervoort, A. A. (2001). Knee bracing for medial compartment osteoarthritis: effects on proprioception and postural control. *Rheumatology*, *40*(3), 285-289.

36- Brandt, K., Dieppe, P. and Radin, E. (2008). Etiopathogenesis of osteoarthritis. *Rheumatic Disease Clinics of North America, 34*(3), 531-559.

37- Briem, K., & Snyder-Mackler, L. (2009). Proximal gait adaptations in medial knee OA. *Journal of Orthopaedic Research*, *27*(1), 78-83.

38- Briem, K., Ramsey, D. K., Newcomb, W., Rudolph, K. S., & Snyder-Mackler, L. (2007). Effects of the amount of valgus correction for medial compartment knee osteoarthritis on clinical outcome, knee kinetics and muscle co-contraction after opening wedge high tibial osteotomy. *Journal of orthopaedic research*, *25*(3), 311-318.

39- Brinkmann, J. R., & Perry, J. (1985). Rate and range of knee motion during ambulation in healthy and arthritic subjects. *Physical therapy*, *65*(7), 1055-1060.

40- Brouwer, R. W., Van Raaij, T. M., Verhaar, J. A. N., Coene, L. N. J. E. M., & Bierma-Zeinstra, S. M. A. (2006). Brace treatment for osteoarthritis of the knee: a prospective randomized multi-centre trial. *Osteoarthritis and cartilage*, *14*(8), 777-783.

41- Brucini, M., Duranti, R., Galletti, R., Pantaleo, T., & Zucchi, P. L. (1981). Pain thresholds and electromyographic features of periarticular muscles in patients with osteoarthritis of the knee. *Pain*, *10*(1), 57-66.

42- Buchanan, T. S., Kim, A. W., & Lloyd, D. G. (1996). Selective muscle activation following rapid varus/valgus perturbations at the knee. *Medicine and science in sports and exercise*, *28*(7), 870-876.

43- Buckwalter, J. A., Saltzman, C., & Brown, T. (2004). The impact of osteoarthritis: implications for research. *Clinical orthopaedics and related research*, *427*, S6-S15.

44- Carvalho, N. A. D. A., Bittar, S. T., Pinto, F. R. D. S., Ferreira, M., & Sitta, R. R. (2010). Manual for guided home exercises for osteoarthritis of the knee. *Clinics*, *65*(8), 775-780.

45- Cappozzo, A., Catani, F., Leardini, A., Benedetti, M. G., & Della Croce, U. (1996). Position and orientation in space of bones during movement: experimental artefacts. *Clinical biomechanics*, *11*(2), 90-100.

46- Cappozzo, A., Della Croce, U., Leardini, A., & Chiari, L. (2005). Human movement analysis using stereophotogrammetry: Part 1: theoretical background. *Gait & posture*, *21*(2), 186-196.

47- Cereatti, A., Camomilla, V., Vannozzi, G., & Cappozzo, A. (2007). Propagation of the hip joint centre location error to the estimate of femur vs pelvis orientation using a constrained or an unconstrained approach. *Journal of biomechanics*, *40*(6), 1228-1234.

48- Chaipinyo, K., & Karoonsupcharoen, O. (2009). No difference between home-based strength training and home-based balance training on pain in patients with knee osteoarthritis: a randomised trial. *Australian Journal of Physiotherapy*, *55*(1), 25-30.

49- Chang, A., Hayes, K., Dunlop, D., Song, J., Hurwitz, D., Cahue, S., & Sharma, L. (2005). Hip abduction moment and protection against medial tibiofemoral osteoarthritis progression. *Arthritis & Rheumatism*, *52*(11), 3515-3519.

50- Childs, J. D., Sparto, P. J., Fitzgerald, G. K., Bizzini, M., & Irrgang, J. J. (2004). Alterations in lower extremity movement and muscle activation patterns in individuals with knee osteoarthritis. *Clinical biomechanics*, *19*(1), 44-49.

51- Christina, K. A., & Cavanagh, P. R. (2002). Ground reaction forces and frictional demands during stair descent: effects of age and illumination. *Gait & posture*, *15*(2), 153-158.

52- Chuang, S. H., Huang, M. H., Chen, T. W., Weng, M. C., Liu, C. W., & Chen, C. H. (2007). Effect of knee sleeve on static and dynamic balance in patients with knee osteoarthritis. *The Kaohsiung journal of medical sciences*, *23*(8), 405-411.

53- Cicuttini, F. M., Baker, J. R., & Spector, T. D. (1996). The association of obesity with osteoarthritis of the hand and knee in women: a twin study. *J Rheumatol*, *23*(7), 1221-1226.

54- Cicuttini, F. M., Wluka, A. E., Wang, Y., Davis, S. R., Hankin, J., & Ebeling, P. (2002). Compartment differences in knee cartilage volume in healthy adults. *The Journal of rheumatology*, *29*(3), 554-556.

55- Coggon, D., Croft, P., Kellingray, S., Barrett, D., McLaren, M., & Cooper, C. (2000). Occupational physical activities and osteoarthritis of the knee. *Arthritis & Rheumatism*, *43*(7), 1443-1449.

56- Collins, T. D., Ghoussayni, S. N., Ewins, D. J., & Kent, J. A. (2009). A six degrees-of-freedom marker set for gait analysis: repeatability and comparison with a modified Helen Hayes set. *Gait & posture*, *30*(2), 173-180.

57- Cook, T. M., Farrell, K. P., Carey, I. A., Gibbs, J. M., & Wiger, G. E. (1997). Effects of restricted knee flexion and walking speed on the vertical ground reaction force during gait. *Journal of Orthopaedic & Sports Physical Therapy*, *25*(4), 236-244.

58- Cooke, T., Li, J. & Scudamore, R. A. (1994). Radiographic assessment of bony contributions to knee deformity. *The Orthopedic clinics of North America, 25*, 387.

59- Cooper, C., McAlindon, T., Coggon, D., Egger, P., & Dieppe, P. (1994). Occupational activity and osteoarthritis of the knee. *Annals of the Rheumatic Diseases*, *53*(2), 90-93.

60- Cooper, C., Snow, S., McAlindon, T. E., Kellingray, S., Stuart, B., Coggon, D., & Dieppe, P. A. (2000). Risk factors for the incidence and progression of radiographic knee osteoarthritis. *Arthritis & Rheumatism*, *43*(5), 995-1000.

61- Costigan, P. A., Deluzio, K. J., & Wyss, U. P. (2002). Knee and hip kinetics during normal stair climbing. *Gait & posture*, *16*(1), 31-37.

62- Creaby, M. W., Wang, Y., Bennell, K. L., Hinman, R. S., Metcalf, B. R., Bowles, K. A., & Cicuttini, F. M. (2010). Dynamic knee loading is related to cartilage defects and tibial plateau bone area in medial knee osteoarthritis. *Osteoarthritis and Cartilage*, *18*(11), 1380-1385.

63- Crenshaw, S. J., Pollo, F. E., & Calton, E. F. (2000). Effects of lateral-wedged insoles on kinetics at the knee. *Clinical Orthopaedics and Related Research*, *375*, 185-192.

64- Culliford, D. J., Maskell, J., Beard, D. J., Murray, D. W., Price, A. J., & Arden, N. K. (2010). Temporal trends in hip and knee replacement in the United Kingdom 1991 TO 2006. *Journal of Bone & Joint Surgery, British Volume*, *92*(1), 130-135.

65- Davidson, P. L., Sanderson, D. J., & Loomer, R. L. (1998). Kinematics of valgus bracing for medial gonarthrosis: technical report. *Clinical Biomechanics*, *13*(6), 414-419.

66- Deie, M., Shibuya, H., Toriyama, M., Kumahashi, N., Uchio, Y., Sasashige, Y., & Ochi, M. (2013). The Effects of an Unloading Knee Brace and Insole with Subtalar Strapping for Medial Osteoarthritis of the Knee. *International Journal of Clinical Medicine*, *4*(12), 6.

67- Della Croce, U., & Bonato, P. (2007). A novel design for an instrumented stairway. *Journal of biomechanics*, *40*(3), 702-704.

68- Della Croce, U., Cappozzo, A., Kerrigan, C. and Lucchetti, L. (1997). Bone position and orientation errors: pelvis and lower limb anatomical landmark identification reliability. *Gait and Posture, 5*(2), pp. 156-157.

69- Della Croce, U., Leardini, A., Chiari, L., & Cappozzo, A. (2005). Human movement analysis using stereophotogrammetry: Part 4: assessment of anatomical landmark misplacement and its effects on joint kinematics. *Gait & posture*, *21*(2), 226-237.

70- Deluzio, K. and Astephen, J. (2005). Changes in frontal plane dynamics and the loading response phase of the gait cycle are characteristic of severe knee osteoarthritis application of a multidimensional analysis technique. *Clinical Biomechanics, 20*, 209-217.

71- Dennis, D. A., Komistek, R. D., Nadaud, M. C., & Mahfouz, M. (2006). Evaluation of off-loading braces for treatment of unicompartmental knee arthrosis. *The Journal of arthroplasty*, *21*(4), 2-8.

72- Deyle, G. D., Allison, S. C., Matekel, R. L., Ryder, M. G., Stang, J. M., Gohdes, D. D., & Garber, M. B. (2005). Physical therapy treatment effectiveness for osteoarthritis of the knee: a randomized comparison of supervised clinical exercise and manual therapy procedures versus a home exercise program. *Physical therapy*, *85*(12), 1301-1317.

73- Deyle, G. D., Henderson, N. E., Matekel, R. L., Ryder, M. G., Garber, M. B., & Allison, S. C. (2000). Effectiveness of manual physical therapy and exercise in osteoarthritis of the knee: a randomized, controlled trial. *Annals of internal medicine*, *132*(3), 173-181.

