The effect of a knee ankle foot orthosis on lower limb kinematics and kinetics in an individual with varus knee alignment

Huda Al-fatafta

School of Health Sciences

University of Salford, Salford, UK

Submitted in Partial Fulfilment of the Requirements of the Degree of Master of Science, March 2015

Contents

Table of Figures

Chapter one:

Chapter two:

Chapter three:

Chapter four:

List of Tables

Chapter three:

Chapter four:

Acknowledgments

I would sincerely like to express my gratitude to a number of people without whom this thesis would not have been written. Firstly and foremost, I wish to express my sincere thanks to my supervisor Prof. Richard Jones. It was my pleasure to have supervisor like you with your friendly features and your brilliant experience in research and biomechanics. Thank you very much for your advices, your time, and your support. I always appreciate that.

Also, I would like to thank and my co-supervisors Dr. Anmin Liu and Dr. Stephen Hutchins. Thank you very much for your help, and your kindly support. Also, I would thank all team in University of Salford for their help and University of Jordan for the financial support.

I would like to give special thanks to my colleagues for their help, advices and participation in my study; especially, Dr. Yousef al-Zahrani and Mr. Faisal Salem. I never have felt that I am away from my family between you.

I also wish to acknowledge the assistance given to me by Ottobock and Ossur companies who assisted me with knee joints and knee valgus braces to collect my data.

My gratitude finally goes to all of my lovely family members, my grandfather and best friends for their encouragement, love, enthusiasm, and motivation during my hard times in this work. I wish you always feel proud of me.

Abstract

Introduction: Increased knee loading and a varus knee deformity have been linked with progression of knee osteoarthritis and thus, reducing both of these are key treatment principles. There are different types of orthoses which are recommended to correct knee load and varus deformity, for individuals with medial knee OA, with knee valgus braces being one of these. However, these braces have been found not to reduce knee load, nor varus deformity effectively due to the need for a high force to be applied on the knee which consequently alters kinematics at the knee and hip. In order to overcome these limitations, a knee ankle foot orthosis (KAFO) may be an option. However, no such study has assessed the effect a KAFO has on the knee joint during walking and stair climbing and if it is more effective than knee valgus braces. The purpose of this thesis was therefore to assess the effectiveness of a knee-ankle-foot-orthosis (KAFO) on the kinematics and kinetics of the lower limb in the sagittal and frontal planes compared to a custom made and off-the-shelf (OTS) knee valgus braces during walking and stair climbing.

Methods: One male individual (43 years) with 10 degrees of knee varus deformity was assessed in a control shoe, OTS and a custom made UnloaderOne knee valgus brace, and a custom-made KAFO during walking and stair climbing. Three-dimensional kinematics and kinetics of the hip, knee, and ankle joints were collected where the maxima and minima of the sagittal and coronal plane angles and moments were assessed with a repeated measures analysis of variance.

Results: The KAFO significantly reduced external knee adduction moment (EKAM), knee adduction angular impulse (KAAI), knee varus angle, and ankle eversion compared to both valgus knee braces. In addition, the KAFO significantly improved the knee and hip flexion angles and hip range of motion in sagittal plane during level walking compared to the shoe and OTS. Neither the custom nor the OTS knee valgus braces significantly reduced EKAM or knee varus compared to the shoe.

Conclusion: The KAFO has been shown to reduce knee loading and knee deformity in this individual, and much better than the commonly used knee valgus braces. From the increased

lever arm and improved fit, this could be a potential avenue for treatment of these impairments in individuals when other conservative options are not successful.

Chapter one: Literature review

1.1.Definition of Osteoarthritis

There are several types of arthritis which may be grouped into four main areas: inflammatory arthritis (such as rheumatoid arthritis and ankylosing spondylitis), soft tissue arthritis (such as lateral epicondylitis), connective tissue arthritis (such as deratomyositis) and degenerative or mechanical arthritis such as osteoarthritis (OA) (Arthritis Care, 2004). OA is defined as a chronic, progressive musculoskeletal disorder characterised by articular joint cartilage degeneration with articular bone enlargement due to new bone formation. However, it is defined by the American Rheumatism Association as a heterogeneous group of conditions that leads to joint symptoms and signs that are associated with the defective integrity of cartilage in addition to the related changes in the underlying bone and at the joint margin (Altman et al., 1986).

1.2. Epidemiology of Osteoarthritis

It has been estimated that 41% of individuals aged 56 and over have OA in the UK (Dawson et al., 2004) and around 8.4 million in the UK complain from symptoms associated with OA (Arthritis Care, 2004). For instance, it is on record that in England and Wales alone up to 1.75 million individuals have systemic OA (Reginster, 2002) which means the condition is a serious problem for the older population not only because OA causes a health burden, such as reducing the quality of life and functional activity, but also an economic burden such as increased medical costs, hospital cost, research costs, and absenteeism from work (Reginster, 2002). Evidence has shown that between 10% and 15% of individuals aged 60 years and above have some degree of OA, and are primarily suffering from some form of disability, in particular during walking and climbing of stairs (Haq and Darce, 2003).

In the USA, 21 million individuals suffer from OA and this figure is continuously increasing (D'Ambrosia, 2005), particularly in individuals aged 56 years and over due to age and obesity.

Also, 32.6% of the population sampled was found to complain of knee pain and 19.2% complained from hip pain due to OA (Dawson et al., 2004).

1.3. OA classification

OA is divided into two main categories: primary and secondary. Primary (idiopathic) OA is mainly hereditary and can be localised whereby it affects one joint, or can be generalised which impacts on more than one joint. Secondary OA is more related to trauma, previous injury such as hip dislocation, ligament tears, bone disorders (necrosis, osteochondritis), metabolic disease (e.g. hemochromatosis), endocrine disease such as hyperthyroidism, and calcium deposition disease **(**Altman et al., 1986). Primary OA is mainly associated with Heberden's nodes in the distal interphalangeal joints (DIP) with other affected joints such as knee or hip joint (Petersson and Jacobsson, 2004), and is more common than secondary OA. Moreover, it is estimated that 97% of total knee replacements (TKR) are due to primary OA which is more prominent with the older population, while TKRs due to secondary OA are commonly associated in the younger population and more prominent in men than women ≥ 50 years old (Julin et al., 2010).

1.4. Sites of OA

OA is more commonly seen in weight bearing joints such as the hip, knee, and spine than in the wrist, elbow, and shoulder joints. OA also affects most hand joints particularly the joint which participates in the pincer grip such as the distal interphalangeal joint (DIP), proximal interphalangeal joint (PIP), and at the base of thumb; which leads to a reduction in hand function, deformity, and reduced joint motion (Zhang et al., 2002). OA also affects the first metatarsophalangeal (MTP) joint which is the most affected joint in feet, and 10% of individuals aged between 20-40 years and 44% of those aged over 80 years suffer the most from radiological OA in the first MTP joint. In addition, in the vertebral column (spine), OA is strongly associated with age, particularly in the cervical spine. OA has a higher recorded prevalence in the cervical spine (84.8% men, 84.3% women) followed by the lumbar spine (71% men, 67.3% women) (Van Saase et al., 1989). The incidence of OA in the hip joint is between 4% and 9% (Felson and

Zhang, 1998, Lawrence et al., 1998); whilst, the incidence of OA in the knee joint is the greatest at between 3.4% and 30% (Kellgren and Lawrence, 1958, Felson et al., 2000, Spector and Hart, 1992) (Figure 1.1); with women more affected than men (11%, 7%, respectively) (Felson et al., 1987).

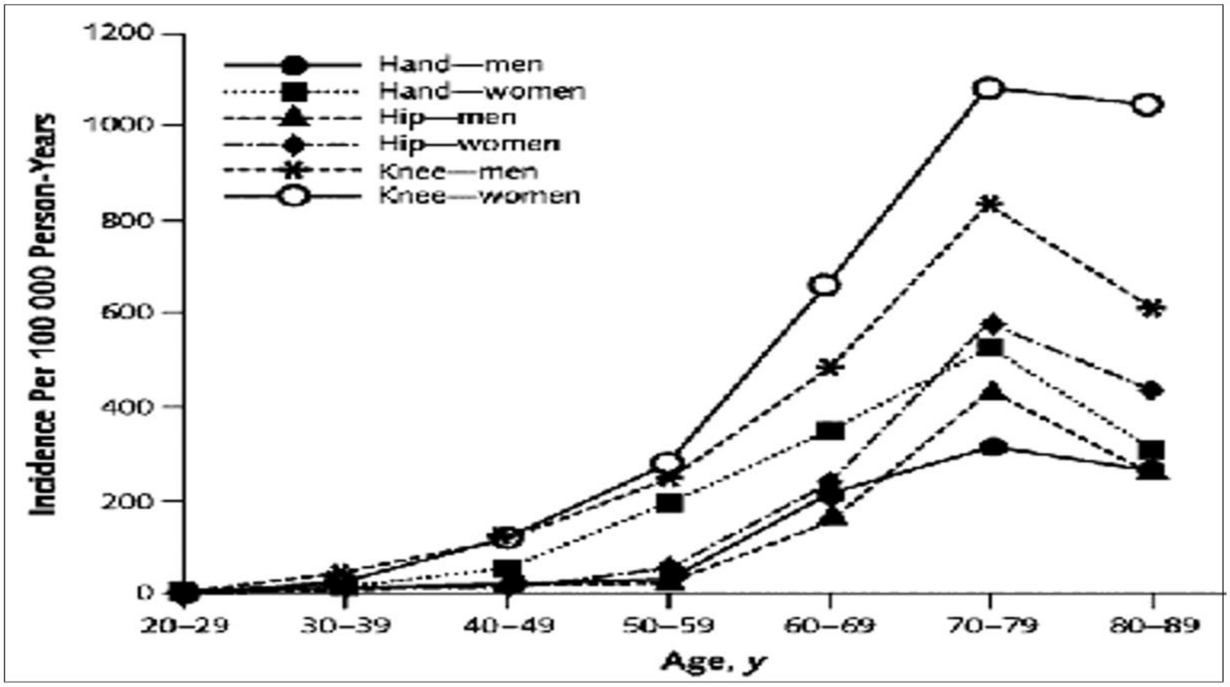


Figure 1.4: The effects of age and gender on specific joint incidence of osteoarthritis. The knee joint is more affected than the hip joint, especially within females (Felson et al., 2000).

1.5. Risk factors for OA

The risk factors for OA can be systemic (general) which can happen in any joint or can be local (biomechanical) which primarily affect specific joints (Felson et al., 2000). Systemic factors include age, gender, ethnicity, dietary, and genetic factors; whereas, biomechanical factors include basically muscles weakness, obesity, joint alignment deformity, and ligament laxity. A brief overview of these is given below.

1.5.1 Systemic factors

1.5.1.1 Age

OA is strongly related to age particularly in middle aged and older people (Beaupre et al., 2000) due to changes in the characteristics of cartilage and also the loss of its flexibility. Thus, the ability to provide shock absorption, and the ability to maintain the equilibrium between the production and breakdown of cartilage cells becomes more difficult with age. Nonetheless, the thickness of cartilage will decrease until the hydrostatic pressure inside the cartilage is decreased and replaced with a new bone formation (Carter et al., 2004, Eckstein et al., 2002, Felson et al., 1987). According to the Framingham study, it was also emphasised that OA is associated with both age and gender; since, radiological OA was found in 27% of individuals aged below 70 years, but was found in 44% for individuals aged 80 years and over.

1.5.1.2 Gender differences

Gender also plays an influence whereby it is estimated that women have a higher prevalence (11%) than men (7%) to develop symptomatic OA; In addition, the incidence of radiological OA change is greater in women (34%) than men (31%) (Felson et al., 1987). Until 50 years of age, men and women have the same prevalence, but after 50 years of age, women have a higher prevalence than men due to a drop in oestrogen level caused by the menopause which reduces the cartilage metabolism, which then increases cartilage breakdown (Beaupre et al., 2000, Nevitt et al., 1996).

1.5.1.3 Ethnicity

Ethnicity has a role in the increased risk of developing some types of OA in specific countries more than others. For example, the African American population has a higher likelihood of developing knee OA than the white population (Anderson et al., 1988, Felson et al., 2000). Furthermore, Felson et al. (2002) also states that different racial populations have a different prevalence to developing knee OA in different compartments; for example, the Chinese populations whose ages fall within 60-88 are at risk of having lateral knee OA compartment more than Americans. Evidence of this is that 28.5% of Chinese women complain from lateral knee OA versus 11% of Framingham women's knees, also men in China have a higher prevalence of lateral knee OA than Framingham men’s knees by 32.3%, 8.8% respectively. This difference can be explained by a high knee valgus alignment which is common within the Chinese population compared to the population in the USA cohort (Felson et al., 2002). Race not only affects OA prevalence, but also the severity of pain and the resultant limitation in activity levels. In the USA, the black population complains of joint pain 1.9 times more, and activity level impairment with work limitation 1.7 times more than the white population when associated with OA (Bolen et al., 2010).

1.5.1.4 Diet and nutrition

Some vitamins have a direct impact on cartilage health and bone metabolism such as vitamin C and vitamin D. For instance, vitamin C reduces the risk of knee OA progression three fold, and also reduces pain severity compared to those who do not take it (McAlindon et al., 1996b). Whereas, vitamin D, which controls chondrocytes (cartilage cell) and bone metabolism, may reduce knee OA progression and reduce joint space narrowing by up to three fold (McAlindon et al., 1996a), and also reduce hip OA development amongst white women (Lane et al., 1999).

1.5.1.5 Genetic factors

More than 50% of OA disease is related to genetic factors principally for the joints in the hand, but approximately 39% of knee OA is related to genetic factors associated with Heberden's nodes; specifically in women (Spector et al., 1996).

1.5.2 Local biomechanical factors

1.5.2.1 Muscle weakness

The strength of the quadriceps muscles help to dissipate shock absorption at initial contact (IC) when the body weight is transferred suddenly to the support limb; thus, loss of muscle strength will increase the load which is carried by the cartilage (Baker et al., 2005). Therefore, quadriceps muscle weakness could be a risk factor and a symptom. Quadriceps weakness becomes a risk factor when it loses its ability to control the knee joint, as it can cause knee pain and symptoms associated with knee OA, and is a secondary reason for knee pain amongst women (Baker et al., 2005). In addition, quadriceps weakness is strongly related to an increase in the disability and activity level impairment of individuals (O'Reilly et al., 1998). Generally, individuals with knee OA suffer from muscle weakness in the knee extensors (quadriceps) (Baker et al., 2005) and hip abductors (Costa et al., 2010).

1.5.2.2 Body mass index (BMI) and obesity

Body mass index (kg/m^2) is calculated by dividing mass (kg) by square of the height (M) of the individual. Individuals who have a high body mass index have a higher incidence of developing OA due to increase load on weight bearing joints such as the knee (Zhang et al., 2000).

When the body weight is 10% more than the average weight, this is considered as obesity (Spector et al., 1996) which is equal to a BMI of ≥ 30 (Flegal et al., 2005). Obesity is an important factor for the development and progression of OA (Cooper et al., 2000), and the most important risk factor for primary and secondary knee OA (Spector et al., 1994). Amongst women, it estimated that about 44 % have OA due to being overweight, while just 27 % of males who are known to have OA are also obese (Goldin et al., 1976). Moreover, obesity increases the risk of OA two to three times (Murphy et al., 2008) and OA progression. For instance, obese women have a 22% greater risk to progress to knee OA and 36% to develop contra-lateral knee OA after two years (Spector et al., 1994).

Nevertheless, it has being established that an estimated two unit decrease in one's BMI is able to reduce the risk of OA by 50% (Beaupre et al., 2000). Furthermore, 5.7% of body weight reduction can reduce knee pain and physical disability by 30% and 24% respectively as calculated using the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) scale after 18 months (Messier et al., 2004). A reduction of 20% in BMI by losing weight is able to reduce knee pain 50 ± 26 mm on a visual analogue scale (VAS) and also improve activity levels by reducing the degree of inflammation and increasing collagen production by 32% (Richette et al., 2011).

1.5.2.3 Joint angle malalignment

Joint malalignment is a major problem in OA because it increases the load on the non-weight bearing area and develops OA with time (Andriacchi et al. 2004). In medial compartment knee OA, the knee varus rotates the knee centre of motion laterally and increases the load on the medial side of the knee which further increases the load on the medial side leading to a bow-legged deformity (Mills and Hull, 1991). This deformity eventually increases the knee load on the medial side to 100% (Johnson et al., 1980), increasing joint instability, and functional impairment (particularly if the varus degree angle is $\geq 5^0$) such as the ability to sit to stand from a chair (Chang et al., 2004). Additionally, varus alignment increases the pain during this activity four-fold with a greater loss in the medial cartilage space (Sharma et al., 2001).

The osseous mechanical axis is used to evaluate the degree of knee varus and valgus. A full length frontal plane radiograph during double limb support is needed to examine the medial angle between two lines: the hip line (the line between the hip centre to the knee centre) and the ankle line (the line between the knee centre to the centre of talus). This angle gives a general idea about lower limb alignment (Figure 1.2) (Mündermann et al., 2008b). The normal angle is between 179-181 degrees; an angle less than 179 degrees is considered as a varus deformity, while a valgus deformity is said to be present when the angle is more than 181 degrees (Hayashi et al., 2012). The normal varus angle is limited to between 1.5± 2 degrees (Moreland et al., 1987); and therefore, individuals are considered to have a knee varus deformity if the varus angle is 7.2 ±4.8 degrees or more (Cooke et al., 2003).

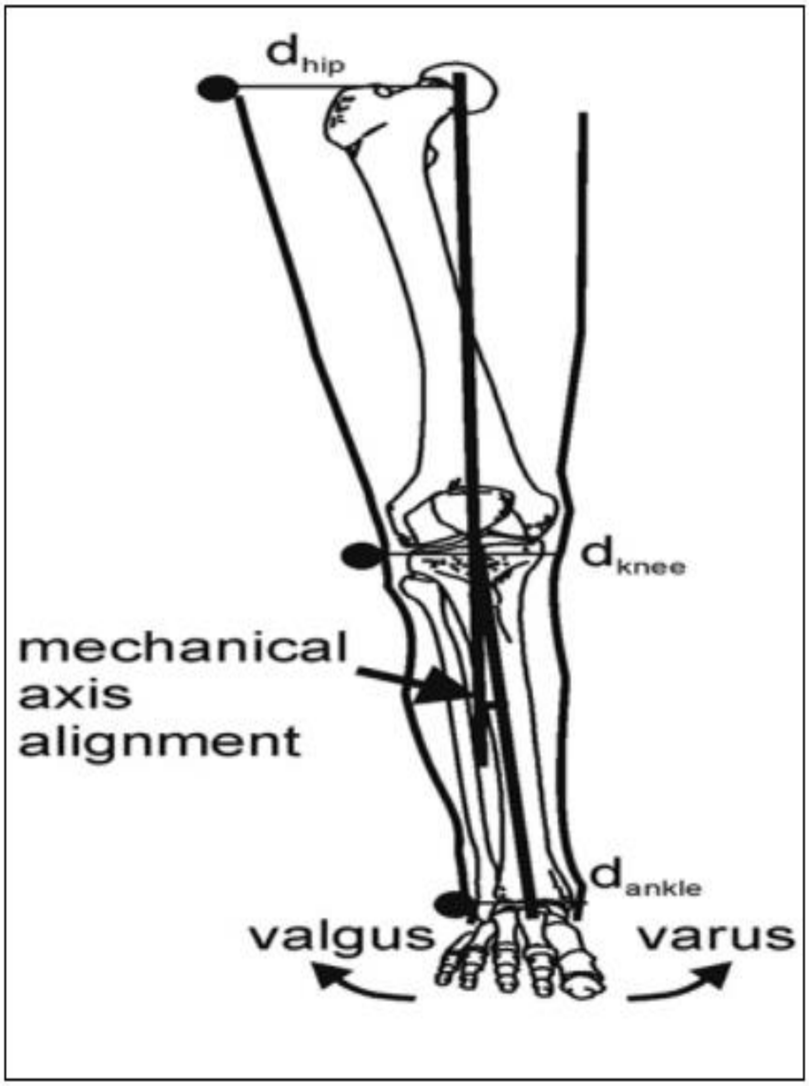


Figure 1. 2: Mechanical axis alignment to evaluate varus and valgus deformity (Mündermann et al., 2008b).

1.5.2.4 Joint laxity and Trauma

Joint laxity is generally associated with joint instability with a feeling of shifting and buckling in the joint during physical activity (Fitzgerald et al., 2004) which increases the risk of tripping and falling (Fallah Yakhdani et al., 2010). Greater joint laxity increases joint malalignment which would increase the load on the weight bearing area, increase cartilage degeneration, and advance disease progression (Roos, 2005). Furthermore, direct trauma can lead to soft tissue tears or bone malalignment which occurs mainly due to a sports or occupational injury. Sports which induce high loads on the joint and twisting movements and increase the risk of knee OA are football, rugby, volleyball and netball (Felson et al., 2000). Some types of occupation also have a role in the increase of OA in specific joints; for instance, mine workers are more affected by knee OA and lumbar degenerative than office workers (Kellgren and Lawrence, 1952). Thus, the activities which require a high lifting of loads, kneeling, and stair climbing many times during the day increase the risk of ligament tears (Roos et al., 1998) and subsequent OA.

For medial knee OA, injury to the anterior cruciate ligament (ACL), medial collateral ligament injury (MCL) (Noyes et al., 1992), and meniscectomy increase the risk of knee OA developing (Davies-Tuck et al., 2008) by increasing the knee load (Noyes et al., 1992). Further research has demonstrated that a torn ACL has a risk factor of 60-90% in developing knee OA after 15 years (Dayal et al., 2005) because tearing of the ACL reduces the degree of flexion to complete the screw home mechanism (end of femur rotates laterally and externally to make knee flexion) and increases the anterior/posterior tibial displacement which leads to increase in the knee load and varus deformity (Andriacchi et al., 2006).

1.6. Knee OA

The knee joint is considered as a modified diathrodial hinge joint because it allows the ends of the bones which form the joint to rotate. It is the largest joint in the human body and the most injured joint due to the frequent stresses and strains it experiences. The stability of the knee joint is derived mainly from ligaments and muscles rather than its osseous structure; and therefore, any disturbance to soft tissues such as ligaments or muscles around the knee joint can impact on knee stability (Lippert, 2006). The knee joint is one of the most common weight bearing joints affected by OA (Ahlbäck, 1968, Oliveria et al., 1995) and one of the main causes of disability amongst older people (18.4%), which is double the prevalence of disability caused by stroke and pulmonary disease (Guccione et al., 1994).

The knee joint contains three compartments: the medial and lateral tibiofemoral compartment and the patellofemoral compartment. Knee OA can impact on all the compartments of the knee, but the medial side is the most affected part compared to other parts (Altman et al., 1986).

Evidence has shown that the medial compartment is ten times more likely to be affected by OA than the lateral side (Buckwalter et al., 2004), because normally during walking the medial compartment bears two or three times of one's body weight (D'Lima et al., 2012), whilst on the lateral side during walking is only 1.7 times body weight (Winby et al., 2009). This gives a greater chance of developing OA in the medial side more than the lateral side due to the excessive load on the medial aspect. When compared the patellofemoral joint to the medial compartment with regards to OA incidence, a study by McAlindon, et al. (1992) demonstrated that patellofemoral OA is present in 11% and 24% among men and women respectively; however, medial knee OA is present in 21% and 12% among men and women.

During the developmental stage of medial knee OA, various changes in knee structures have been noted such as radiological changes (bone enlargement and joint space narrowing), and clinical variations (muscle weakness, inflammation, pain, and stiffness). Additional biomechanical changes (kinematics and kinetics) may be expected during walking and stair climbing such as a reduction in knee range of motion (ROM) mainly during flexion, and a varus knee alignment due to the high external knee adduction moment (EKAM) being applied. These changes will be explained in greater depth later in the thesis.

1.6.1 Prevalence of knee OA

In the UK, 10% of individuals aged 55 years and over have knee OA (Duncan et al., 2006). In 2004, it was estimated that around 0.5 million of individuals in the UK had moderate to severe knee OA (Arthritis Care, 2004), but this increased to 4.7 million in 2010 and it is expected to reach 5.4 million in 2020 (Arthritis Research UK, 2013). Knee OA is more common than in the hip and women are more affected than men (14.9%, 10.1% respectively) (Guillemin et al., 2011). According to the Framingham study, the prevalence of knee OA in adults aged ≥45 is 19.2% (Felson et al., 1987). In the USA, women are more affected by knee OA as compared to men (42.1% vs. 31.2% respectively) (Dillon et al., 2006).

1.6.2 Clinical and Radiological criteria of knee OA

OA affects all joint structures: articular bone, cartilage, subchondral bone, the synovium, ligaments, and muscles (Lippert, 2006). Therefore, OA has both a clinical and radiological criteria. The relationship between clinical features and radiological features are weak in the early stage of OA. On average, 50% of individuals over 50 years of age have radiological OA without symptoms, where also clinical features such as pain can be found without any defined radiological criteria in early stage of OA progression, but at the later stages, the overlap between clinical features and radiological are better matched (Peat et al., 2006). Nonetheless, OA can be divided into symptomatic (pathological) or asymptomatic depending on whether individuals suffer from clinical symptoms or radiological symptoms (Dieppe and Lohmander, 2005) or both. Therefore, there are primary two classifications which are used in defining knee OA, namely the American College of Rheumatology criteria (ACR) for clinical criterion and the Kellgren and Lawrence grading for radiological severity (Kellgren and Lawrence, 1957).

1.6.2.1 The ACR criteria

The ACR criteria for diagnostic purposes and classification for OA of the knee, hip and hand have been recommended for the diagnosis of OA in clinical and epidemiological studies (Brooks and Hochberg, 2001). The sensitivity of this scale is 89% and its specificity is 88% (Altman, 1991a). Clinical features of knee OA are characterised by bony enlargement due to new bone growth near to ligament insertions (osteophytes) or a reduced joint margin, the existence of joint pain, morning stiffness for less than 30 minutes, loss of function, crepitus during motion (the sound of cracking), joint instability, joint alignment deformity due to cartilage breakdown and reduced range of motion and joint laxity (Altman et al., 1991a, Altman et al., 1990, Altman, 1991b). Local inflammation, swelling, joint effusion, muscle atrophy and pain during passive movement and gait deformities are also clinical features of knee OA and become clear during a physical examination (Hunter et al., 2008).

1.6.2.2 The Kellgren and Lawrence radiological grade

The use of a diagnostic X ray (radiograph) is the standard way to evaluate radiological knee OA (Emrani et al., 2008) using an anterior/ posterior view with equal weight bearing on both feet and with the toes pointing straight ahead (Jacobson, 1996). This is despite the fact that a 30 degree flexion position is recommended because individuals reach this position during walking and the flexed knee position increases the load on the cartilage. Thus, the real cartilage degeneration level can be reflected in this situation more than in a full knee extension view (Davies et al., 1999).

Radiological OA criteria are cartilage degeneration which could break down due to excessive load (Griffin and Guilak, 2005); inflammation due to cartilage debris in the synovial fluid; effusion; new bone growth such as osteophytes near to joint margins; and subchondral cysts (Jacobson, 1996) due to the load increase on the non-weight bearing area of the joint because of cartilage breakdown (Kellgren et al., 1963). Radiological OA assessment which depends on Kellgren and Lawrence (K-L) scale is the accepted grading scale for OA by the World Health Organisation (WHO scientific group, 1992). This scale depends on the amount of space narrowing due to cartilage loss and osteophytes development (Kellgren and Lawrence, 1957). It is therefore valid to examine and estimate radiological osteoarthritis severity, but has moderate sensitivity to the real degeneration level of the articular cartilage (Kijowski et al., 2006). This scale has five grades from zero to four. The K-L grade zero is none, K-L grade one is doubtful to have osteoarthritis, K-L2 indicates mild OA, K-L3 indicates moderate and K-L4 is severe. For diagnostic purposes, K-L grades which are equal to and greater than two are considered as confirmation of the existence of OA (Kellgren and Lawrence, 1957) (Figure 1.3).

Figure 1. 3: The Grades of knee OA (Ryu et al., 2012).

As the knee joint structure changes due to OA, the load line position (via the ground reaction force) is modified. These changes have a maximal influence on knee biomechanics and also affect joints as a secondary adaptation or compensation during activities such as walking on level ground and stair climbing. Therefore, an understanding of the biomechanical features present by individuals with healthy lower limb joints during walking and stair climbing, especially for the knee joint is important before discussing how knee OA causes biomechanical changes.

1.7. The biomechanics of walking and stair climbing

1.7.1 Walking

Human daily activities can be divided into three loading categories: moderate loading such as walking; high loading such as ascending and descending stairs; and thirdly, high flexion activities such as sit to stand or stand to sit, and squatting. However, walking is most common daily activity undertaken by humans (Mündermann et al., 2008c).

Walking is considered to be a repetitive lower limb motion following an approximated pattern which starts from one initial contact to the following initial contact for the same side (0% - 100%). A complete gait cycle is divided into two phases: stance phase (approximately 60% of the gait cycle) when the foot is in contact with the floor, swing phase (approximately 40% of the gait cycle) when the foot is swinging through the air (Perry, 1992). Furthermore, each phase has sub phases such as first double limb support (1DS), single limb support, which includes early stance (IS), mid stance (MS), and late stance (LS); and second limb support (2DS) in stance phase. Early swing, mid swing, and late swing occur during swing phase (Baker, 2013) (Figure 1.4) (Meng, 2012).

During the first double limb support (0-10% of the gait cycle), the lower limb rapidly holds the body mass by hip flexion, knee flexion and a neutral ankle position to allow shock absorption during that phase. During the single limb support (10-50% of the gait cycle), the body mass is progressed forward by hip extension and knee extension with the ankle in a dorsiflexed position. In the second double limb support (50-60% of the gait cycle), the body weight starts to be transferred to the opposite side by hip flexion, knee flexion, and ankle plantarflexion. After that, in the early swing phase (60-75%) the body weight is already transferred to opposite side as the hip and knee reach maximum flexion, while the ankle is still in plantarflexion. In the mid swing (75%- 85% of the gait cycle), the tibia starts to be vertical when knee is extended and ankle joint is moved to a neutral position, while the hip stays flexed. Finally, in the late stance (85%-100% of the gait cycle) hip, knee and ankle joints start to return to the first limb support phase again (Baker, 2013, Perry, 1992).

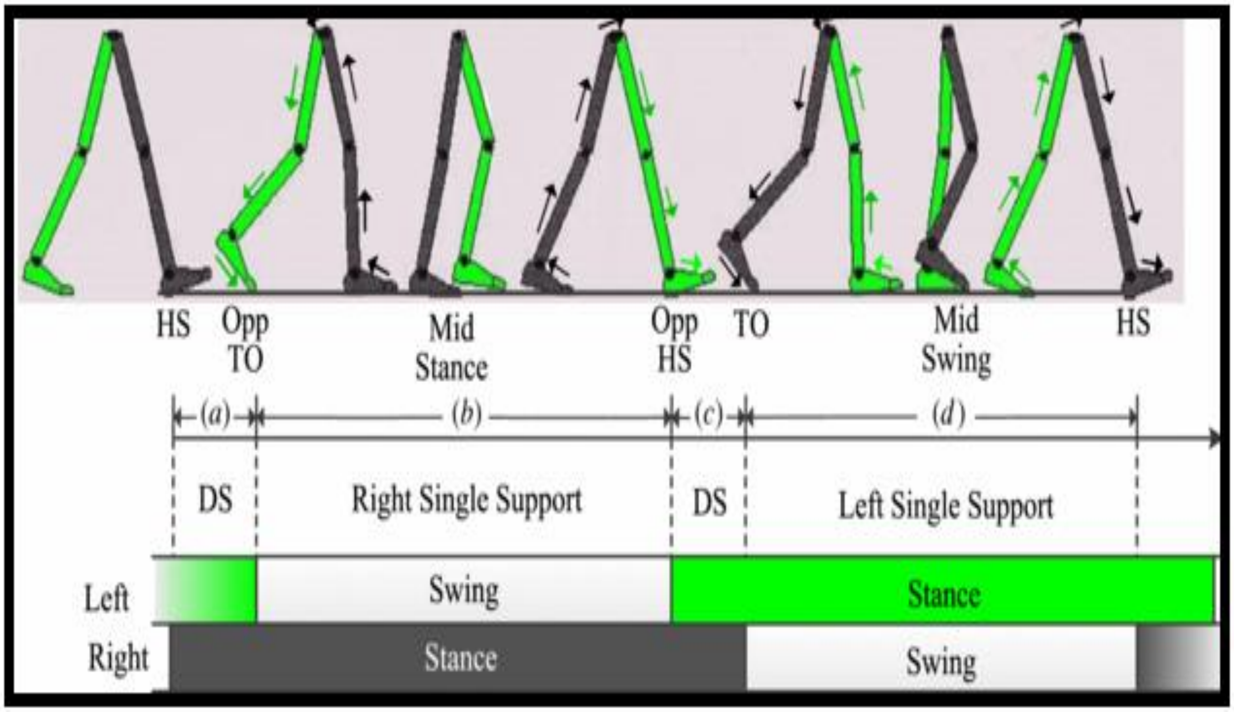


Figure 1.4: Typical gait cycle for healthy knee individuals during walking (Meng, 2012).

1.7.2 Stair climbing

Ascending and descending stairs are important daily activities and one of the main challenges for the elderly population; primarily due to muscle weakness and a high risk of falling (Williamson and Fried, 1996). This could be due to a reduction in the torque and power in lower limb because of muscle weakness, biomechanical changes, and neuromuscular adaptation. Older individuals therefore try to adapt their gait by walking slowly with shorter steps and high cadence compared to young individuals (DeVita and Hortobagyi, 2000). Furthermore, some individuals try to ascend and descend stairs by a stepping climb pattern (step over step) instead of the normal climb pattern (step by step) due to pain even though this gait pattern requires high energy consumption (Shiomi, 1994).

In a similar way to walking, ascending and ascending has two phases: stance and swing (Novak et al., 2010). During an ascending cycle (AC), stance phase (65% ±4% of the gait cycle) has three sub-phases (Figure 1.5):

- Weight acceptance (0-17% of the gait cycle), during this phase the ankle reaches maximum dorsiflexion while the hip and knee in flexion position to controlling pelvic drop and shifting the body into an optimal position to be pulled up.
- A pull-up or vertical thrust phase (vertical centre of mass displacement) which occupies 17-37% of the stair gait cycle. In this phase, hip and knee extensor muscles along with the plantar flexors are working to pull the body mass against the gravity to full support on the next step.
- The forward continuance phase (37-65%), when ascent of a step has been completed and progression continues by the firing of hip and knee extensors muscles.

The swing phase is subdivided into two sub-phases:

- Foot clearance (65%- 82%), when the leg is raised to clear of the intermediate step by hip and knee flexion and ankle dorsiflexion.
- The foot placement phase (82-100% of the gait cycle), when the swing leg is positioned for foot placement on the next step (McFadyen and Winter, 1988, Zachazewski et al., 1993).

The stance phase of a descending cycle (DC), which occupies 68% ± 2% of gait cycle, is divided into three sub-phases: weight acceptance (0-14%) when ankle starts the gait cycle with plantarflexion to descend; forward continuance (14-34%) when the ankle moves in dorsiflexion position to start of single limb support, forward body movement and controlled lowering (34-68% of gait cycle) when the body's mass is lowered onto the support limb by eccentric contraction of the knee extensor muscles. The swing phase has two sub-phases: leg pull through (68-84% of the gait cycle) the swing limb is pulled forward by ankle plantarflexion; the foot placement phase (84-100% of the gait cycle) (McFadyen and Winter, 1988, Zachazewski et al., 1993).

Ascending movements demand more energy consumption for healthy individuals than descending because the hip and knee angles and joint moments are higher during AC than DC.

However, ankle dorsiflexion and plantarflexion is higher during DC than AC (Protopapadaki et al., 2007). Mean maximum knee flexion has been shown to be 98.6 degrees during AC, 90.3 degrees during DC and 64.6 degrees during walking (Jevsevar et al., 1993). Evidence shows that the external knee flexion moment during AC is 2.7 times more than when walking, whilst hip flexion moments are1.5 times more than walking (Andriacch et al., 1980). Moreover, the knee joint keeps in abduction in the stance phase of AC and DC which means that ground reaction force (GRF) always passes medially to the knee joint during stance phase (Kowalk et al., 1996). Yu et al. (1997b) also found that the knee varus during stair climbing is higher than walking, while knee valgus is close to that demonstrated during walking activities.