74- Dieppe, P. A., & Lohmander, L. S. (2005). Pathogenesis and management of pain in osteoarthritis. *The Lancet*, *365*(9463), 965-973.

75- Dillon, C. F., Rasch, E. K., Gu, Q., & Hirsch, R. (2006). Prevalence of knee osteoarthritis in the United States: arthritis data from the Third National Health and Nutrition Examination Survey 1991-94. *The Journal of rheumatology*, *33*(11), 2271-2279.

76- Draganich, L., Reider, B., Rimington, T., Piotrowski, G., Mallik, K., & Nasson, S. (2006). The effectiveness of self-adjustable custom and off-the-shelf bracing in the treatment of varus gonarthrosis. *The Journal of Bone & Joint Surgery*, *88*(12), 2645-2652.

77- Draper, E. R. C., Cable, J. M., Sanchez-Ballester, J., Hunt, N., Robinson, J. R., & Strachan, R. K. (2000). Improvement in function after valgus bracing of the knee AN ANALYSIS OF GAIT SYMMETRY. *Journal of Bone & Joint Surgery, British Volume*, *82*(7), 1001-1005.

78- El-Azab, H. M., Morgenstern, M., Ahrens, P., Schuster, T., Imhoff, A. B., & Lorenz, S. G. (2011). Limb alignment after open-wedge high tibial osteotomy and its effect on the clinical outcome. *Orthopedics*, *34*(10), 767.

79- Ettinger Jr, W., Burns, R., Messier, S., Applegate, W., Rejeski, W., Morgan, T., Shumaker, S., Berry, M., O'Toole, M., Monu, J. and Craven, T. (1997). A randomized trial comparing aerobic exercise and resistance exercise with a health education program in older adults with knee osteoarthritis. The Fitness Arthritis and Seniors Trial (FAST). *The Journal of the Americam Medical Association, 277*(1), pp. 25-31.

80- Fantini Pagani, C. H., Potthast, W., & Brüggemann, G. P. (2010). The effect of valgus bracing on the knee adduction moment during gait and running in male subjects with varus alignment. *Clinical Biomechanics*, *25*(1), 70-76.

81- Fantini Pagani, C. H., Willwacher, S., Kleis, B., & Brüggemann, G. P. (2013). Influence of a valgus knee brace on muscle activation and co-contraction in patients with medial knee osteoarthritis. *Journal of Electromyography and Kinesiology*, *23*(2), 490-500.

82- Felson, D. T., Lawrence, R. C., Dieppe, P. A., Hirsch, R., Helmick, C. G., Jordan, J. M., & Fries, J. F. (2000). Osteoarthritis: new insights. Part 1: the disease and its risk factors. *Annals of internal medicine*, *133*(8), 635-646.

83- Felson, D. T., Naimark, A., Anderson, J., Kazis, L., Castelli, W., & Meenan, R. F. (1987). The prevalence of knee osteoarthritis in the elderly. The Framingham Osteoarthritis Study. *Arthritis & Rheumatism*, *30*(8), 914-918.

84- Felson, D. T., & Nevitt, M. C. (1998). The effects of estrogen on osteoarthritis. *Current opinion in rheumatology*, *10*(3), 269-272.

85- Felson, D. T., Niu, J., McClennan, C., Sack, B., Aliabadi, P., Hunter, D. J., & Englund, M. (2007). Knee buckling: prevalence, risk factors, and associated limitations in function. *Annals of internal medicine*, *147*(8), 534-540.

86- Felson, D. T., Zhang, Y., Hannan, M. T., Naimark, A., Weissman, B., Aliabadi, P. & Levy, D. 1997. Risk factors for incident radiographic knee osteoarthritis in the elderly. *The framingham study. Arthritis & Rheumatism, 40*, 728-733.

87- Felson, D. T., Zhang, Y., Hannan, M. T., Naimark, A., Weissman, B. N., Aliabadi, P., & Levy, D. (1995). The incidence and natural history of knee osteoarthritis in the elderly, the framingham osteoarthritis study. *Arthritis & Rheumatism*, *38*(10), 1500-1505.

88- Felson, D. T. (2004). Obesity and vocational and avocational overload of the joint as risk factors for osteoarthritis. *Journal of Rheumatology-Supplement-*, 2-5.

89- Felson, D. T., & Zhang, Y. (1998). An update on the epidemiology of knee and hip osteoarthritis with a view to prevention. *Arthritis & Rheumatism*, *41*(8), 1343-1355.

90- Fisher, N. M., & Pendergast, D. R. (1997). Reduced muscle function in patients with osteoarthritis. *Scandinavian journal of rehabilitation medicine*, *29*(4), 213-221.

91- Fisher, N. M., White, S. C., Yack, H. J., Smolinski, R. J., & Pendergast, D. R. (1997). Muscle function and gait in patients with knee osteoarthritis before and after muscle rehabilitation. *Disability & Rehabilitation*, *19*(2), 47-55.

92- Fransen, M., Bridgett, L., March, L., Hoy, D., Penserga, E., & Brooks, P. (2011). The epidemiology of osteoarthritis in Asia. *International journal of rheumatic diseases*, *14*(2), 113-121.

93- Fregly, B. J., D'Lima, D. D., & Colwell, C. W. (2009). Effective gait patterns for offloading the medial compartment of the knee. *Journal of Orthopaedic Research*, *27*(8), 1016-1021.

94- Fregly, B. J., Reinbolt, J. A., Rooney, K. L., Mitchell, K. H., & Chmielewski, T. L. (2007). Design of patient-specific gait modifications for knee osteoarthritis rehabilitation. *Biomedical Engineering, IEEE Transactions on*, *54*(9), 1687-1695.

95- Fregly, B. J. (2008). Computational assessment of combinations of gait modifications for knee osteoarthritis rehabilitation. *Biomedical Engineering, IEEE Transactions on*, *55*(8), 2104-2106.

96- Friel, N. A., & Chu, C. R. (2013). The role of ACL injury in the development of posttraumatic knee osteoarthritis. *Clinics in sports medicine*, *32*(1), 1-12.

97- Gaasbeek, R. D., Groen, B. E., Hampsink, B., Van Heerwaarden, R. J., & Duysens, J. (2007). Valgus bracing in patients with medial compartment osteoarthritis of the knee: A gait analysis study of a new brace. *Gait & posture*, *26*(1), 3-10.

98- Garnero, P., Piperno, M., Gineyts, E., Christgau, S., Delmas, P. D., & Vignon, E. (2001). Cross sectional evaluation of biochemical markers of bone, cartilage, and synovial tissue metabolism in patients with knee osteoarthritis: relations with disease activity and joint damage. *Annals of the rheumatic diseases*, *60*(6), 619-626.

99- Gaudreault, N., Hagemeister, N., Poitras, S., & de Guise, J. A. (2013). Comparison of knee gait kinematics of workers exposed to knee straining posture to those of non-knee straining workers. *Gait & posture*, *38*(2), 187-191.

100- Gaudreault, N., Mezghani, N., Turcot, K., Hagemeister, N., Boivin, K., & de Guise, J. A. (2011). Effects of physiotherapy treatment on knee osteoarthritis gait data using principal component analysis. *Clinical Biomechanics*, *26*(3), 284-291.

101- Gelber, A. C., Hochberg, M. C., Mead, L. A., Wang, N. Y., Wigley, F. M., & Klag, M. J. (2000). Joint injury in young adults and risk for subsequent knee and hip osteoarthritis. *Annals of internal medicine*, *133*(5), 321-328.

102- Griffin, T., Rowden, N., Morgan, D., Atkinson, R., Woodruff, P., & Maddern, G. (2007). Unicompartmental knee arthroplasty for the treatment of unicompartmental osteoarthritis: a systematic study. *ANZ journal of surgery*, *77*(4), 214-221.

103- Giori, N. J. (2004). Load-shifting brace treatment for osteoarthritis of the knee: a minimum 2 1/2-year follow-up study. *Journal of rehabilitation research and development*, *41*(2), 187-194.

104- Glass, G. V., Peckham, P. D. & Sanders, J. R. (1972). Consequences of failure to meet assumptions underlying the fixed effects analyses of variance and covariance. *Review of educational research, 42*, 237-288.

105- Gök, H., Ergin, S., & Yavuzer, G. (2002). Kinetic and kinematic characteristics of gait in patients with medial knee arthrosis. *Acta Orthopaedica*, *73*(6), 647-652.

106- Growney, E., Meglan, D., Johnson, M., Cahalan, T., & An, K. N. (1997). Repeated measures of adult normal walking using a video tracking system. *Gait & Posture, 6*(2), 147-162.

107- Guccione, A. A., Felson, D. T., & Anderson, J. J. (1990). Defining arthritis and measuring functional status in elders: methodological issues in the study of disease and physical disability. *American Journal of Public Health*, *80*(8), 945-949.

108- Guichet, J. M., Javed, A., Russell, J., & Saleh, M. (2003). Effect of the foot on the mechanical alignment of the lower limbs. *Clinical orthopaedics and related research*, *415*, 193-201.

109- Guo, M., Axe, M. J., & Manal, K. (2007). The influence of foot progression angle on the knee adduction moment during walking and stair climbing in pain free individuals with knee osteoarthritis. *Gait & posture*, *26*(3), 436-441.

110- Guskiewicz, K. M., & Perrin, D. H. (1996). Research and clinical applications of assessing balance. *Journal of Sport Rehabilitation*, *5*, 45-63.

111- Haara, M. M., Manninen, P., Kröger, H., Arokoski, J. P. A., Kärkkäinen, A., Knekt, P., & Heliövaara, M. (2003). Osteoarthritis of finger joints in Finns aged 30 or over: prevalence, determinants, and association with mortality. *Annals of the rheumatic diseases*, *62*(2), 151-158.

112- Hamel, K. A., Okita, N., Bus, S. A., & Cavanagh, P. R. (2005). A comparison of foot/ground interaction during stair negotiation and level walking in young and older women. *Ergonomics*, *48*(8), 1047-1056.

113- Haq, S. A., & Davatchi, F. (2011). Osteoarthritis of the knees in the COPCORD world. *International journal of rheumatic diseases*, *14*(2), 122-129.

114- Hart, D. J., Mootoosamy, I., Doyle, D. V., & Spector, T. D. (1994). The relationship between osteoarthritis and osteoporosis in the general population: the Chingford Study. *Annals of the rheumatic diseases*, *53*(3), 158-162.

115- Hart, D. J., & Spector, T. D. (2003). Kellgren & Lawrence grade 1 osteophytes in the knee—doubtful or definite? *Osteoarthritis and cartilage*, *11*(2), 149-150.

116- Harwell, M. R., Rubinstein, E. N., Hayes, W. S. & Olds, C. C. (1992). Summarizing monte carlo results in methodological research: The one-and two-factor fixed effects anova cases. *Journal of Educational and Behavioral Statistics, 17*, 315-339.

117- Hassan, B. S., Doherty, S. A., Mockett, S., & Doherty, M. (2002). Effect of pain reduction on postural sway, proprioception, and quadriceps strength in subjects with knee osteoarthritis. *Annals of the rheumatic diseases*, *61*(5), 422-428.

118- Hassan, B. S., Mockett, S., Doherty, M. (2001). Static postural sway, proprioception, and maximal voluntary quadriceps contraction in patients withknee osteoarthritis and normal control subjects. *Ann Rheum Dis; 60:612–*618.

119- Henriksena, M., Aaboea J., Henning Bliddala, H. (2012). The relationship between pain and dynamic knee joint loading in knee osteoarthritis varies with radiographic disease severity. A cross sectional study. *The Knee, 19*(4): 392–398.

120- Henriksen, M., Graven-Nielsen, T., Aaboe, J., Andriacchi, T. P., & Bliddal, H. (2010). Gait changes in patients with knee osteoarthritis are replicated by experimental knee pain. *Arthritis care & research*, *62*(4), 501-509.

121- Herrington, L., Hatcher, J., Hatcher, A. and McNicholas, M. (2009). A comparison of Star Excursion Balance Test reach distances between ACL deficient patients and asymptomatic controls. The Knee, 16(2), pp. 149-152.

122- Hertel, J., Miller, S. J., & Denegar, C. R. (2000). Intratester and intertester reliability during the Star Excursion Balance Tests. *Journal of Sport Rehabilitation*, *9*(2), 104-116.

123- Hewett, T. E., Noyes, F. R., Barber-Westin, S. D., & Heckmann, T. P. (1998). Decrease in knee joint pain and increase in function in patients with medial compartment arthrosis: a prospective analysis of valgus bracing. *Orthopedics*, *21*(2), 131-140.

124- Hicks-Little, C. A., Peindl, R. D., Hubbard, T. J., Scannell, B. P., Springer, B. D., Odum, S. M., & Cordova, M. L. (2011). Lower extremity joint kinematics during stair climbing in knee osteoarthritis. *Medicine and science in sports and exercise*, *43*(3), 516-524.

125- Hinman, R. S., & Bennell, K. L. (2009). Advances in insoles and shoes for knee osteoarthritis. *Current opinion in rheumatology*, *21*(2), 164-170.

126- Hinman, R. S., Bennell, K. L., Metcalf, B. R., & Crossley, K. M. (2002). Balance impairments in individuals with symptomatic knee osteoarthritis: a comparison with matched controls using clinical tests. *Rheumatology*, *41*(12), 1388-1394.

127- Horak, F. B. (1997). Clinical assessment of balance disorders. *Gait & Posture*, *6*(1), 76-84.

128- Horak, F. B., Shupert, C. L., & Mirka, A. (1989). Components of postural dyscontrol in the elderly: a review. *Neurobiology of aging*, *10*(6), 727-738.

129- Hortobágyi, T., Westerkamp, L., Beam, S., Moody, J., Garry, J., Holbert, D., & DeVita, P. (2005). Altered hamstring-quadriceps muscle balance in patients with knee osteoarthritis. *Clinical Biomechanics*, *20*(1), 97-104.

130- http://www.nhs.uk/Conditions/Arthritis/Pages/Introduction.aspx

131- Huang, S. C., Wei, I. P., Chien, H. L., Wang, T. M., Liu, Y. H., Chen, H. L., & Lin, J. G. (2008). Effects of severity of degeneration on gait patterns in patients with medial knee osteoarthritis. *Medical engineering & physics*, *30*(8), 997-1003.

132- Hubley-Kozey, C. L., Deluzio, K. J., Landry, S. C., McNutt, J. S., & Stanish, W. D. (2006). Neuromuscular alterations during walking in persons with moderate knee osteoarthritis. *Journal of Electromyography and Kinesiology*, *16*(4), 365-378.

133- Hubley-Kozey, C., Deluzio, K., & Dunbar, M. (2008). Muscle co-activation patterns during walking in those with severe knee osteoarthritis. *Clinical Biomechanics*, *23*(1), 71-80.

134- Hubley-Kozey, C. L., Hill, N. A., Rutherford, D. J., Dunbar, M. J., & Stanish, W. D. (2009). Co-activation differences in lower limb muscles between asymptomatic controls and those with varying degrees of knee osteoarthritis during walking. *Clinical Biomechanics*, *24*(5), 407-414.

135- Huch, K., Kuettner, K. E. & Dieppe, P. 1997.Osteoarthritis in ankle and knee joints. *Elsevier,* 667-674.

136- Hughes, C., Kaufman, K., Morrey, B., Morrey, M. & An, K. (2000). Gender differences in knee kinematics and kinetics during stair climbing and level walking in adults with osteoarthritis of the knee. *Journal of Orthopaedic Research, 15*, 348-352.

137- Hunt, M. A., Birmingham, T. B., Bryant, D., Jones, I., Giffin, J. R., Jenkyn, T. R., & Vandervoort, A. A. (2008). Lateral trunk lean explains variation in dynamic knee joint load in patients with medial compartment knee osteoarthritis. *Osteoarthritis and Cartilage*, *16*(5), 591-599.

138- Hurley, S. T., Hatfield Murdock, G. L., Stanish, W. D., & Hubley-Kozey, C. L. (2012). Is there a dose response for valgus unloader brace usage on knee pain, function, and muscle strength? *Archives of physical medicine and rehabilitation*, *93*(3), 496-502.

139- Hurley, M. V., Scott, D. L., Rees, J., & Newham, D. J. (1997). Sensorimotor changes and functional performance in patients with knee osteoarthritis. *Annals of the Rheumatic Diseases*, *56*(11), 641-648.

140- Hurwitz, D., Ryals, A. R., Block, J. A., Sharma, L., Schnitzer, T. J., & Andriacchi, T. P. (2000). Knee pain and joint loading in subjects with osteoarthritis of the knee. *Journal of Orthopaedic Research*, *18*(4), 572-579.

141- Hurwitz, D. E., Ryals, A. B., Case, J. P., Block, J. A., & Andriacchi, T. P. (2002). The knee adduction moment during gait in subjects with knee osteoarthritis is more closely correlated with static alignment than radiographic disease severity, toe out angle and pain. *Journal of Orthopaedic Research*, *20*(1), 101-107.

142- Hurwitz, D. E., Sumner, D. R., Andriacchi, T. P., & Sugar, D. A. (1998). Dynamic knee loads during gait predict proximal tibial bone distribution. *Journal of biomechanics*, *31*(5), 423-430.

143- Jadelis, K., Miller, M. E., Ettinger, W. H., & Messier, S. P. (2001). Strength, balance, and the modifying effects of obesity and knee pain: results from the Observational Arthritis Study in Seniors (OASIS). *Journal of the American Geriatrics Society*, *49*(7), 884-891.

144- Jenkyn, T. R., Hunt, M. A., Jones, I. C., Giffin, J. R., & Birmingham, T. B. (2008). Toe-out gait in patients with knee osteoarthritis partially transforms external knee adduction moment into flexion moment during early stance phase of gait: a tri-planar kinetic mechanism. *Journal of biomechanics*, *41*(2), 276-283.

145- Jinks, C., Jordan, K., Ong, B. N., & Croft, P. (2004). A brief screening tool for knee pain in primary care (KNEST). 2. Results from a survey in the general population aged 50 and over. *Rheumatology*, *43*(1), 55-61.

146- Jones, G., Ding, C., Scott, F., & Cicuttini, F. (2004). Genetic mechanisms of knee osteoarthritis: a population based case–control study. *Annals of the rheumatic diseases*, *63*(10), 1255-1259.

147- Jones, G. Posture. In: Kandel E, Schwartz J, Jessell T. (2000). Principles of neural science. *New York: McGraw-Hill, (4),* 816–31.

148- Jones, R. K., Chapman, G. J., Findlow, A. H., Parkes, M., Forsythe, L., & Felson, D. T. (2013). A new approach to prevention of knee osteoarthritis: reducing load in the contralateral knee. *The Journal of rheumatology, 40(3), 309-315.*

149- Jones, R. K., Nester, C. & Richards, J. 2006. Effects of different profiles of lateral wedging on knee adduction moments during the loading period of the gait cycle. *Osteoarthritis and Cartilage, 11*, 147.