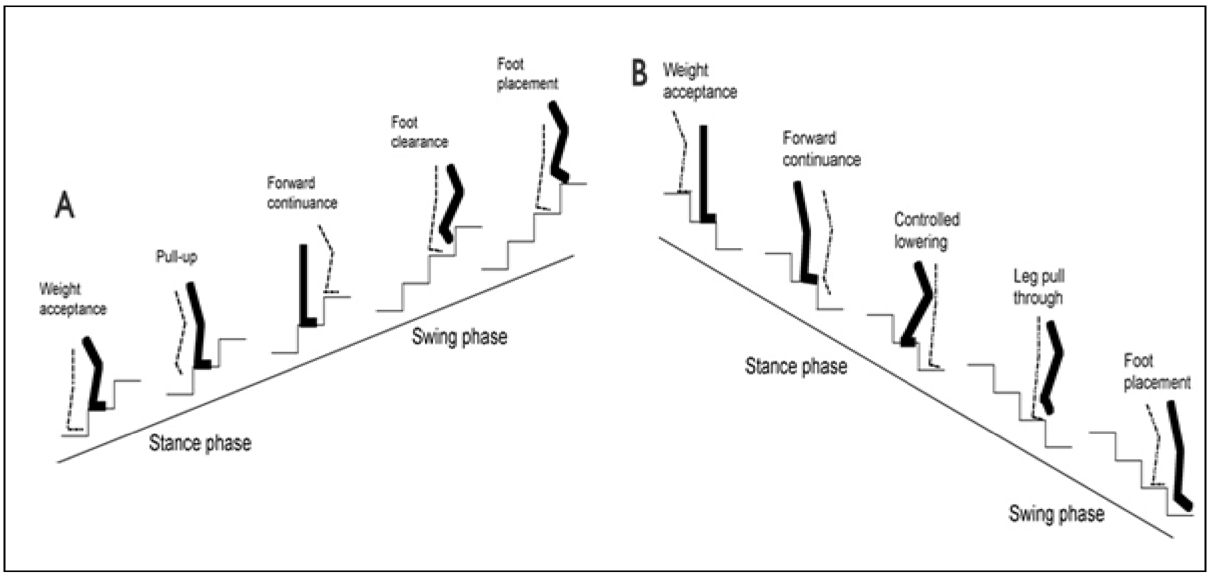


Figure 1.5: Ascending and descending gait cycles (Novak et al., 2010).

1.8. Gait in individuals with medial compartment knee OA

Individuals with medial compartment knee OA demonstrate many adaptive gait patterns compared to the control (healthy) population. These gait alterations are mainly related to pain levels and the severity of OA present, and are also due to muscle weakness which consequently leads to reduced knee and hip ranges of motion (Hurwitz et al., 2000). As the human body systems are working relative to each other, the joints cannot work separately and as such any deformity in one joint could impact on others directly or indirectly. Even though, individuals with medial compartment knee OA complain mainly about knee problems, other joints such as the hip could be severely affected by the application of increasing load on them which could develop hip OA in the future (Valente et al., 2013).

1.8.1 Temporal-spatial parameters

As the speed of walking mainly affects the vertical ground reaction force magnitude (Andriacchi et al., 1977), individuals with knee OA adapt their speed depending on the severity of the disease (Zeni Jr et al., 2009). For example, individuals with a K-L3 classification will walk slower than those with K-L2 (Thorp et al., 2006). Besides that, individuals with knee OA mainly have a high cadence, shorter stride length with higher stance phase percentage and double limb support compared to a healthy non-OA older population (Al-Zahrani and Bakheit, 2002) in order to reduce pain by a rapid dynamic load transfer from affected side to the unaffected side (Baliunas et al., 2002, Takacs et al., 2012). During stair climbing, individuals with medial compartment knee OA have similar characteristics as of walking, but some differences are found between ascending and descending the velocity is slower in AC compared to DC because the movement is against the gravity, while the step width is more in DC compared with AC to provide balance during DC. In addition, the time taken during double limb support is longer in AC to add stability by means of muscle concentric contraction, while the swing phase is longer in DC to control the body mass and control downward acceleration (Hicks-Little et al., 2012).

1.8.2 Kinematics

Medial compartment knee OA impacts on the hip, knee, and ankle joints in the sagittal and frontal planes, but sagittal plane motion is more affected (Al-Zahrani and Bakheit, 2002). Individuals with medial compartment knee OA were shown to have lower knee flexion values than a control group during walking both quickly or slowly (Landry et al., 2007), and walk with six degrees less knee ROM than normal groups (54±7 vs. 60±4) (Kaufman et al., 2001). At IC, individuals with knee OA start with a more extended knee joint (1.8-5.3 degrees) (Mündermann et al., 2008a). This flexion limitation depends on knee OA severity (Astephen et al., 2008a).

During ascending, individuals with knee OA show less knee flexion than their healthy counterparts (Hicks-Little et al., 2011). Evidence has shown that individuals with knee OA climb stairs with less knee range of motion and knee flexion angle (62 and 80 degrees, respectively) than a control group (74 and 130 degrees respectively) (Walker et al., 2001). In stance phase, the results show that the peak of knee flexion angle during ascending is earlier for healthy individuals and individuals with knee OA (19±7 and 32±23% of the gait cycle time, respectively) than descending (51±6 and 54±4% of the gait cycle time respectively). Furthermore, individuals with knee OA have a delay in knee flexion compared to healthy individuals during stair climbing (Kaufman et al., 2001).

Furthermore, Mündermann et al. (2005) found no difference between hip ROM between individuals with medial knee OA and healthy individuals during walking. Also, Hicks-Little et al. (2011) found that there was no significant difference in hip range of motion between individuals with knee OA and a control group during ascending, but the individuals with knee OA show a delay in reaching peak hip flexion.

Trunk and pelvic ranges of motion are also affected by OA. Alterations such as increased anterior pelvic tilt (Linley et al., 2010) and lateral trunk bending towards the swing side have been reported. Amongst unilateral medial compartment knee OA subjects, trunk bending has been shown to be 3.7±0.9 degrees when the involved limb is loaded and 3.3± 1.4 degrees for the non-involved limb more than the control group (Tanaka et al., 2008), which consequently leads to asymmetry in their gait. With regards to the ankle joint, Ko et al. (2010) found that individuals with symptomatic knee OA have a higher ankle range of motion in the sagittal plane than healthy individuals, which can be explained as a compensatory gait due to decrease knee range of motion during walking.

In the frontal plane, individuals with knee OA walk with a greater degree of knee varus during stance phase due to a narrow medial joint space, while the lateral part of knee is open and also walk with a relatively high valgus knee angle during swing phase which could be due to internal rotation of the limb during swing phase (Gök et al., 2002). During descending, they walk with a greater knee varus angle than a control group; however, there is no significant difference in the ankle abduction angle between both groups. A delay in achieving maximum ankle ROM within individuals with medial knee OA is noticed compared to a control group. In addition, individuals with knee OA start ascending with high hip abduction angles and less hip adduction angles (Hicks-Little et al., 2011).

1.8.3 Kinetics

The load transmitted through the knee joint has a role in the development and progression of knee OA. It has suggested that increasing the load on the joint leads to an increase in cartilage breakdown and joint alignment deformity (Arokoski et al., 2000). Therefore, it is important to understand any kinetics changes at the knee and try to alleviate these.

1.8.3.1 Sagittal plane

During level walking, individuals with severe knee OA have a lower internal hip flexion moment in early stance, but a higher internal flexion moment in mid stance than individuals with moderate knee OA. In addition, individuals with severe knee OA have lower external hip extension and ankle dorsiflexion in the late stance during level walking than moderate knee OA groups (Astephen et al., 2008b). With regards to knee joint moments, reduced external knee flexion and extension moments during stance phase are commonly reported as this type of gait is adopted to reduce knee pain (Landry et al., 2007).

However, it has suggested that during stair climbing the net of external knee flexion moment is higher compared to walking on level (7.5 and 4% body weight into height respectively) (Nagura et al. (2002). Furthermore, Kaufman et al., (2001) found that external knee extension moment is higher during descending which mainly increase knee pain and makes the descending task more demanding and a harder activity compared to the ascending for individuals with knee OA.

1.8.3.2 Frontal plane

The most important variable in the frontal plane in medial compartment knee OA is the external knee adduction moment (EKAM) or knee varus moment which is the result of the ground reaction force (GRF) and its distance from the knee joint centre (Hurwitz et al., 2002) passing medially during dynamic loading. It is expressed in units of percentage of the body weight and height (%Bw-Ht.) or Newton metres per kilogram (Nm/kg) (Andriacchi, 1994).

When knee varus is increased, the knee will rotate externally more (Mills and Hull, 1991) which consequently leads to an increase in the lever arm distance between the GRF and the knee centre by shifting the knee joint centre more laterally and centre of pressure more medially (Haim et al., 2008). The EKAM has two peaks and a trough: The first peak is a sharp one after initial contact during early stance phase, while the second one is in the late stance phase (Figure 6). The first peak is affected by the amount of knee varus, joint space narrowing, OA severity, and progression level, while the second one is more correlated to the amount of toe out and pain levels. So, the first peak is more important to distinguish between different severity levels of knee osteoarthritis groups (Sasaki and Neptune, 2010); where, individuals with severe knee OA have a higher first external knee adduction peak than less severe and the less severe group has lower second peak than a control group.

The knee adduction angular impulse (KAAI) is the area under the knee adduction moment curve (Figure 1.6) (Thorp et al., 2006). Therefore, it measures the loading throughout the duration of EKAM, and it is considered more sensitive than EKAM to distinguish between mild and moderate knee osteoarthritis. Also, it is suggested that high KAAI is associated with greater bone marrow lesions and cartilage degeneration (Bennell et al., 2011b). Both peaks of KAAI are affected by walking speed, while slow speed is correlated with high KAAI. Also, the two peaks of EKAM are affected by speed (Kean et al., 2012); however, the trough part of EKAM curve is less affected by speed (van der Esch et al., 2011). Therefore, one should control speed by using a metronome, for example, to eliminate speed effects on EKAM value when any conventional treatments such as orthoses are evaluated in a gait laboratory.

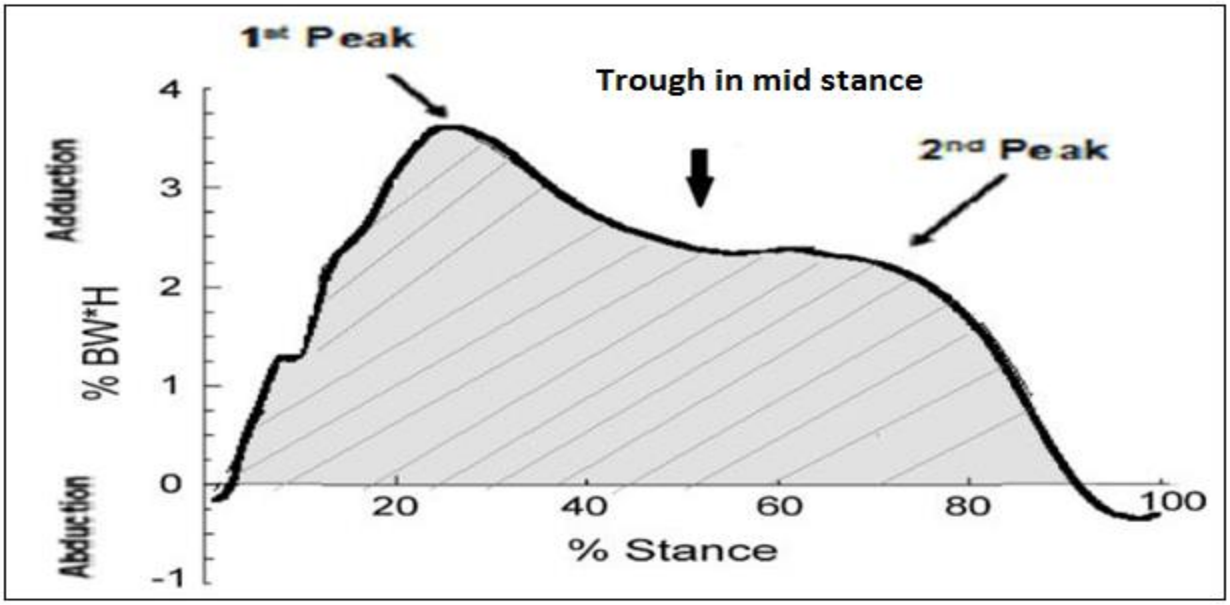


Figure 1.6: KAAI which is the highlighted area under the graph (Thorp et al., 2006).

Individuals with medial knee OA show a higher peak EKAM and knee adduction angular impulse (KAAI) than healthy individuals during walking (Landry et al., 2007, Linley et al., 2010) (Figure 1.7). Moreover, the peak EKAM is higher during ascending and descending than walking, but during descending the EKAM peak is the highest (Guo et al., 2007). Also, symptomatic and asymptomatic individuals with knee OA do not have similar EKAM peaks; for instance, Kean et al. (2012) stated that symptomatic individuals with knee OA have a higher impulsive EKAM than asymptomatic group. The first peak is high for a symptomatic group only; while the second one is high for symptomatic and asymptomatic, but normally the first one is higher than second one.

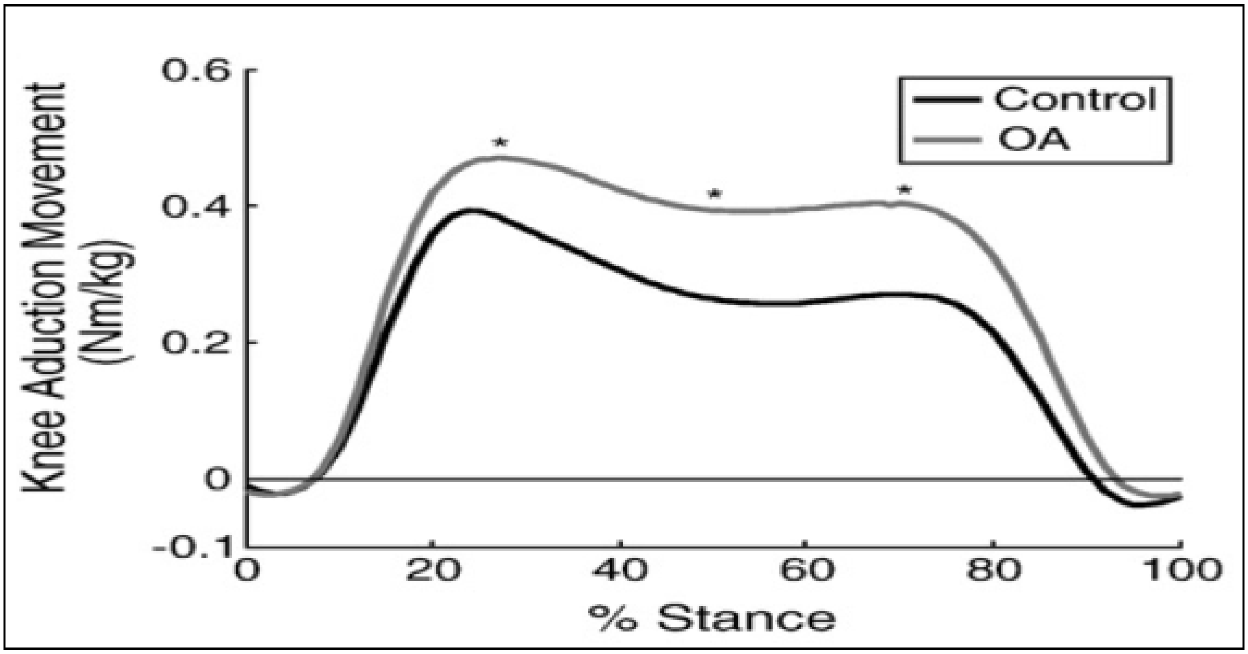


Figure 1.7: EKAM has 2 peaks and it is higher for OA group more than control group (Linley et al., 2010).

Previous studies have shown that when the EKAM increases, the joint space becomes narrower (Miyazaki et al., 2002), stress or load on medial knee cartilage increases (Nicholas et al., 2010), and also bone density under medial plateau increases (Thomas et al., 2000). The anterior cruciate ligament (ACL) will also be affected by an increasing EKAM and an increased risk of ACL tears, ligament laxity and joint instability also can result (Noyes et al., 1992). Progression of knee OA has been shown to increase in individuals with a high EKAM level, as with a 1% increment in EKAM, the risk of OA progression is six-fold (Andriacchi, 1994). Moreover, a 1% EKAM increment leads to 0.63 mm loss in the joint space (Sharma et al., 2004). Therefore, the reduction of EKAM is the primary aim of all interventions by reducing the distance between the centre of pressure (CP) and the centre of knee (Haim et al., 2008). It is suggested that 1 mm displacement of COP laterally can lessen the EKAM by 2% and the load on the knee joint by 1% (Shelburne, et al., 2008). In summary, the EKAM evaluates the load on medial compartment (Thorp et al., 2006), disease progression (Miyazaki et al., 2002), and severity of knee osteoarthritis (Mündermann et al., 2004); and also predicts the severity of pain (Hurwitz et al., 2000), and it is the primary outcome variable of choice in knee intervention studies.

Another variation that could be associated with OA is a high external hip abduction moment and a reduced hip external adduction moment compared to a control group (Figure 1.8). After initial contact, individuals with knee OA have a higher external hip abduction moment (93.3% more than control groups) due to a high hip adductor force to control pelvic drop during single limb support. Low first and second peaks of external hip adduction moment are more commonly seen among individuals with medial compartment knee OA than healthy individuals, and more severe knee OA produces a lower external hip adduction moment than less severe disease (Mündermann et al., 2005).

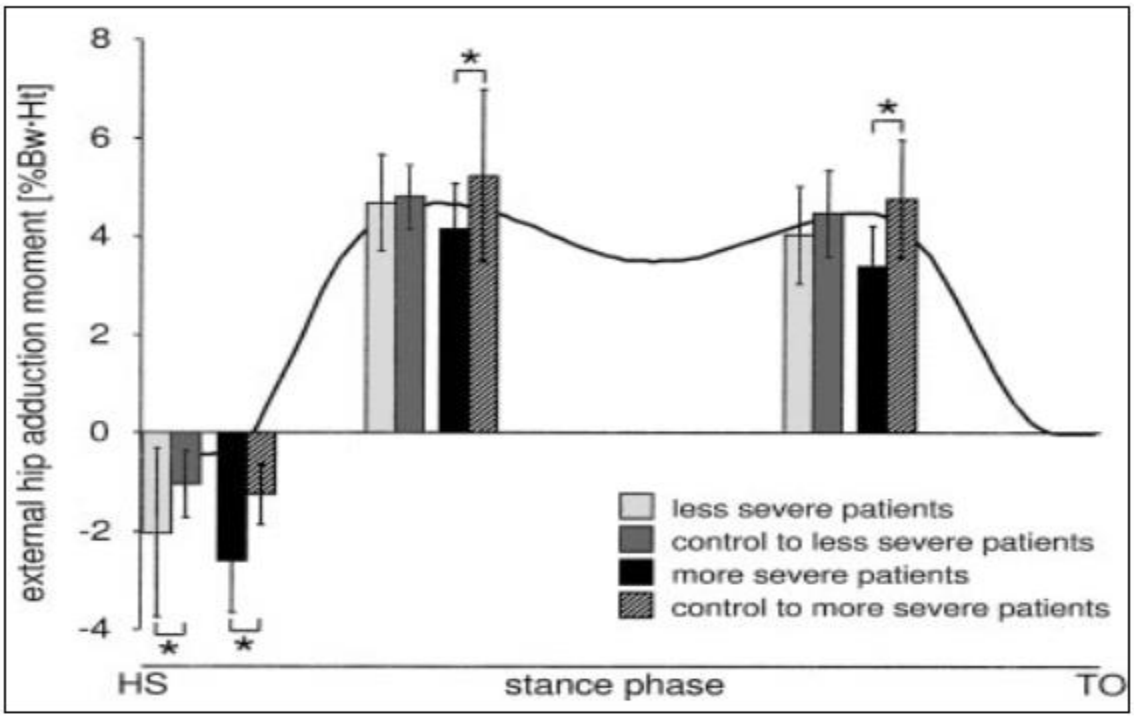


Figure 1.8: Hip adduction and abduction moment for knee OA and control individuals (Mündermann et al., 2005).

1.9. Gait adaptation strategies to reduce EKAM

Due to pain and a higher EKAM, an individual with medial knee OA will try to adapt their gait to reduce the knee load. These adaptations can be characterised by lateral trunk bending, slow walking speeds and toe out and toe in walking.

1.9.1 Lateral trunk bending

It has been demonstrated that pelvic drop increases EKAMs significantly along with OA progression (Zeni and Higginson 2009). It increases the EKAM by shifting the knee load more medially toward the swinging limb (Valente et al., 2013). Also, it has suggested that a pelvic drop increases the load on the knee and hip joints by 18.3% and 19.4% respectively (Valente et al., 2013). To compensate for this, a high hip external abduction moment (lateral bending) will be necessary as a gait strategy to support the pelvis and to reduce the EKAM. Mündermann et al. (2008a) evaluated the effects of lateral bending within a healthy group of older people, and demonstrated that lateral bending reduced hip and knee adduction moments by 57% and 56% respectively, but increased hip and knee abduction moments during walking which suggested that this gait pattern could be helpful for individuals with medial compartment knee OA. However, lateral bending (a waddling gait) may increase pain in the lumbar region during walking (Toriyama et al., 2011, Valente et al., 2013), and increase low back pain (Gombatto et al., 2007, Mcneill et al., 1980). Furthermore, it increases disability and functional impairment for individuals over time (Simmonds et al., 1996) which suggests that it may increase the risk of developing hip OA in the future by increasing the load on the hip (Mündermann et al., 2005, Toriyama et al., 2011).

1.9.2 Reducing speed

Zeni et al. (2009) suggested that speed of walking could be correlated to OA severity; individuals with more severe knee OA walk slower than less severe individuals. Slow walking speed could be a strategy to reduce pain, reduce knee flexion during walking, and then reduce the need for the quadriceps muscles to control this movement; thus, reducing the knee loads (Zeni et al., 2009, Zeni et al., 2011). Individuals with less severe knee OA demonstrated a greater EKAM reduction with a slower gait speed compared to those with severe knee OA. The difference noted was thought to be due to the existence of a high EKAM and varus angle alignment within individuals with severe knee OA which a slower speed cannot reduce extensively (Mündermann et al., 2004).

However, it is worthy to mention that walking slowly can reduce knee load but does not reduce the exposure time of load because walking slowly increases KAAI (Robbins and Maly, 2009). However, walking with a slower speed and shortened stride length is thought to reduce the EKAM (Mündermann et al., 2004).

1.9.3 Toe-out/toe-in walking

A toe-out gait (for example with the foot externally rotated more than seven degrees) can reduce the second peak of EKAM raised to 40 % during walking (Guo et al., 2007, Hurwitz et al., 2002) (figure 1.9a). This may be achieved by shifting the COP laterally and reducing the applied moment distance from the COP to the knee centre and thus reducing the EKAM (Jenkyna et al., 2008). However, no change in first peak value was seen in either of the studies.

During ascending, toe out walking increases the first peak, while second peak decreases by 11% (Figure 1.9b). Nevertheless, no significant differences have been shown between these parameters during descending (figure 1.9c) (Guo et al., 2007).

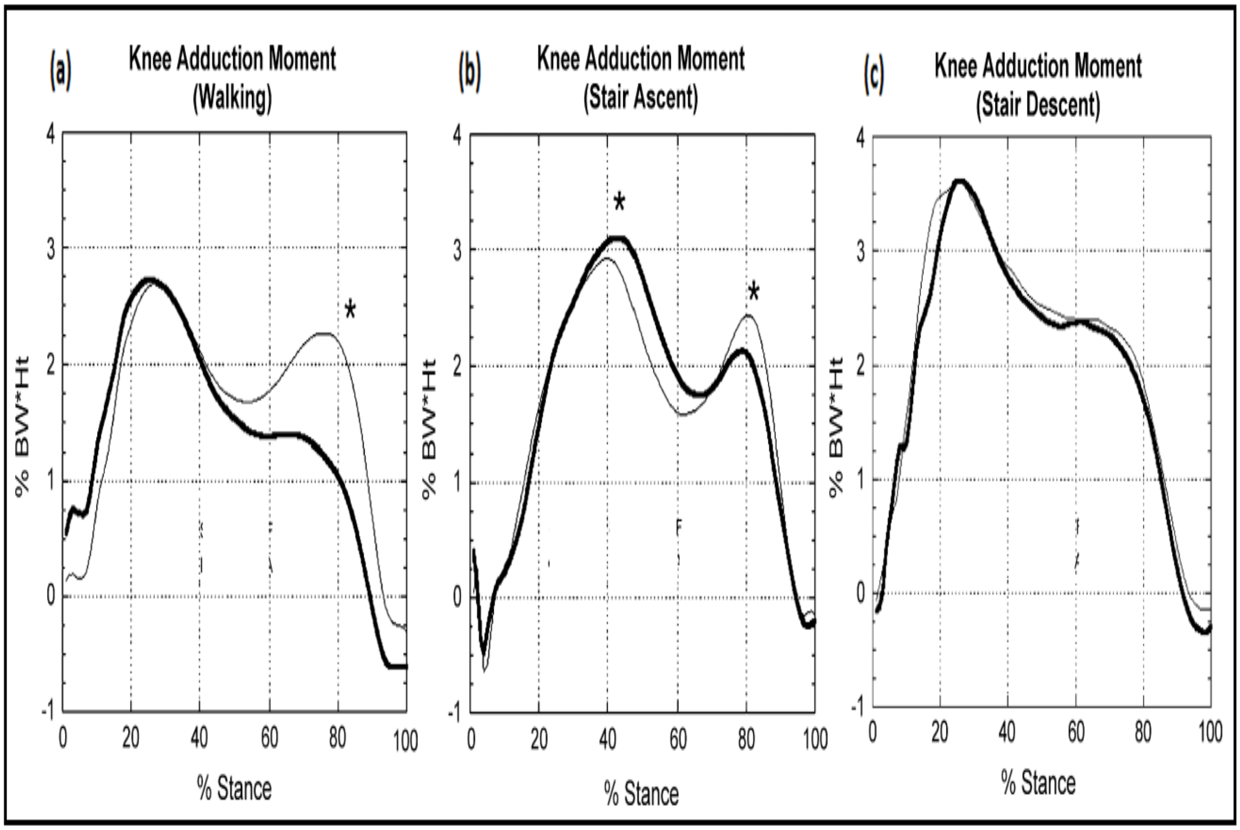


Figure 1.9: The effects of toe-out gait during walking (a), stair ascent (b), and descent (c) Thick black line: increased foot progression angle (toe out), Thin grey line: self-selected foot progression angle (Guo et al., 2007).

However, evidence suggests that a toe-out gait reduces pain (Sasaki et al., 2010), but it also increases knee flexion during walking especially at 10% of gait cycle, and the tension on the quadriceps muscles and the load on patellofemoral joint will increase to control flexion (Jenkyn et al., 2008). As a result, Walter et al. (2010) stated that when an individual increases the external knee flexion moment it may increase load and compression on the knee joint; therefore toe-out walking may not be suitable for individuals with knee OA: even though it can reduce the second peak of EKAM, but it could increase pain during walking as a knee load is increased.

In contrast, toe-in walking (average five degrees) shows a reduction in the first peak of EKAM by 13% and does not increase the external knee flexion moment for individuals with OA during walking and does not affect trunk lateral bending or the tibia angle (Shull et al. 2013). Toe out walking is accomplished by internal rotation of the forefoot and heel lateral rotation which is able to shift the knee center of pressure laterally and the knee center of joint more medially (Shull et al. 2013). Due to the fact that reducing the first peak is considered more important than reducing the second one, it is recommended as a non-surgical treatment rather than toe-out walking.

1.10. Osteoarthritis treatments

Many treatments have been developed for individuals with medial compartment knee OA. Generally, all the treatments aim to reduce pain, symptoms, reduce progression of joint damage, improve activity, and the functional level for knee OA. Therefore, different treatment options are available to the individual depending on disease severity, pain intensity, their degree of activity level impairment, and other knee OA symptoms such as effusion or inflammation. The rehabilitation strategy for medial knee OA consists of surgical interventions, pharmacological treatments, and conservative non- pharmacology treatments (Jordan et al., 2003).

1.10.1 Surgical intervention

Surgical treatment can be by arthroscopy, osteotomy, and arthroplasty surgery. Invasive treatment (arthroscopy) is used when the medical treatment cannot manage the knee joint inflammation. During this procedure, a small needle passes inside the knee joint to remove cartilage and inflammatory debris. This intervention is widely used nowadays because it has a lower risk factor than other surgical interventions (National Collaborating Centre for Chronic Conditions, 2008), and improves the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), which scores within a range between 0 to 2400 points (a high score indicates more severe symptoms). For instance, two years after surgery WOMAC is improved by 874±624 points compared to control group 897±583 points (Kirkley et al. 2008).

Surgery involving a high tibial osteotomy is another intervention used to correct the knee joint malalignmet deformity and for pain relief. During this surgery a wedge of bone is removed from the non-healthy side of the tibia to redistribute the body weight over both tibial condyles

(Benjamin and Trickey, 1969). This intervention is suitable for individuals in middle-age with medial knee OA who have a good knee range of motion without ligament instability. Furthermore, the aims of this surgery are to reduce pain by reducing the load on the medial side and delay OA progression, and also to delay the time before total knee replacement is necessary (Wright et al., 2005). In a study by Billings et al. (2000), 43 individuals with medial knee OA had good to excellent clinical outcomes after this surgery after an average of 8.5 years post-surgery, while 21 of these individuals had a total knee replacement after this surgery at an average of 65 months. This result could be explained by Prodromos et al. (1985) whose study which found that an individual with a high EKAM pre-surgery had a lower clinical outcome than one with a low EKAM pre-surgery.

Arthroplasty (total joint replacement or partial compartment replacement) is the last and the only solution when other interventions cannot manage the knee OA progression, where pain is intolerable, presents at rest and night which limits the activity level of medial OA individuals (Dreinhöfer et al., 2006). Moreover, when an individual’s activity level is impaired such that the individual with medial knee OA cannot climb stairs, walk for six metres to one km, and complains of pain during activity and rest, surgery will be indicated (Swift, 2012). In the UK, around 120,000 knee joint replacement operations are conducted annually (National Collaborating Centre for Chronic Conditions, 2008). Before deciding to perform joint replacement surgery, it is extremely important to know the factors which are related to the outcome after surgery such as the patient’s age as well as their fitness levels to be able to tolerate post-surgery risk; thus, it is not recommended for very old individuals (Chang et al., 2010). Also, obese individuals have a poor outcome after surgery compared to those with a normal weight due to the high risk of artificial joint dislocation (Swift, 2012), and with a high risk of post-surgery infection and skin ulcers (Järvenpää et al., 2010). As there are major risks associated with surgery, surgery is the last resort and other options should be considered first.

1.10.2 Pharmacology treatments

Pharmacology treatments normally include analgesic, non-steroidal anti-inflammatory drugs (NSAIDs), or corticosteroid injections. Analgesics are routinely used as a first choice in knee OA treatment such as Acetaminophen which is able to reduce pain for individuals with mild knee OA over six months, but it is less effective for more severe pain. Diclofenac and Misoprostol are more effective for severe pain, but have more adverse events than Acetaminophen (Pincus et al., 2001).

NSAIDs are the most commonly prescribed drugs for long term use (Brater, 1988). It has been shown that 8.6% of the Dutch community uses it regularly and 17% of them use NSAIDs for the long term (Leufkens et al., 1990). However, there are side effects experienced from using these drugs. According to British Community on the Safety of Medicines, 25% of reported side effect drugs were due to NSAIDs such as Piroxicam, Naproxen, and Ibuprofen (Update, 1986). The side effects of these drugs are high toxicity; for instance, Indomethacin is three times more toxic than Ibuprofen with high risk of peptic ulcer development (Griffin et al., 1991), gastrointestinal bleeding and balance impairment after a long term use (Richy et al., 2004). However, whilst these treatments reduce pain in the individual, there are increase in bone degeneration and OA progression. The annual bone loss for patients who are using NSAIDs was calculated to be 3.4% by Reid et al., (1986). Individuals who ingest NSAIDs enables them to walk with no gait adaptations due to pain and therefore an excessive load on affected joint occurs without pain being felt which consequently leads to increase cartilage and bone degeneration (Richmond et al., 2009). The one aspect of these treatments is that they are only dealing with the clinical pain symptoms and whilst of utmost importance, OA is a mechanical condition, so conservative strategies targeting pain without the complication of toxicity are attractive treatments with additional mechanical benefits. However, using NSAIDs reduces pain, but they increase the knee load and knee OA progression (Schnitzer et al., 1993)

1.10.3 Conservative non-pharmacology treatments

Non-pharmacology treatments are mainly recommended for individuals with less severe knee OA to improve their quality of life, reduce pain during daily activities, and delay surgery time. These types of treatments generally include changing their lifestyle, reducing activities which increase knee loading, performing targeted exercises, and using suitable shoes and orthoses.

1.10.3.1 Education

It is very important to inform individuals with knee OA about their health, how to manage it, and how to adapt their lifestyle according to their health level. Such information includes the advantages of losing weight particularly if their body mass index > 25 as it is a totally essential recommendation and the first step in a rehabilitation program. Other recommendations are to avoid excessive load activity and replace it with walking and low-impact aerobic fitness exercises to avoid joint stiffness or muscles contraction (Richmond et al., 2009).

1.10.3.2 Physical therapy and Exercise

Exercise therapy has been shown to have a significant effect by reducing pain and improving the activity levels for individuals with knee OA after three months follow up assessment (Angst et al., 2001). The evidence shows that exercises may reduce OA progression (Slemenda et al., 1997, Manninen et al., 2001), and may delay the requirement for total knee replacement for individuals with severe knee OA for both men and women (Manninen et al., 2001). Different exercises can be used for knee OA, but these rehabilitation programs have to be without tensional load on the knee joint, contain low impact activities such as walking, swimming, and avoid excessive load exercise such as weight lifting and running because these increase the load on the knee joint and OA progression (Richmond et al., 2009).

Muscle strengthening exercises aim to improve the kinematics and kinetics of the knee joint (Bashaw and Tingstad, 2005), and have been shown to decrease OA symptoms such as pain and improve quality of life for knee OA by 42% (Bennell et al., 2005). Exercise can be active or passive such as mobilization, soft tissue massage, stretching, manipulation, passive movements to the joints and soft tissues to prevent joint contortion or muscles atrophy (National Collaborating Centre for Chronic Conditions, 2008). Muscle strengthening has been shown to provide pain improvement after three weeks of treatment by 73% (Hinman et al., 2003). However, this improvement increases the walking speed in the individuals and increases the overall load on the knee joint; and thus, increases the EKAM (Hunt et al., 2010). Thorstensson et al. (2007) also supports this result as a quadriceps strengthening does not reduce EKAM significantly after eight weeks for individuals with mild and moderate knee OA, and similarly for individuals with severe knee OA after 12 weeks of therapy (King et al., 2008). Likewise, hip muscle strengthening can improve activity levels and reduce pain during daily activity after 12 weeks, but does not significantly alter EKAM values (Bennell et al., 2010). Therefore, whilst exercise addresses the clinical and functional impairments associated with medial knee OA, the mechanical element is still not improved and needs addressing.

1.10.3.3 Footwear and Orthoses

Many different footwear and orthoses (assistive external device) have been designed with the aim to reduce the mechanical load on the knee joint and thus improve clinical symptoms. These assistive devices can be footwear, laterally-wedged insoles, unloader knee valgus braces, and knee-ankle-foot orthoses. Each one has a specific function with the aim to reduce EKAM (Miyazaki et al., 2002) and each will be discussed hereafter.

i. Footwear

The type of shoe which the individual with knee OA uses has to be evaluated carefully because footwear has been shown to have different effects on the EKAM. High heeled shoes should be avoided, as it is suggested that (1.5 inch) heel high is able to increase the second peak of EKAM by 9-14%, and thereby increase knee load particularly with women. However, no significant changes have been seen in the first peak of the EKAM (Kerrigan et al., 2005). Shoes with a six cm heel height with a narrow heel could increase both peak values of EKAM significantly by 18.7% and 19.2% respectively and increase medial knee compression force by 23% compared to barefoot walking (Kerrigan et al., 1998). One shoe which has been designed to reduce this parameter is the mobility shoe (Shakoor et al., 2008) which has been shown to reduce both EKAM and KAAI values by 8% and 6% respectively compared to an individual's own shoe, and also increase walking speed and decrease cadence compared to a barefoot condition. This shoe is lightweight, flexible, has a single thin insole, and a heel height of 1-1.5 cm with grooves inserted at the main flexion point of the foot (Shakoor et al., 2008).

A second shoe has been developed called the variable stiffness shoe which has shown to produce improvement in knee pain and function according to the WOMAC scale after one year of use. This shoe design has 1.3-1.5 more lateral sole stiffness than on the medial side and has been shown to be more suitable for individuals with mild knee OA than those with more severe knee OA (Erhart-Hledik et al., 2012). It also has been shown to reduce the EKAM after six months of use by up to 4.7% compared to normal high street footwear (Erhart et al., 2010), and to reduce the average of EKAM between 2.4% and 6.2% compared to control shoe after short term use (Erhart et al., 2008).

The Gel Melbourne OA shoe is also used for medial knee OA group as a footwear intervention. This modified shoe incorporates a lateral wedge (four to six degrees) with a variable stiffness sole (the lateral midsole is stiffer than the medial midsole and extends to more than two thirds of shoe length. This shoe also produces a significant reduction in EKAM values (mean 7.9 ± 8.9%, 4.7±5.4%, 3.5 ±8.2% for knee OA, healthy overweight group, and healthy weight (control) group, respectively); and KAAI (mean 8.7±11.2%, 7.3±5.6%, 7.8±6.6% for knee OA, overweight, and control group, respectively) (Bennell et al. 2013).

ii. Lateral wedge insoles

Different lateral wedge insoles have been developed which are an attractive, simple and inexpensive treatment. The insoles can be just a heel wedge which fits the heel part only or it can be a full length insole (Figure 1.10 a, b). The lateral wedge started to be used as a conservative interventions for individuals with medial OA in the late 1980s (Sasaki and Yasuda, 1987). The main function of the lateral wedge is reducing the external adduction moment (varus moment), thereby reducing load on medial compartment of the knee with the aim of improving the pain level and improve the quality of life (Bennell et al., 2007, Koca et al., 2009, Skou et al., 2013). A lateral wedge insole reduces the first EKAM peak by applying an abduction moment (valgus moment) by shifting the COP laterally and centre of the knee joint more medially; and thus the EKAM is reduced (Kakihana et al., 2005).

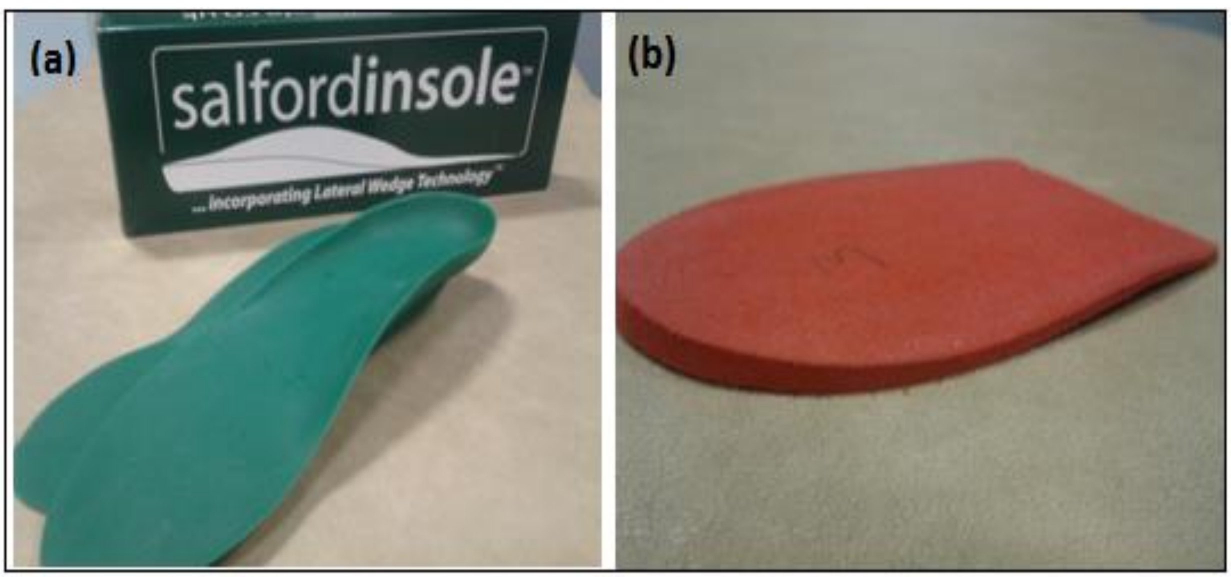


Figure 1.10: (a) full length insole, (b) a heel wedge.

Lateral wedge insoles reduce EKAM by 4-12% for 1 and 2 K-L grade and insignificantly change in EKAM by 3-5% for 3 and 4 K-L grade; therefore, they are recommended for individuals with mild to moderate medial knee OA rather than severe knee OA (Shimada et al., 2005). The full length insole shows best results by reducing EKAM values by 12 % more than a heel wedge and has been shown to be more comfortable because it has a longer lever arm than a heel wedge

(Hinman et al., 2008) and it is able to shift COP laterally by up to five mm (Shelburne et al., 2008). Also a full length lateral wedge characteristic is different depending on type of materials the insole made of, such as cork, silicon, or soft foam. In addition, different wedge inclinations have different effects. For instance, the amount of lateral wedge inclination normally ranges between five degrees (3mm) and ten degrees (6mm). Increased inclination leads to more significant effects on EKAM values, but is less comfortable to be used for a long time. Most insole users have found that a five degrees lateral wedge is more comfortable than a ten degrees one (Kerrigan et al., 2002). It is also recommended that subjects use a laterally-wedged insole for between five to ten hours daily to get the best benefit (Toda et al., 2005).

Many studies investigating the effect of laterally-wedged insoles have been conducted during walking activities, but only one study has been conducted on stairs. In this study the lateral wedge insole demonstrated a significant reduction for first peak of EKAM during ascending (0.37±0.02 Nm/Kg) and descending (0.33±0.05 Nm/Kg) and also reduced the KAAI (Alshawabka et al., 2014).

Using a lateral wedge insole not only reduces the EKAM, but also enhances knee OA clinical symptoms such as pain and activity level (Jones et al. 2013, Arazpour et al., 2013, Bennell et al., 2007, Bennell et al., 2011a). For instance, a study by Baker at al. (2007) demonstrated that pain scores can be reduced by 13.8 points on a visual analog scale (VAS) scale which is considered clinically insignificant. However, Parkes et al. (2013) found that using a lateral wedge can only reduce pain by 2.12 points out of 20 using the WOMAC scale when compared to a neutral insole.

One of drawbacks of using lateral wedge insoles is even though they are a cheaper intervention and more acceptable to use, it has been shown that the decrease in EKAM values was insignificant for severe medial knee OA (Shimada et al., 2006). Also, using lateral wedge insoles increases the external subtalar eversion (subtalar valgus degree) during walking (Abdallah and Radwan, 2011, Kakihana et al., 2004, Pinto et al., 2008), and during stair climbing also (Alshawabka et al., 2014). Also, there is a non-responder group (20%) whose EKAM increased with lateral wedge insole due to high eversion angles which are increased by using lateral wedge insole (Jones et al. 2014).

iii. Knee valgus brace (Unloader)

A knee valgus brace (or unloader brace) is designed to apply an external abduction moment through a three point pressure system and transfer the knee load from the affected side to the unaffected side (Richards et al., 2005, Stamenović et al., 2008) (Figure 1.11). The main difference between the knee valgus brace and other conservative treatments such as lateral wedge insoles is that a brace applies a valgus force directly on the knee joint to reduce the varus moment (Draper et al., 2000). One study, has shown that using an insole with five degrees of inclination reduced both the EKAM and KAAI (12%, 16.1%, respectively) more than knee valgus brace with six degrees of valgus (7%, 8.6%, respectively) during walking for individuals with medial knee OA, and the knee valgus brace was less acceptable to individuals with medial knee OA than an insole (Jones et al., 2013) with the duration of wear being much less. In contrast, a knee valgus brace (with between two to nine degrees of valgus correction has been shown to reduce the first (2.98±1.05, 2.82±0.97 respectively) and second peak (2.78±1.01, 2.61±0.94) of EKAM better than an insole with a three to nine mm inclination for individuals with medial knee OA(Moyer et al., (2013).

The knee valgus brace has been proven to have some biomechanical benefit for individuals with medial OA such as reducing EKAM, pain and improving activity levels (Draper et al., 2000, Ramsey et al., 2007, Richards et al., 2005, Self et al., 2000). EKAM values have been shown to improve between 5.5% up to 33% (Deie et al., 2013, Fantini Pagani et al., 2010b, Lindenfeld et al., 1997, Self et al., 2000).

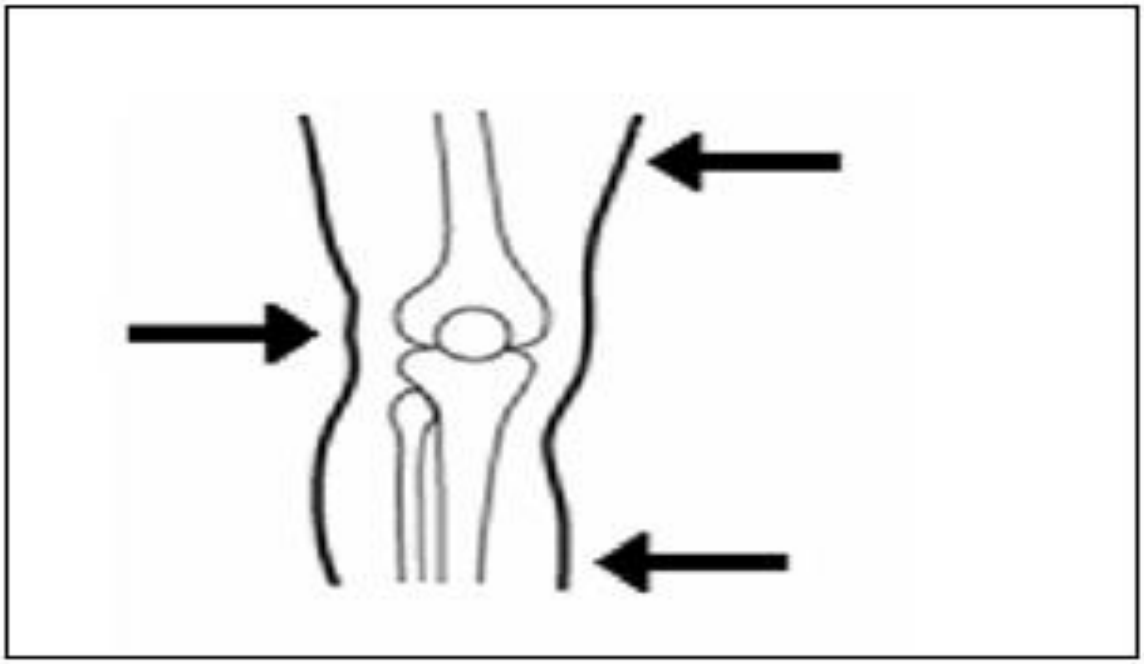


Figure 1.11: The three-point pressure system applied by knee unloader braces (Stamenović et al., 2008).

Knee valgus braces have also been used to evaluate the knee load for healthy participants where a reduction in EKAM raised to 18% was found compared to a no brace condition (Fantini Pagani et al., 2010b). Knee braces with a valgus correction angle of 4 and 8 degrees using an off-the-shelf (OTS) type have also been shown to significantly reduce EKAM by 18%, 21% respectively, and KAAI values by 14% and 18% respectively during walking (Fantini Pagani et al. 2012). Also, walking with the knee valgus brace in four degrees of correction reduced KAAI and EKAM values by 29% and 25% during walking, while these parameters were only reduced by just 15% and 12.5% respectively when using a flexible knee brace for individuals with knee OA (Fantini Pagani et al., 2010a).

Arazpour et al. (2013) in their study of a bespoke knee valgus brace showed that wearing a knee valgus brace reduced the knee adduction angle and increased the knee ROM in sagittal plane significantly, but that improvement in knee ROM was still three degrees less than that produced by an insole (46 degrees vs. 49 degrees respectively). In contrast, total knee ROM can be reduced significantly due to reducing knee flexion during swing phase compared to baseline (55±9.3 and 60.1±8.8 degrees, respectively), and prevented full extension at late swing (Fantini

Pagani et al. 2012) which might be due to the weight of brace. Knee valgus braces have been shown to reduce knee flexion angles by up to 10.5 degrees and knee adduction angles up to six degrees during walking (Taghi Karimi et al., 2012). Also, no significant changes were noted in knee ROM after using a knee valgus brace for three months during walking and stair climbing (Al-Zahrani, 2014).

Besides the positive biomechanical benefits, using a knee valgus brace has also shown clinical benefits such as reduce knee load and pain with improved activity levels for individuals with medial knee OA (Draper et al., 2000, Richards et al., 2005, Shelburne et al., 2009). It has also been suggested that a knee valgus brace is more effective in improving activity levels (walking distance according to Lequesne scale) and pain than an insole; in particular for moderate to severe individuals (Sattari et al., 2011). For example, using a knee valgus brace for individuals with medial knee OA (K-L3) reduced pain by 48% on a VAS scale and improved activity levels by 79% based on the Cincinnati knee rating system compared to healthy individuals (Lindenfeld et al., 1997).

A knee valgus brace can be off-the-shelf (OTS) or custom made. The custom made brace shows better overall results for pain reduction, activity improvement with better fitting, more comfort, and proprioception level. The custom-made knee valgus braces also show a significant difference in knee adduction angle reduction (1.3 degree), and EKAM is also reduced more with using custom knee valgus brace compared to OTS during walking (the average peak EKAM was 5.9%± 2.0%, 6.6% ± 2.2% Nm/kg, respectively compared to the baseline (6.9% ± 1.9% Nm/kg) and during one-stair stepping (average was 5.2% ± 2.5%, 6.3% ± 2.2% Nm/kg, respectively compared to baseline (6.9% ± 2.3% Nm/kg) (Figure 1.12) (Draganich et al., 2006). However, there is a 50% increase in cost for a custom knee valgus brace in comparison to an off-the-shelf device.

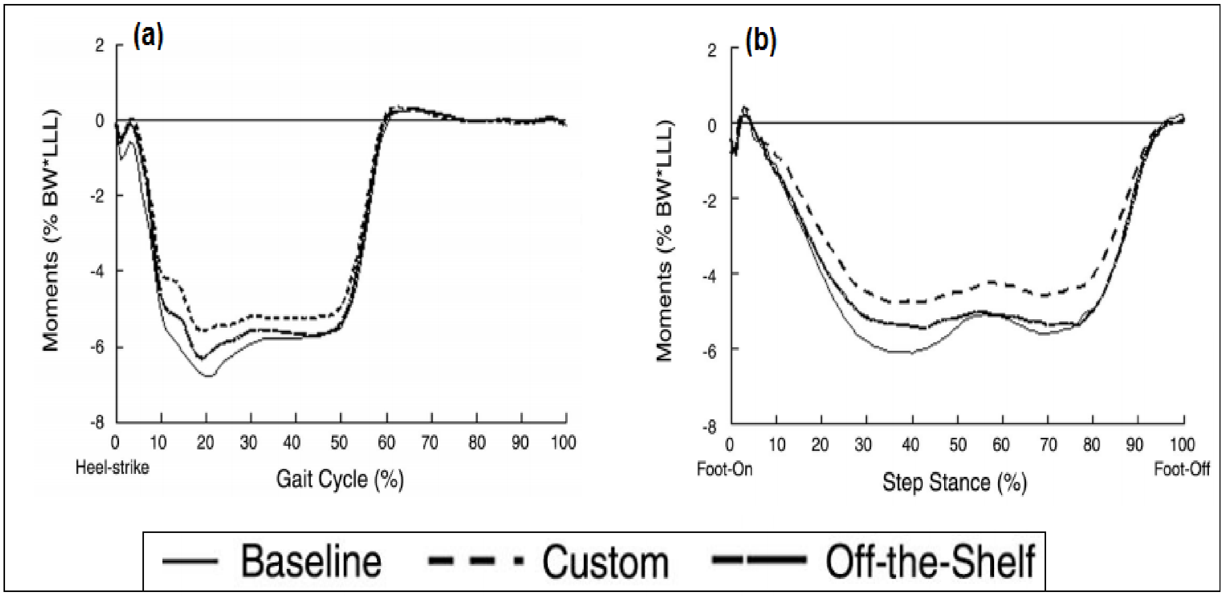


Figure 1.12: EKAM after using knee valgus brace during walking (a) and stairs stepping (b).LLL: lower limb length (Draganich et al., 2006).

During stair climbing, knee valgus braces show some advantages in the treatment of medial knee OA. For example, the custom GII knee valgus brace has been shown to reduce the varus deformity over a period of two months use from 185 degrees to 183 degrees during walking and also to decrease pain during ascending and descending according to Matsuno et al., (1997). However, using UnloaderOne knee valgus brace for three month insignificantly reduced knee adduction angle by 9.8%, 0.7%, and 9.5% during walking, stair ascent, and stair descent respectively compared to the shoe at baseline according to Al-Zahrani study (2014).

With regards to hip moments, a knee valgus brace has been shown to produce a reduction in the second peak of external hip abduction moment by 7.14%. This is because the knee valgus brace is associated with lateral pelvic tilting to reduce the knee load by shifting the load closer to the knee centre, and producing a reduction in hip adduction angle by 2.5 degrees. However, no changes in hip flexion and extension moment were seen during walking with UnloaderOne Ossur knee valgus brace (Taghi Karimi et al., 2012, Toriyama et al., 2011) (Figure 1.13).

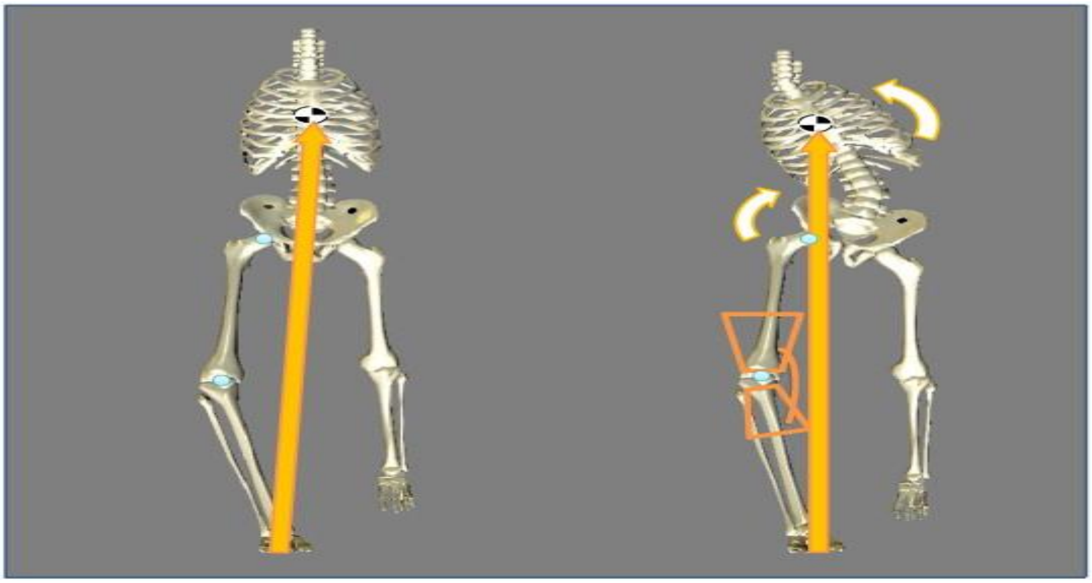


Figure 1.13: Lateral bending toward the stance phase side is associated with using knee valgus brace (Toriyama et al., 2011).

Further literature, in knee valgus braces such as those offering eight degrees of correction, show significantly reduced peak ankle eversion angles (5.7 ±1.9 and 6.7 ± 2.0 degrees respectively) and peak ankle eversion moments (0.067±0.045 and 0.074 ± 0.049 Nm/kg, respectively) during walking compared to walking without a knee valgus brace test condition. However, no significant changes were seen with using four degrees knee valgus brace (Fantini Pagani et al. 2012).

Contrastingly, 11 medial knee OA participants who were treated with custom knee valgus brace reported insignificant reductions in EKAM between using four degrees and without a knee valgus brace condition which could be due to high varus angle in participants (was up to ten degrees) (Pollo et al., 2002). Additional studies show that after using an off-the- shelf knee valgus brace for almost one year no significant changes were seen for EKAM, hip adduction moment, knee flexion/extension moment, and ankle inversion/ eversion moment (Hewett et al., 1998). Furthermore, according to a study by Al-Zahrani (2014), no significant changes in EKAM and KAAI were found after using an UnloaderOne brace for six months during walking and stair climbing for individuals with medial knee OA. Gaasbeek et al., (2007) in their study which investigated the effect of OTS knee valgus braces type with an air chamber for six weeks for individuals with medial knee OA with average 5.1 degrees of knee varus deformity shows that the peak value of EKAM did not reduced significantly and knee range of motion in sagittal plane was reduced significantly due to reduce knee extension at mid-stance and mid swing phase. These results could be due to the short length of knee valgus braces which reduces the ability to apply enough force to correct the knee varus deformity, thereby the knee load.

Furthermore, using a knee valgus brace has some limitations such as the ability to rotate during walking and providing a limitation in walking ability (Redford et al., 2005). It is difficult to fit individuals with high body mass which leads them to abandon its usage due to pressure on distal aspect of the tibia (Divine et al., 2005); also a knee valgus brace may restrict knee flexion and reduce knee ROM (Richards et al., 2005, Jones et al., 2013). Additionally, some types of OTS knee valgus braces have a bulky design, and are uncomfortable to use for long period because of the tight straps around the knee joint (Stamenović et al., 2008). As a result, 20% of individuals with medial knee OA stop using knee valgus brace after six months due to knee swelling or possible development of a thrombosis (Giori, 2004) or after one year and half due to knee instability (Liu et al., 1998). A total of 25% of individuals with knee OA reported continued regular use of a knee valgus brace for two years; however, no radiological or clinical changes are reported with ongoing usage, while the rest complain of skin irritation, discomfort, poor fit (Squyer et al., 2013); thereby only 1% of 5,187 individuals with knee OA within five years were recommended in a study to use knee valgus bracing (Dhawan et al., 2014).

iv. Knee Ankle Foot Orthoses (KAFOs)

One other option is to use a Knee Ankle Foot Orthoses (KAFOs) which are another type of lower limb above knee orthoses to control the hip, knee and ankle joints. A KAFO design mainly consists of a thigh shell, a shank shell, and an ankle/foot section with lateral or bilateral side bars (uprights). They also can incorporate single or bilateral orthotic knee joints with or without an orthotic ankle joint. Many types of KAFOs have been developed, but generally KAFO can be conventional (metal with leather) or cosmetic (plastic or carbon fibre). A conventional KAFO design has metal or carbon fibre side members (uprights) with proximal thigh structures made from leather with a padded inner surface mounted on a metal superstructure. Cosmetic types can be manufactured using thermoplastic, laminated plastic, or carbon fibre for the superstructures which are less heavy than conventional KAFO, more cosmetically acceptable, and easier to don and doff (Bowker, 1993).

KAFOs are routinely prescribed for neuromuscular diseases such as poliomyelitis, Gullian Barre syndrome, and quadriplegia, osteomyelitis of the femur, genu valgum, genu varum, genu recurvatum, femoral fractures, or Blount's disease (Taktak and Bowker, 1995). A KAFO manages a knee varus deformity by maintaining the tibia in a neutral position and controls the ankle joint. The orthotic knee joint restricts adduction and abduction of the knee; usually by the addition of corrective forces via the superstructure. One orthotic knee joint (the offset joint) can correct a knee varus/ valgus deformity up to ±75 mm (Johnson et al., 2004), and produce a 50-90% reduction in tibia varum (Whiteside, 2011). Furthermore, KAFOs with offset knee joints are able to increase knee flexion and prevent hyper extension because the centre of movement for the offset orthotic knee joint is located posterior to the upright which means the wearer can achieve knee flexion with a lower flexion moment (Johnson et al., 2004). Therefore, a KAFO can be expected to support the anatomical knee joint in all planes. Furthermore, the absence of straps around the knee joint may be more comfortable for long term use without restricting knee flexion unlike the knee valgus brace.

In addition, walking with a KAFO alters the knee moment in the frontal plane by applying three point pressure to correct knee alignment deformity (Brehm et al., 2007) (Figure 1.14), which potentially decreases load on the knee and may delay osteoarthritis progression (Hurwitz et al., 1997). In one study, a light weight KAFO has been shown to increase speed (3%), increase knee flexion (2.2 degrees), improve COP progression in mid-stance (1.3 mm) compared to an old heavy weight KAFO by improving the foot and ankle rockers to give a more effective push off for 20 polio patients (Brehm et al., 2007).

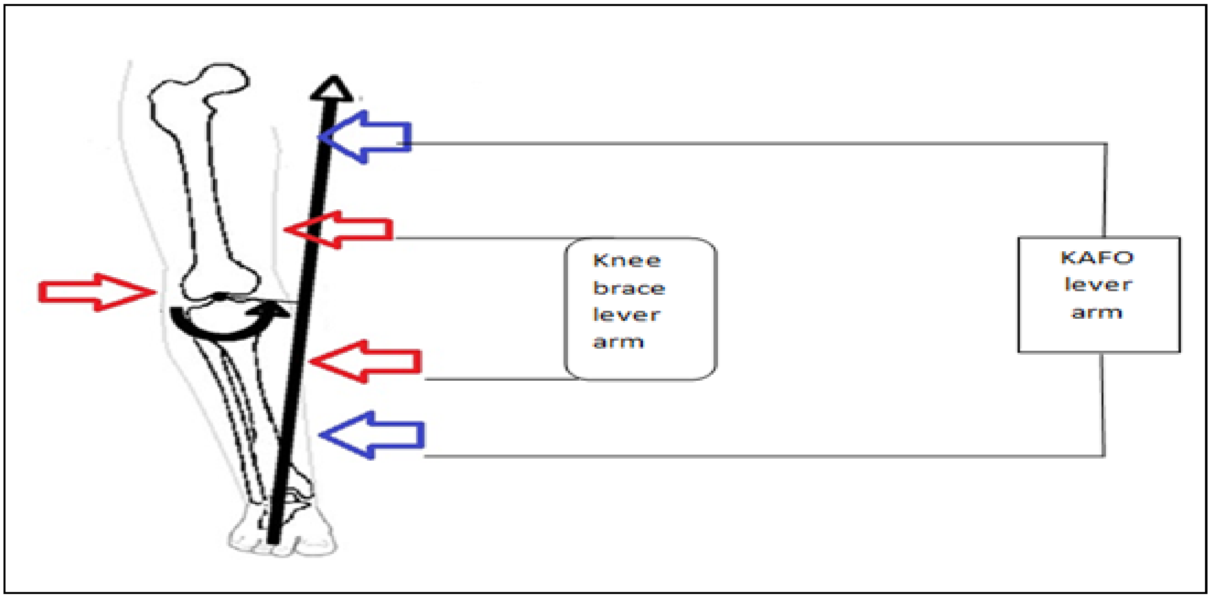


Figure 1.14: Difference in length between a knee brace and a KAFO.

Furthermore, it has been shown that a KAFO is able to reduce lateral trunk bending by six degrees (Hebert and Liggins, 2005). The mechanism by which a KAFO reduces lateral bending could be explained by the fact that it can increase hip adduction, which negates the need to bend the trunk laterally so much, because a KAFO can prevent an excessive hip abduction by means of the higher thigh shell compared to the knee valgus brace (Figure 1.14), which is able to support the hip joint and the hip abductor muscles (Yakimovich et al., 2006). Secondly, KAFOs with an unlocked orthotic knee joint allow increased knee flexion during swing phase to help avoid hip hiking or bending to make toe clearance (Yakimovich et al., 2006). Also, this type of KAFO reduces hip bending and controls hip coronal plane motion more effectively than a locked one (Yakimovich et al., 2006). However, it is not known whether a KAFO would benefit an individual with medial knee OA or an individual with a varus deformity whom is likely to develop into medial knee osteoarthritis, it is suggested that KAFO could be able to reduce knee varus angle and EKAM.

In summary, using a lateral wedge insole is cheap, but does not change EKAM to a large amount and there are inconsistent reductions between individuals. In addition, using a knee valgus brace reduces EKAM better than lateral wedge in some studies, but this increases lateral trunk bending and reduces knee flexion during swing phase. Therefore, this study aims to evaluate the biomechanical benefits of using a custom made KAFO in comparison to a standard shoe, well-established custom-made and off-the-shelf Ossur UnloaderOne knee valgus braces on knee load in a healthy individual with a knee varus angulation. Moreover, the hip and knee range of motion will be examined to find which intervention is more useful to improve and support the hip and knee joints. Ankle joint data will also be examined as a secondary outcome to evaluate the effects of a KAFO on ankle joint alignment and range of motion. The results of the study will help us to further understand the biomechanical effects of a KAFO in a varus knee deformity and will help to determine if a KAFO is suitable to be used for individuals with medial knee OA as a conservative intervention in future. However, before embarking with the comparative KAFO study, it was necessary to examine the reliability of the interlaced stairway which was used during the KAFO study for the stair climbing condition. Therefore, Chapter two will discuss the methodology, while Chapter three will review several studies exploring the reliability of different stairway designs.

Therefore, the following aims and hypotheses are presented:

- To determine if a KAFO is able to reduce knee load significantly.

Hypothesis: A KAFO reduces EKAM values significantly more than custom or off-the-shelf knee valgus braces during walking and during stair climbing in subjects with knee varus angulation.

- To determine if a KAFO is able to increase hip and knee ranges of motion significantly.

Hypothesis: A KAFO increases hip and knee ROMs significantly more than custom or off-the-shelf knee valgus braces when walking and during stair climbing in subjects with knee varus angulation.

Chapter two: Methods

Chapter one detailed how a KAFO could be effective in correcting primary knee alignment problems associated with individuals with medial compartment knee OA. A KAFO could be a viable alternative form of orthotic intervention in this group; especially in those individuals who are not responsive to other forms of orthotic treatment. The long corrective lever arms associated with KAFOs compared to unloader knee valgus braces makes KAFOs potentially more suitable to those individuals who are unable to tolerate high interface forces and for individuals whose knees are more resistant to coronal plane correction, plus those with more advanced disease or with excessive femuro-tibial varus angulation.

It was therefore logical to test a specific design of KAFO on the subjects suffering from a knee varus deformity whilst undertaking specific activities in a gait laboratory setting to determine its efficacy in improving specific primary outcome measures. Alterations to the EKAM, gait kinetics and kinematics and other pertinent parameters were chosen as parameters to be tested to provide a comparison to other types of knee orthoses to enable an analysis of the efficacy of a KAFO as a form of orthotic intervention, and the feasibility of offering this type of orthosis as a viable alternative for individuals with medial compartment knee OA. However, due to short time of the project and the specific criteria which the subjects should have, only one subject was accepted in the main study.

The general methodological details utilised in this thesis such as the gait laboratory equipment, data reduction techniques, the processing of the data collection, and the data analysis procedures which were used are detailed in the following sections. The participant demographics and also the interventions and procedures utilised are presented in chapters three and four.

It was thought prudent to perform an initial feasibility study to confirm that the method used during biomechanical testing was robust and repeatable and also to give an indication of the effect size which may be expected in a future larger study.

2.1. Measurement system

Sixteen Qualisys Oqus computerised motion analysis system (Qualisys AB, Gothenburg, Sweden) infra-red motion cameras were used during gait laboratory testing to obtain raw three-dimensional coordinates of retro reflective markers which were placed on the lower limbs of the individuals during walking and stair climbing activities. A sampling frequency of 100 Hz was used. Two force platforms (AMTI: Advanced Mechanical Technology Incorporation, Watertown, USA, model BP600400) embedded in a walkway were used to collect kinetic data at a frequency of 1000 Hz. An interlaced staircase (AMTI, USA) with three steps which were 18 cm in height, 26 cm depth and 60 cm wide (Figure 2.1a) was attached to two force platforms by six securely fitting screws within the walkway (15 metres long, 6 metres wide) (Figure 2.1b). The lowest step and the highest step were attached with the second platform, and the middle step was attached with the first floor. Thus, the first platform measured the force applied to the floor which is immediate before the lowest step and the second step, while the second platform measured the force applied to the first and third step of the staircase in order to enable data capture for the same leg.

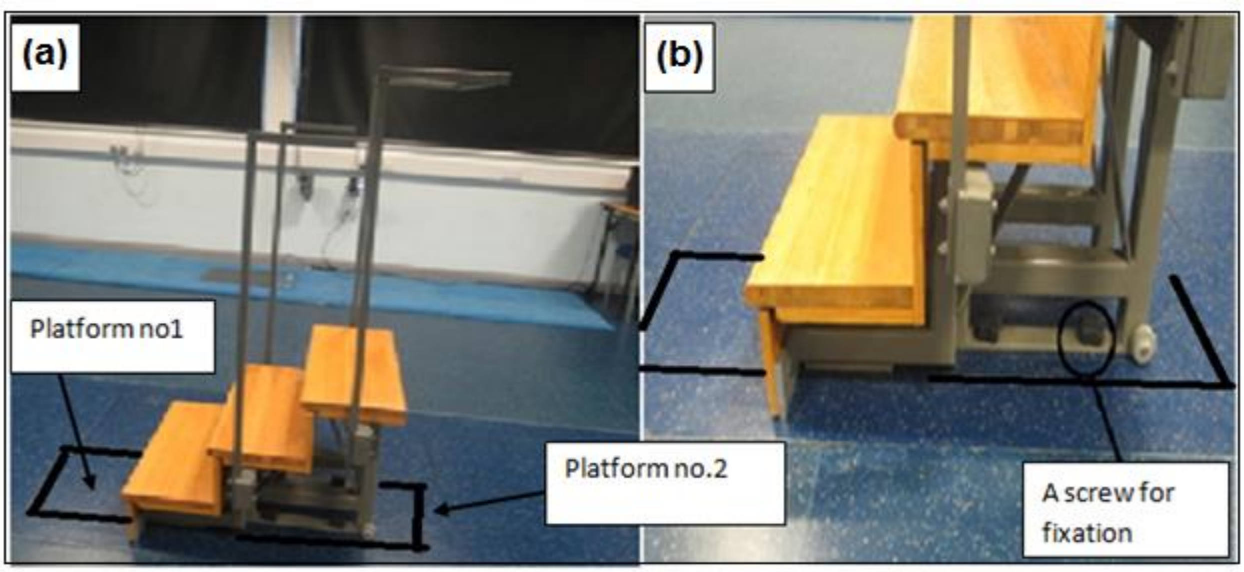


Figure 2.1: Stairway design with two platforms to collect the kinetic data (a): screws for fixation (b).

2.1.1 System calibration

Calibration of the system to produce a calibrated volume was carried out using an ‘L’-shaped metallic structure to represent the global coordinate system (Figure 2.2b). This was undertaken without the staircase in place. The ‘L’ frame contains four markers: three markers attached to the X-axis and two markers to the Y-axis. A dynamic calibration as performed by fixing the ‘L’ shape structure on the medial corner of the first platform and the calibration wand (with a fixed distance between three markers) (Figure 2.2c) was waved within the location of the walking data to provide a data capture. The calibration was accepted if the standard deviation (SD) of the wand and the wand residual were less than one mm to ensure that the camera system covered the most of the motion capture volume (Figure 2.2d). The laboratory coordinate system was then defined by three axes (in positive and negative directions). The X-axis was defined as the anterior-posterior (forward/backward direction), the Y-axis was defined as medio-lateral (left/ right), and the Z-axis as proximal-distal (upward/downward) (Figure 16a).