150- Jones, R. K., Nester, C. J., Richards, J. D., Kim, W. Y., Johnson, D. S., Jari, S., & Tyson, S. F. (2013). A comparison of the biomechanical effects of valgus knee braces and lateral wedged insoles in patients with knee osteoarthritis. *Gait & posture*, *37*(3), 368-372.

151- Jordan, J. M., Helmick, C. G., Renner, J. B., Luta, G., Dragomir, A. D., Woodard, J., & Hochberg, M. C. (2007). Prevalence of knee symptoms and radiographic and symptomatic knee osteoarthritis in African Americans and Caucasians: the Johnston County Osteoarthritis Project. *The Journal of rheumatology*, *34*(1), 172-180.

152- Kadaba, M. P., Ramakrishnan, H. K., & Wooten, M. E. (1990). Measurement of lower extremity kinematics during level walking. *Journal of Orthopaedic Research*, *8*(3), 383-392.

153- Kadaba, M. P., Ramakrishnan, H. K., Wooten, M. E., Gainey, J., Gorton, G., & Cochran, G. V. B. (1989). Repeatability of kinematic, kinetic, and electromyographic data in normal adult gait. *Journal of Orthopaedic Research*, *7*(6), 849-860.

154- Kakihana, W., Akai, M., Nakazawa, K., Takashima, T., Naito, K., & Torii, S. (2005). Effects of laterally wedged insoles on knee and subtalar joint moments. *Archives of physical medicine and rehabilitation*, *86*(7), 1465-1471.

155- Kang, X., Fransen, M., Zhang, Y., Li, H., Ke, Y., Lu, M., & Lin, J. (2009). The high prevalence of knee osteoarthritis in a rural Chinese population: the Wuchuan osteoarthritis study. *Arthritis Care & Research*, *61*(5), 641-647.

156- Karimi, M. T., Esrafilian, A. and Amiri, P. (2012). Design and Evaluation of a New Type of Knee Orthosis to Align the Mediolateral Angle of the Knee Joint with Osteoarthritis.

157- Kaufman, K. R., Hughes, C., Morrey, B. F., Morrey, M., & An, K. N. (2001). Gait characteristics of patients with knee osteoarthritis. *Journal of biomechanics*, *34*(7), 907-915..

158- Kaufman, K. and Sutherland, D. (2006). Kinematics of normal human walking. *In: Rose, J. and Gamble, J. (eds.) Human walking. Philadelphia: Lippincoti Williams and Wilkins*

159- Kean, C. O., Birmingham, T. B., Garland, S. J., Bryant, D. M., & Giffin, J. R. (2011). Preoperative strength training for patients undergoing high tibial osteotomy: a prospective cohort study with historical controls. *Journal of orthopaedic & sports physical therapy*, *41*(2), 52-59.

160- Kean, C. O., Hinman, R. S., Bowles, K. A., Cicuttini, F., Davies-Tuck, M., & Bennell, K. L. (2012). Comparison of peak knee adduction moment and knee adduction moment impulse in distinguishing between severities of knee osteoarthritis. *Clinical Biomechanics*, *27*(5), 520-523.

161- Kean, W. F., Kean, R. & Buchanan, W. W. (2004). Osteoarthritis: Symptoms, signs and source of pain. *Inflammopharmacology, 12*, 3-31.

162- Fitzgerald, G. K., Childs, J. D., Ridge, T. M., & Irrgang, J. J. (2002). Agility and perturbation training for a physically active individual with knee osteoarthritis. *Physical therapy*, *82*(4), 372-382.

163- Kellgren J., Lawrence J. (1963). The epidemiology of chronic rheumatism. *Atlas of standard radiographs*. Oxford: Blackwell Scientific.

164- Kerrigan, D. C., Lelas, J. L., Goggins, J., Merriman, G. J., Kaplan, R. J., & Felson, D. T. (2002). Effectiveness of a lateral-wedge insole on knee varus torque in

patients with knee osteoarthritis. *Archives of physical medicine and rehabilitation*, *83*(7), 889-893.

165- Kim, S. (2008). Changes in surgical loads and economic burden of hip and knee replacements in the US: 1997–2004. *Arthritis Care & Research*, *59*(4), 481-488.

166- Kim, W. Y., Richards, J., Jones, R. K., & Hegab, A. (2004). A new biomechanical model for the functional assessment of knee osteoarthritis. *The Knee*, *11*(3), 225-231.

167- Kington, R. S., & Smith, J. P. (1997). Socioeconomic status and racial and ethnic differences in functional status associated with chronic diseases. *American Journal of Public Health*, *87*(5), 805-810.

168- Kinzey, S. J., & Armstrong, C. W. (1998). The reliability of the star-excursion test in assessing dynamic balance. *Journal of Orthopaedic & Sports Physical Therapy*, *27*(5), 356-360.

169- Kirkley, A., Webster-Bogaert, S., Litchfield, R., Amendola, A., MacDonald, S., McCalden, R., & Fowler, P. (1999). The Effect of Bracing on Varus Gonarthrosis*. *The Journal of Bone & Joint Surgery*, *81*(4), 539-48.

170- Koceja, D. M., Allway, D., & Earles, D. R. (1999). Age differences in postural sway during volitional head movement. *Archives of physical medicine and rehabilitation*, *80*(12), 1537-1541.

171- Kohatsu, N.D., Schurman, D.J. (1990). Risk factors for the development of osteoarthritis of the knee. *Clin Orthop Rel Res, 261*,242–246.

172- Komistek, R. D., Dennis, D. A., Northcut, E. J., Wood, A., Parker, A. W., & Traina, S. M. (1999). An in-vivo analysis of the effectiveness of the osteoarthritic knee brace during heel-strike of gait. *The Journal of arthroplasty*, *14*(6), 738-742.

173- Kutzner, I., Küther, S., Heinlein, B., Dymke, J., Bender, A., Halder, A. M., & Bergmann, G. (2011). The effect of valgus braces on medial compartment load of

the knee joint–in vivo load measurements in three subjects. *Journal of biomechanics*, *44*(7), 1354-1360.

174- Landry, S. C., McKean, K. A., Hubley-Kozey, C. L., Stanish, W. D., & Deluzio, K. J. (2007). Knee biomechanics of moderate OA patients measured during gait at a self-selected and fast walking speed. *Journal of biomechanics*, *40*(8), 1754-1761.

175- Lange, A. and Vanwanseele, B. (2008). Strength training for treatment of osteoarthritis of the knee: a systematic review. *Arthritis Care and Research, 59*(10), pp. 1488-1494.

176- Larsen, B. L., Jacofsky, M. C., Brown, J. A., & Jacofsky, D. J. (2013). Valgus bracing affords short-term treatment solution across walking and sit-to-stand activities. *The Journal of arthroplasty*, *28*(5), 792-797.

177- Lawrence, R.C., Felson D.T, Charles Helmick, C.G, Arnold, L.M, Choi H., Deyo R.A, Gabriel, S., Hirsch, R, Hochberg, M.C, Hunde, G.G, Jordan, J. M, Katz, J.K, Kremers, H.M, Frederick, W. (2008). Estimates of the prevalence of arthritis and other rheumatic conditions in the United States: Part II. *Arthritis & Rheumatism, 58*(1), 26-35.

178- Lee, H., Park, H., Chae, Y., Kim, S., Kim, S., Kim, S., Kim, J., Yin, C., and Lee, H. (2009). Tai Chi Qigong for the quality of life of patients with knee osteoarthritis: a pilot, randomized, waiting list controlled trial. *Clinical Rehabilitation, 23*(6), pp. 504-511.

179- Levinger, P., Menz, H. B., Fotoohabadi, M. R., Feller, J. A., Bartlett, J. R., & Bergman, N. R. (2010). Foot posture in people with medial compartment knee osteoarthritis. *J Foot Ankle Res*, *3*, 29.

180- Lewek, M. D., Rudolph, K. S., & Snyder-Mackler, L. (2004). Control of frontal plane knee laxity during gait in patients with medial compartment knee osteoarthritis. *Osteoarthritis and Cartilage*, *12*(9), 745-751.

181- Lewek, M. D., Scholz, J., Rudolph, K. S., & Snyder-Mackler, L. (2006). Stride-to-stride variability of knee motion in patients with knee osteoarthritis. *Gait & posture*, *23*(4), 505-511.

182- Lidtke, R. H., Muehleman, C., Kwasny, M., & Block, J. A. (2010). Foot center of pressure and medial knee osteoarthritis. *Journal of the American Podiatric Medical Association*, *100*(3), 178-184.

183- Lim, B. W., Hinman, R. S., Wrigley, T. V., Sharma, L., & Bennell, K. L. (2008). Does knee malalignment mediate the effects of quadriceps strengthening on knee adduction moment, pain, and function in medial knee osteoarthritis? A randomized controlled trial. *Arthritis Care & Research*, *59*(7), 943-951.

184- Lin, D. H., Lin, C. H. J., Lin, Y. F., & Jan, M. H. (2009). Efficacy of 2 non-weight-bearing interventions, proprioception training versus strength training, for patients with knee osteoarthritis: a randomized clinical trial. *Journal of orthopaedic & sports physical therapy*, *39*(6), 450-457.

185- Lindenfeld, T. N., Hewett, T. E., & Andriacchi, T. P. (1997). Joint loading with valgus bracing in patients with varus gonarthrosis. *Clinical orthopaedics and related research*, *344*, 290-297.

186- Litwic, A., Edwards, M. H., Dennison, E. M., & Cooper, C. (2013). Epidemiology and burden of osteoarthritis. *British medical bulletin*, lds038.