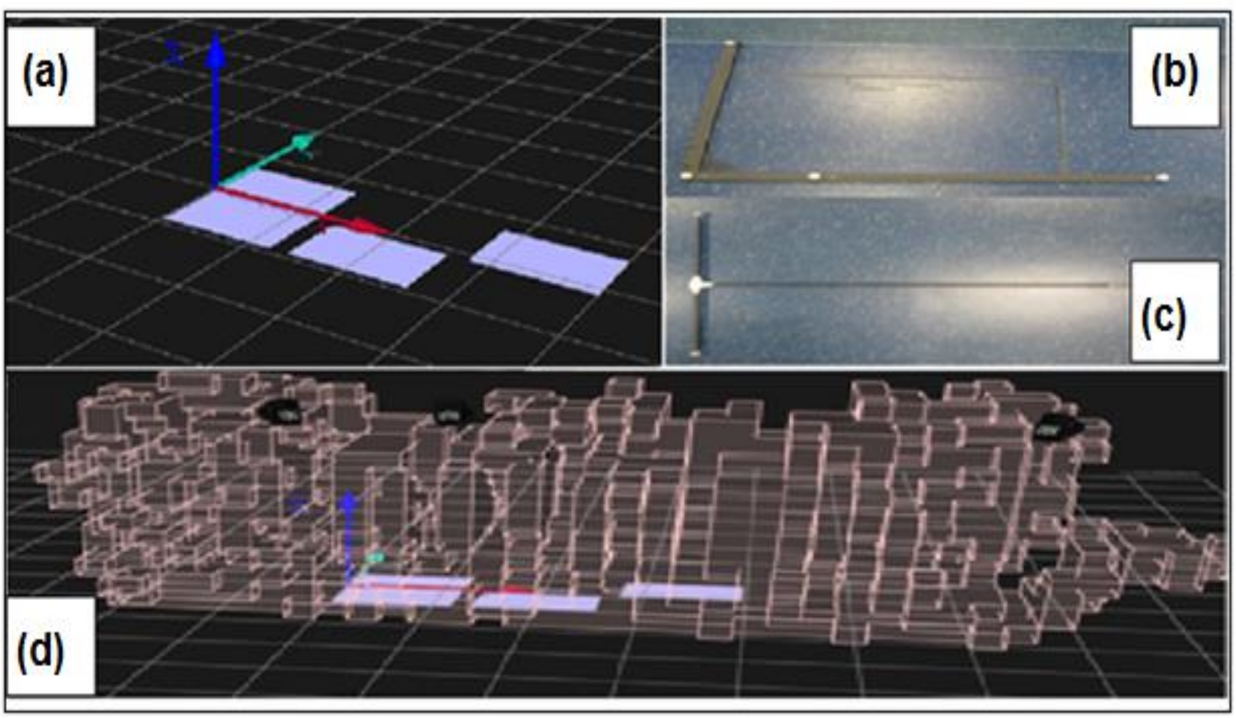


Figure 5: system calibration process. Red is positive X axis, green arrow: positive Y axis, blue arrow: positive Z axis (a). L-shaped metallic structure (b), wand (c), and image space (d).

2.1.2 Reflective markers

Lightweight passive reflective markers were used so that the infra-light was reflected from the markers into the infra-red camera lenses (Figure 2.3a, b). These markers were placed either directly on the skin or fixed on rigid clusters (which utilised a rigid polypropylene plate on which four markers were mounted to make them dynamic tracking markers to identify the anatomical body segments and joints) (Figure 2.3c). The reason for using the clusters was to reduce soft tissue artifacts during movement (Cappozzo et al. 1995). This marker placement system is called the calibration anatomical system technique (CAST) which was developed by Cappozzo et al. (1995). According to this system, the markers are located on the medial and the lateral aspects of the anatomical landmarks (anatomical frame), and proximal and distal part of body segments, while a cluster (technical frame) is placed over the fleshy area of each body segment. Thus, the CAST system identifies the body segment by the relation between the anatomical landmark coordinate frame and technical coordinate frame (cluster) during static calibration. The majority of the anatomical passive markers can then be removed after the static calibration and then the system utilizes the movement from the clusters to reduce the absolute error of passive markers.

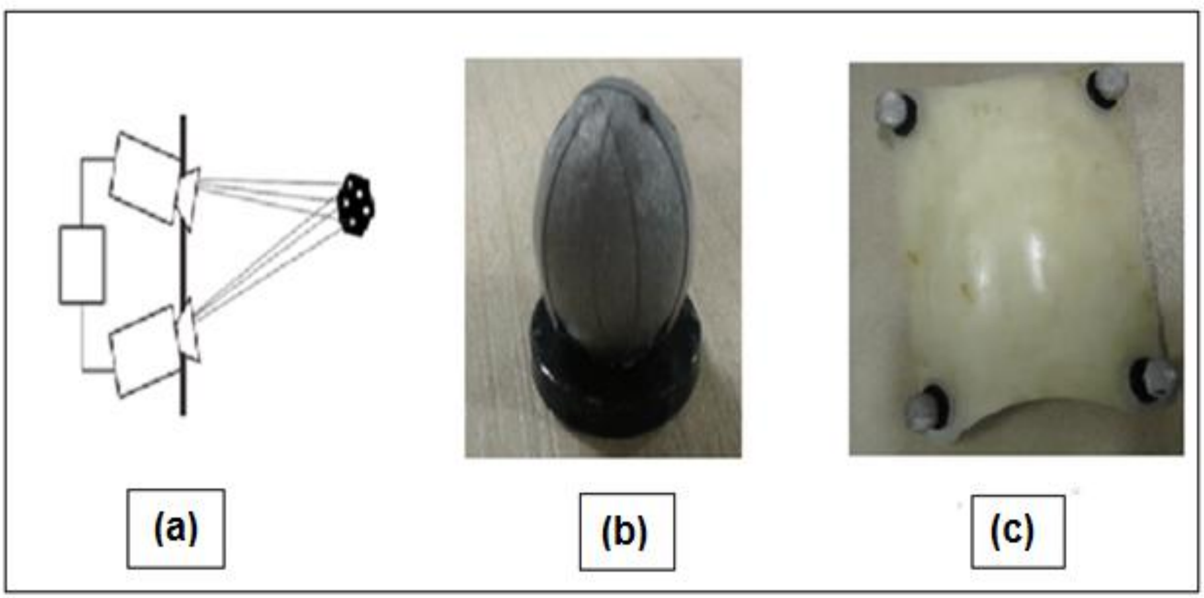


Figure 2.3: Marker reflect light back to the cameras (a), passive reflective marker (b), and cluster marker (c).

2.1.3 Subject procedures and calibration

All participants for the both studies (the reliability and KAFO studies) were examined in Podiatric laboratory in University of Salford (for the reliability study two different sessions over a week, for the intervention study a one visit session was used). Before any session, the laboratory was prepared by checking the cameras connectivity, conducting the system calibration, and preparing the markers as per the manufacturer's recommendation.

Upon the participants arriving at the gait laboratory, the individual was briefed through each study and the objectives of the investigations were explained. The consent form was completed and signed and their demographic details such as date of birth, height, and mass were recorded. Retro-reflective markers (12 markers for each lower limb side) were attached to bony landmarks using hypo-allergenic adhesive tape over bony landmarks on both of the lower limbs at the foot /shoe (on the first, second and fifth of metatarsal heads, and calcaneal tubercle), the ankle (medial and lateral malleolus), the knee (lateral and medial femoral epicondyle), thigh (greater trochanter), and the pelvis (anterior superior iliac spine, posterior superior iliac spine, iliac crest). Also five fixed cluster pads made of polypropylene (with four markers on each) were attached anteriorly to the mid of the shank, mid of thigh, and on the sacrum (mid line of the back) using fabiofoam super wrap bandages and a pelvic belt to ensure that migration of these plates down the limbs was minimised (figure 2.4).

Figure 2.4: Location of the markers and clusters.

The static alignment was captured by asking the individual to stand over one of the force platforms whilst crossing their hands on their chest and a static three-dimensional image from the sixteen infra-red cameras was obtained. After checking that all of the markers were present, the anatomical landmarks were removed leaving only the plastic cluster plates on the shank, thigh and pelvis, and the markers on the foot/shoe. The details of the individual procedures for the different studies are discussed later in this document (section 2.4 and 3.3).

2.2. Data processing (Reduction)

2.2.1 Digitising and Labeling

After each data collection session, the data were saved on a secured protected computer which was accessible to the research team only. The three-dimensional trajectory markers were labeled using Qualisys Track Manger (QTM™) software (Qualisys AB, Sweden). Data gaps were filled to a maximum of ten frames using a polynomial interpolation cubic spline which is able to smooth the small random digitising errors of the markers during the movement (Woltring e al., 1985).

2.2.2 Modeling

All data were then exported to C3D files to be imported into Visual 3D™ software (C-Motion, USA, version five). A six-degree of freedom model was built to give a full picture of the joints' coordination and orientation in space after labeling the markers (Figure 2.5 a, b). This model examines the linear movement and the angular movement in the three planes (three rotations and three translations) by establishing a rigid body frame based on segments linking the hip, knee, and ankle joints (Figure 2.5c). The hip joint centre was determined by anterior superior iliac spine markers (ASIS) which uses a regression equation and it is determined by 14% of average distance between the left and right ASIS, and also a position 30% distally and 19% posterior to this point (Bell et al., 1990). The knee centre was determined by the medial and lateral knee markers, and the ankle joint centre was identified by the medial and lateral malleoli. The participant's height and mass were entered and the model then calculated the segments centre of mass, and segment radius based on the anthropometrical indices published by Dempster (1955).

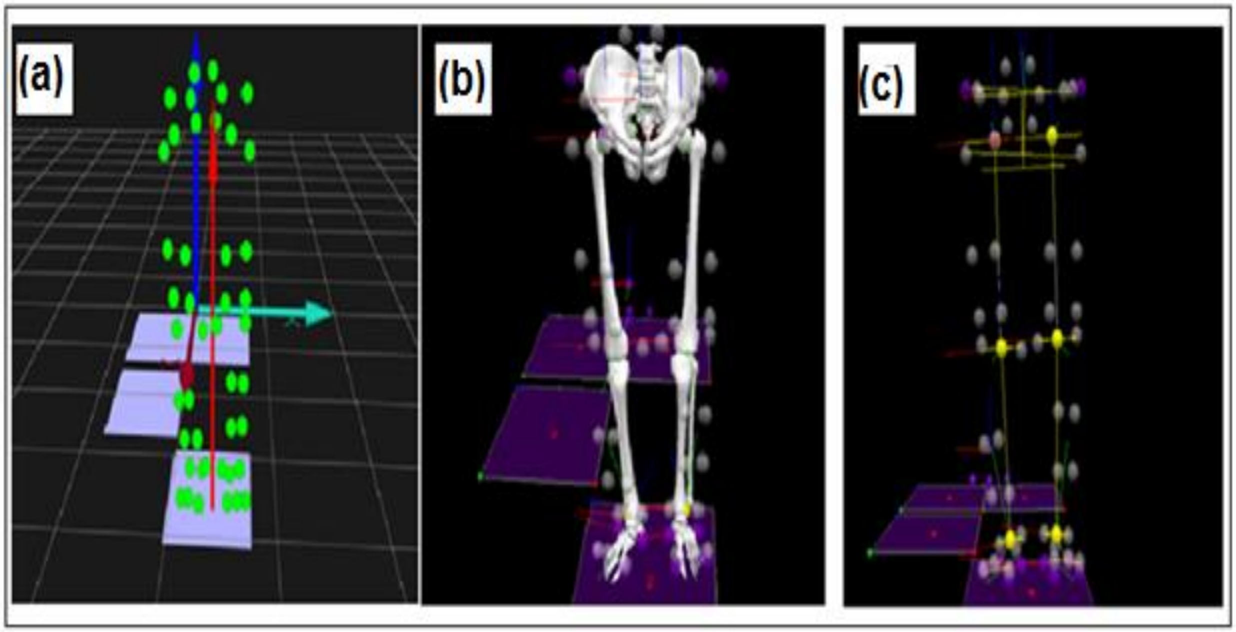


Figure 2.5: Modeling process. Labelling (a), modelling (b), joint centres of motion (yellow) (c).

To collect kinetic data during stair climbing, two force structures in Visual 3D™ were added. The location and dimensions between stair corners were computed in relation to the global coordinates and the two force platforms using AMTI force structures (figure 2.6).

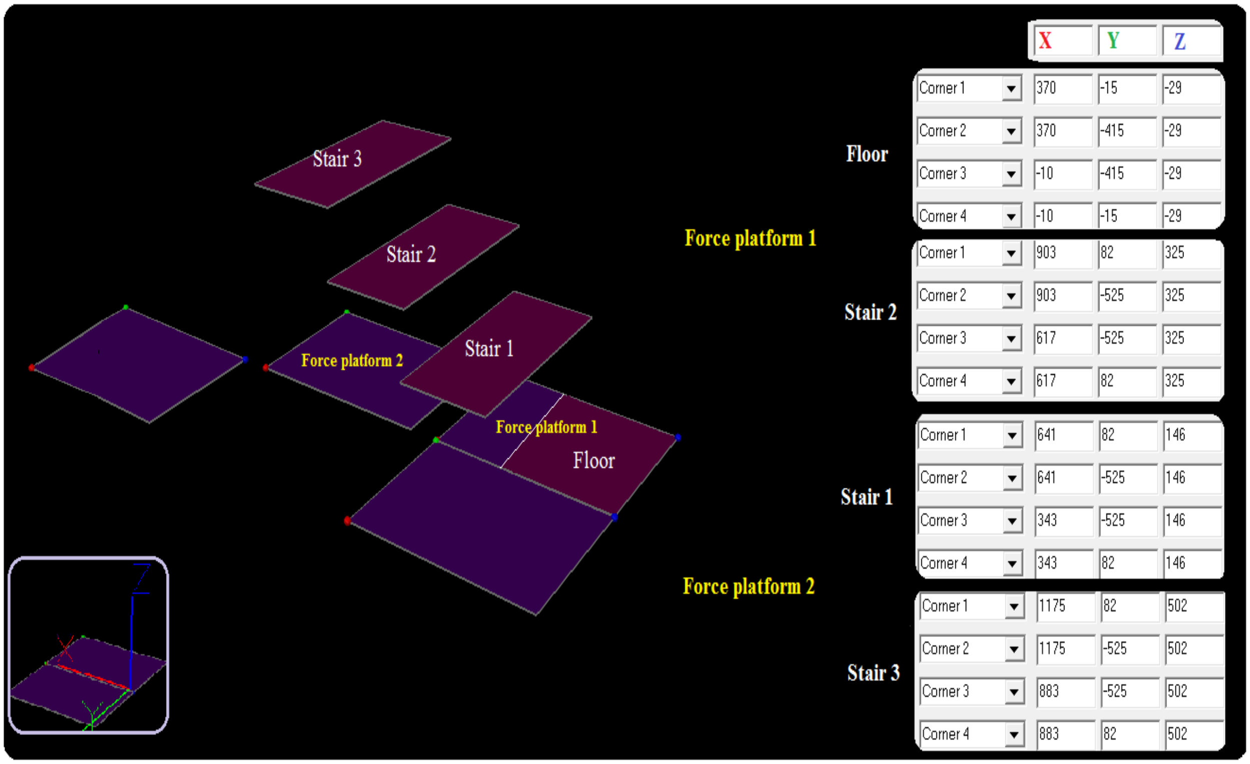


Figure 2.6: AMTI stairway force structures.

2.2.3 Data processing

A Butterworth fourth order bi-directional low-pass filter with cut-off frequencies of 6Hz and 25Hz for kinematics and kinetics respectively was used. This type of filter accepts the low frequency signals and prevents the high frequency data which are mainly due to noisy results from random movement of markers (random error) and soft tissue artifacts.

During stair ascending and descending, gait cycle events needed to be identified in order to normalise data to allow comparisons to be made between the orthotic test conditions. The gait cycle starts when any part of the foot touches the stair structure until the same foot (ipsilateral) touches the next step. For the ascending condition, the gait cycle starts when the foot touches the first step and ends when the ipsilateral foot contacts the third step, while the single limb support period starts when the non-selected left foot leaves the floor until same foot touches the second step (Figure 2.7). During walking, the gait cycle starts when the selected foot is placed over the force plate entirely and finishes when the same foot is placed on the next platform.

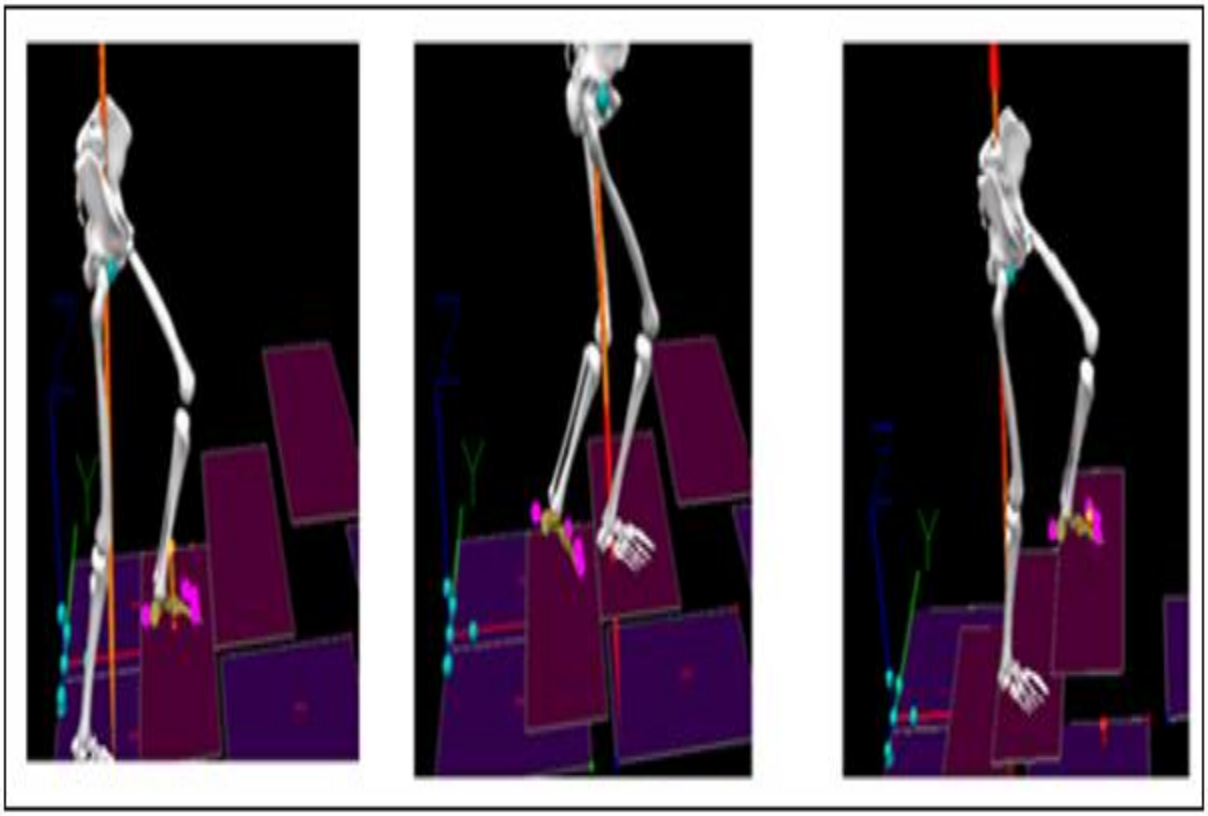


Figure 2.7: An ascending gait cycle of the left leg from the first step to the third step.

During stair descent, a gait cycle consists of initial contact, which begins when the foot touches the second step, until the same foot contacts the floor which means that that foot which touches the second step will be the start of a gait cycle. The single limb support period begins when the non-selected foot leaves the third step until same foot touches the first step (Figure 2.8).

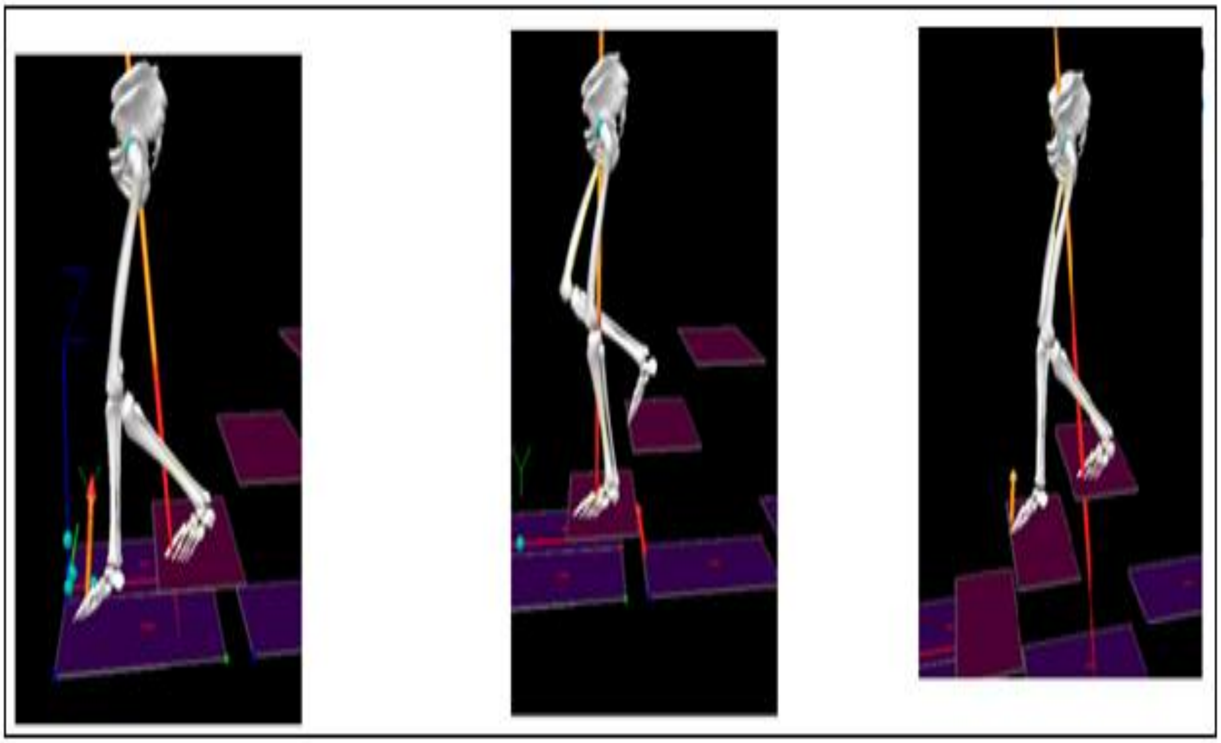


Figure 2.8: Descending gait cycle for the right leg from the second step to the floor.

2.2.4 Joint angle and joint moment calculations

The angle between segments was calculated according to the relative position between the segments using the Euler rotation sequence equivalent XYZ (flexion/extension, abduction/adduction, internal and external rotation). For example, the proximal segment for knee joint is the thigh, while the shank is the distal segment; therefore, knee range of motion during the gait cycle (initial contact to ipsilateral initial contact) in the sagittal and frontal plane depends on the orientation between these two segments.

Knee moments were computed using an inverse dynamic approach. This approach examines the external ground reaction vectors (GRF) of the body segments and moments on the anatomical joints which are due to internal muscle activity. The result of this approach relies on equilibrium mathematical formulae which start by calculating the moment and force for every joint from toe to hip (Silva and Ambrósio, 2002). During the inverse dynamic approach, the location and magnitude of the mass for each segment were used to calculate the inertial moment for each segment based on the subject's anthropometric parameters (Dempster, 1955).

2.3. Data analysis

All the data were exported as a text file to Microsoft Excel to facilitate the analysis and presentation. Lower limb joint angles and moments were exported as well as the temporal and spatial data which were collected during the trials.

However, before any study could be initiated with the three interventions (i.e. the bespoke and OTS unloader braces plus the KAFO), a reliability study was needed to ensure that reliable data could be collected and prove to be repeatable during stair climbing and descending. This will be discussed in the next chapter.

Chapter three: Reliability of knee kinematics and kinetics using an interlaced stairway

3.1. Introduction

Stair climbing is one of the most important daily activities and the main challenge for the older person who has muscle weakness. Previous studies have shown that 10.7% of falls in the older population are due to stair climbing, particularly during outdoor activities (Bergland et al., 2003). Additionally, women have a higher risk of falling compared to men amongst the 65 years old population which leads to 230,000 of them having a hip fracture in the USA annually (Sattin, 1992). Falls due to stair usage can have an impact on the older individual by making them feel scared of falling down again, forcing them to use handrails, modifying their gait, or reducing their speed. Previous studies have shown that after falling down women become less confident and use handrails more often than the men (Hamel and Cavanaugh, 2004).

In chronic diseases such as knee OA, where knee stiffness and range of motion limitations occur, these individuals have difficulty in rising from a chair, and standing and walking for long periods, and also when climbing and descending stairs (Kaufman et al., 2001, Whatling et al., 2007). This limitation during stair climbing can be explained by Yu et al. (1997b) who stated that the knee varus angle and the internal knee abduction moment are higher during stair climbing than walking on a flat surface due to the large amount of knee flexion which is needed to ascend or descend stairs. However, since the varus deformity is the main problem associated with medial knee osteoarthritis, many individuals with knee OA try to avoid stair climbing, or adapt their gait by walking slowly and decreasing the knee flexion angle (Kaufman et al., 2001), or using assistive devices such as canes and crutches.

One additional explanation could be due to the high internal knee extension moment which is correlated with ascending and descending (Andriacchi et al., 1980). This moment increases the knee load by 12-25% (Morrison, 1969); and as a result the severity of pain forces individuals to avoid using stairs in order to reduce their overall activity level.

The gait cycle during walking is different from the gait cycle during stair climbing. The main difference between them is that the degree of maximum knee flexion is higher during stair climbing than normal walking on a level surface, but differs depending on the height of the steps. Furthermore, the ascending and descending gait cycles also consist of different tasks. For instance, the stance phase of the ascending gait cycle contains three main phases: weight acceptance, pull up, and forward continuation (McFadyen and Winter, 1988, Zachazewski et al., 1993). The knee joint is the dominant joint during ascending to support the hip and ankle joint, while the ankle joint generates more energy to facilitate moving up stairs with primarily concentric muscle contractions. The stance phase of descending contains three main phases: weight acceptance, forward continuance, and controlled lowering. The hip joint is the dominant joint which supports the lower limb moving downstairs. Additionally, reduced muscle power is needed (Svensson and Holmberg, 2007) with primarily eccentric contractions to control the body weight against the rapid acceleration due to gravity and add more stability and safety to avoid sudden falling down (McFadyen and Winter, 1988).

3. 2. Literature review

Lower limb biomechanics for healthy and individuals with pathology during stair climbing have been evaluated by some studies, but unfortunately there are still some areas of little knowledge about stairs and the reliability of different stair designs. Stairs are usually one of the daily encountered activities; therefore, stairways have been designed to be used in gait laboratories recently to evaluate individuals' behavior during stair ascent and descent, to discriminate between different pathology groups and control groups, and to evaluate the benefit of using interventions for some patient groups. From a kinematic and kinetic standpoint, reliability of the data captured with stairs is of utmost importance, especially if one is determining the effect of an intervention period. It could be that the variability of stair climbing is greater than steady state walking as the task is more difficult, but there is a very limited evidence base for reliability studies.

Reliability analysis is mainly measured with intraclass correlation coefficients (ICC), Coefficients of Variation (CVs), and Correlation Coefficients (r). The error of reliability results are examined by the standard error of measurement (SEM) and Root Mean Square Deviation (RMSD). ICC represents the reliability among the participants by dividing the true variance by the total variance (Bruton et al., 2000, Stratford and Goldsmith, 1997). However, CVs are calculated by dividing standard deviation by the mean of the data and multiplied by 100% to give score as a percentage (Bruton, et al., 2000). ICC is recommended to be used for reliability more than CVs because the percentage expression depends on the size of observation and result could be different clearly between small and large sample size (Chinn, 1991). Correlation Coefficient (r) represents how two sets of data are varying together, but it does not calculate the systemic measurement error.

Furthermore, the standard error of measurement (SEM) represents the measurement error for a single participant without the influence by other measurements for other participants, but influenced by error variation only, and smaller SEM's indicate a high reliability; whereas, the calculation of Root Mean Square Deviation (RMSD) gives the overall error in the measurement of the joint angles (Bruton et al., 2000, Stratford and Goldsmith, 1997).

The reliability of different stairway designs to measure the kinematics and kinetics of the lower limb has also been examined previously. Protopapadaki et al. (2007) reported the kinematic and kinetic patterns in the lower limb (hip, knee, and ankle) during climbing four steps (with a height of 18 cm, tread length 28.5 cm, and with a force platform embedded on step two only) for a young healthy population (18-39 years), The results were variable (coefficient of variation) particularly for the hip extension moment which varied from 4.65% (SD 2.99) to 21.34% (SD 19.64) for stair ascent and from 8.65% (SD 7.42) to 40.73% (SD 24.27) for stair descent (Table 3.1). This was explained by the individuals changing their trunk movement which was not included in the data. Joint angles (hip, knee, and ankle) were less widely varied between 2.35% (SD 1.83) to 5.77% (SD 4.18) during stair ascent and descent indicating good reliability. The exception was during plantarflexion during stair ascent, which was 17.53% (SD 13.62), which was likely to be due to gait changes during testing such as making contact with the stairs with a flatfoot or with the forefoot only.

Table 3.1: Coefficient of variation for angles and moments during stair ascent and descent (Protopapadaki et al., 2007).

Coefficients of variation (mean (SD)) in percentage of hip, knee and ankle angles and moments during stair ascent and descent ($n = 11$)

	Stair ascent	Stair descent
	CV	CV
Joint angles		
Hip flexion	2.99 (1.76)	4.30 (3.34)
Knee flexion	2.35 (1.83)	2.90 (2.69)
Ankle dorsiflexion	3.31 (3.53)	4.94 (3.42)
Ankle plantar flexion	17.53 (13.62)	5.77 (4.18)
Joint Moments		
Hip flexion	6.41 (5.01)	23.45 (18.14)
Hip extension	–	40.73 (24.27)
Knee flexion	21.34 (19.64)	13.22 (9.21)
Knee extension	11.51 (9.68)	21.84 (16.73)
Ankle dorsiflexion	4.65 (2.99)	8.65 (7.42)

– indicates no data.

Kowalk et al. (1996) reported the knee moment in the sagittal and frontal plane when climbing three steps of with a 20 cm height and 25cm width with force plates embedded in two of the stairs for ten healthy adults (22-40 years old). The results demonstrated good repeatability with CVs ranging from 0.09- 0.45(lower CVs show less percentage error).

McFadyen et al. (1988) examined stair repeatability to evaluate the kinematics and kinetics in the sagittal plane only for lower limb joints for three young healthy (mean 24.6 years old) men during ascending and descending five steps (height 22cm and 28cm tread width) with two platforms added to the second and fourth to examine the kinetic data from second to fourth step. The results showed that inter-person variability (r) for the three joint angles was more 0.95, while the moments varied between 0.82 and 0.98. For instance, knee moments were 0.96 and 0.88 during stair ascending and descending respectively. The hip moments showed the greatest variability, which demonstrates that hip musculature strength was the dominant factor in to controlling single limb support (Table 3.2). The number of participants was, however, limited.

Table 3.2: Inter subject correlation coefficient (r) during stair ascent (a), and descent (b) (McFadyen et al., 1988).

(a)	Joint angles			Moments			Power		
	Ankle	Knee	Hip	Ankle	Knee	Hip	Ankle	Knee	Hip
WM24/WM86	0.996	0.997	0.980	0.948	0.984	0.815	0.946	0.986	0.731
WM24/WM87	0.954	0.993	0.986	0.823	0.967	0.575	0.661	0.947	0.739
WM86/WM87	0.959	0.994	0.987	0.845	0.968	0.117	0.577	0.969	0.252

(b)	Joint Angles			Moments			Power		
	Ankle	Knee	Hip	Ankle	Knee	Hip	Ankle	Knee	Hip
WM24/WM86	0.986	0.993	0.971	0.983	0.913	0.909	0.977	0.912	0.846
WM24/WM87	0.995	0.987	0.988	0.956	0.8877	0.781	0.988	0.913	0.815
WM86/WM87	0.989	0.979	0.964	0.975	0.958	0.628	0.955	0.966	0.727

Ground reaction force (GRF) reliability has been examined by some studies. Stacoff et al., (2005) examined GRF data for participants with three different age groups (between 33 and 60 years old) and with three different steps inclinations (mean 13.3cm height, and 29.6cm width. This study found that the variability was higher during descending than ascending. The coefficient of variation (CV) was between 5-10% during ascending, and 15-20% during descending which are considered normal (i.e. more variability than that could be considered as a gait asymmetry). Leitner et al (2011) examined the GRF reliability during stair climbing for 42 older individuals (aged 80.1 years ±6.4) using two platforms under the third and fourth step of a staircase with six steps (17cm height, and 29 cm width). The reliability results were considered to be moderate to good (with ICCs of between 0.739 and 0.918 and CVs between 8.79% and 12.52%) for both stair ascent and descent.

In stair climbing studies, the measurement of the kinetics depends on the design of the stairway. All of the previous studies have primarily used two main designs of staircase: those with embedded force platforms in the steps (the original design) or using different rigid blocks over the platforms to form stairs (a later design). The original design is expensive and needs setting up at a determined place and would not allow for a quick change over for walking gait to be collected. The later design uses different rigid blocks lengths over platforms to form stairs with the stairs dependent on the number of platforms in gait laboratory and that they are situated on top of them.

Another unique option is an interlaced stairway (Della Croce and Bonato. 2007) which was developed to utilise the force platforms which are situated in a walkway with a secure fixation into the surface of the forceplate. This allows the examination of the ground reaction force and centre of pressure (COP) progression from the two platforms embedded in walkway and not embedded in the steps. By using that unique structure, the force is examined on each step separately, and the estimated COP coordination shows a good agreement with the horizontal coordinates of the geometric centre of the calibration object utilized to assess accuracy and precision of the CP estimates (max difference <6 mm) (Della Croce and Bonato. 2007).

However, the repeatability of using such a staircase design on the kinematics and kinetics of ascent and descent has not been demonstrated as there are only three steps to the staircase design and this may cause some variability in the movements. This is important for future studies when assessing interventions given that individuals may come at different time points so ensuring reliability is of utmost importance. In addition, the previous studies have not measured SEM which is important to find out the measurement error for every participants and supports the reliability results. Therefore, the purpose of this study was to determine the inter-session reliability of an interlaced stairway whilst ascending and descending stairs and to measure SEM and RMSD for inspection of the overall error in angular measurements. Thus, this study evaluated the primary outcome of the further planned trial (knee sagittal and frontal angles and moments) using 16 cameras in five males and five females during climbing three steps. This information will be important for future studies which depend on interlaced stairway to evaluate an individual's performance and interventions' effects during climbing the interlaced stairway.

3.3. Method

3.3.1 Subjects

Ten healthy participants took part in this feasibility study (five males, five females), aged 32.1 ±6.8 years; height 167.9± 7 m; and mass 69.35 ±10.4 kg. The participants were recruited by volunteering via a poster intended to recruit university students and staff (Appendix 6c). The inclusion criteria included being generally fit, with no previous knee injury or knee pain, the ability to ascend and descend stairs without using a handrail, and the ability to walk without using external assistive devices such as crutches, and be aged between 20-60 years. The study was approved by the University Research and Governance ethical committee and informed consent was obtained from each individual (Appendix 6D).