187- Lix, L. M., Keselman, J. C. & Keselman, H. (1996). Consequences of assumption violations revisited: A quantitative review of alternatives to the one-way analysis of variance f test. *Review of educational research, 66*, 579.

188- Lloyd, D. G., & Buchanan, T. S. (2001). Strategies of muscular support of varus and valgus isometric loads at the human knee. *Journal of biomechanics*, *34*(10), 1257-1267.

189- Lohmander, L. S., Östenberg, A., Englund, M., & Roos, H. (2004). High prevalence of knee osteoarthritis, pain, and functional limitations in female soccer

players twelve years after anterior cruciate ligament injury. *Arthritis & Rheumatism*, *50*(10), 3145-3152.

190- Lonner, J. H. (2009). Indications for unicompartmental knee arthroplasty and rationale for robotic arm-assisted technology. *Am J Orthop (Belle Mead NJ)*, *38*(2 Suppl), 3-6.

191- Maly, M., Costigan, P., and Olney, S. (2006). Role of knee kinematics and kinetics on performance and disability in people with medial compartment knee osteoarthritis. *Clinical Biomechanics, 21*(10), pp. 1051-1059.

192- Maly, M. R., Culham, E. G., & Costigan, P. A. (2002). Static and dynamic biomechanics of foot orthoses in people with medial compartment knee osteoarthritis. *Clinical Biomechanics*, *17*(8), 603-610.

193- Mann, R.A. (1985). Biomechanics of the foot. In Bunch WH, (eds): *Atlas of Orthotics: Biomechanical Principles and Application, ed 2*. St. Louis, MO, C V Mosby Co, pp 112-125

194- March, L. M., & Bachmeier, C. J. (1997). 10 Economics of osteoarthritis: a global perspective. *Baillière's clinical rheumatology*, *11*(4), 817-834.

195- Mary, M. R. (1988). Dynamic biomechanics of the normal foot and ankle during walking and running. *Physical Therapy: 68*:1822-1830.

196- Matsuno, H., Kadowaki, K. M., & Tsuji, H. (1997). Generation II knee bracing for severe medial compartment osteoarthritis of the knee. *Archives of physical medicine and rehabilitation*, *78*(7), 745-749.

197- McAlindon, T. E., Felson, D. T., Zhang, Y., Hannan, M. T., Aliabadi, P., Weissman, B., & Jacques, P. (1996). Relation of dietary intake and serum levels of vitamin D to progression of osteoarthritis of the knee among participants in the Framingham Study. *Annals of internal medicine*, *125*(5), 353-359.

198- McCarthy, C. J., Mills, P. M., Pullen, R., Roberts, C., Silman, A., & Oldham, J. A. (2004). Supplementing a home exercise programme with a class-based exercise

programme is more effective than home exercise alone in the treatment of knee osteoarthritis. *Rheumatology*, *43*(7), 880-886.

199- McFadyen, B. J., & Winter, D. A. (1988). An integrated biomechanical analysis of normal stair ascent and descent. *Journal of biomechanics*, *21*(9), 733-744.

200- McKnight, P. E., Kasle, S., Going, S., Villanueva, I., Cornett, M., Farr, J., & Zautra, A. (2010). A comparison of strength training, self-management and the combination for early osteoarthritis of the knee. *Arthritis care & research*, *62*(1), 45-53.

201- McNair, P. J., Stanley, S. N., & Strauss, G. R. (1996). Knee bracing: effects on proprioception. *Archives of physical medicine and rehabilitation*, *77*(3), 287-289.

202- Messier, S. P., DeVita, P., Cowan, R. E., Seay, J., Young, H. C., & Marsh, A. P. (2005). Do older adults with knee osteoarthritis place greater loads on the knee during gait? A preliminary study. *Archives of physical medicine and rehabilitation*, *86*(4), 703-709.

203- Messier, S.P., Loeser, R.F., Hoover, J.L., Semble, E.L., and Wise, C.M. (1992). Osteoarthritis of the knee: effects on gait, strength, and flexibility. *Archives of physical medicine and rehabilitation, 73*(1), 29-36.

204- Mikesky, A. E., Mazzuca, S. A., Brandt, K. D., Perkins, S. M., Damush, T., & Lane, K. A. (2006). Effects of strength training on the incidence and progression of knee osteoarthritis. *Arthritis Care & Research*, *55*(5), 690-699.

205- Miyazaki, T., Wada, M., Kawahara, H., Sato, M., Baba, H., & Shimada, S. (2002). Dynamic load at baseline can predict radiographic disease progression in medial compartment knee osteoarthritis. *Annals of the rheumatic diseases*, *61*(7), 617-622.

206- Misra, D., Booth, S. L., Tolstykh, I., Felson, D. T., Nevitt, M. C., Lewis, C. E., & Neogi, T. (2013). Vitamin K deficiency is associated with incident knee osteoarthritis. *The American journal of medicine*, *126*(3), 243-248.

207- Moffet, H., Richards, C. L., Malouin, F., & Bravo, G. (1993). Load-carrying during stair ascent: a demanding functional test. *Gait & Posture*, *1*(1), 35-44.

208- Moyer, R. F., Birmingham, T. B., Dombroski, C. E., Walsh, R. F., Leitch, K. M., Jenkyn, T. R. & Giffin R. (2012). Combined effects of a valgus knee brace and lateral wedge foot orthotic on the external knee adduction moment in patients with varus gonarthrosis. *Archives of Physical Medicine and Rehabilitation, 40*, 677-686.

209- Müller-Rath, R., Cho, H. Y., Siebert, C. H., & Miltner, O. (2011). [Clinical and gait analytical investigation of valgus knee bracing in therapy for medial degenerative joint disease of the knee]. *Zeitschrift fur Orthopadie und Unfallchirurgie*, *149*(2), 160-165.

210- Mündermann, A., Asay, J. L., Mündermann, L., & Andriacchi, T. P. (2008). Implications of increased medio-lateral trunk sway for ambulatory mechanics. *Journal of biomechanics*, *41*(1), 165-170.

211- Mündermann, A., Dyrby, C. O., & Andriacchi, T. P. (2005). Secondary gait changes in patients with medial compartment knee osteoarthritis: increased load at the ankle, knee, and hip during walking. *Arthritis & Rheumatism*, *52*(9), 2835-2844.

212- Mündermann, A., Dyrby, C. O., Hurwitz, D. E., Sharma, L., & Andriacchi, T. P. (2004). Potential strategies to reduce medial compartment loading in patients with knee osteoarthritis of varying severity: reduced walking speed. *Arthritis & Rheumatism*, *50*(4), 1172-1178.

213- Murray, C. J. and Lopez, A. D. (1996). Evidence-based health policy – lessons from the Global Burden of Disease Study. *Science 274* (5288) 740-3.

214- Nadaud, M. C., Komistek, R. D., Mahfouz, M. R., Dennis, D. A., & Anderle, M. R. (2005). In vivo three-dimensional determination of the effectiveness of the osteoarthritic knee brace: a multiple brace analysis. *The Journal of Bone & Joint Surgery*, *87*(suppl_2), 114-119.

215- Nadeau, S., McFadyen, B. J., & Malouin, F. (2003). Frontal and sagittal plane analyses of the stair climbing task in healthy adults aged over 40 years: what are the challenges compared to level walking? *Clinical Biomechanics*, *18*(10), 950-959.

216- Nevitt, M. C., & Felson, D. T. (1996). Sex hormones and the risk of osteoarthritis in women: epidemiological evidence. *Annals of the rheumatic diseases*, *55*(9), 673-676.

217- Newell, R. S., Hubley-Kozey, C. L., Stanish, W. D., & Deluzio, K. J. (2008). Detecting differences between asymptomatic and osteoarthritic gait is influenced by changing the knee adduction moment model. Gait & posture, 27(3), 485-492.

218- Nigg, B.M., MacIntosh, B.R., Mester, J., (2003). Biomechanics and Biology of Movement. *Human Kinetics, Windsor Ontario.*

219- Novak, A. C., Reid, S. M., Costigan, P. A. and Brouwer, B. (2010). Stair negotiation alters stability in older adults. *Lower Extremity review, 2*, 47-51.

220- O'Reilly, S. C., Jones, A., Muir, K. R., & Doherty, M. (1998). Quadriceps weakness in knee osteoarthritis: the effect on pain and disability. *Annals of the rheumatic diseases*, *57*(10), 588-594.

221- O'Reilly, S. C., Muir, K. R., & Doherty, M. (1999). Effectiveness of home exercise on pain and disability from osteoarthritis of the knee: a randomised controlled trial. *Annals of the Rheumatic Diseases*, *58*(1), 15-19.

222- Otis, J., Backus, S. (1996). Valgus bracing for knee osteoarthritis: A biomechanical and clinical outcome study. *Gait Posture, 4*(2): 189.

223- Pai, Y. C., Rymer, W. Z., Chang, R. W., & Sharma, L. (1997). Effect of age and osteoarthritis on knee proprioception. *Arthritis & Rheumatism*, *40*(12), 2260-2265.

224- Parkes, M. J., Maricar, N., Lunt, M., LaValley, M. P., Jones, R. K., Segal, N. A., & Felson, D. T. (2013). Lateral wedge insoles as a conservative treatment for pain in patients with medial knee osteoarthritis: a meta-analysis. *JAMA*, *310*(7), 722-730.

225- Patla, A. (1990). Assessment of balance control in the elderly: major issues. *Physiotherapy Canada*, *42*(2), 89-97.

226- Payton, C. and Bartlett, R. (2008). Biomechanical evaluation of movement in sport and exercise: the British Association of Sport and Exercise Sciences guidelines. *New York: Taylor and Francis.*

227- Peat, G., McCarney, R., and Croft, P. (2001). Knee pain and osteoarthritis in older adults: a review of community burden and current use of primary health care. *Annals of the Rheumatic Diseases, 60*(2), pp. 91-97.