3.3.2 Test procedures

After capturing the static alignment, the participants were then asked to ascend and descend the stairs for one minute to ensure that they felt comfortable and were able to use stairs properly. After they had familiarised themselves with the task, they were asked to ascend the three steps with their normal self-selected walking speed, without using the handrail. When they reached the third step, they were asked to stop for few seconds and then turn around and descend the two steps until they reached the floor. This test was repeated five to eight times, but no more to avoid fatigue. In the next session, every participant repeated the test again under the same conditions. One hour was required for each session to collect the data.

3.3.3 Outcome measures

The key variables assessed included the averaged maxima of kinetic and kinematic parameters at initial contact (0% of gait cycle), loading response (10%), mid stance (30%), late stance (50%) and mid swing (73% of gait cycle) (Figure 3.1a), and range of motion of the knee in the sagittal plane. The following primary outcome measures were investigated:

- The average maximum frontal plane knee moment in early and late stance.
- The average minimum for mid stance (Figure 3.1d).
- The average of knee adduction angular impulsive (KAAI), which is the area under knee adduction moment curve (Kean et al., 2012).
- The average maximum and minimum sagittal knee moment (Figure 3.1c).

- The average maximum of vertical GRF in early and late stance, and average minimum at mid stance (Figure 3.2).
- The average of speed and stance phase time for the selected side.

The average maximum or minimum for selected data for single participants were calculated firstly for every single trial, and then the average of five trials were calculated. This process was repeated for every participant, and then an average of all of the participants were calculated together to produce one graph which collated the results of all participants. It was also necessary to examine GRF and walking speed data, as these parameters can affect the reliability of the results. For example, uncontrolled speed could have reduced the kinetic data reliability.

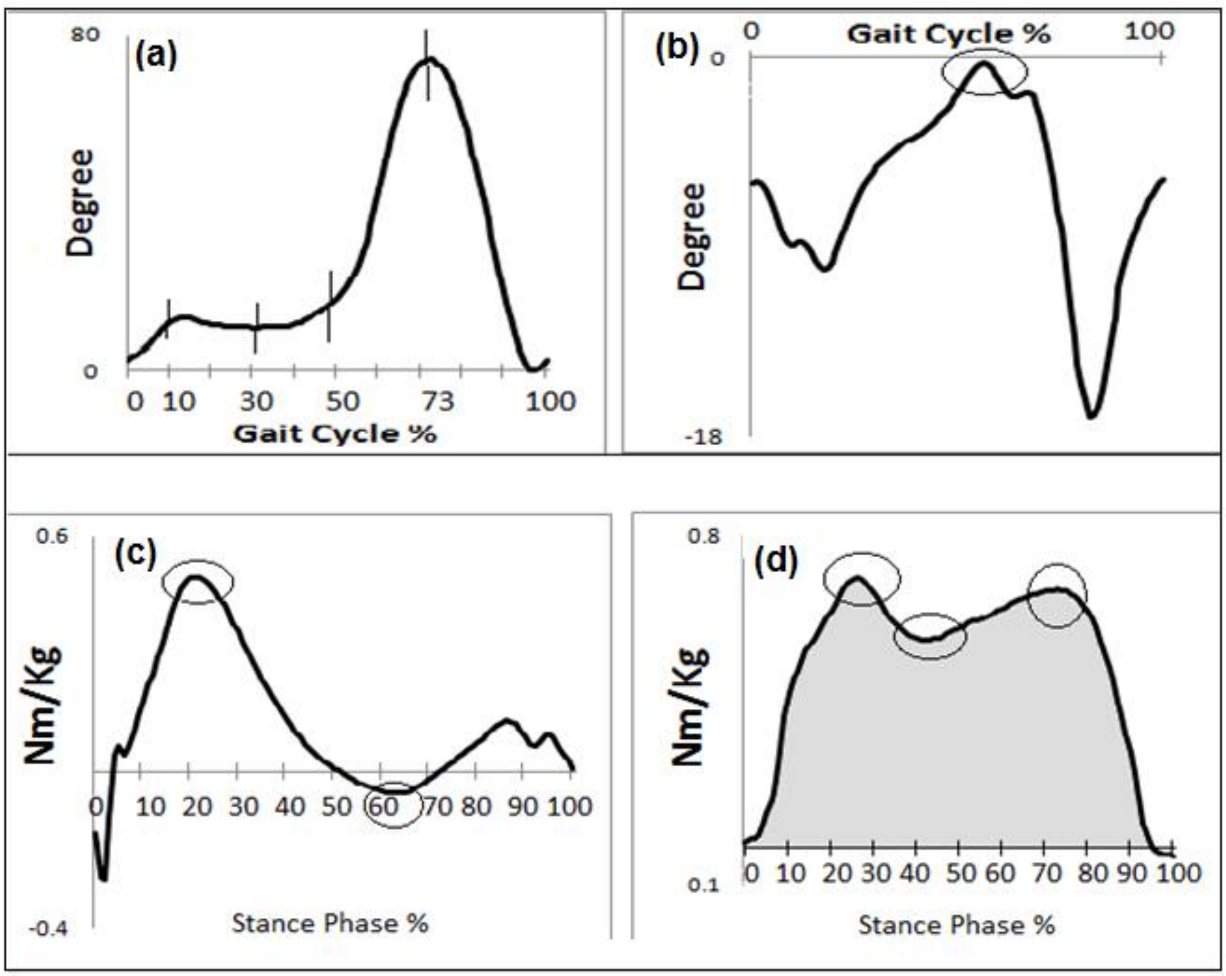


Figure 3.1: Representation of data for sagittal knee angle (a), frontal knee angle (b), sagittal knee moment (c), frontal knee moment (Nm/kg) and the shaded area represents the KAAI (Nm/kg*s)(d).

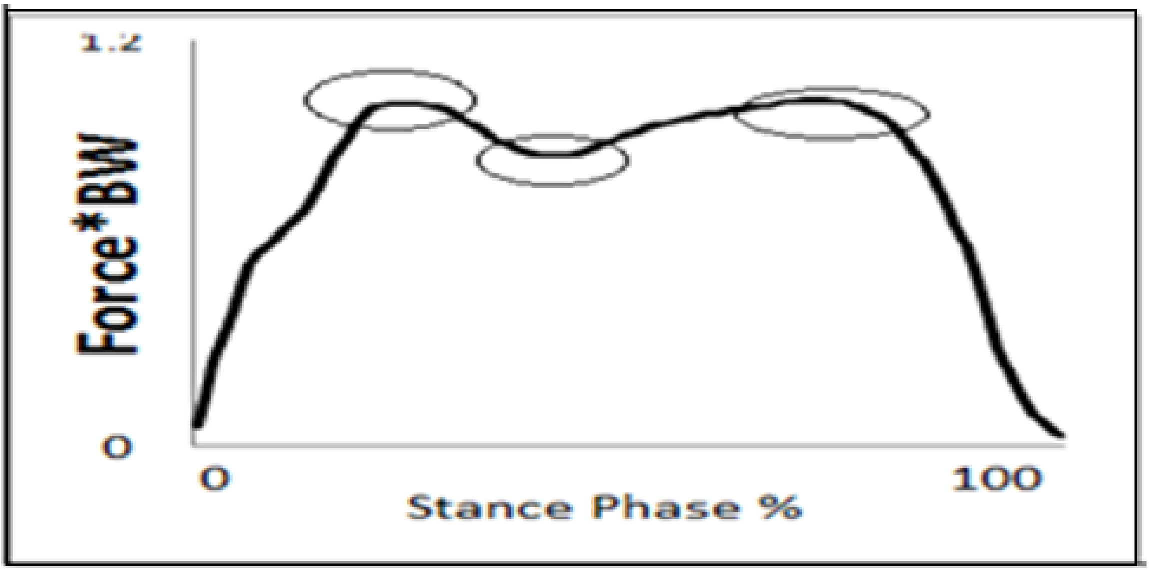


Figure 3.2: A typical vertical GRF plot.

3.3.4 Statistics

The reliability analysis of the data collected at the two sessions was assessed with intraclass correlation coefficients (ICC) type (3, k) for all variables within the five trials for each participant. The absolute reliability error was calculated by the standard error of measurement (SEM) and root mean square deviation (RMSD) to given an overall error in the measurement of the angles. The level of significance was at 95% confidence interval ($p<0.05$).

3.4. Results

All ten healthy participants completed the five trials of ascending and descending stairs without using the handrail, over two sessions to evaluate the reliability of an interlaced stairway design to examine knee angles and moments in both the sagittal and frontal planes.

3.4.1 Primary outcomes

3.4.1.1 Knee joint kinematics during ascending and descending

The average maximum for knee flexion/extension angle repeatability at initial contact (0% of gait cycle), loading response (0-10%), mid stance (11-30%), late stance (31-50%), mid swing (73% of gait cycle), and range of motion (difference between mid-swing and initial contact) were excellent for ascending and descending (ranging from ICC 0.85- 0.93 and 0.96- 0.98 respectively). The SEM raised to 2.2 degree, and the RMSD raised to 3.6 degrees (Table 3.3 and 3.4, Figure 3.3 and 3.4). The average maximum of knee angle ICC in the frontal plane was 0.96 in ascending and 0.98 in descending.

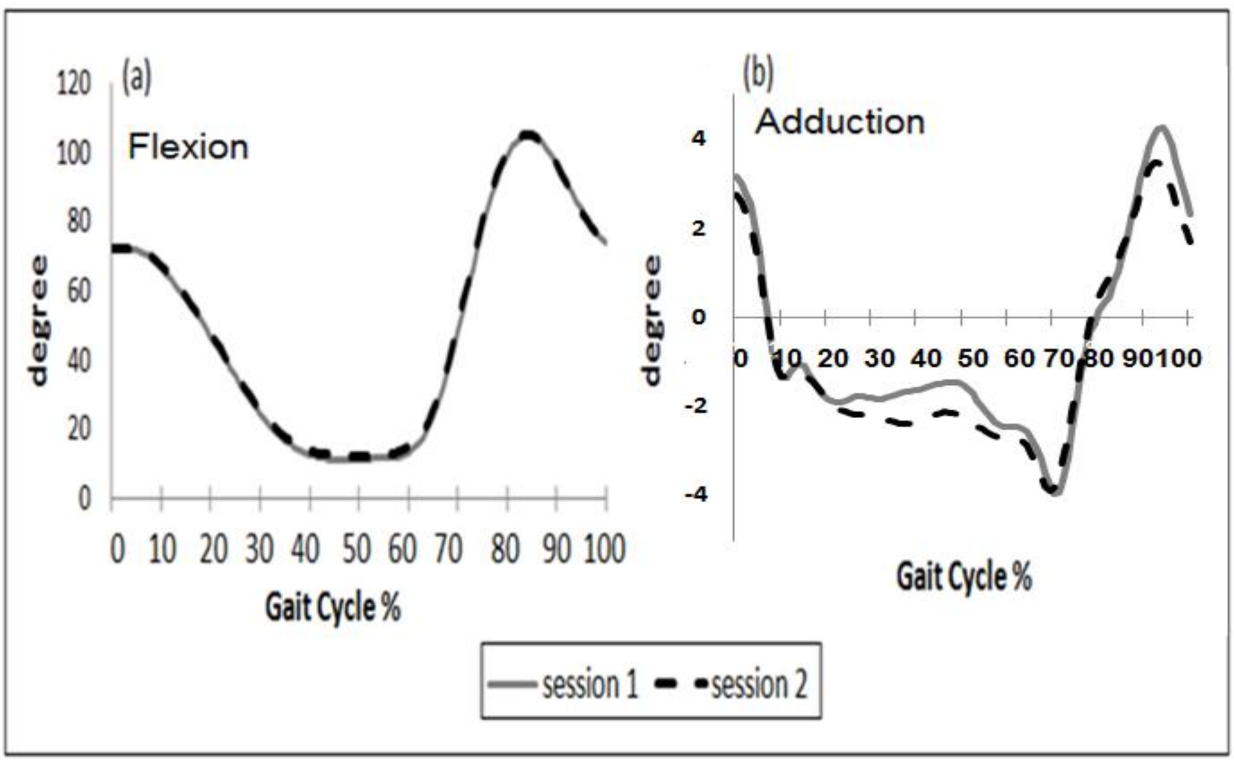


Figure 3.3: Knee angle in two session during stair ascent (sagittal plane (a), frontal plane (b)).

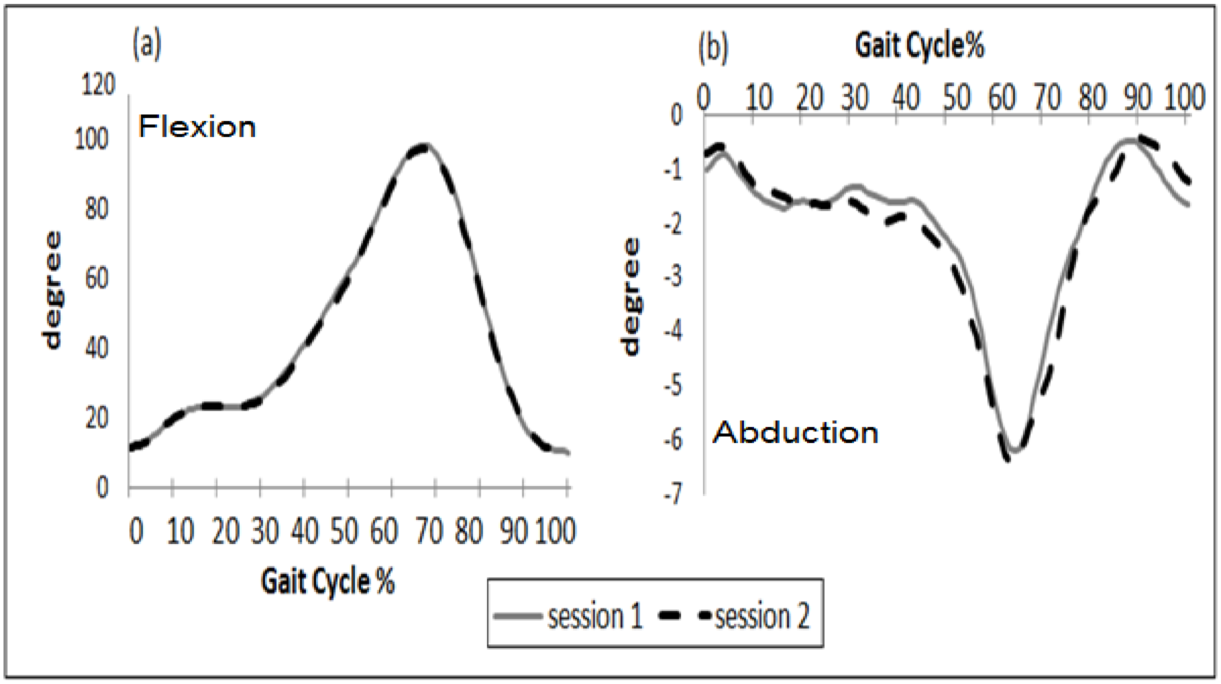


Figure 3.4: Knee angle in two sessions during stair descent (sagittal plane (a), frontal plane (b)).

Table 3.3: Reliability knee joint kinematics variables.

Variable	Ascending Mean (±SD)	Ascending ICC	95% CI		SEM	Descending Mean (±SD)	Descending ICC	95% CI		SEM
			Lower Bound	Upper Bound				Lower Bound	Upper Bound	
Sagittal knee angle at initial contact	72.9±4.7	0.88	0.54	0.97	1.42	10.9±3.8	0.92	0.69	0.98	1.18
Sagittal knee angle at loading response	69.2±3.8	0.90	0.61	0.97	1.16	18.6±5.8	0.90	0.60	0.97	1.78
Sagittal knee angle in midstance	35.2±6.4	0.85	0.41	0.96	1.92	25.2±7.1	0.9	0.86	0.99	2.23
Sagittal knee angle in terminal stance	18.4±4.9	0.86	0.46	0.96	1.46	59.6±6.9	0.95	0.81	0.98	2.13
Sagittal knee angle in mid swing	106.6±7.4	0.93	0.72	0.98	2.27	100.2±6.8	0.98	0.93	0.99	2.15
Sagittal knee range of motion	33.6±4.9	0.92	0.69	0.98	1.52	89.2±6.2	0.96	0.85	0.99	1.95
Maximum frontal knee angle	3.9.1±2.1	0.96	0.85	0.99	1.51	6.3±1.5	0.98	0.94	0.99	1.98

Table 3.4: RMSD between two sessions.

Variable	Ascending		Descending	
	RMSD	SD	RMSD	SD
Sagittal plane	3.64	1.53	3.07	1.54
Frontal plane	1.33	0.62	1.44	0.86

3.4.1.2 Knee joint kinetics during ascending and descending

The results show that the ICC of average maximum of knee moment in sagittal plane was higher in ascending than descending (0.98 and 0.85 respectively), whilst the average maximum ICC of frontal plane for knee moment during stair ascent and descent ranged between 0.93-0.97. Additionally, ICC of KAAI was 0.7 in descending and 0.86 in ascending (Table 3.5, Figure 3.5, 3.6).

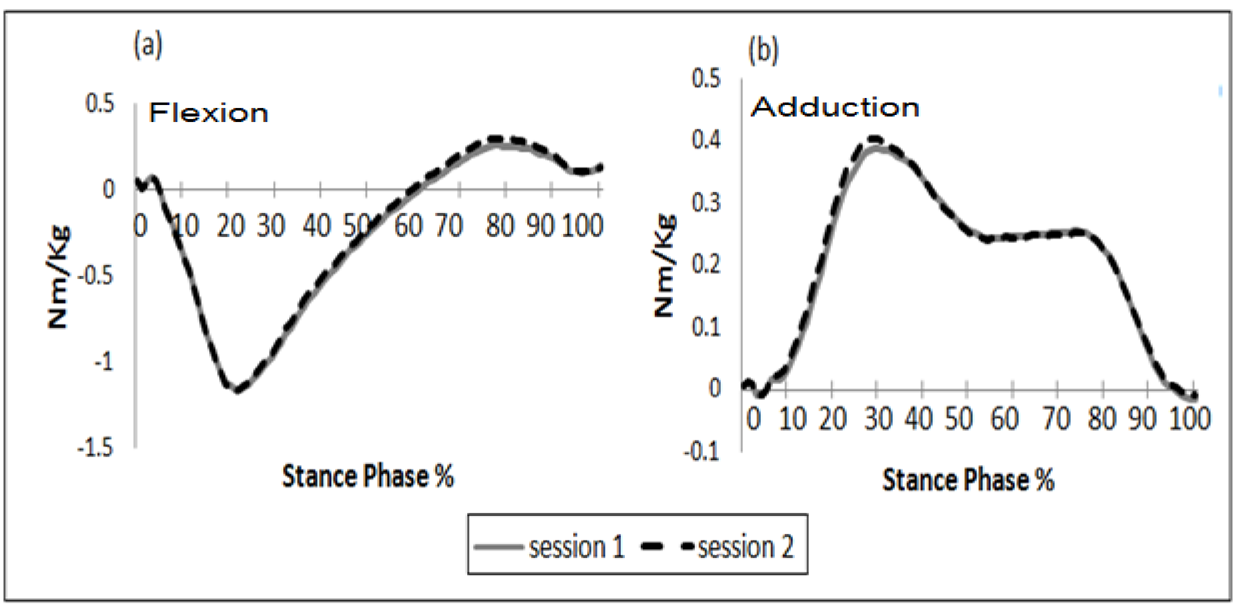


Figure 3.5: Averaged knee moment moments for the two sessions during stair ascent (sagittal plane (a), frontal plane (b)).

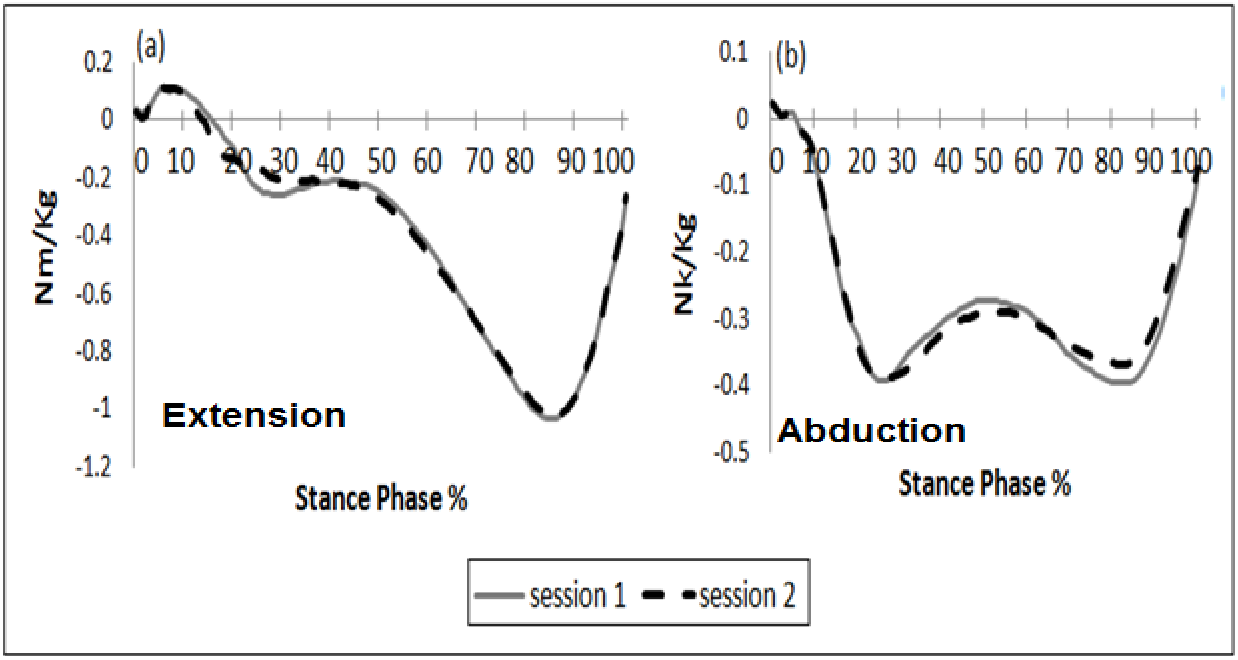


Figure 3.6: Averaged knee moments for the two sessions during stair descent (sagittal plane (a), frontal plane (b)).

Table 3.5: Reliability of knee joint kinetic variables.

Variable	Ascending Mean (±SD)	Ascending ICC	95% CI		SEM	Descending Mean (±SD)	Descending ICC	95% CI		SEM
			Lower Bound	Upper Bound				Lower Bound	Upper Bound	
KAAI	0.25±0.07	0.86	0.46	0.96	0.02	0.03±0.01	0.70	-0.18	0.92	0.00
First peak of EKAM	0.41±0.12	0.97	0.89	0.99	0.05	0.06±0.07	0.95	0.80	0.98	0.02
Trough of EKAM	0.40±0.17	0.97	0.90	0.99	0.05	0.24±0.16	0.98	0.93	0.99	0.05
Second peak of EKAM	0.30±0.12	0.93	0.75	0.98	0.03	0.08±0.08	0.94	0.78	0.98	0.02
Maximum sagittal knee moment	0.75±0.2	0.97	0.89	0.99	0.07	0.16±0.0	0.85	0.43	0.96	0.02
Minimum sagittal knee moment	1.5±0.13	0.83	0.32	0.95	0.03	1.03±0.12	0.90	0.63	0.97	0.03

3.4.1.3 Repeatability results for vertical ground reaction force (VGRF) data

The results following analysis of the vertical GRF data are illustrated in table 3.6, which demonstrates that for the average maximum ICCs of GRF during early stance, mid stance, and late stance were more repeatable in ascending than descending, especially during mid and late stance (table 3.6, Figure 3.7).

Table 3.6: Vertical GRF reliability during ascending and descending.

Time variable	Mean ± (SD)	ICC	95% Confidence Interval		SEM
			Lower Bound	Upper Bound	
During ascending					
First peak of GRF	1.05±0.06	0.94	0.75	0.98	0.02
Trough of GRF	0.97±0.05	0.87	0.48	0.96	0.01
Second peak of GRF	1.04±0.06	0.94	0.76	0.98	0.01
During descending					
First peak of GRF	1.17±0.16	0.93	0.74	0.98	0.05
Trough of GRF	0.98±0.04	0.61	-0.56	0.90	0.01
Second peak of GRF	0.96±0.06	0.83	0.33	0.95	0.02

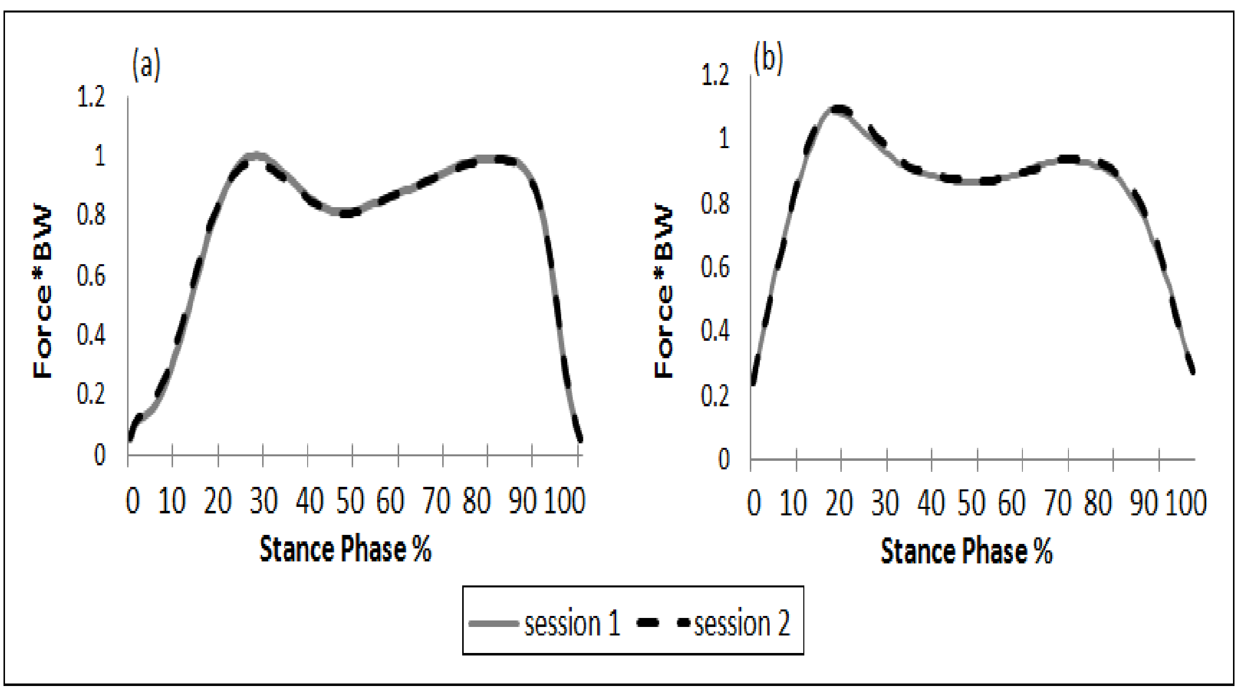


Figure 3.7: Averaged GRF data for the two sessions during ascending (a) and descending (b).

3.4.1.4 Speed and stance time

Speed was slightly higher during stair descent than ascent (0.40±0.02 and 0.37±0.02 m/s, respectively), while the stance phase time was shorter during stair descent than ascent (1.0 ±0.06 versus 0.2±0.06 seconds, respectively). However, the reliability of speed and stance time was higher during stair descent (Table 3.7).

Table 3.7: Speed and stance time reliability during ascending and descending.

Time variable	ICC	95% Confidence Interval		Mean± (SD)	SEM
		Lower Bound	Upper Bound		
During ascending					
Speed (M/s)	0.88	0.5	0.97	0.37 (0.02)	0.02
Stance time (s)	0.92	0.6	0.98	1.2 (0.06)	0.06
During descending					
Speed (M/s)	0.91	0.67	0.98	0.40 (0.02)	0.02
Stance time (s)	0.93	0.74	0.98	1.0 (0.06)	0.06

3.4.2 Secondary outcomes

3.4.2.1 Ankle joint kinematics during stairs ascending and descending

The table 3.8 below shows that ankle joint kinematics reliability in the sagittal plane was higher during descending than (ICC 0.96) ascending (ICC 0.85). However, RMSD was similar during ascending and descending (2.3 degrees).

Table 3.8: Ankle joint reliability during stair ascent and descent.

Variable	Mean (±SD)	Ascending ICC (IC95%)	RMSD (SD)	SEM	Mean (SD)	Descending ICC (IC 95%)	RMSD (SD)	SEM
Sagittal ankle angle	26.6 (2.5)	0.85 (0.42-0.96)	2.3 (0.6)	0.79	35.2 (4.3)	0.96 (0.87-0.99)	2.3 (1.1)	1.32

3.5 Discussion

3.5.1 Discussion

Stair climbing is one of the most commonly performed daily activities and can be one of most challenging tasks for some individuals such as those with neuromuscular impairments, painful lower limb symptoms, or the older population. Different stair designs have been used in gait laboratories in order to distinguish gait patterns between healthy and pathological groups and also to evaluate the efficacy of different interventions for pathology groups. In all previous reliability studies on stairs, the two-stairway designs have primarily been used. Initial designs embedded force platforms in the steps, but more recently different rigid blocks have been added over the force platforms to simulate steps. However, the interlaced design which was utilised in this study has not been evaluated before. Therefore, this study looked at the reliability of an interlaced stairway design to examine knee kinematics and kinetics during stair ascent and descent in ten healthy adult individuals. To the author's knowledge no previous studies have evaluated the reliability of this interlaced stairway design, where force platforms are embedded in a walkway and not in the steps, to evaluate knee kinetics and kinematics in both the sagittal and frontal planes.

The results attained in this study, as in previous studies (Leitner et al., 2011, McFadyen et al. 1988, Protopapadaki et al., 2007, Stacoff et al., 2005), show that reliability during stair ascent and descent are not same, and the reliability of the variables in the sagittal plane are better than in the frontal plane. In the current study, the reliability for the interlaced stairway for knee kinematics and kinetics were high with ICCs of knee moments and angles between 0-83 and 0.97 and 0.85-0.96, respectively during stair ascent, and between 0.70- 0.98 and 0.90-0.98 during stair descent, respectively. The results of this study show that ICCs of knee moments in the sagittal and frontal planes were higher during stair ascent, whereas ICCs for angles were higher during stair descent for ten healthy participants. However, all the results were placed between moderate and excellent reliability according to Fleiss' classifications (Fleiss, 1986). To evaluate the measurement error in this study SEM and RMSD were used. The SEM was raised to 2.2 and the

RMSD was raised to 3.4 and 1.4 degrees in sagittal and frontal planes (which are less than 4 degrees). This implies that this test is reliable, and would be perceived to be sensitive enough to detect any small changes and effects of any interventions for pathological groups.

This distinction between stair ascent and descent could be explained by the uncontrolled speed during the test, as speed has a crucial role in changing the kinetics and gait pattern within the same session (Kean et al., 2012). Additionally, the reliability of knee kinematics was less during stair ascent than stairs descant. This result could be related to the inconsistency of the ankle joint position during stair ascent and our result shows that ankle reliability was less during stair ascent (ICCs 0.88) than descent (ICCs 0.96). For example, in the same session the participants touched the stairs with the flatfoot (ankle neutral position) or the forefoot (ankle plantarflexion), these changes in ankle position could alter the knee flexion angle position, and thereby the knee reliability will be less during stair ascent. In the study by Protopapadaki et al. (2007) and Yu et al. (1997a) studies they also presented similar results since the ankle joint reliability during stair ascent was less than during stair descent due to changes in foot placement on the steps

3.5.2 Limitation

The current study evaluated the reliability of a three step stairway, and one aspect was the number of steps are not enough to evaluate the full reliability of the contra-lateral side at the same time as the ipsilateral side. This is because the two platforms in the interlaced stairway design measure kinetics between first and third step during stair ascent and between second step and floor during stair descent . Therefore, extra steps could be added in the future (with no plates attached or a portable plate in situ) and reliability of this stairway design will be examined again. Moreover, the speed of the participants was not controlled during the test which could have had an effect on the result although this does make it more generalisable as this is their natural speed. However, controlling for speed will contain whether this was in fact a limitation.

3.5.3 Future work

This study has helped to evaluate the reliability of the interlaced stair way which may potentially be used to evaluate gait for different pathological groups during stair ascent and descent and the effect of interventions such as knee valgus braces and insoles. Further studies with more steps should be used to show the reliability of interlaced stairways to examine both lower limbs in the same ascent or descent. The reliability in pathology populations should also be assessed as this may differ when the individual has pain or neuromuscular deficits.

3.5.4 Conclusion

The current results show that the interlaced stairway is a reliable method to examine the kinematics and kinetics for healthy individuals in gait laboratory during different time intervals with moderate to excellent reliability. A small measurement error was found during this test showing that the interlaced stairway is a sensitive design to evaluate clinical changes after using any interventions for pathological groups. It has further been shown that the reliability of knee kinematics and kinetics are not same during stair ascent and descent; as kinematics is more reliable during stair ascent while kinetics is more reliable during stair descent.

Chapter four: The effect of a KAFO on kinematics and kinetics of the lower limb.

This study investigated the effect of a KAFO with an ankle joint in comparison to both custom and off-the-shelf (OTS) knee valgus braces on hip and knee angles and moments during walking and climbing the interlace stairway design. Although not one of the main hypotheses, the ankle joint angles in the sagittal and frontal planes were also examined to examine any changes. The following details the procedures undertaken in this study, the interventions and outcome measures and the results of the study.

4.1. Test procedures

4.1.1 Participant

One male participant, aged 45 years with a height of 168cm and mass of 86 kg, took part in the study. The participant gave written informed consent via a form in accordance with policies of the University Research and Governance ethical committee (Appendix 6a). The inclusion criteria were that they were aged between 20 and 60 years old had a body mass index of ≤ 30, and a knee varus angle of more than seven degrees. Exclusion criteria were the existence of severe knee pain, signs of clinical or radiological knee OA, a history of ligament tears, a history of trauma accident, a history of high tibial osteotomy or other realignment surgery, or a history of total knee replacement on the affected side; finally, have any foot and ankle problems that would contra-indicate the use of the KAFO.

4.1.2 Clinical examination

The maximum knee flexion and extension, active knee range of motion, and maximum passive knee valgus and varus alignment for both lower limbs were examined manually using a goniometer. The centre of the goniometer was fixed on the mid portion of the patella, while the fixed arm was placed to indicate the femur alignment and the lower part was directed towards the midline between the malleoli with the subject in a supine position. It was found that the left side knee angle for the participant was ten degrees of varus, but this was five degrees for right side; and therefore, the left side was used in this study. The SEM of the goniometer was raised to 2 degrees for hip adduction/abduction measurements (Nussbaumer et al, 2010) and no study shows the SEM of the goniometer for knee adduction/abduction measurements.

4.1.3 Casting

The participant was seated on a casting table and cotton stockinet was applied over the left limb. An indelible pencil was used to mark the positions of the following anatomical landmarks: the medial and lateral malleoli, the head of the fibula, and the outline of the patella. A plastic tube was placed over the left anterior aspect to facilitate cast removal (Figure 4.1). An elastic plaster bandage was applied from just below the greater trochanter to the toes. The plaster was strengthened over the knee and ankle joint areas to avoid cast breakage during cast removal. The participant was positioned in ten degrees of knee flexion, which is the best position for knee joint to start movement (the functional position), and a valgus force directed was applied over the knee joint, while the ankle joint was fixed in a neutral position. Manual varus correction was then applied up to a maximal position where the participant felt he could tolerate. The limb was held in this position until the plaster had set. Then, the negative cast was removed by a cast cutter along the plastic tube, and the stockinet was cut off and removed. After that, measurements were taken for the left side (circumstances above and below the knee joint, the foot length, and the knee joint diameter).

Then, liquid plaster of Paris was poured inside the negative and placed in upright position. A pipe was inserted inside the cast, but kept away from bottom until the cast was set and had become rigid. After that, the outer plaster shell was removed to obtain the positive cast.

Figure 4.1: Casting the left side to take a negative model for participant's size.

4.1.4 Modifications

The positive cast was smoothed by a surform (surface forming blade). The orthotist’s hand pressure on the negative cast during the casting procedure was used as a reference to level of compression on the soft tissues for the positive cast modification. Plaster was removed from the lateral side just above and below the patella to apply a valgus directed force without exerting excessive pressure depending on the negative cast model shape (Figure 4.2 a) to act as counter forces to the medially-applied forces at the proximal and distal aspect of the KAFO. For the foot section, the medial longitudinal arch was accentuated, the plantar surface of foot was flatted; and any excessive plaster around the Achilles tendon was removed. Finally, the entire cast was smoothed by gauze (Figure 4.2 b, c).

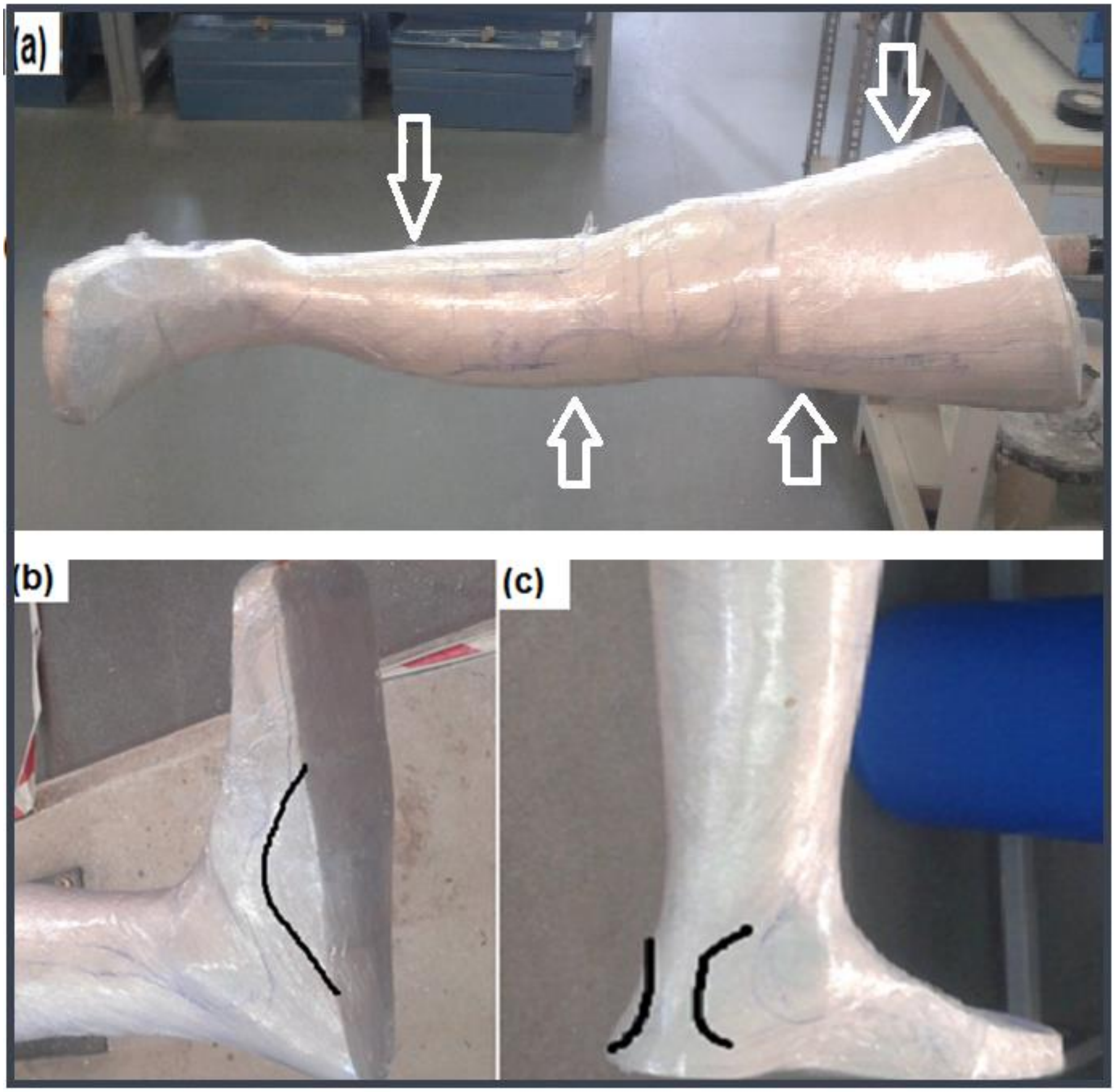


Figure 4.2: The cast modification process. A four point pressure system was used to apply a valgus correction force with long lever arms to make wearing the orthoses more comfortable (a), modification of the medial arch (b), and removal of excessive plaster around the Achilles tendon (c).

A six mm polypropylene plastic sheet was vacuum moulded over the cast. After the plastic had dried, the medial upright was shaped over the plastic shell (Figure 4.3a). A stainless steel free offset joint (Ottobock model 17lk1=L/R1-5, Ottobock, Germany) which tolerates up to 100kg user weight with an eight mm thickness, 23.6mm width. Five degrees knee flexion is the neutral position for this joint. This joint is not a completely posterior offset joint, and also it can be locked or free depending on the case by just removing the washers and ring. The free joint was used for this participant because he had good quadriceps muscle power (score of 4 on the Oxford scale since the participant can flex his knee against gravity when apply sight resistance) and was able to control the knee flexion and extension (Figure 4.3b). An aluminum side bar was used to provide structural strength for the design and extended from five cm below the medial brim to two-thirds of leg length so as to not impinge on the ankle. The joint was placed in a position as recommended by the manufacture instructions at a position 60/40 behind the sagittal plane knee centre; based on the external contours of the knee (Nietert 1975).

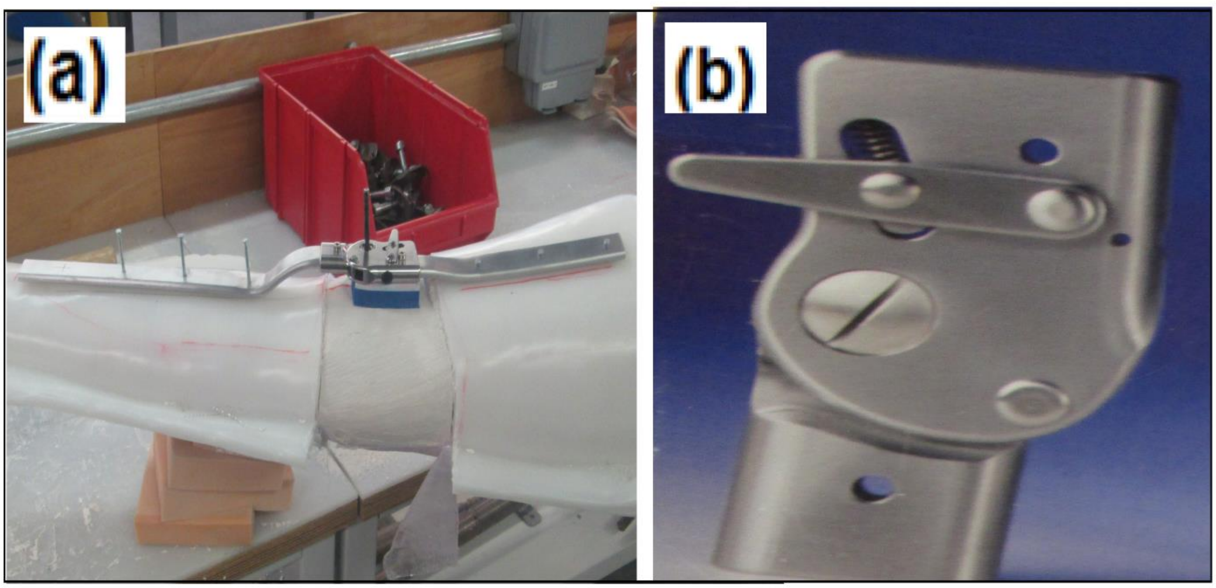


Figure 4.3: KAFO design including a single medial upright (a), and an Ottobock free offset knee joint (b, c).

A further piece of plastic sheet was then vacuumed over the foot section to form a simple hinge free ankle joint (Figure 4.4a). It is worthy to mention that a standard KAFO without an ankle joint was initially tested, but it was deemed to be uncomfortable during stair use and limited the ankle joint movement excessively. Given that the individual only had a varus deformity at the knee and no ankle pathology, it was therefore necessary to add a simple ankle joint to the KAFO to allow ankle joint motion and indeed is recommended rather than a standard KAFO without an ankle joint particular if consumers habitually use stairs. The plastic shell covered two thirds of the thigh and shin to distribute the loads applied to the lower limb over a large area. The posterior part of the two shells was trimmed away from the knee joint to allow free knee flexion during walking or stair climbing. The medial side of the thigh shell was trimmed lower than the lateral trim line for more comfort and to prevent pinching during sitting. The shank section was trimmed at a position five cm below the head of fibula to ensure the common peroneal nerve was not impinged with the KAFO in situ.

After cutting the plastic shell and polishing, the side bar was fixed on the shells by screws. Subsequently, two straps (two cm) were sewn and fixed on the medial thigh shell and one velcro strap (five cm) for the leg shell with the loops fixed on the lateral side to apply more valgus force and secure the KAFO to the lower limb (Figure 4.4b). Finally, the KAFO was checked to ensure that the user felt comfortable and was able to flex the knee adequately.

Figure 4.4: KAFO design. Plastic was vacuumed over the lower parts (a). Final model of the KAFO with an ankle joint (b).

4.1.4.1 Ossur knee valgus braces

The Ossur (Ossur, Iceland) UnloaderOne off-the-shelf (OTS) and custom knee valgus braces were ordered depending on the participant's leg size. This type of unloader knee valgus brace is used for unicompartmental knee OA. This design is easy to apply on the affected side, lightweight, cosmetically acceptable, comfortable to use because of silicon pads inside the design, and has a three points of leverage system. Additionally, it contains a polycentric free knee joint with a zero degree extension stop, dynamic force systems applied by two straps around the knee, and valgus directed system applied by the thigh and calf sections. The applied force is based on the amount of user's pain relief and their tolerance level (Figure 4.5). The off-the-shelf brace has five standard sizes depending on the circumference of the calf at a position six inches (15cm) below the middle of the patella: x small, small, medium, large, and x large. The custom-made design is a bespoke fit and depends on the circumstance of the thigh and calf, and a suitable length of device which is usually shorter than OTS one and potentially generally fits better (Table 4.1). The main function of the UnloaderOne knee valgus brace is to transfer the load from medial compartment to the lateral side by applying a valgus moment to reduce the EKAM and thus relieve pain. The custom device was measured and ordered by a representative from Ossur.

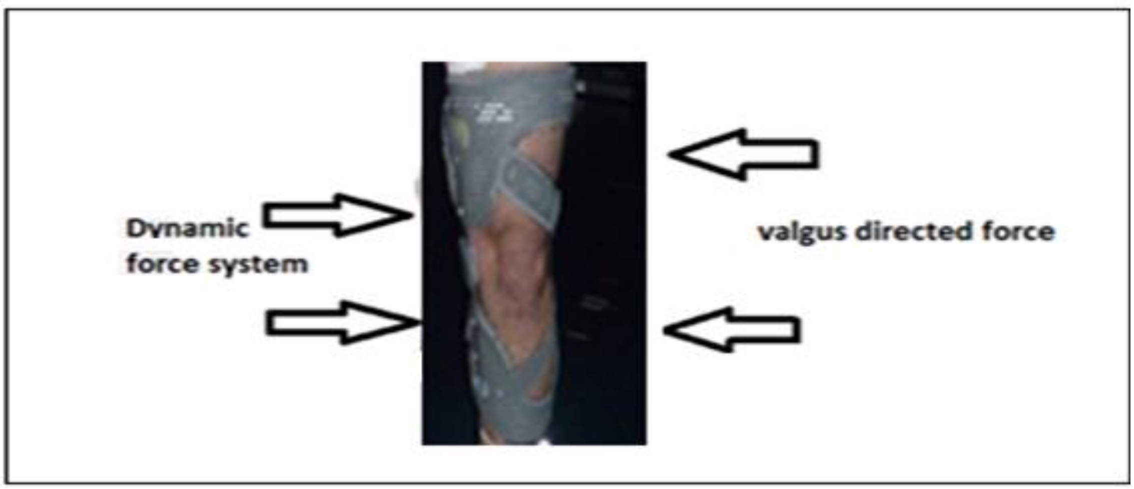


Figure 4.5: The mechanism of the Unloader One knee valgus brace is to transfer the load to the un-affected side.

Table 4.1: KAFO and knee valgus braces features.

Orthoses types	Mass (Kg)	Proximal part length from knee joint centre	Distal part length from knee joint centre
KAFO	1.20	30 cm	40 cm
Custom made knee valgus brace	0.45	17 cm	17 cm
OTS knee valgus brace	0.45	20 cm	20 cm

4.2. Data collection

After being fitted for the knee valgus brace and KAFO, the participant was asked to walk until he was familiarised to all of the interventions in a gait laboratory. When the subject felt comfortable with them, two static alignments were captured with two different shoe sizes. It was necessary to provide a shoe size which allowed room for the KAFO and one with a normal control shoe for the unloader braces. This is because the shoe size was changed during the test to fit the foot and ankle section of the KAFO, but both of shoes were identical (Ecco Zen shoes). The participant was asked to perform two activities: walking and stair climbing (ascending and descending).

4.2.1 Walking

The individual was asked to walk and climb stairs at a controlled speed using a metronome, which is a device which produces fixed beats per minute, in each one of the conditions: walking with control shoe, off-the-shelf knee valgus brace, custom knee valgus brace, and KAFO with ankle joint design (Figure 4.6). The frequency of the metronome was set at 120 and 100 steps per minute during walking and stair climbing respectively for the individual.

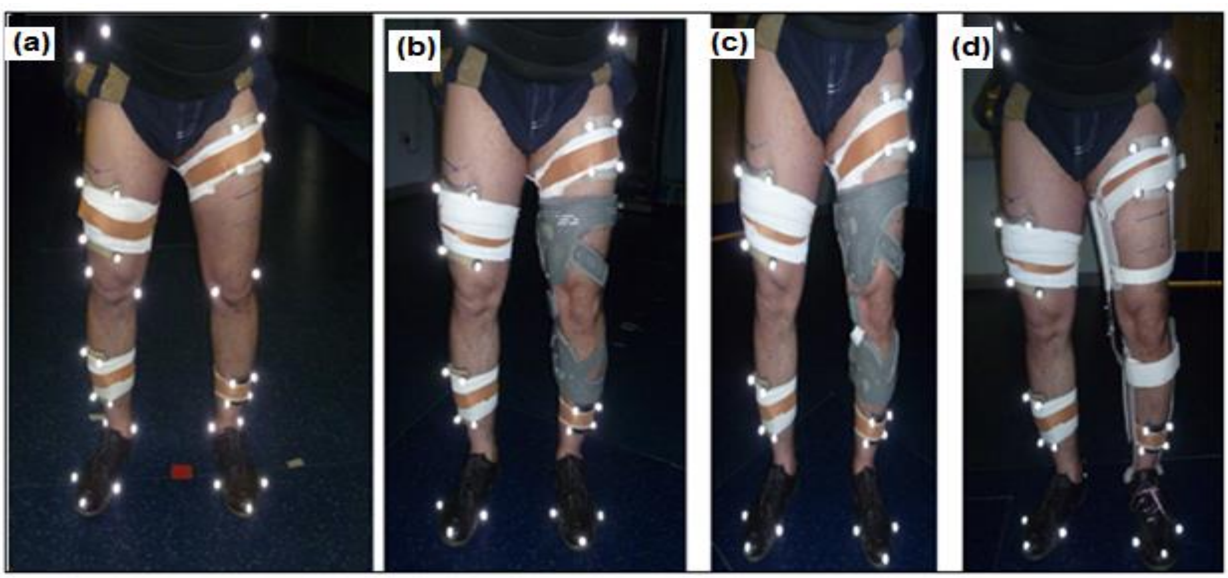


Figure 4.6: Control condition (a), off-the-shelf Ossur Unloader One knee valgus brace (b), custom made Ossur Unloader One knee valgus brace (c), and KAFO (d).

4.2.2 Ascending and Descending

The participant was asked to ascend and descend (Figure 4.7 and 4.8 respectively) three stairs five times without using the handrail or any other assistive devices using the control shoe, off-the-shelf knee valgus brace (OTS), custom knee valgus brace, and KAFO (with a larger shoe size). The shoes were identical except for shoe size. This allowed the determination of the individual's EKAM and joints angles whilst using the different conditions. The total duration of the test was two hours.

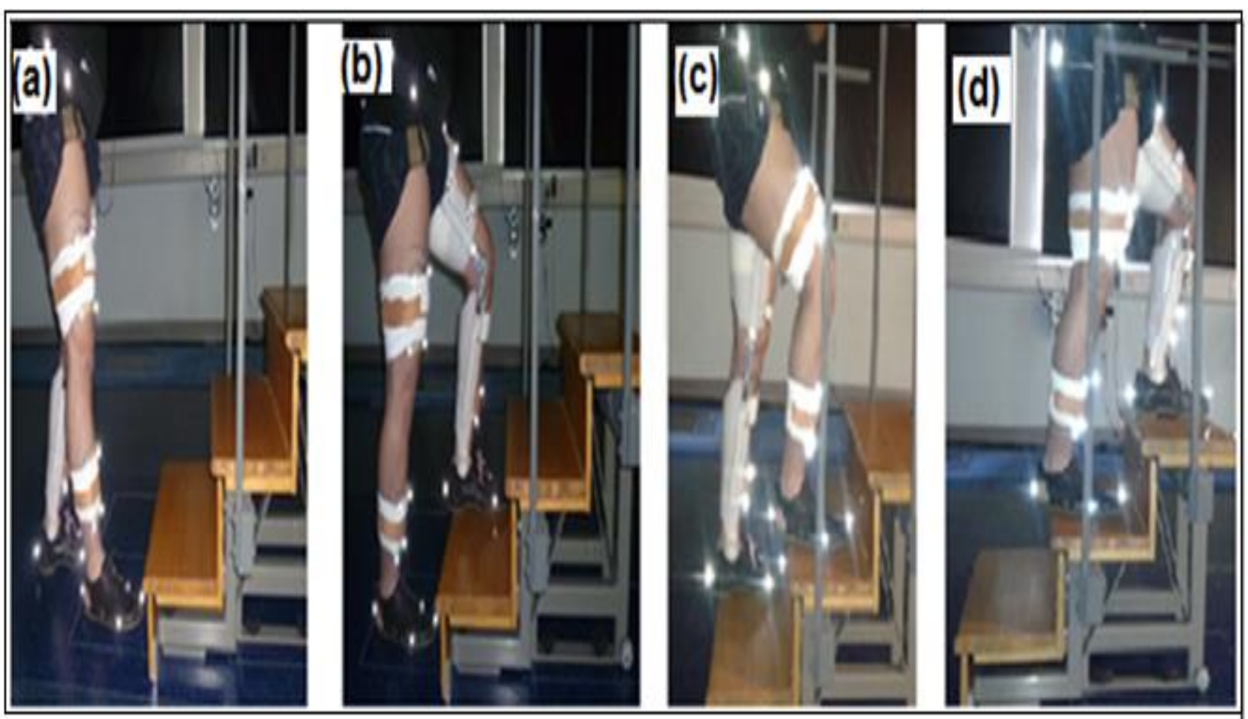


Figure 4.7: An ascending gait cycle for left leg starts with right leg of floor. (a), left side touches the first step (b). Right leg on the second step (c) and the foot loads up the third step (end of the gait cycle) (d).

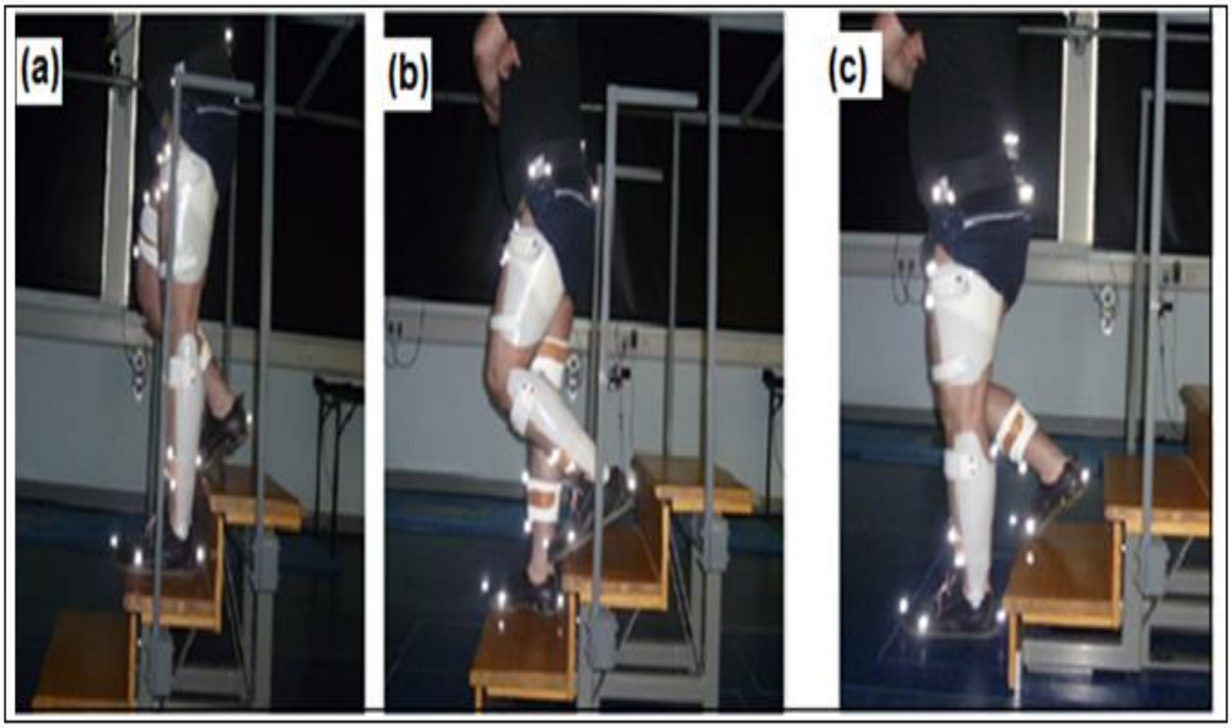


Figure 4.8: Descending gait cycle for left side. Left leg starts descending (a), right leg on first step (b), and gait cycle ends when the left side touches the floor (c).

4.3. Outcome measures

For the KAFO study, the same previous variables recorded in the reliability study such as maxima of knee flexion angles at initial contact and mid swing (Figure 3.1a), range of the knee motion in sagittal plane, EKAM, KAAI (Figure 3.1d), the maximum and minimum of sagittal knee moment during gait cycle and minimum of sagittal knee moment at late stance during walking were examined (Figure 3.1c). Moreover, vertical GRF in early and late stance were calculated for every single trial instead of calculating the average for five trials together due to the small sample size. Additionally, the maximum and minimum of the knee angle in the frontal plane were evaluated during the stance phase only to examine the effects of the KAFO and knee valgus braces on shank movement in stance phase instead of the whole gait cycle. Additional variables which were also assessed as follows: maximum and minimum of the sagittal and frontal angles for hip and ankle, and the three joints (hip, knee, and ankle) ROMs in the sagittal plane (as illustrated in figure 4.9 a, b, c, d). Furthermore, the maximum and minimum of sagittal and frontal hip moment (Figure 4.10a, b), and the maximum of single limb support moment for every trial were evaluated (Figure 4.10c).

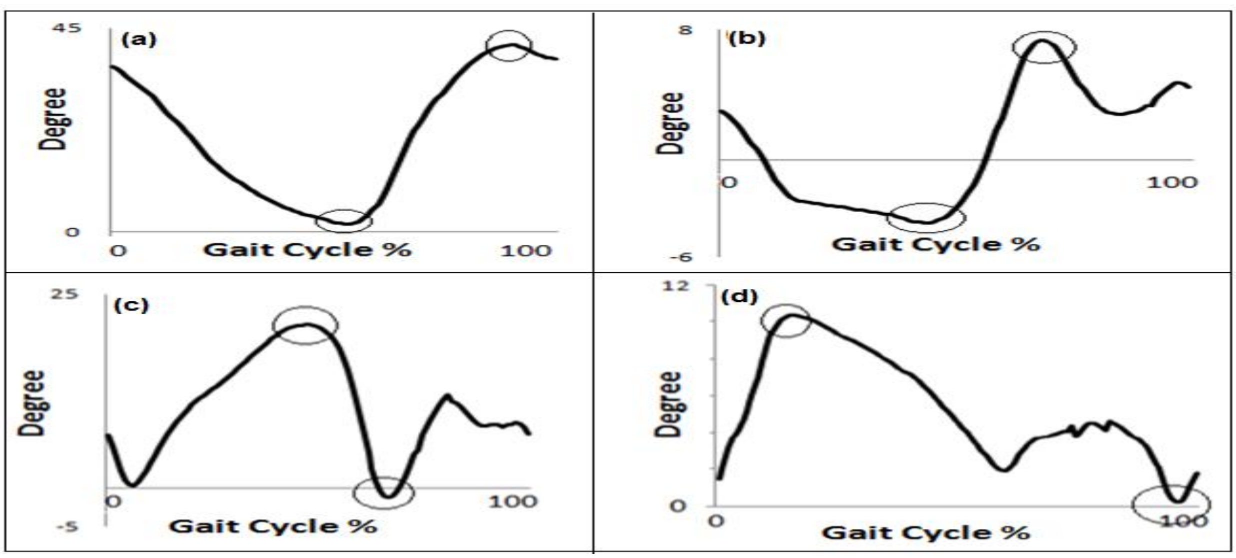


Figure 4.9: Data for sagittal hip angle (a), frontal hip angle (b), sagittal ankle angle (c), and frontal ankle angle (d).

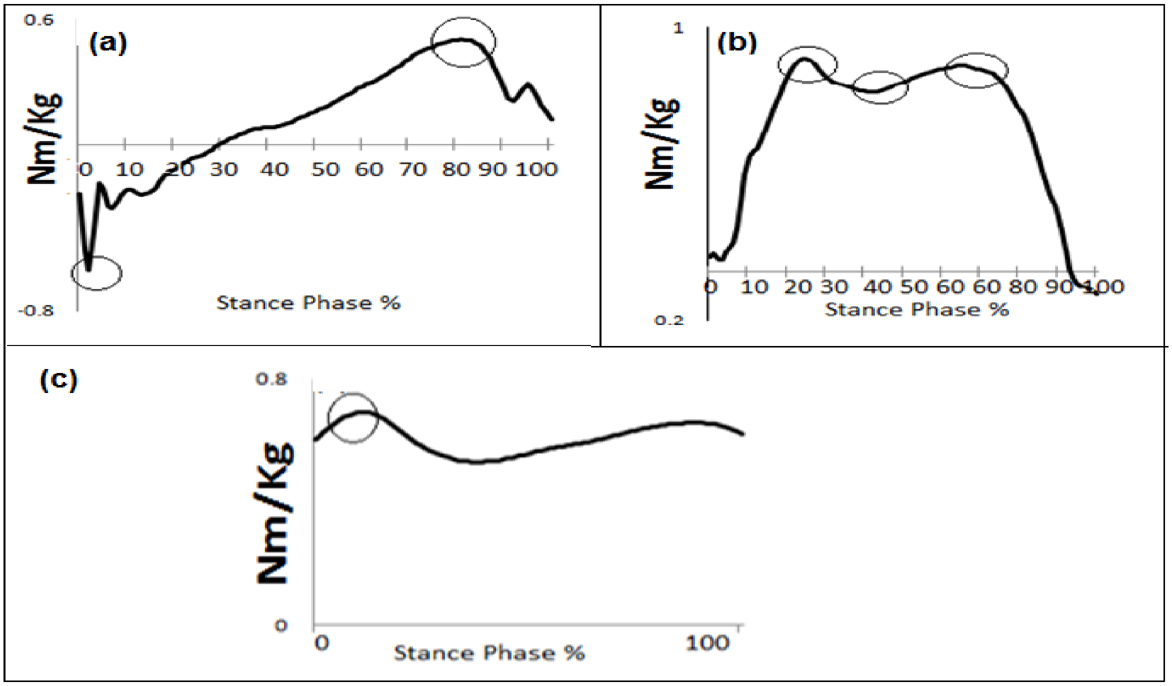


Figure 4.10: Sagittal hip moment (a), frontal hip moment (b), and single limb support (c).

4.3.1 Statistics

The statistical Package for the Social Sciences (SPSS version 20, IBM SPSS, Chicago, IL) was used to undertake the statistical analysis of the data collected. A repeated measures analysis of variance (ANOVA) was used with four factors (shoe, off-the-shelf, custom knee valgus braces, and KAFO) with a post-hoc bonferroni correction to determine statistical differences, which is used to reduce type I error of multiple comparisons where p value would be significant if it was less than 0.025 (Perneger, 1998). Due to the small sample size (n=one), each trial of data collected was used for the analysis.

4.4. Results

4.4.1 Temporal and Spatial results

The individual walked, ascended, and descended the stairs with a controlled mean (SD) speed of 0.97±0.04, 0.40±0.0, 0.45±0.0 m/s respectively. The stance phase time also was similar between conditions during walking and stair climbing (Table 4.2). Due to this controlled speed, no significant differences were found between conditions.

Table 4.2: Stance time betweens conditions.

Variables	**Mean ± (SD)**				
	Phase	**Shoe**	**OTS**	**Custom**	**KAFO**
Stance time (s)	**Walking**	0.82±0.03	0.81±0.05	0.75±0.05	0.81±0.02
	Ascending	1.02±0.03	1.06±0.08	1.02±0.06	0.9±0.06
	Descending	0.75±0.04	0.82±0.06	0.79±0.06	0.79±0.04

4.4.2 GRF results

The results showed no significant difference in the vertical GRF values during the test conditions. GRF was higher during stair descent than when walking or ascending the stairs (Table 4.3).

Table 4.3: VGRF during the four conditions.

Variables	Mean ±SD				P value (IC 95%)					
	Shoe	*OTS*	*Custom*	*KAFO*	*Shoe vs. OTS*	*Shoe vs. Custom*	*Shoe vs. KAFO*	*KAFO vs.Custom*	*KAFO vs. OTS*	*Custom vs. OTS*
1. Walking										
First peak of GRF	1.03±0.01	1.06±0.02	1.09±0.01	1.10±0.0	1.0 (-0.15- 0.09)	0.29 (-0.18-0.04)	0.12 (-0.17-0.02)	1.0 (-0.10-0.08)	0.54 (-0.15-0.05)	0.99 (-0.14-0.07)
Trough of GRF	1.01±0.01	1.01±0.0	0.99±0.01	0.99±0.0	1.0 (-0.06- 0.05)	1.0 (-0.07-0.09)	0.85(-0.02-0.05)	1.0 (-0.05-0.06)	0.15 (-0.00-0.05)	1.0 (-0.04-0.08)
Second peak of GRF	1.02±0.01	1.02±0.0	1.00±0.01	1.00±0.0	1.0 (-0.09- 0.10)	1.0 (-0.06-0.10)	1.00 (-0.06-0.10)	1.0 (-0.07-0.08)	0.18 (-0.01-0.05)	1.0 (-0.05-0.09)
2. Ascending										
First peak of GRF	1.04±0.1	1.03±0.0	1.01±0.1	1.08±0.1	1.0 (-0.08- 0.11)	1.0 (-0.09-0.15)	1.00 (-0.15-0.07)	0.09 (-0.15-0.01)	1.0 (-0.14-0.03)	0.29 (-0.03-0.07)
Trough of GRF	1.03±0.01	1.02±0.0	1.04±0.0	1.06±0.01	1.0 (-0.06- 0.08)	1.0 (-0.10-0.08)	0.03 (-0.04--0.00)	1.0 (-0.013-0.08)	0.83 (-0.13-0.05)	1.0 (-0.07-0.03)
Second peak of GRF	1.0±0.02	1.04±0.1	1.09±0.2	1.07±0.2	1.0 (-0.10- 0.18)	1.0 (-0.13-0.02)	1.0 (-0.14-0.11)	1.0 (-0.14-0.15)	1.0 (-0.10-0.14)	0.17 (-0.18 0.12)
3. Descending										
First peak of GRF	1.29±0.3	1.28±0.03	1.39±0.04	1.19±0.03	1.0 (-0.12- 0.14)	0.76 (-0.37-0.16)	0.71 (-0.14-0.34)	0.16 (-0.08-0.49)	1.0 (-0.17-0.35)	0.21 (-0.28-0.06)
Trough of GRF	0.98±0.01	1.05±0.02	1.01±0.01	1.01±0.02	0.49 (-0.2-0.07)	0.77 (-0.10-0.04)	1.0 (-0.18-0.12)	1.0 (-0.11-0.11)	1.0 (-0.08-0.15)	1.0 (-0.09-0.17)
Second peak of GRF	1.00±0.01	0.98±0.02	1.00±0.02	0.95±0.01	1.0 (-0.04-0.09)	1.0 (-0.09-0.10)	0.16 (-0.02-0.12)	0.80 (-0.07-0.17)	0.83 (-0.05-0.11)	1.0 (-0.15-0.12)

4.4.3 Kinematics of the knee joint

4.4.3.1 Walking

In the sagittal plane, the KAFO increased the knee flexion angle at initial contact (IC) significantly compared to the shoe and OTS knee valgus brace (mean difference 8.6, 4.1 degrees, p=0.00, p=0.03 respectively) (Figure 4.11, Table 4.4). Also, using the OTS and custom knee valgus braces increased the knee flexion at IC in comparison to the shoe only (mean difference 4.5, 5.3 degrees, p=0.03, p=0.02 respectively) (Figure 4.11, Table 4.4).

For knee flexion in mid swing, no significant change was found between the KAFO and the knee valgus braces compared to the shoe during walking. For minimum value of knee flexion during the gait cycle, using the custom knee valgus brace and the OTS knee valgus braces significantly increased the minimum value of knee flexion in comparison to the shoe (mean difference 2, 2.2 degrees, p=0.02, p=0.08 respectively), but KAFO did not increase that variable significantly compared to the shoe.

Therefore, all conditions reduced knee ROM in sagittal plane. The KAFO reduced it significantly during walking in comparison to the shoe (mean difference 10.5 degrees, p=0.03). Furthermore, using OTS and custom knee valgus braces reduced it by 8.2 and 7.9 degrees, p=0.44, p=0.05 respectively compared to the shoe (Figure 4.11, Table 4.4). However, no significant difference was shown between KAFO and both knee valgus braces related to knee ROM.

In the frontal plane, the maximum knee adduction angle was reduced in all conditions, but the KAFO was superior to all in magnitude as well as statistically (Figure 4.12, Table 4.5) since the mean difference between the KAFO and the shoe, OTS, and custom knee valgus braces was 8.2, 2.7, and 3 degrees, (p=0.00, p=0.04, p=0.00) respectively. Also, using the custom knee valgus brace and OTS knee valgus brace significantly reduced the maximum value of the knee adduction angle during walking compared to the shoe (mean difference 5.2, 5.5 degrees, p=0.0, p=0.0 respectively) but there was no difference between the two knee valgus braces.

4.4.3.2 Stair ascent and descent

Using the KAFO insignificantly increased knee flexion at IC during stair ascent and descent compared to the shoe, but this variable was significantly less compared to that produced by the OTS brace during stair descent (mean difference 4.3 degrees, p=0.01) (Figure 4.11, Table 4.4). In contrast, when using the OTS knee valgus brace this increased the degree of knee flexion at IC during stair ascent and descent compared to the shoe, but was only significant during stair descent (mean difference 5.2 degrees, p= 0.01). In addition, when using the custom knee valgus brace an increase in the knee flexion at IC during stair ascent and descent was seen, but this was not significantly reduced. When we compare both knee valgus braces together, the results show that the OTS increased the knee flexion angle at IC during stair descent more than custom knee valgus brace (mean difference 2 degrees, p=0.00).

At mid swing, the KAFO and OTS knee valgus brace reduced the maximum knee flexion during stair ascent and descent, but was only significantly different during the stair ascent condition compared to the shoe (mean difference 5.5, 3.9 degrees, p=0.05, p=0.01 respectively) (Figure 4.11, Table 4.4). However, the custom knee valgus brace reduced the maximum knee flexion during mid-swing during both conditions (by 7 and 3 degrees respectively) compared to the shoe but not significantly.