228- Pelland, L., Brosseau, L., Wells, G., MacLeay, L., Lambert, J., Lamothe, C., Robinson, V., and Tugwell, P. (2004). Efficacy of strengthening exercises for osteoarthritis. (Part I): A meta-analysis. *Physical Therapy Reviews, 9*(2), pp. 77-108.

229- Perry, J. (1992). Gait analysis: Normal and pathological function, SLACK incorporated. *Journal of Pediatric Orthopaedics, 12*, 815.

230- Perttunen, J. (2002). Foot loading in normal and pathological gait. *Thorfare: slack Incoroporated.*

231- Plisky, P. J., Rauh, M. J., Kaminski, T. W., & Underwood, F. B. (2006). Star Excursion Balance Test as a predictor of lower extremity injury in high school basketball players. *Journal of Orthopaedic & Sports Physical Therapy*, *36*(12), 911-919.

232- Pollo, F. E., Otis, J. C., Backus, S. I., Warren, R. F., & Wickiewicz, T. L. (2002). Reduction of medial compartment loads with valgus bracing of the osteoarthritic knee. *The American Journal of Sports Medicine*, *30*(3), 414-421.

233- Prodromos, C. C., Andriacchi, T. P., & Galante, J. O. (1985). A relationship between gait and clinical changes following high tibial osteotomy. *The Journal of Bone & Joint Surgery*, *67*(8), 1188-1194.

234- Protopapadaki, A., Drechsler, W. I., Cramp, M. C., Coutts, F. J., & Scott, O. M. (2007). Hip, knee, ankle kinematics and kinetics during stair ascent and descent in healthy young individuals. *Clinical Biomechanics*, *22*(2), 203-210.

235- Ramsey, D. K., Briem, K., Axe, M. J., & Snyder-Mackler, L. (2007). A mechanical theory for the effectiveness of bracing for medial compartment osteoarthritis of the knee. *The Journal of Bone & Joint Surgery*, *89*(11), 2398-2407.

236- Ramsey, D. K., & Russell, M. E. (2009). Unloader braces for medial compartment knee osteoarthritis: implications on mediating progression. *Sports Health: A Multidisciplinary Approach*, *1*(5), 416-426.

237- Ramsey, D. K., Snyder-Mackler, L., Lewek, M., Newcomb, W., & Rudolph, K. S. (2007). Effect of anatomic realignment on muscle function during gait in patients with medial compartment knee osteoarthritis. *Arthritis Care & Research*, *57*(3), 389-397.

238- Rau, G., Disselhorst-Klug, C., & Schmidt, R. (2000). Movement biomechanics goes upwards: from the leg to the arm. *Journal of Biomechanics*, *33*(10), 1207-1216.

239- Ravaud, P., Giraudeau, B., Logeart, I., Larguier, J. S., Rolland, D., Treves, R., ... & Dougados, M. (2004). Management of osteoarthritis (OA) with an unsupervised home based exercise programme and/or patient administered assessment tools. A cluster randomised controlled trial with a 2× 2 factorial design. *Annals of the rheumatic diseases*, *63*(6), 703-708.

240- Reeves, N. D., & Bowling, F. L. (2011). Conservative biomechanical strategies for knee osteoarthritis. *Nature Reviews Rheumatology*, *7*(2), 113-122.

241- Reeves, N. D., Spanjaard, M., Mohagheghi, A. A., Baltzopoulos, V., & Maganaris, C. N. (2008). Influence of light handrail use on the biomechanics of stair negotiation in old age. *Gait & posture*, *28*(2), 327-336.

242- Reid, S. M., Lynn, S. K., Musselman, R. P. & Costigan, P. A. 2007. Knee biomechanics of alternate stair ambulation patterns. Medicine & Science in Sports & Exercise, 39, 2005.

243- Reilly, K., Barker, K., Shamley, D., Newman, M., Oskrochi, G. R., & Sandall, S. (2009). The role of foot and ankle assessment of patients with lower limb osteoarthritis. *Physiotherapy*, *95*(3), 164-169.

244- Richards, C. L., Malouin, F., Durand, A., & Moffet, H. (1989). Muscle activation level comparisons for determining functional demands of locomotor tasks. *Semin Orthop*, *4*, 120-129.

245- Richards, J. D., Sanchez-Ballester, J., Jones, R. K., Darke, N., & Livingstone, B. N. (2005). A comparison of knee braces during walking for the treatment of osteoarthritis of the medial compartment of the knee. *Journal of Bone & Joint Surgery, British Volume, 87*(7), 937-939.

246- Riener, R., Rabuffetti, M., & Frigo, C. (2002). Stair ascent and descent at different inclinations. *Gait & posture*, *15*(1), 32-44.

247- Risberg, M. A., Holm, I., Steen, H., Eriksson, J., & Ekeland, A. (1999). The Effect of Knee Bracing After Anterior Cruciate Ligament Reconstruction A Prospective Randomized Study with Two Years' Follow-up. *The American Journal of Sports Medicine*, *27*(1), 76-83.

248- Rose, J., & Gamble, J. G. (Eds.). (2006). *Human walking* (pp. 111-114). Philadelphia: Lippincott Williams & Wilkins.

249- Rudolph, K. S., Schmitt, L. C., & Lewek, M. D. (2007). Age-related changes in strength, joint laxity, and walking patterns: are they related to knee osteoarthritis? *Physical therapy*, *87*(11), 1422-1432.

250- Sandmark, H and Vingard, E. (1999). Sport and risk for severe osteoarthrosis of the knee. *Scandinavian Journal Med Sci Sports, 9*(5), 279-284.

251- Sasaki, T., & Yasuda, K. (1987). Clinical evaluation of the treatment of osteoarthritic knees using a newly designed wedged insole. *Clinical orthopaedics and related research*, *221*, 181-187.

252- Schilke, J. M., Johnson, G. O., Housh, T. J., & O'Dell, J. R. (1996). Effects of muscle-strength training on the functional status of patients with osteoarthritis of the knee joint. *Nursing research*, *45*(2), 68-72.

253- Schipplein, O. D., & Andriacchi, T. P. (1991). Interaction between active and passive knee stabilizers during level walking. *Journal of Orthopaedic Research*, *9*(1), 113-119.

254- Schmalz, T., Knopf, E., Drewitz, H., & Blumentritt, S. (2010). Analysis of biomechanical effectiveness of valgus-inducing knee brace for osteoarthritis of knee. *J Rehabil Res Dev*, *47*(5), 419-429.

255- Schmitt, L. C., & Rudolph, K. S. (2007). Influences on knee movement strategies during walking in persons with medial knee osteoarthritis. *Arthritis Care & Research*, *57*(6), 1018-1026.

256- Schneider, E., & Chao, E. Y. (1983). Fourier analysis of ground reaction forces in normals and patients with knee joint disease. *Journal of biomechanics*, *16*(8), 591-601.

257- Schnitzer, T. J., Popovich, J. M., Andersson, G. B., & Andriacchi, T. P. (1993). Effect of piroxicam on gait in patients with osteoarthritis of the knee. *Arthritis & Rheumatism*, *36*(9), 1207-1213.

258- Schwartz, M. H., Trost, J. P., & Wervey, R. A. (2004). Measurement and management of errors in quantitative gait data. *Gait & posture*, *20*(2), 196-203.

259- Segal, N. A., & Glass, N. A. (2011). Is quadriceps muscle weakness a risk factor for incident or progressive knee osteoarthritis? *Phys Sportsmed*, *39*(4), 44-50.

260- Self, B. P., Greenwald, R. M., & Pflaste, D. S. (2000). A biomechanical analysis of a medial unloading brace for osteoarthritis in the knee. *Arthritis Care & Research*, *13*(4), 191-197.

261- Shakoor, N., & Block, J. A. (2006). Walking barefoot decreases loading on the lower extremity joints in knee osteoarthritis. *Arthritis & Rheumatism*, *54*(9), 2923-2927.

262- Shakoor, N., Furmanov, S., Nelson, D. E., Li, Y., & Block, J. A. (2008). Pain and its relationship with muscle strength and proprioception in knee OA: results of an 8-week home exercise pilot study. *J Musculoskelet Neuronal Interact*, *8*(1), 35-42.

263- Sharma, L., Dunlop, D. D., Cahue, S., Song, J., & Hayes, K. W. (2003). Quadriceps strength and osteoarthritis progression in malaligned and lax knees. *Annals of Internal Medicine*, *138*(8), 613-619.

264- Sharma, L., Hurwitz, D. E., Thonar, E. J., Sum, J. A., Lenz, M. E., Dunlop, D. D., & Andriacchi, T. P. (1998). Knee adduction moment, serum hyaluronan level, and disease severity in medial tibiofemoral osteoarthritis. *Arthritis & Rheumatism*, *41*(7), 1233-1240.

265- Sharma, L., Pai, Y. C., Holtkamp, K., & Rymer, W. Z. (1997). Is knee joint proprioception worse in the arthritic knee versus the unaffected knee in unilateral knee osteoarthritis? *Arthritis & Rheumatism*, *40*(8), 1518-1525.

266- Sharma, L., Song, J., Felson, D. T., Cahue, S., Shamiyeh, E., & Dunlop, D. D. (2001). The role of knee alignment in disease progression and functional decline in knee osteoarthritis. *JAMA*, *286*(2), 188-195.

267- Shelburne, K. B., Torry, M. R., & Pandy, M. G. (2006). Contributions of muscles, ligaments, and the ground-reaction force to tibiofemoral joint loading during normal gait. *Journal of orthopaedic research*, *24*(10), 1983-1990.