Furthermore, the minimum value of knee flexion during the gait cycle was considerably reduced with the KAFO during stair ascent compared to the shoe, custom, and OTS knee valgus braces (mean difference 3.5, 2.4, 3.8 degrees, p=0.00, p= 0.05, p=0.01 respectively), and during stair descent with mean differences of 4.8, 5, and 3.9 degrees (p= 0.00, p=0.00, and p=0.00 respectively). Likewise, the custom knee valgus brace significantly reduced the minimum value of knee flexion compared to the shoe during stair descent (p=0.02), but the OTS knee valgus brace did not significantly affect the minima value of knee flexion during stair climbing. For the knee ROM in the sagittal plane, no significant change was seen in any condition although reductions were seen.

In the frontal plane, the maximum knee adduction angle during stance phase was significantly less after using KAFO compared to all other conditions during stair ascent and descent. Up to 12 and 6 degrees mean difference (p=0.0, p=0.0 respectively) were found between the KAFO and the shoe during stair ascent and descent respectively, raised to 15.2 and 6.8 degrees mean difference (p=0.0, p=0.0 respectively) compared to custom knee valgus brace, and raised to 12.2 and 4.5 degrees mean difference (p=0.0, p=0.01 respectively) were found compared to OTS knee valgus brace during stair ascent and descent respectively (Figure 4.12, Table 4.5). Moreover, OTS knee valgus brace showed a significant reduction in knee adduction angle during stair descent compared to the shoe (mean difference 1.5 degree, p=0.03). However, the custom knee valgus brace increased the knee adduction raised to 3.2 degrees during stair ascent although this was not significant.

When we compare both knee valgus braces together, the custom knee valgus brace significantly increased the maximum value of knee adduction angle during stair ascent compared to OTS knee valgus brace (mean difference 3 degrees, p=0.00) (Figure 4.12, Table 4.5), but no significant changes were seen during stair descent between them.

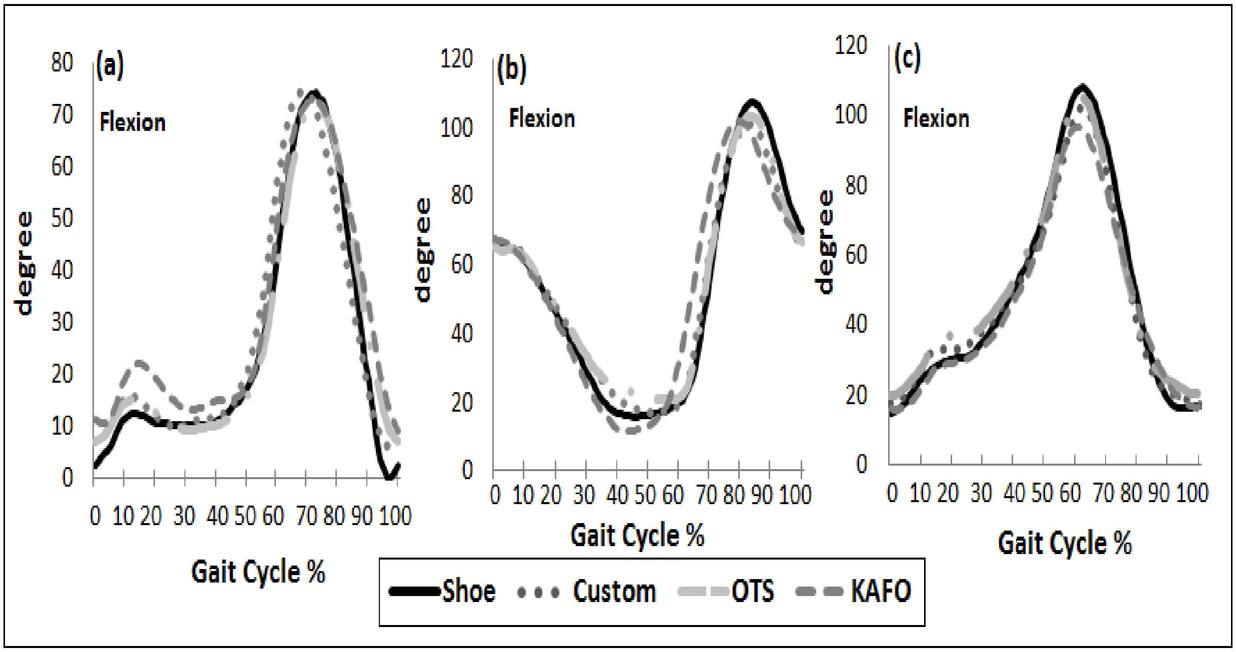


Figure 4.11: Knee angles in the sagittal plane during walking (a), stair ascent (b), and stair descent (c) for the four conditions.

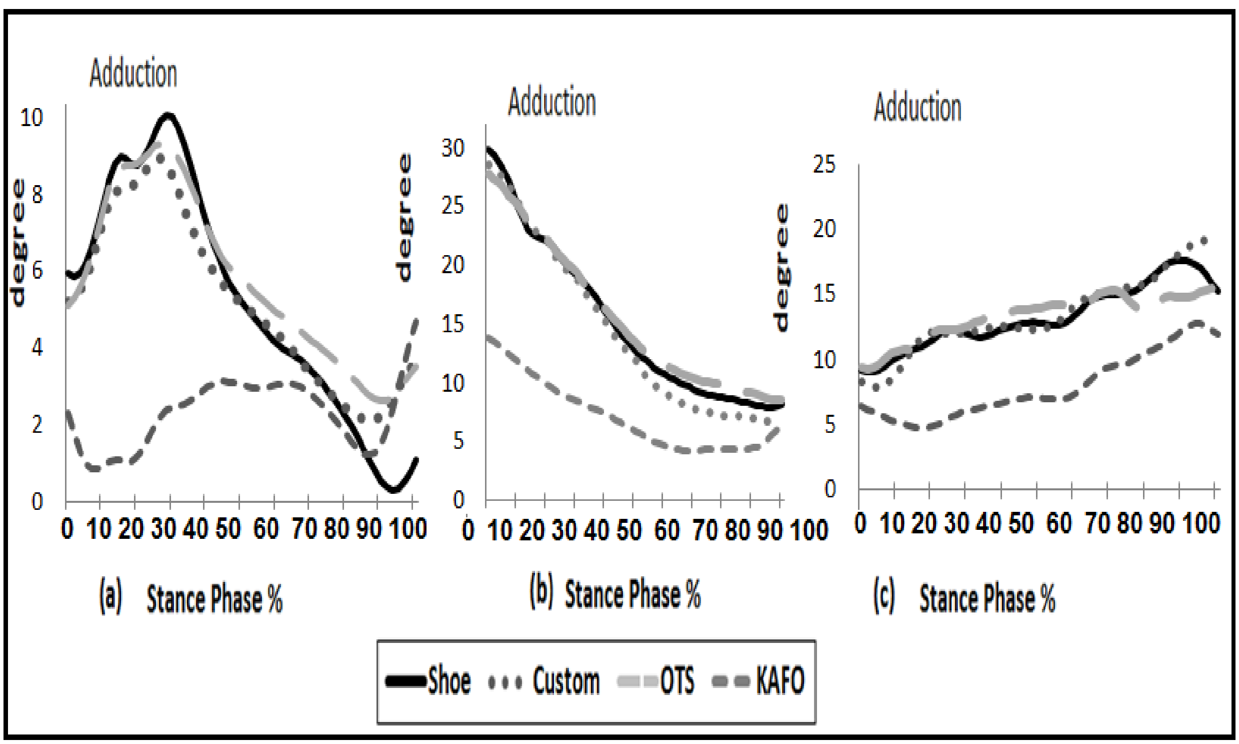


Figure 4.12: Knee angles in frontal plane during walking (a), stair ascent (b), and stair descent (c) for the four conditions.

Table 4.4: Knee angles in sagittal plane for the four conditions. Wa: walking, As: ascending, De: descending. **Bold indicates significance**

		Mean ±SD				P value (CI 95%)					
		Shoe	OTS	Custom	KAFO	Shoe vs. .OTS	Shoe vs. Custom	Shoe vs. KAFO	KAFO vs. Custom	KAFO vs. OTS	Custom vs. OTS
Knee flexion at IC	**Wa**	2.5±0.6	7.0±0.5	7.8±0.6	11.1±0.6	**0.03 (8.54-0.502)**	**0.02 (9.85-0.80)**	**0.00 (13.0-4.19)**	0.28 (-8.86-2.32)	**0.03 (7.73-0.41)**	1.0 9-5.31-3.70)
	As	66.8±1.1	65.2±0.7	67.2±0.9	67.3±0.6	1.0 (-5.42-8.68)	1.0 (-10.45-9.56)	1.0 (-3.83-2.76)	1.00 (-7.77-7.57)	0.36 (-6.21-1.87)	1.0 (-8.27-4.12)
	De	14.7±0.4	19.9±0.4	17.9±0.5	15.6±0.8	**0.01 (8.82-1.51)**	0.10 (-7.00-0.70)	1.00 (-6.40-4.73)	0.31 (-1.80-6.42)	**0.01 (1.21-7.45)**	**0.00 (0.95-3.08)**
Knee flexion at mid swing	**Wa**	74.1±0.2	70.5±3.2	72.3±1.3	72.4±0.4	1.0 (-15.9-23.0)	1.0 (-6.09-9.69)	0.313 (-1.62-4.90)	1.0 (-7.38-7.06)	1.0 (-21.4-17.5)	1.0 (-14.44-10.92)
	As	107.0±0.8	103.1±0.8	100.3±1.5	101.5±1. 7	**0.01 (1.33-6.48)**	0.24 (-4.20-17.46)	0.05 (0.05-10.89)	1.0 (-14.9-12.68)	1.0 (-5.49-8.61)	1.0 (-8.39-13.82)
	De	105.9±1.4	104.3±1.2	102.9±1.2	98.8±0.8	1.0 (-4.08-7.25)	1.0 (-9.32-15.31)	0.15 (-2.88-17.17)	0.05 (-0.02-8.33)	0.22 (-3.26-14.3)	1.0 (-10.65-13.46)
ROM	**Wa**	71.9±0.9	63.7±2.3	64.0±1.3	61.4±1.0	0.44 (-10.6-26.93)	**0.05 (-0.16-16.02)**	**0.03 (0.88-20.0)**	1.0 (-10.7-15.82)	1.0 (-20.6-25.3)	1.0 (-11.0-10.5)
	As	40.1±1.0	37.8±1.3	33.0±1.6	34.1±1.7	0.56 (-2.77-7.33)	0.31 (-5.47-19.61)	0.142 (-2.18-14.20)	1.00 (-15.1-12.9)	0.06 (-0.31-7.77)	0.98 (-8.86-18.44)
	De	91.1±1.7	84.4±1.3	85.0±1.4	83.2±1.4	0.08 (-1.06-14.57)	0.77 (-9.4-21.7)	0.33 (-6.54-22.5)	0.53 (-2.14-5.81)	1.00 (-9.65-12.1)	1.0 (-12.45-11.23)
Minima of knee flexion	**Wa**	0.09±0.5	2.3±0.3	2.1±0.2	0.60±0.1	0.08 9-0.34-4.77)	**0.02 (0.44-3.68)**	1.0 (-2.10-3.13)	0.06 (-3.20-.106)	0.08 (-3.66-0.27)	1.0 (-1.64-1.34)
	As	7.7±0.3	8.0±0.4	6.6±0.3	4.2±0.2	1.0 (-2.10-2.66)	0.69 (-3.62-1.50)	**0.00 (5.40-1.62)**	**0.05 (5.40-1.62)**	**0.01 (6.56-1.03)**	0.25 (-3.54-.877)
	De	8.8±0.2	9.0±0.2	7.9±0.2	4.0±0.3	1.0 (-1.77-2.13)	**0.02 (1.72-0.19)**	**0.00 (7.37-2.24)**	**0.00 (5.92-1.77)**	**0.00 (6.40-3.56)**	0.16 (-2.77-0.49)

Table 4.5: Knee angles in frontal plane for the four conditions. Wa: walking, As: ascending, De: descending. **Bold indicates significance.**

Variables	Mean ±SD					P value (CI 95%)					
	Phase	Shoe	OTS	Custom	KAFO	Shoe vs. OTS	Shoe vs. Custom	Shoe vs. KAFO	KAFO vs. Custom	KAFO vs. OTS	Custom vs. OTS
Minimum knee adduction angle	**Wa**	0.09±0.5	2.3±0.3	2.1±0.2	0.60±0.1	0.08 (-0.34- 4.77)	**0.02 (0.44- 3.68)**	1.0 (-2.10- 3.13)	0.063 (-3.20-0.10)	0.083 (-3.66-0.27)	1.0 (-1.64-1.34)
	As	7.7±0.3	8.0±0.4	6.6±0.3	4.2±0.2	1.0 (-2.10- 2.66)	0.69 (-3.62-1.50)	**0.0 (5.40-1.62)**	**0.05 (4.92-0.00)**	**0.01 (6.56- 1.03)**	0.25 (-3.54-0.87)
	De	8.8±0.2	9.0±0.2	7.9±0.2	4.0±0.3	1.0 (-1.77- 2.13)	**0.02 (1.72-0.02)**	**0.0 (7.37-2.24)**	**0.00 (5.92- 1.77)**	**0.00 (6.40- 3.56)**	0.16 (-2.77-0.49)
Maximum knee adduction angle	**Wa**	17.4±0.4	11.9±0.3	12.2±0.1	9.20±0.2	**0.0 (-6.34- 4.58)**	**0.00 (7.57-2.85)**	**0.00 (-10.7-5.69)**	**0.00 (4.12-1.89)**	**0.04 (5.39-0.12)**	1.0 (-1.95- 2.45)
	As	30.3±0.6	30.5±0.3	33.5±0.3	18.3±0.1	1.0 (-4.44-4.87)	0.08 (-0.48-6.92)	**0.00 (-15.0-8.92)**	**0.00 (17.1- 13.2)**	**0.00 -14.4- 9.97)**	**0.00 (1.74- 4.25)**
	De	21.4±0.5	19.9±0.4	22.2±0.4	15.4±0.3	**0.03 (2.78-0.18)**	1.0 (-2.78-4.47)	**0.00 (9.53-2.40)**	**0.00 (8.36- 5.25)**	**0.01 (7.33- 1.62)**	0.10 (-0.58-5.23)

4.4. Knee kinetics in the frontal plane

4.4.1 Walking

The external knee adduction moment was significantly reduced with the KAFO. In early stance, the first peak of the external knee adduction moment (EKAM) was significantly reduced with the KAFO by 11.4% ($p=0.04$) compared to the shoe condition and by 15% and 12.6% ($p=0.07$, $p=0.07$ respectively) compared to the OTS and custom knee valgus braces (Figure 4.13, Table 4.6). The second peak of EKAM was also reduced by 12% compared to the shoe but not significantly ($p=0.09$). The KAFO reduced the second peak of EKAM significantly more (12.3%) than the custom knee valgus brace during walking ($p=0.00$) and insignificantly compared to the OTS (9.5%, $p=0.07$). Neither the custom knee valgus brace, nor the OTS knee valgus brace significantly reduced the first or second peak of the EKAM during walking compared to the shoe.

4.4.2 Stair ascent and descent

Using the KAFO and both knee valgus braces reduced EKAM during stair climbing, but the KAFO was superior. In early stance, the KAFO reduced the first and second peaks by 7% and 10.8% respectively compared to the shoe during ascending, but was not significantly different (Figure 4.13, Table 4.6). During stair descent, no significant changes were shown when using the KAFO. However, a greater reduction in the EKAM trough was seen after using KAFO in comparison to the shoe and OTS knee valgus brace during stair ascent (16.2% and 20%, $p=0.04$, $p= 0.02$ respectively).

Using both the custom knee valgus brace and OTS knee valgus brace reduced the first peak by 8.2% and 7%, but not significantly and the OTS brace increased the second peak of EKAM up to 4.3% compared to the shoe during stair ascent. During stair descent, both the OTS and custom knee valgus braces increased the first peak of EKAM by 11.2% and 19.7% respectively, but this was not statistically significant ($p=0.17$, $p=0.38$ respectively).

When looking at the single support aspect of the stance phase (Table 4.7), the KAFO reduced the EKAM during walking and ascending (12.6% and 4.5% respectively) compared to the shoe and was only significant during stair ascent (p=0.02). However, no changes were seen during stair descent. In contrast, the custom and OTS knee valgus braces did not significantly change this variable during walking and stair ascent, but both OTS and custom knee valgus braces increased the EKAM during stair descent compared to the shoe, although not significantly (10%, 19%, p=0.15, p=0.13 respectively).

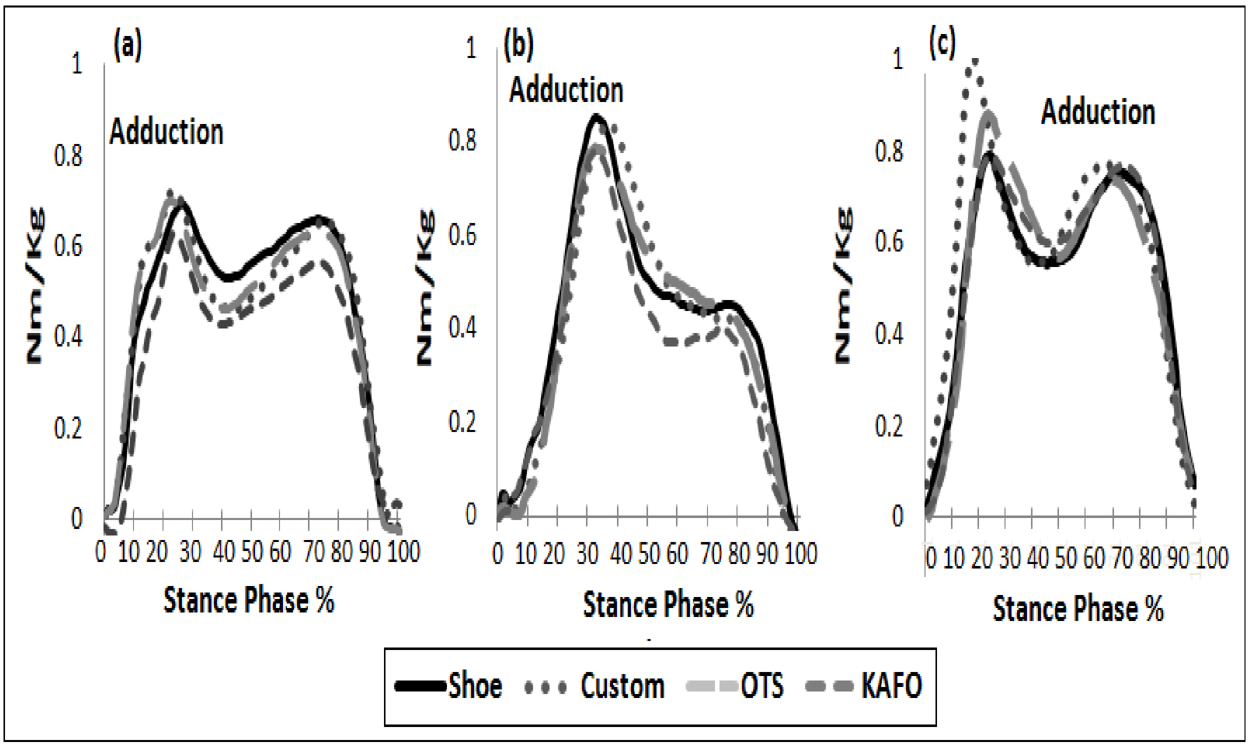


Figure 4.13: EKAM during walking (a), stair ascent (b), and stair descent (c) for the four conditions.

Table 4.6: EKAM during the four conditions. Wa: walking, As: ascending, De: descending. **Bold indicates significance.**

Variables		Mean ±SD				P value (CI 95%)					
		Shoe	**OTS**	**Custom**	**KAFO**	**Shoe vs.OTS**	**Shoe vs. Custom**	**Shoe vs. KAFO**	**KAFO vs.Custom**	**KAFO vs. OTS**	**Custom vs. OTS**
EKAM first peak	**Wa**	0.70±0.01	0.71±0.01	0.73±0.02	0.62±0.0	1.0 (-0.08-0.06)	1.0 (-0.20-0.14)	**0.04** **(0.00-0.14)**	0.07 (-0.01-0.22)	0.07 (-0.00-0.17)	1.0 (-0.19-0.15)
	As	0.85±0.3	0.79±0.4	0.78±0.02	0.79±0.05	1.0 (-0.23-0.36)	1.0 (-0.16-0.31)	1.0 (-0.30-0.43)	1.0 (-0.23-0.20)	1.0 (-0.30-0.30)	1.0 (-0.08-0.10)
	De	0.81±0.1	0.90±0.2	0.97±0.6	0.81±0.4	0.17 (-0.21-0.03)	0.38 (-0.43-0.13)	1.0 (-0.21-0.23)	0.86 (-0.26-0.57)	0.46 (-0.09-0.28)	1.0 (-0.39-0.25)
EKAM Trough	**Wa**	0.52±0.01	0.50±0.03	0.45±0.02	0.42±0.01	1.0 (-0.16-0.20)	0.16 (-0.00-0.17)	**0.04** **(0.00-0.20)**	0.98 (-0.05-0.11)	0.31 (-0.06-0.22)	1.0 (-0.17-0.20)
	As	0.43±0.01	0.45±0.02	0.47±0.02	0.36±0.02	1.0 (-0.13-0.09)	1.0 (-0.18-0.11)	**0.04** **(0.00-0.15)**	0.11 (-0.03-0.26)	**0.02** **(0.01-0.17)**	1.0 (-0.13-0.10)
	De	0.53±0.02	0.55±0.02	0.55±0.02	0.58±0.03	1.0 (-0.16-0.12)	1.0 (-0.4-0.10)	1.0 (-0.23-0.12)	1.0 (-0.15-0.07)	1.0 (-0.20-0.12)	1.0 (-0.19-0.19)
EKAM second peak	**Wa**	0.65±0.01	0.63±0.02	0.65±0.01	0.57±0.01	1.0 (-0.14-0.18)	1.0 (-0.09-0.10)	0.09 (-0.01-0.19)	**0.00** **(0.03-0.12)**	0.07 (-0.00-0.14)	1.0 (-0.09-0.06)
	As	0.46±0.01	0.48±0.02	0.45±0.02	0.41±0.02	1.0 (-0.15-0.12)	1.0 (-0.12-0.14)	0.78 (-0.07-0.18)	0.05 (-0.00-0.08)	0.17 (-0.03-0.16)	1.0 (-0.08-0.13)
	De	0.75±0.02	0.75±0.01	0.77±0.02	0.74±0.01	1.0 (-0.13-0.12)	1.0 (-0.20-0.16)	1.0 (-0.14-0.15)	1.0 (-0.12-0.17)	1.00 (-0.02-0.03)	1.0 9-0.15-0.11)

4.5. Knee adduction angular impulse (KAAI)

The KAAI was reduced after using KAFO compared to the shoe during walking and stair climbing (Table 4.7), but was only statistically significant during ascending compared to the shoe and OTS knee valgus brace (26.2%, 26.2%. p =0.00, p= 0.03 respectively). In contrast, when using custom and OTS valgus braces there was no change in KAAI during walking and stair ascent (p=1.0); however, using the custom knee valgus brace increased KAAI during descending by 10.4%, p=0.06 compared to KAFO (Figure 4.14, Table 4.7).

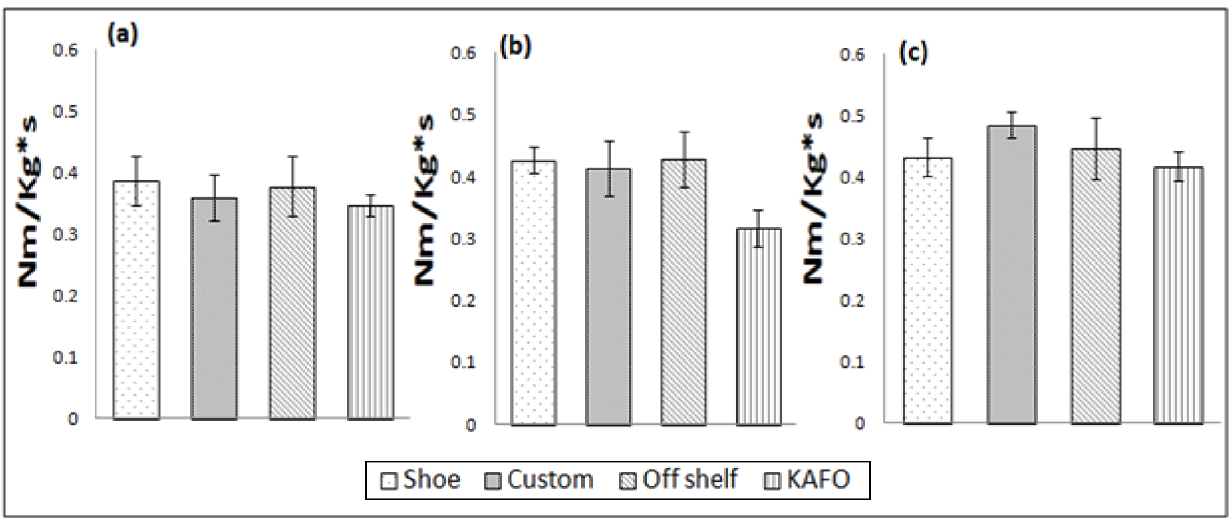


Figure 4.14: Knee KAAI for the four conditions (error bars denote 1SD) during walking (a), stair ascent (b), and stair descent (c).

4.6. Knee kinetics in sagittal plane

Using the KAFO and both knee valgus braces increased the knee flexion moment, but not statistically significantly during walking and stair climbing. During late stance, the KAFO applied more of a knee flexion moment (Figure 4.15, Table 4.6); whereas, the shoe, custom knee valgus brace, and OTS knee valgus brace applied a greater extension moment. However, this difference between KAFO and the shoe was not statistically significant (p=0.08).

For knee extension moment, no significant changes were seen during walking after using all conditions (Figure 4.15, Table 4.6). During stair ascent, also no significant changes were shown using KAFO and custom knee valgus brace compared to the shoe, but OTS knee valgus brace insignificantly reduced knee extension moment more than shoe, custom knee valgus brace and KAFO (33%,27%,46%,p=0.56, p=0.09, p=0.09 respectively). During stair descent, the knee extension moment was reduced more by the KAFO compared to the OTS, custom knee valgus braces, plus the shoe but not significantly (82%, 78%, 82%, p=0.46, p=0.03, p=0.37 respectively).

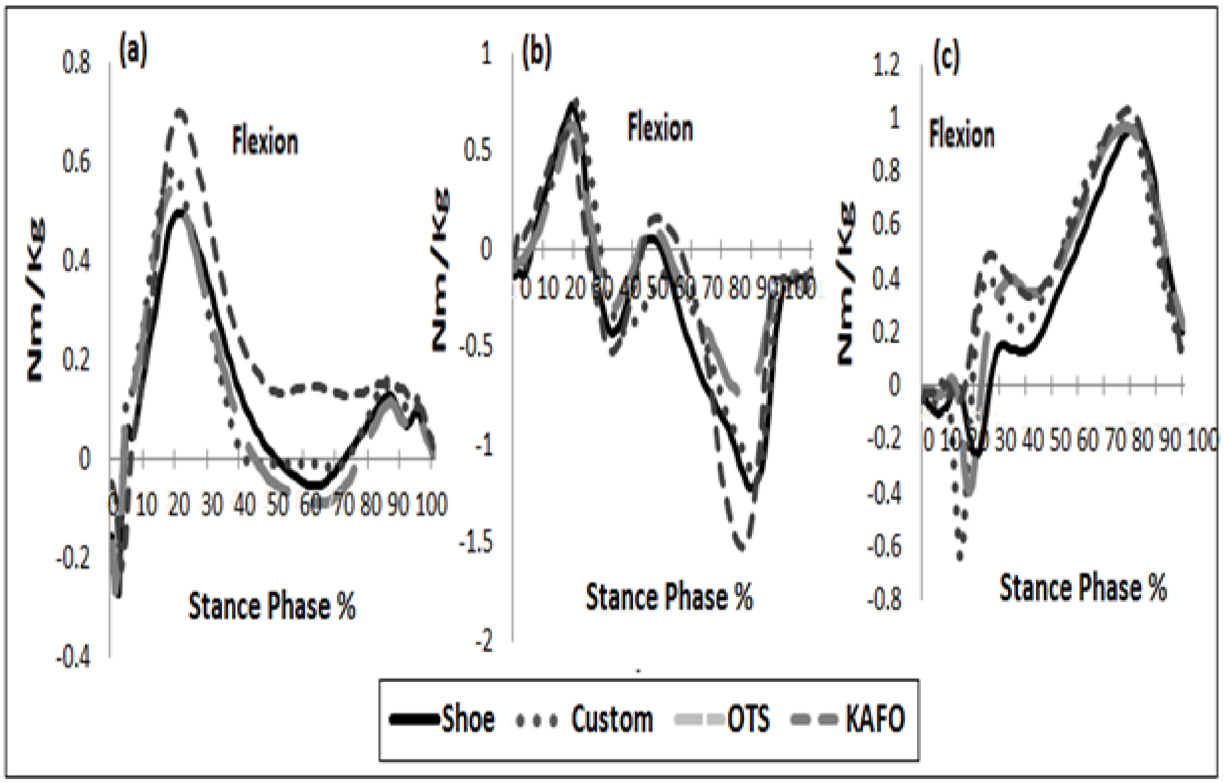


Figure 4.15: Knee moment in sagittal plane during walking (a), stair ascent (b), and stair descent (c) for the four conditions.

Table 4.7: Knee moment during the four conditions. Wa: walking, As: ascending, De: descending. *: extension moment**. Bold indicates significance.**

Variables		Mean ±SD				P value					
		Shoe	OTS	Custom	KAFO	Shoe vs. OTS	Shoe vs. Custom	Shoe vs. KAFO	KAFO vs. Custom	KAFO vs. OTS	Custom vs. OTS
KAAI	**Wa**	0.38±0.02	0.37±0.02	0.35±0.01	0.31±0.0	1.00 (-0.14-0.16)	1.00 (-0.07-0.13)	0.22 (-0.04-0.18)	0.41 (-0.04-0.12)	0.07 (-0.0-0.13)	1.00 (-0.11-0.15
	As	0.42±0.0	0.42±0.0	0.41±0.0	0.31±0.01	1.00 (-0.10-0.10)	1.00 (-0.07-0.09)	**0.00 (0.04-0.17)**	0.05 (-0.00-0.19)	**0.03 (0.013-0.20)**	1.00 (-0.06-0.09)
	De	0.43±0.01	0.44±0.02	0.48±0.01	0.41±0.01	1.00 (-0.18-0.15)	0.12 (-0.12-0.01)	1.0 (-0.03-0.06)	0.06 (-0.00-0.141)	1.0 (-0.12-0.18)	1.00 (-0.15-0.07)
Single Limb Support	**Wa**	0.71±0.01	0.71±0.02	0.73±0.03	0.62±0.0	1.000 (-0.09-0.09)	1.00 (-0.185-0.13)	**0.02 (0.01-0.14)**	0.07 (-0.01-0.22)	0.074 (-0.01-0.17)	1.00 (-0.19-0.15)
	As	0.87±0.02	0.81±0.02	0.87±0.02	0.83±0.03	1.00 (-0.17-0.28)	1.00 (-0.152-0.142)	1.00 (-0.20-0.27)	1.00 (-0.17-0.25)	1.00 (-0.16-0.12)	0.71 (-0.20-0.08)
	De	0.81±0.02	0.90±0.02	1.00±0.05	0.81±0.03	0.15 (-0.21-0.03)	0.13 (-0.442-0.066)	1.00 (-0.23-0.23)	0.32 (-0.14-0.51)	0.46 (-0.09-0.27)	1.00 (-0.42-0.23)
Knee flexion moment	**Wa**	0.48±0.4	0.55±0.03	0.58±0.02	0.70±0.04	1.00 (-0.28-0.15)	0.27 (-0.274-0.071)	0.33 (-0.61-0.17)	0.60 (-0.38-0.15)	0.42 (-0.44-0.14)	1.00 (-0.20-0.13)
	As	0.80±0.5	0.82±0.02	0.78±0.03	0.82±0.03	1.00 (-0.25-0.21)	1.00 (-0.166-0.192)	1.00 (-0.35-0.31)	1.00 (-0.24-0.18)	1.00 (-0.19-0.20)	1.00 (-0.19-0.262)
	De	1.00±0.03	0.98±0.02	0.98±0.02	1.03±0.03	1.00 (-0.14-0.17)	1.00 (-0.137-0.176)	1.00 (-0.32-0.25)	1.00 (-0.23-0.11)	1.00 (-0.2-0.15)	1.00 (-0.17-0.18)
Knee flexion moment at late stance	**Wa**	0.09±.03*	0.09±0.02*	0.03±0.2*	0.12±0.03	1.00 (-0.33-0.4)	0.72 (-0.14-0.07)	0.08 (-0.4-0.03)	0.21 (0.10-0.4)	0.18 (-1.12-0.54)	1.00 (-0.34-0.21)
Knee extension moment	**Wa**	0.28±0.02	0.27±0.02	0.28±0.0	0.24±0.01	1.00 (-0.08-0.06)	1.00 (-0.126-0.113)	1.00 (-0.17-0.08)	1.00 (-0.11-0.04)	1.00 (-0.16-0.10)	1.00 (-0.08-0.09)1
	As	1.2±0.5	0.8±0.9	1.1±0.05	1.5±0.1	0.56 (-1.46-0.55)	1.00 (-0.867-0.674)	1.00 (-0.75-1.30)	0.28 (-0.26-1.00)	0.09 (-0.15-1.61	0.09 (-0.07-0.79)
	De	0.51±0.2	0.62±0.2	0.64±0.01	0.11±0.05	1.00 (-1.2-1.42)	1.00 (-1.152-1.417)	0.37 (-1.17-0.35)	0.30 (-1.48-0.40)	0.46 (-1.5-0.54	1.00 (-0.51-0.55)

4.7. Hip kinematics in sagittal and frontal planes

4.7.1 Walking

There was a significant increase in the maximum hip flexion angle when using the KAFO in comparison to the shoe, off-the-shelf (OTS) and custom UnloaderOne knee valgus brace during walking (mean difference 6.6, 5.3, 6.1 degrees, p=0.0, p=0.0, p=0.01 respectively) (Figure 4.16, Table 4.8). Furthermore, the maximum hip extension angle also increased considerably when using KAFO during walking compared to the shoe, custom, and OTS knee valgus braces (mean difference 0.3, 1.3, 0.9 degrees, p= 0.01, p=0.00, p=0.00 respectively). Therefore, the hip range of motion (ROM) increased significantly during walking when using the KAFO in comparison to the shoe, OTS, and custom knee valgus braces (mean difference 11.7, 9.8, 10 degrees, p=0.00, p=0.002, p=0.00 respectively). However, no significant changes were seen when using the custom and OTS knee valgus braces in hip flexion, hip extension and hip ROM compared to the shoe.

In the frontal plane, the maximum hip abduction angle was significantly less when using the KAFO during walking (Figure 4.17, Table 4.9). The mean difference between KAFO compared to the shoe, OTS and custom knee valgus braces was 5.3, 5.5, 5.3 degrees respectively (p=0.0 for all differences). Furthermore, the KAFO increased the hip adduction angle compared to the shoe (mean difference 3.8 degrees, p=0.02). In contrast, no significant changes in maximum hip adduction and abduction angles were seen between both knee valgus braces and the shoe during walking.

4.7.2 Stair ascent and descent

The maximum hip flexion angle increased with the KAFO during stair ascent by an average increase of 4 degrees compared to the shoe but this was not statistically significant. Additionally, the OTS knee valgus brace increased hip flexion significantly during stair ascent compared to the shoe (mean difference 3.3 degrees, p=0.02). No changes were seen with using custom knee valgus brace during stair climbing and no changes were shown during stair descent between the conditions.