268- Shelburne, K. B., Torry, M. R., Steadman, J. R., & Pandy, M. G. (2008). Effects of foot orthoses and valgus bracing on the knee adduction moment and medial joint load during gait. *Clinical Biomechanics*, *23*(6), 814-821.

269- Shumway-Cook, A., Anson, D., & Haller, S. (1988). Postural sway biofeedback: its effect on reestablishing stance stability in hemiplegic patients. *Archives of physical medicine and rehabilitation*, *69*(6), 395-400.

270- Shumway-Cook, A., Baldwin, M., Polissar, N. L., & Gruber, W. (1997). Predicting the probability for falls in community-dwelling older adults. *Physical therapy*, *77*(8), 812-819.

271- Silman, A. and Hochberg, M. (2001). Epidemiology of the rheumatic diseases (2nd ed.). Oxford: Oxford University Press.

272- Simic, M., Hinman, R. S., Wrigley, T. V., Bennell, K. L., & Hunt, M. A. (2011). Gait modification strategies for altering medial knee joint load: a systematic review. *Arthritis care & research*, *63*(3), 405-426.

273- Sirin, A. V., & Patla, A. E. (1987). Myoelectric changes in the triceps surae muscles under sustained contractions. *European journal of applied physiology and occupational physiology*, *56*(2), 238-244.

274- Sled, E. A., Khoja, L., Deluzio, K. J., Olney, S. J., & Culham, E. G. (2010). Effect of a home program of hip abductor exercises on knee joint loading, strength, function, and pain in people with knee osteoarthritis: a clinical trial. *Physical Therapy*, *90*(6), 895-904.

275- Slemenda, C., Brandt, K. D., Heilman, D. K., Mazzuca, S., Braunstein, E. M., Katz, B. P., & Wolinsky, F. D. (1997). Quadriceps weakness and osteoarthritis of the knee. *Annals of internal medicine*, *127*(2), 97-104.

276- Slemenda, C., Heilman, D. K., Brandt, K. D., Katz, B. P., Mazzuca, S. A., Braunstein, E. M., & Byrd, D. (1998). Reduced quadriceps strength relative to body

weight: a risk factor for knee osteoarthritis in women? *Arthritis & Rheumatism*, *41*(11), 1951-1959.

277- Song, R., Roberts, B., Lee, E., Lam, P., and Bae, S. (2010). A randomized study of the effects of tai chi on muscle strength, bone mineral density, and fear of falling in women with osteoarthritis. *The Journal of Alternative and Complementary Medicine, 16*(3), pp. 227-233.

278- Srikanth, V. K., Fryer, J. L., Zhai, G., Winzenberg, T. M., Hosmer, D., & Jones, G. (2005). A meta-analysis of sex differences prevalence, incidence and severity of osteoarthritis. *Osteoarthritis and cartilage*, *13*(9), 769-781.

279- Stagni, R., Leardini, A., Cappozzo, A., Grazia Benedetti, M., & Cappello, A. (2000). Effects of hip joint centre mislocation on gait analysis results. *Journal of Biomechanics*, *33*(11), 1479-1487.

280- Startzell, J. K., Owens, D. A., Mulfinger, L. M., & Cavanagh, P. R. (2000). Stair negotiation in older people: a review. *Journal of the American Geriatrics Society*, *48*(5), 567-580.

281- Sum, J., Hurwitz, D., Janik, R., Dressander, J., Andriacchi, T., Schnitzer, T. and Andersson, G. (1997). The impact of osteoarthritic knee pain on dynamic loads during gait. *Gait and Posture, 5*, 173-173.

282- Svanström, L. (1974). Falls on stairs: an epidemiological accident study. *Scandinavian Journal of Public Health*, *2*(3), 113-120.

283- Thomas, K. S., Muir, K. R., Doherty, M., Jones, A. C., O'Reilly, S. C., & Bassey, E. J. (2002). Home based exercise programme for knee pain and knee osteoarthritis: randomised controlled trial. *BMJ*, *325*(7367), 752.

284- Thomas, R. H., Resnick, D., Alazraki, N. P., Daniel, D., & Greenfield, R. (1975). Compartmental Evaluation of Osteoarthritis of the Knee: A Comparative Study of Available Diagnostic Modalities 1. *Radiology*, *116*(3), 585-594.

285- Thorp, L. E., Sumner, D. R., Block, J. A., Moisio, K. C., Shott, S., & Wimmer, M. A. (2006). Knee joint loading differs in individuals with mild compared with moderate medial knee osteoarthritis. *Arthritis & Rheumatism*, *54*(12), 3842-3849.

286- Thorp, L. E., Sumner, D. R., Wimmer, M. A., & Block, J. A. (2007). Relationship between pain and medial knee joint loading in mild radiographic knee osteoarthritis. *Arthritis Care & Research*, *57*(7), 1254-1260.

287- Thorstensson, C. A., Henriksson, M., von Porat, A., Sjödahl, C., & Roos, E. M. (2007). The effect of eight weeks of exercise on knee adduction moment in early knee osteoarthritis–a pilot study. *Osteoarthritis and Cartilage*, *15*(10), 1163-1170.

288- Thorstensson, C. A., Petersson, I. F., Jacobsson, L. T. H., Boegård, T. L., & Roos, E. M. (2004). Reduced functional performance in the lower extremity predicted radiographic knee osteoarthritis five years later. *Annals of the rheumatic diseases*, *63*(4), 402-407.

289- Toriyama, M., Deie, M., Shimada, N., Otani, T., Shidahara, H., Maejima, H., & Ochi, M. (2011). Effects of unloading bracing on knee and hip joints for patients with medial compartment knee osteoarthritis. *Clinical Biomechanics*, *26*(5), 497-503.

290- Trepczynski, A., Kutzner, I., Bergmann, G., Taylor, W. R., & Heller, M. O. (2014). Modulation of the relationship between external knee adduction moments and medial joint contact forces across subjects and activities. *Arthritis & Rheumatology*, *66*(5), 1218-1227.

291- Tsushima, H., Morris, M., and McGinley, J. (2003). Test-Retest Reliability and Inter-Tester Reliability of Kinematic Data from a Three-Dimensional Gait Analysis System. *Journal of the Japanese Physical Therapy Association, 6*(1), pp. 9-17.

292- Vad, V., Hong, H. M., Zazzali, M., Agi, N., & Basrai, D. (2002). Exercise recommendations in athletes with early osteoarthritis of the knee. *Sports medicine*, *32*(11), 729-739.

293- Valderrabano, V., Horisberger, M., Russell, I., Dougall, H., & Hintermann, B. (2009). Etiology of ankle osteoarthritis. *Clinical Orthopaedics and Related Research®*, *467*(7), 1800-1806.

294- Wada, M., Imura, S., Nagatani, K., Baba, H., Shimada, S., & Sasaki, S. (1998). Relationship between gait and clinical results after high tibial osteotomy. *Clinical orthopaedics and related research*, *354*, 180-188.

295- Wada, M., Maezawa, Y., Baba, H., Shimada, S., Sasaki, S., & Nose, Y. (2001). Relationships among bone mineral densities, static alignment and dynamic load in patients with medial compartment knee osteoarthritis. *Rheumatology*, *40*(5), 499-505.

296- Wallace, D. A., Pavol, M. J., & Harter, R. A. (2007). Efficacy of lateral wedge orthotics during stair descent in patients with knee osteoarthritis. *Journal of Biomechanics*, *40*, S677.

297- Walter, J. P., D'Lima, D. D., Colwell, C. W., & Fregly, B. J. (2010). Decreased knee adduction moment does not guarantee decreased medial contact force during gait. *Journal of Orthopaedic Research*, *28*(10), 1348-1354.

298- Webster, K. E., Wittwer, J. E., & Feller, J. A. (2003). Quantitative gait analysis after medial unicompartmental knee arthroplasty for osteoarthritis. *The Journal of arthroplasty*, *18*(6), 751-759.

299- Wegener, L., Kisner, C., & Nichols, D. (1997). Static and dynamic balance responses in persons with bilateral knee osteoarthritis. *Journal of Orthopaedic & Sports Physical Therapy*, *25*(1), 13-18.

300- Weidenhielm, L., Olsson, E., Broström, L. A., Börjesson-Hederström, M., & Mattsson, E. (1993). Improvement in gait one year after surgery for knee osteoarthrosis: a comparison between high tibial osteotomy and prosthetic replacement in a prospective randomized study. *Scandinavian journal of rehabilitation medicine*, *25*(1), 25-31.

301- Weidenhielm, L., Svensson, O. K., Broström, L. A., & Mattsson, E. (1993, December). Adduction moment of the knee compared to radiological and clinical parameters in moderate medical osteoarthrosis of the knee. *In Annales chirurgiae et Gynaecologiae*, 83(3), 236-242.

302- Wessel, J. (1996). Isometric strength measurements of knee extensors in women with osteoarthritis of the knee. *The Journal of rheumatology*, *23*(2), 328-331.

303- Whatling, G. (2007). The importance of stair climbing to assess oa knee function. Cardiff University, Wales: Cardiff School of Engineering. Journal of Engineering in Medicine, 145, 885.

304- Wilson, B., Rankin, H., & Lowry Barnes, C. (2011). Long-term results of an unloader brace in patients with unicompartmental knee osteoarthritis. *Orthopedics*, *34*(8), 575.

305- Winter, D. A. (1983). Energy generation and absorption at the ankle and knee during fast, natural, and slow cadences. *Clinical Orthopaedics and Related Research*, *175*, 147-154.

306- Winter, D. A. (1983). Knee flexion during stance as a determinant of inefficient walking. *Physical therapy*, *63*(3), 331-333.

307- Winter, D.A., (1991). Human Gait: The Biomechanics and Motor Control of Human Gait: Normal, Elderly and Pathological, second ed. *UW press, Waterloo, Canada.*

308- Winter, D. A. (2009). *Biomechanics and motor control of human movement*. John Wiley & Sons.

309- Winter, D. A., Patla, A. E., & Frank, J. S. (1990). Assessment of balance control in humans. *Med Prog Technol*, *16*(1-2), 31-51.

310- Wojtys, E. M., Kothari, S. U., & Huston, L. J. (1996). Anterior cruciate ligament functional brace use in sports. *The American journal of sports medicine*, *24*(4), 539-546.

311- Wu, W. L., Huang, P. J., Lin, C. J., Chen, W. Y., Huang, K. F., & Cheng, Y. M. (2005). Lower extremity kinematics and kinetics during level walking and stair climbing in subjects with triple arthrodesis or subtalar fusion. *Gait & posture*, *21*(3), 263-270.

312- Yasuda, K., & Sasaki, T. (1987). The mechanics of treatment of the osteoarthritic knee with a wedged insole. *Clinical orthopaedics and related research*, *215*, 162-171.

313- Yu, B., Kienbacher, T., Growney, E. S., Johnson, M. E., & An, K. N. (1997). Reproducibility of the kinematics and kinetics of the lower extremity during normal stair-climbing. *Journal of orthopaedic research*, *15*(3), 348-352.

314- Zachazewski, J. E., Riley, P. O., & Krebs, D. E. (1993). Biomechanical analysis of body mass transfer during stair ascent and descent of healthy subjects. *Journal of rehabilitation research and development*, *30*, 412-412.

315- Zeni, J. A., Rudolph, K., & Higginson, J. S. (2010). Alterations in quadriceps and hamstrings coordination in persons with medial compartment knee osteoarthritis. *Journal of Electromyography and Kinesiology*, *20*(1), 148-154.

316- Zhang, L. Q., Xu, D. A., Wang, G. U., & Hendrix, R. W. (2001). Muscle strength in knee varus and valgus. *Medicine and science in sports and exercise*, *33*(7), 1194-1199.

317- Zhang, W., Moskowitz, R. W., Nuki, G., Abramson, S., Altman, R. D., Arden, N., & Tugwell, P. (2008). OARSI recommendations for the management of hip and knee osteoarthritis, Part II: OARSI evidence-based, expert consensus guidelines. *Osteoarthritis and cartilage*, *16*(2), 137-162.

318- Zhang, W., Nuki, G., Moskowitz, R. W., Abramson, S., Altman, R. D., Arden, N. K., & Tugwell, P. (2010). OARSI recommendations for the management of hip and knee osteoarthritis: part III: Changes in evidence following systematic cumulative update of research published through January 2009. *Osteoarthritis and Cartilage*, *18*(4), 476-499.

APPENDICES

Appendix one

NHS

Health Research Authority
National Research Ethics Service

NRES Committee North West - Lancaster
Barlow House
3rd Floor
4 Minshull Street
Manchester
M1 3DZ

Telephone: 0161 625 7818
Facsimile: 0161 625 7299

14 May 2012

Mr Yousef Al-Zahrani
PhD student at the University of Salford
University of Salford
Brian Blatchford Building. Room PO30
Fredrick Road Campus
University of Salford
M6 6PU

Dear Mr Al-Zahrani

Study title:	**The effectiveness of UNLOADer knee bracing in subjects with medial knee osteoarthritis: UNLOAD study**
REC reference:	**12/NW/0419**

The Proportionate Review Sub-committee of the NRES Committee North West - Lancaster reviewed the above application on 10 May 2012.

Ethical opinion

On behalf of the Committee, the sub-committee gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, **subject to the conditions specified below.**

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Appendix two

NHS SalfoR+D Director:	Professor Bill Ollier
R&D Lead:	Rachel Georgiou
SalfoR+D web address:	http://www.nhssalfordrd.org.uk/
ReGrouP web address:	http://www.gmregroup.nhs.uk/index.html

2nd August 2012

Mr Yousef AlZahrani
PhD student
University of Salford
Brian Blatchford Building. Room PO30
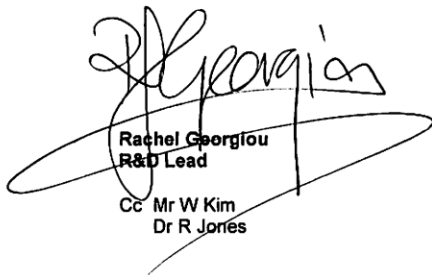Frederick Road Capmus
University of Salford
M6 6PU

Dear Mr AlZahrani

Study Title:	**Effect of UNLOADer Knee Bracing in Knee OA Patients** **(The UNLOAD Study)**
REC Reference No:	12/NW/0419
R&D Reference No:	2012/146ET

Thank you for forwarding all the required documentation for your study as above. I am pleased to inform you that your study has been registered with NHS SalfoR+D. We agree that the following NHS Trusts can be involved as *Patient Identification Centres (PICS):*

• Salford Royal NHS Foundation Trust

Yours sincerely,

Rachel Georgiou
R&D Lead

Cc Mr W Kim
Dr R Jones

Appendix three

Stockport **NHS**

NHS Foundation Trust

Research & Development Office
F08, Pinewood House
Stepping Hill Hospital
Poplar Grove
Stockport
SK2 7JE

Mr Yousef Ahmed Al-Zahrani
School of Health Sciences
University of Salford
Salford
M6 6PU

Tel: 0161 419 5801 / 5814
E-mail: jan.smith@stockport.nhs.uk

17 July 2012

Dear Yousef,

Research Office Reference Number: 2012029
Project Title: The effectiveness of UNLOADer knee bracing in subjects with medial knee osteoarthritis: The UNLOAD study

Thank you for your application for Research Office approval for the above study.

I am pleased to confirm that we have now received and reviewed all necessary documentation, and Stockport NHS Foundation Trust has no objection to being a Participant Identification Centre (PIC) for this study.

Activity at Stockport will be limited to the screening and identification of suitable participants, who will be handed an invitation letter and participant information sheet (PIS). PIS on University of Salford letterhead must be provided to this site.

I would like to take this opportunity to wish you well with your research.

Yours sincerely,

Jan Smith
Research & Development Manager

cc: David Johnson

Documents reviewed and covered by this Permission Letter

Appendix four

Central Manchester University Hospitals NHS

NHS Foundation Trust

Research & Development
1st Floor Post Graduate Centre
Manchester Royal Infirmary
Oxford Road
Manchester M13 9WL
Tel: 0161-276-3340
Fax: 0161-276-5766
Lorraine.Broadfoot@cmft.nhs.uk

Dr Richard Jones
Room PO-18
Brian Blatchford Building
University of Salford
M6 6PU
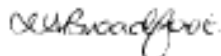
Our Ref. CMFT-PIC-R02126

Dear Mr Al-Zahrani,

Study: The effectiveness of UNLOADer knee bracing in subjects with medial knee osteoarthritis: UNLOAD study
Sponsor: University of Salford
Chief Investigator: Mr Yousef Al-Zahrani
Local Liaison: Mr Mobeen Ismail

We have received a request for authorisation for our Trust to become involved as a *Participant Identification Centre (PIC)* for the above study.

Following receipt of the documentation listed at the foot of this letter, we have completed the minimum governance checks required (for PICs) and can confirm our Trust's agreement.

I would like to take this opportunity to wish you well with your research.

Yours sincerely

Lorraine Broadfoot
Research Operations Manager
Date: 18th October 2012

Encl.   Non-NHS SSI form

cc.   Mr Yousef Al-Zahrani – University of Salford
         Mr Mobeen Ismail – Central Manchester University Hospitals NHS Foundation Trust
         Alison Robinson – Central Manchester University Hospitals NHS Foundation Trust

Documents Acknowledged	Version Number / Reference	Date
Non-NHS SSI form	IRAS 3.4	4th May 2012
REC conditions met letter	12/NW/0419	21st May 2012
Participant consent form	2	21st May 2012
Participant information sheet	2	21st May 2012
REC conditional opinion letter	12/NW/0419	14th May 2012
Investigator CV	Yousef Ahmad Al-Zahrani	n/a
Investigator CV	Richard Keith Jones	n/a

Letter of invitation to participant	1.0	30th April 2012
GP letter – completed study	1.0	30th April 2012
Knee brace telephone pack	1.0	30th April 2012
Demographics	1.0	30th April 2012
Appointment card	1.0	30th April 2012
Knee injury and osteoarthritis	1.0	30th April 2012
Protocol	1.0	30th April 2012
Questionnaire: pain and comfort	1.0	30th April 2012
REC application	IRAS 3.4	4th May 2012
Lead site approval letter	University of Salford	9th August 2012

cc   Mr Yousef Al-Zahrani – University of Salford
        Mr Mobeen Ismail – Central Manchester University Hospitals NHS Foundation Trust
        Alison Robinson – Central Manchester University Hospitals NHS Foundation Trust

Appendix five

9 August 2012

Dear Yousef,

RE: ETHICS APPLICATION HSCR12/42 – The effectiveness of UNLOADer knee bracing in subjects with medial knee osteoarthritis: UNLOAD study

Following your responses to the Panel's queries, based on the information you provided, I am pleased to inform you that application HSCR12/42 has now been approved, on the condition that you forward the two outstanding Trust approval letters as soon as you have them.

If there are any changes to the project and/ or its methodology, please inform the Panel as soon as possible.

Yours sincerely,

Rachel Shuttleworth

Rachel Shuttleworth
College Support Officer (R&I)