Maximum hip extension was reduced with the KAFO during stair climbing. The reduction was significantly different during stair descent compared to the shoe, OTS, and custom knee valgus braces (mean difference 4.2, 5.9, 3.7 degrees, p=0.01, p=0.00, p=0.02 respectively), and it was significantly different during stair ascent compared to both custom and OTS knee valgus braces (mean difference 6.4, 7.6 degrees, p=0.03, p=0.02 respectively). In contrast, both knee valgus braces increased the hip extension angle during stair climbing, but it was significantly different during stair ascent by the OTS knee valgus compared to the shoe (p=0.04). As a result, hip ROM significantly increased with the KAFO during stair ascent in comparison to the shoe and OTS knee valgus brace (8.4, 9 degrees, p=0.00, p=0.01 respectively) and during stair descent compared to the OTS (p=0.04). Both the custom and OTS knee valgus braces increased hip ROM during stair climbing but these did not approach significance.

In the frontal plane, the maximum hip abduction angle was significantly reduced when using the KAFO during stair ascent and descent compared to the shoe, OTS, and custom knee valgus braces by a mean difference of 5, 5.5, 4.3 degrees (p=0.02, p=0.02, p=0.00 respectively) during stair ascent and during stair descent by a mean difference of 4.9, 4.9, 3.9 degrees respectively (p=0.0 for all conditions). However, maximum hip adduction angle was significantly greater when using the KAFO during stair ascent compared to the shoe, OTS, and custom knee valgus braces (mean difference 7.5, 6.6, 5.9 degrees, p=0.02, p=0.00, p=0.01 respectively), and during stair descent compared to the shoe, OTS, and custom knee valgus brace (mean difference 5.9, 6, 5.9 degrees, p=0.00, p=0.00, p=0.02, respectively) (Figure 4.17, Table 4.9). No significant differences were shown between both knee valgus braces and the shoe in the maximum value of the hip abduction angle during walking and stair climbing. However, maximum hip adduction angle was increased with custom knee valgus brace in comparison to the shoe during stair ascent (mean difference 1.6 degree, p=0.00).

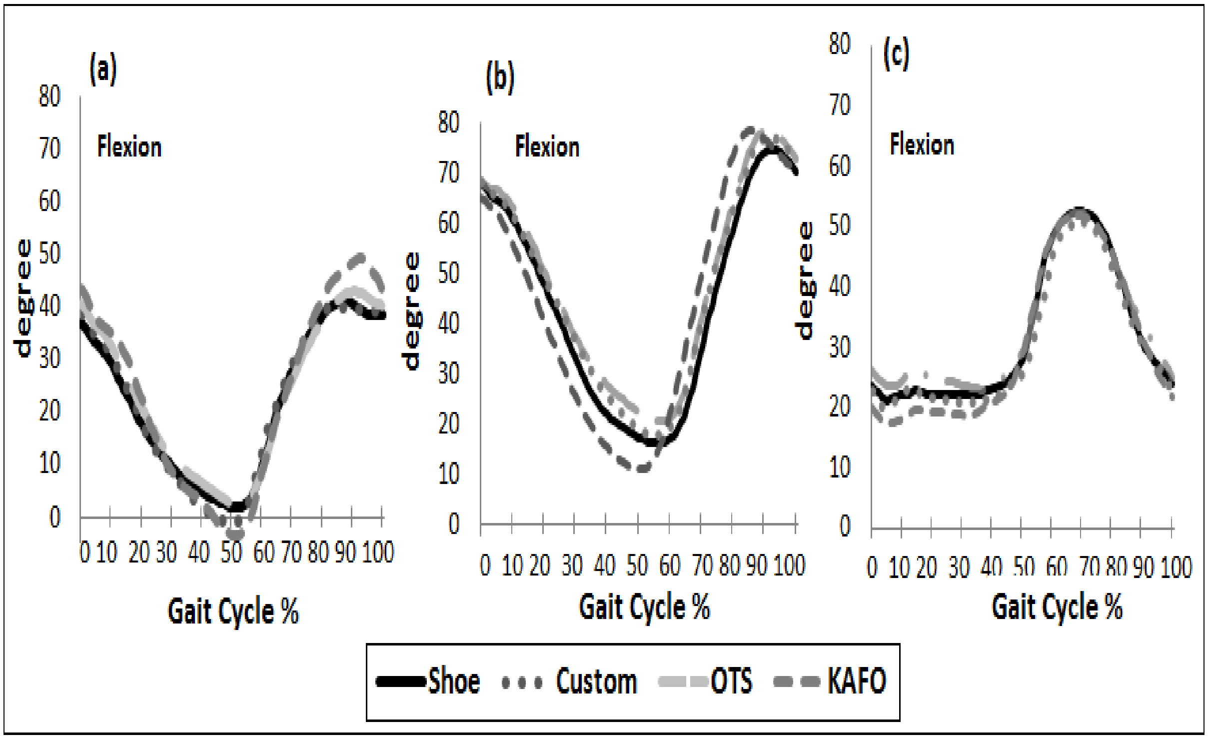


Figure 4.16: Hip sagittal plane angles during walking (a), stair ascent (b), and stair descent (c) for the four conditions.

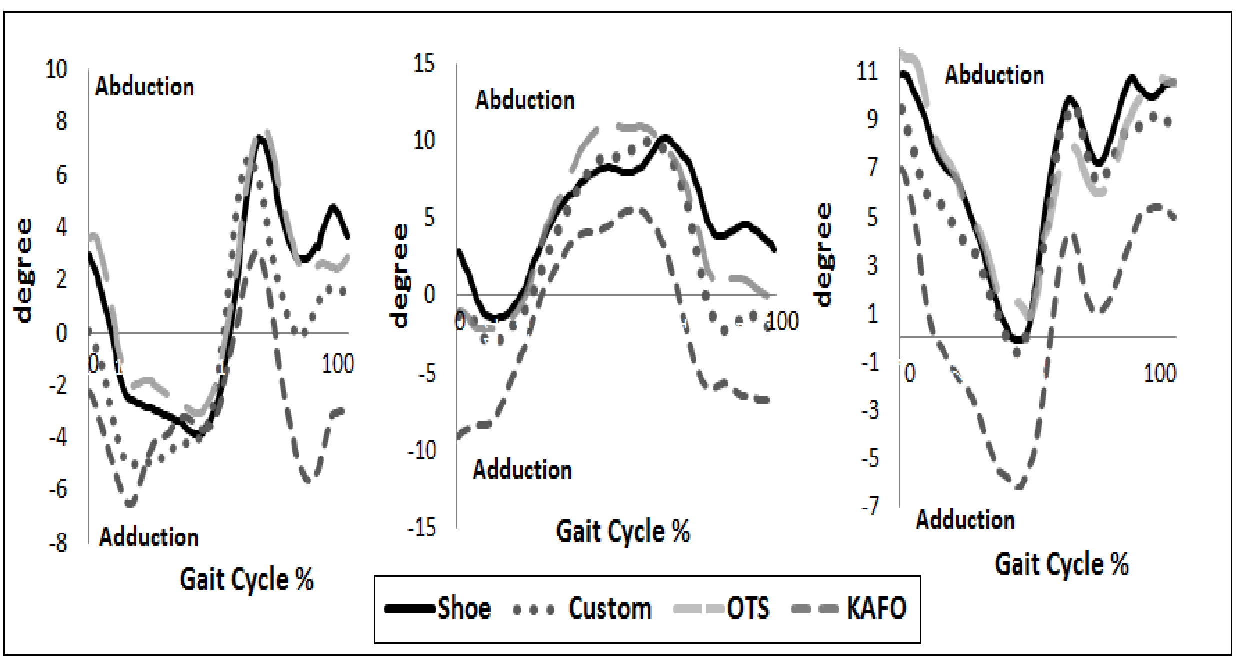


Figure 4.17: Hip frontal plane angle during walking (a), stair ascent (b), and stair descent (c) for the four conditions.

Table 4.8: Hip angles in sagittal plane during the four conditions. Wa: walking, As: ascending, De: descending. **Bold indicates significance.**

Variables		Mean ±SD				P value (CI 95%)					
		Shoe	OTS	Custom	KAFO	Shoe vs.OTS	Shoe vs. Custom	Shoe vs. KAFO	KAFO vs.Custom	KAFO vs. OTS	Custom vs. OTS
Hip flexion angle	**Wa**	42.0±0.4	43.3±0.5	42.5±0.7	48.6±0.4	0.85 (-4.70-2.16)	1.0 (-5.86-4.85)	**0.00 (8.39-4.90)**	**0.01 (10.34-1.94)**	**0.00 (8.07-2.61)**	1.0 (-2.74-4.34)
	As	74.7±0.6	78.0±0.5	77.3±0.6	78.5±0.8	**0.02 (5.97-0.63)**	0.60 (-8.41-3.28)	0.143 (-8.94-1.38)	1.0 (-7.27-4.83)	1.0 (-5.39-4.44)	1.0 (-3.79-5.28)
	De	52.0±0.7	52.5±0.4	51.0±0.8	52.0±0.5	1.0 (-5.53-4.83)	1.0 (-4.89-7.21)	1.0 (-4.72-5.04)	0.75 (-3.51-1.51)	1.0 (-2.44-3.45)	0.74 (-2.25-5.26)
Hip extension angle	**Wa**	2.3±0.4	1.7±0.5	1.3±0.2	2.6±0.3	1.0 (-2.16-3.32)	0.74 (-1.70-3.98)	**0.01 (1.57-8.48)**	**0.00 (2.93-4.85)**	**0.00 (1.77-7.12)**	1.0 (-1.722.83)
	As	15.9±0.5	19.8±0.9	17.6±0.5	11.2±0.9	**0.04 (7.75-0.06)**	0.58 (-5.71-2.20)	0.17 (-2.18-11.54)	**0.03** (0.66-12.19)	**0.02 (1.28-15.88)**	0.65 (-2.93-7.25)
	De	20.3±0.4	22.0±0.7	19.8±0.3	16.1±0.5	0.23 (-4.28-1.00)	1.0 (-2.67-3.66)	**0.01 (1.43-7.05)**	**0.02 (0.80-6.69)**	**0.00 (2.69-9.07)**	0.44 (-2.17-6.43)
ROM	**Wa**	39.6±0.5	41.5±0.8	41.2±0.8	51.3±0.6	1.0 (-7.95-4.18)	1.0 (-8.02-4.74)	**0.00 (-15.9--7.43)**	**0.00 (14.5-5.54)**	**0.00 (14.1-5.46)**	1.0 (-2.98-3.46)
	As	58.8±0.5	58.2±0.7	59.6±1.0	67.2±0.6	1.0 (-3.75-4.96)	1.0 (-7.54-5.92)	**0.00 (11.3-5.57)**	0.05 (-15.38-0.08)	**0.01 (14.9-3.13)**	0.74 (-4.94-2.11)
	De	31.8±0.7	30.5±1.0	31.1±1.0	35.9±0.6	1.0 (-6.13-8.71)	1.0 (-7.16-8.49)	0.13 (-9.52-1.34)	0.07 (-10.09-0.59)	**0.04 (10.6-0.07)**	1.0 (-8.16-6.91)

Table 4.9: Hip angles in frontal planes for the four conditions. Wa: walking, As: ascending, De: descending. **Bold indicates significance.**

Variable		Mean ±SD				P value					
		Shoe	**OTS**	**Custom**	**KAFO**	**Shoe vs. OTS**	**Shoe vs. Custom**	**Shoe vs. KAFO**	**KAFO vs. Custom**	**KAFO vs. OTS**	**Custom vs. OTS**
Hip abduction angle	**Wa**	8.6±0.2	8.8±0.4	8.6±0.3	3.3±0.3	1.0 (-1.39-1.39)	1.0 (-1.73-1.86)	**0.00** **(4.18-6.5)**	**0.00** **(3.67-6.91)**	**0.00** **(2.96-8.14)**	1.0 (-2.19-2.69)
	As	10.9±0.5	11.4±0.6	10.2± 0.3	5.9±0.5	1.0 (-4.86-3.91)	1.0 (-2.6-4.10)	**0.02** **(0.95-9.11)**	**0.00** **(6.23-2.40)**	**0.02** **(1.01-10.0)**	0.72 (-1.74-4.11)
	De	12.1±0.1	12.1±0.4	10.8± 0.3	7.2±0.06	1.00 (-1.91-1.85)	0.182 (-0.59-3.11)	**0.00** **(4.21-5.51)**	**0.00** **(1.60-5.61)**	**0.00** **(2.67-7.12)**	0.62 (-1.69-4.26)
Hip adduction angle	**Wa**	3.2±0.2	2.8±0.6	4.1±0.9	7.0±0.5	1.0 (-3.02-2.17)	1.0 (-2.93-4.82)	**0.02** (0.73-6.5)	0.49 (-3.14-8.84)	0.05 (-0.02-8.45)	1.0 (-3.20-5.94)
	As	1.6±0.2	2.5±0.3	3.2±0.5	9.1±0.5	0.43 (-0.82-2.47)	**0.00** **(0.97-4.16)**	**0.02** **(5.26-9.67)**	**0.01** **(1.60-10.13)**	**0.00** **(5.25-8.0)**	1.0 (-2.35-3.88)
	De	0.7±0.4	0.6±0.9	0.7±0.9	6.6±0.3	1.0 (-6.7-3.9)	1.0 (-4.53-4.60)	**0.0** **(3.17-8.74)**	**0.02** **(1.22-10.62)**	**0.00** **(3.13-11.5)**	1.0 (-6.36-9.23)

4.8. Hip kinetics

4.8.1 Frontal plane

The first peak of the external hip adduction moment was increased and the second peak reduced slightly when using the KAFO and both knee valgus braces during walking but neither were different compared to the shoe. However, during stair ascent and descent the KAFO increased both peaks and both knee valgus braces reduced both peaks of external hip adduction moment insignificantly compared to the shoe. However, the difference is seen clearly between the KAFO and off-the- shelf (OTS) knee valgus brace as the KAFO increased the second peak of external hip adduction moment during descending more than OTS knee valgus brace (mean difference 13.7%, p= 0.03) (Figure 4.18, Table 4.10). Furthermore, when comparing both of the knee valgus braces, the results show that no significant changes were found during in the both peaks of hip adduction walking and stair climbing.

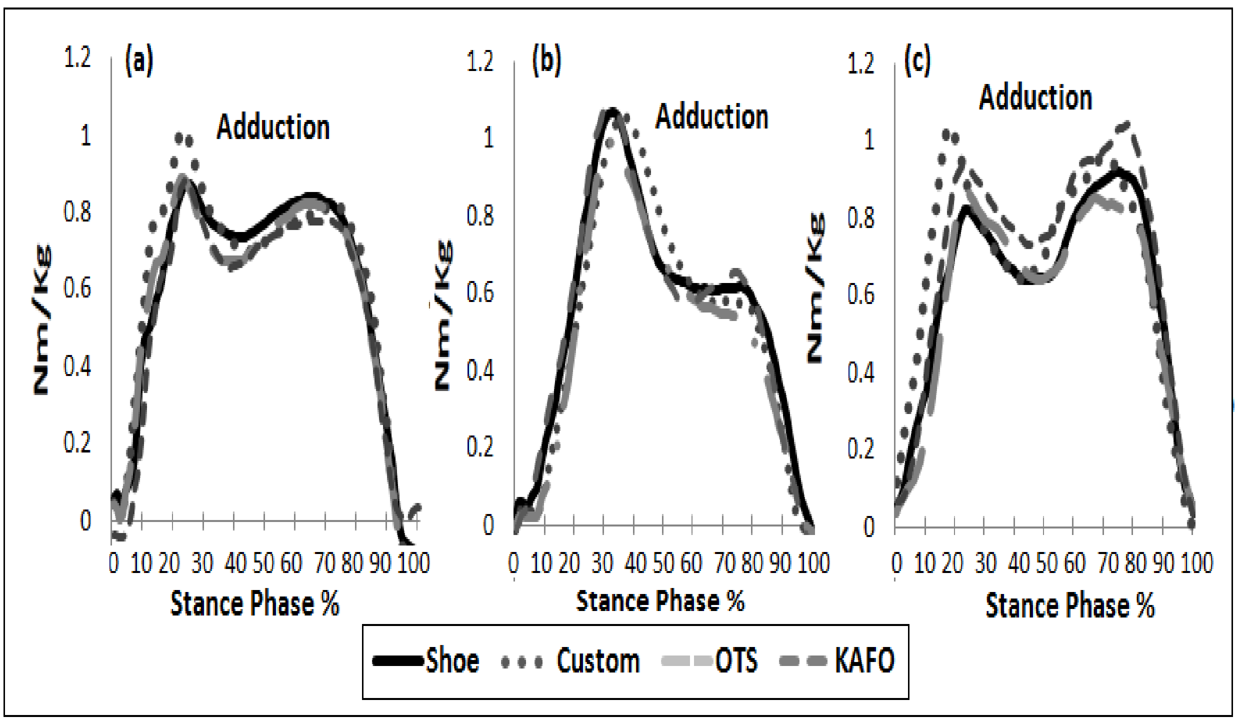


Figure 4.18: Hip moment in frontal plane during walking (a), stair ascent (b), and stair descent (c) for the four conditions.

Table 4.10: Hip moment in Frontal plane during the four conditions. Wa: walking, As: ascending, De: descending. **Bold indicates significance.**

variable		Mean ±SD				P value					
		Shoe	OTS	Custom	KAFO	Shoe vs. OTS	Shoe vs. Custom	Shoe vs. KAFO	KAFO vs. Custom	KAFO vs. OTS	Custom vs. OTS
First peak of hip adduction moment	**Wa**	0.87±0.01	0.90±0.01	0.97±0.04	0.90±0.03	0.40 (-0.08-0.02)	0.50 (-0.30-0.11)	1.00 (-0.24-0.1)	1.00 (-0.27-0.40)	1.00 (-0.19-0.19)	1.00 (-0.31-0.17)
	As	1.07±0.0	0.98±0.05	0.99±0.03	1.10±0.0	1.00 (-0.27-0.44)	1.00 (-0.23-0.39)	1.00 (-0.47-0.40)	1.00 (-0.45-0.23)	1.00 (-0.55-0.32)	1.00 (-0.14-0.13)
	De	0.86±0.04	0.87±0.03	0.98±0.06	0.97±0.03	1.00 (-0.15-0.11)	0.85 (-0.44-0.20)	0.74 (-0.39-0.16)	1.00 (-0.36-0.38)	0.82 (-0.34-0.15)	0.43 (-0.31-0.10)
Trough of hip adduction moment	**Wa**	0.72±0.01	0.67±0.02	0.66±0.02	0.65±0.01	0.66 (-0.07-0.18)	0.76 (-0.09-0.21)	0.05 (-0.00-0.14)	1.00 (-0.11-0.13)	1.00 (-0.07-0.10)	1.00 (-0.06-0.07)
	As	0.60±0.01	0.58±0.01	0.55±0.02	0.57±0.02	1.00 (-0.06-0.08)	0.59 (-0.05-0.13)	1.00 (-0.09-0.17)	1.00 (-0.15-0.16)	1.00 (-0.07-0.14)	1.00 (-0.05-0.11)
	De	0.61±0.03	0.62±0.02	0.60±0.03	0.70±0.02	1.00 (-0.12-0.09)	1.00 (-0.0-0.09)	0.36 (-0.26-0.07)	0.17 (-0.28-0.05)	0.43 (-0.23-0.07)	1.00 (-0.13-0.19)
Second peak of hip adduction moment	**Wa**	0.84±0.01	0.82±0.01	0.81±0.01	0.73±0.01	0.11 (-0.00-0.05)	0.16 (-0.01-0.06)	0.18 (-0.0-0.17)	0.55 (-0.05-0.14)	0.27 (-0.03-0.13)	1.00 (-0.04-0.04)
	As	0.62±0.02	0.56±0.01	0.59±0.02	0.65±0.02	0.51 (-0.07-0.19)	1.00 (-0.07-0.14)	1.00 (-0.16-0.11)	0.19 (-0.14-0.03)	0.14 (-0.21-0.03)	0.97 (-0.12-0.05)
	De	0.96±0.02	0.88±0.2	0.95±0.4	1.02±0.3	0.19 (-0.04-0.20)	1.00 (-0.23-0.26)	1.00 (-0.24-0.13)	1.00 (-0.32-0.1810	**0.03 (0.26-0.01)**	1.00 (-0.29-0.16)

4.8.2 Sagittal plane

For hip flexion/extension moment, no statistically difference was seen in any condition compared to the shoe; however, KAFO, custom and OTS knee valgus braces increased the hip flexion moment during walking and stair climbing, but not significantly as it illustrated in (Figure 4.19, Table 4.11). For hip extension, no significant changes are seen during walking and stair ascent; however, KAFO reduced hip extension moment by 43%, while both knee valgus braces increased it up to 19% compared to the shoe during stair descent.

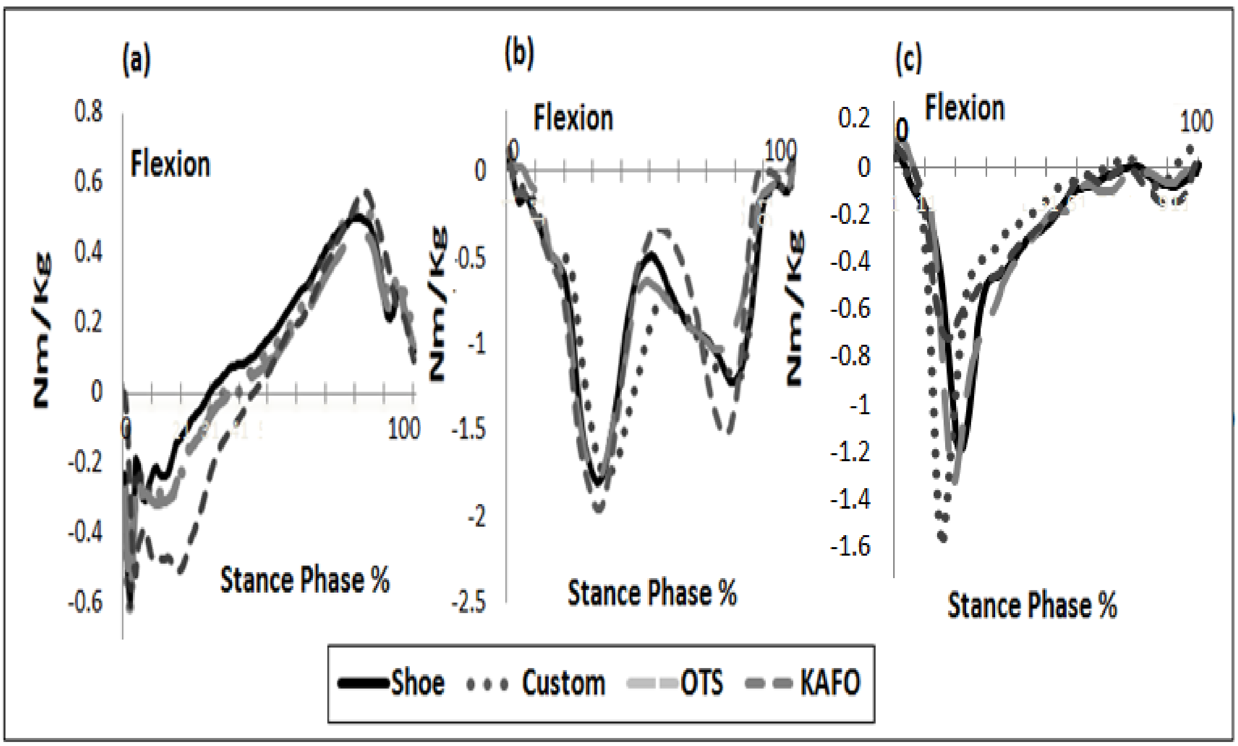


Figure 4.19: hip moment in sagittal plane during walking (a), stair ascent (b), and stair descent (c) for the four conditions.

Table 4.11: Hip moment in sagittal plane during the four conditions. As: ascending, Wa: walking, De: descending.

variable		Mean ±SD				P value					
		Shoe	OTS	Custom	KAFO	Shoe vs. OTS	Shoe vs. Custom	Shoe vs. KAFO	KAFO vs. Custom	KAFO vs. OTS	Custom vs. OTS
Hip flexion moment	**Wa**	0.49±0.03	0.45±0.03	0.50±0.02	0.57±0.2	1.0 (-0.19-0.02)	1.0 (-0.20-0.18)	0.71 (-0.28-0.21)	0.32 (-0.09-0.34)	1.00 (-0.14-0.29)	1.0 (-0.25-0.14)
	As	0.09±0.02	0.16±0.03	0.16±0.0	0.14±0.03	0.62 (-0.22-0.00)	0.10 (-0.14-0.01)	0.90 (-0.32-0.15)	1.0 (-0.17-0.13)	1.0 (-0.25-0.21)	1.0 (-0.14-0.01)
	De	0.06±0.01	0.11±0.01	0.10±0.03	0.13±0.02	0.67 (-0.16-0.06)	1.0 (-0.15-0.07)	0.86 (-0.24-0.11)	1.0 (-0.22-0.16)	1.0 (-0.11-0.07)	1.0 (-0.11-0.13)
Hip extension moment	**Wa**	0.60±0.04	0.61±0.03	0.67±0.02	0.61±0.02	1.0 (-0.06-0.08)	1.0 (-0.02-0.36)	1.0 (-0.15-0.17)	1.0 (-0.22-0.1)	1.0 (-0.12-0.12)	1.0 (-0.01-0.31)
	As	1.8±0.2	1.7±0.1	1.7±0.01	2.1±0.01	1.0 (-1.08-0.93)	1.0 (-0.08-0.74)	0.67 (-0.47-1.15)	0.46 -0.43-1.24)	0.95 (-0.74-1.57)	1.0 (-0.03-0.38)
	De	1.32±0.1	1.60±0.2	1.63±0.02	0.75±0.1	1.0 (-1.07-1.61)	1.0 (-1.30-1.90)	0.14 (-1.36-0.21)	0.29 (-2.40-0.65)	0.27 (-2.2-0.58)	1.0 (-0.47-0.53)

4.9. Ankle kinematics (Secondary outcomes)

4.9.1 Walking

In the sagittal plane the KAFO showed a significantly higher dorsiflexion angle during walking than the shoe, OTS, and custom knee valgus brace (mean difference 5.6, 5.1, and 6 degrees. p=0.00, p=0.02, p=0.00 respectively) (Figure 4.20, Table 4.12). However, no effects were seen using either of the knee valgus braces on ankle dorsiflexion angle during walking. For ankle plantarflexion angle, the KAFO and OTS knee valgus brace reduced plantarflexion by 3.1 and 2.3 degrees respectively compared to the shoe (but not significantly), while no change is shown when using the custom knee valgus brace.

As a result, the ankle ROM was increased significantly with the KAFO compared to the OTS brace (mean difference 4.2 degrees, p=0.04) and insignificantly compared to the shoe and custom knee valgus brace (mean difference 2.2, 2.6 degrees. p=0.61, p=0.60 respectively). No significant differences were demonstrated between the knee valgus braces and the shoe during walking.

In the frontal plane, there was significantly less eversion ankle angle when using KAFO during walking compared to the shoe, OTS, and custom knee valgus brace (mean difference 5.7, 5.3, 6.7 degrees respectively (p=0.0 for all conditions) (Figure 4.21, Table 4.13). No significant changes were shown in inversion angle between the KAFO and shoe and between both knee valgus braces (Figure 4.21, Table 4.13).

4.9.2 Stair ascent and descent

In the sagittal plane, ankle dorsiflexion angles were similar among conditions during stair ascent and descent (Figure 4.20, Table 4.12). However, the maximum plantarflexion angle was significantly reduced with the KAFO during stair ascent compared to the shoe, OTS, and custom knee valgus braces (mean difference 8.9, 4.9, 5.9 degrees. p=0.04, p=0.01, p=0.02 respectively) and during stair descent in comparison to the shoe (mean difference 5.9 degrees. p=0.02). Therefore, ankle ROM in sagittal plane was reduced significantly with the KAFO during stair ascent in comparison to the shoe (mean difference 7.8 degrees, p=0.05), and during stair descent compared to the shoe and custom knee valgus brace (mean difference 7.8, 3.7 degrees. p=0.01, p=0.02 respectively). Furthermore, using the custom and OTS knee valgus braces reduced the plantarflexion angle and ROM insignificantly during stair ascent and descent respectively compared to the shoe.

In the frontal plane, there was significantly less maximum eversion ankle angle during mid stance when using KAFO during stair ascent compared to the shoe, OTS, and custom knee valgus braces (mean difference 5, 5.5, 4.3 degrees. p=0.02, p=0.02, p=0.00 respectively); and during stair descent compared to the custom knee valgus brace (mean difference 3.3 degrees, p=0.01) (Figure 4.21, Table 4.13). Furthermore, no significant changes were shown after using both knee valgus braces.

For ankle inversion, no significant changes were shown between KAFO compared to shoe during stair ascent and descent respectively, but the KAFO reduced ankle inversion significantly compared to the OTS and custom knee valgus braces during stair ascent (mean difference 3.4, 2.9 degrees, p=0.04, 0.01 respectively) (Figure 4.21, Table 4.13). Moreover, stair ascent with the OTS knee valgus brace showed a significantly higher ankle inversion compared to shoe (mean difference 2.9 degrees. p=0.00). Nevertheless, there were no significant differences demonstrated during stair descent and no significant changes between both knee valgus braces.

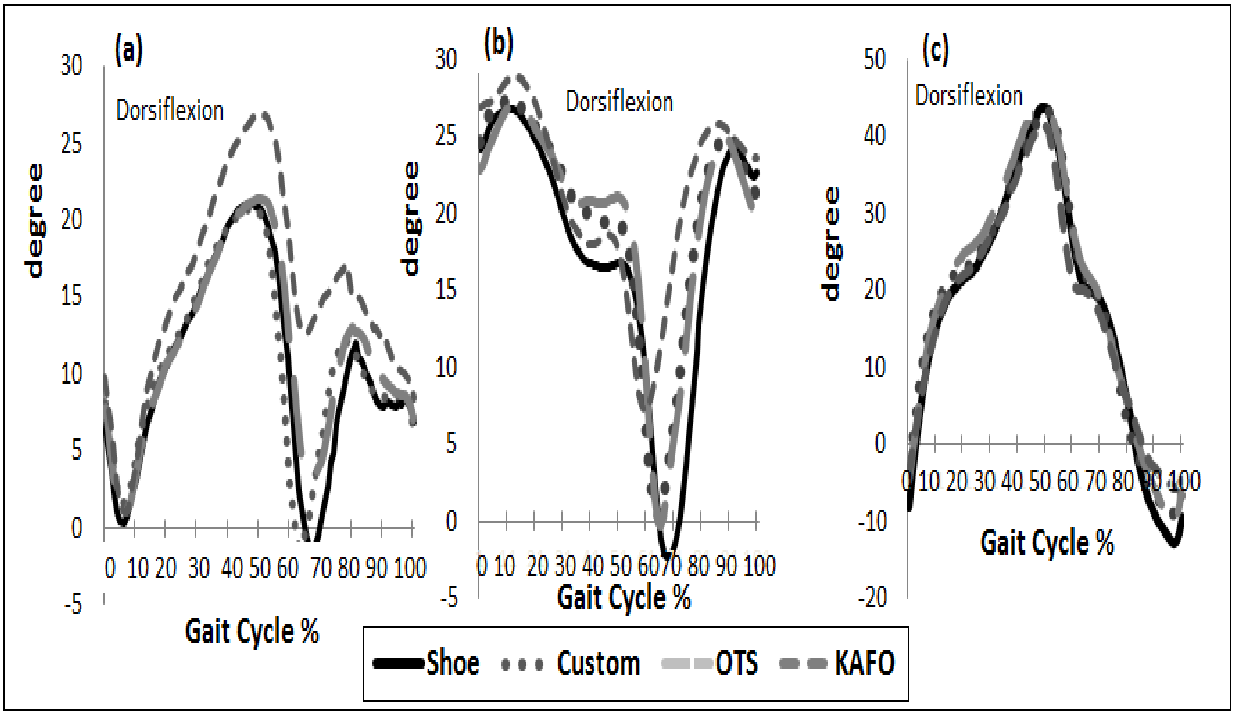


Figure 4.20: Ankle angles in sagittal plane during walking (a), stair ascent (b), and stair descent (c) for the four conditions.

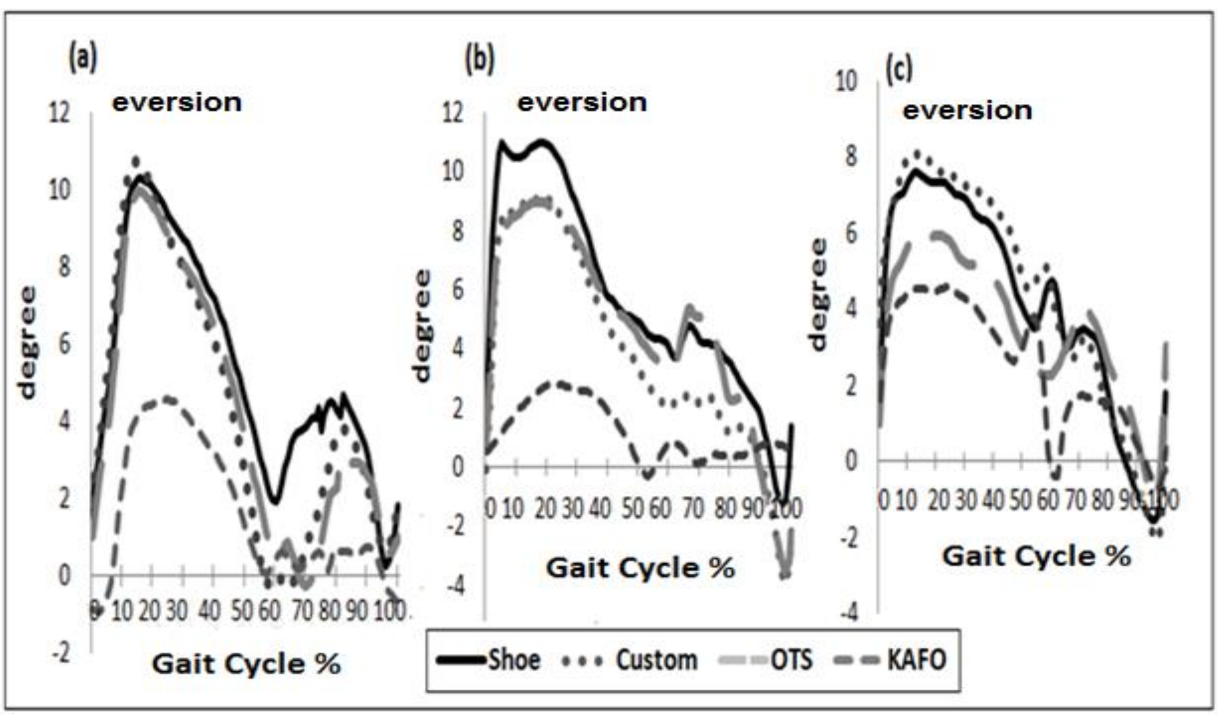


Figure 4.21: Ankle angles in frontal plane during walking (a), stair ascent (b), and stair descent (c) for the four conditions.

Table 4.12: Ankle angle in sagittal plane for the four conditions. Wa: walking, As: ascending, De: descending. *: dorsiflexion degree. **Bold indicates significance.**

variable		**Mean ±SD**				**P value (CI 95%)**					
		Shoe	**OTS**	**Custom**	**KAFO**	**Shoe vs. OTS**	**Shoe vs. Custom**	**Shoe vs. KAFO**	**KAFO vs. Custom**	**KAFO vs. OTS**	**Custom vs. OTS**
Ankle dorsiflexion angle	**Wa**	21.3±0.2	21.8±0.6	20.9±0.7	26.9±0.3	1.0 (-2.9-2.00)	1.0 (-3.46-4.33)	**0.00 (8.02-3.12)**	**0.00 (9.44-2.57)**	**0.02 (9.46-0.77)**	1.0 (-5.41-7.18)
	As	27.5±0.7	27.0±0.4	27.5±0.5	28.8±0.7	1.0 (-4.95-6.12)	1.0 (-5.97-5.95)	0.53 (-3.95-1.45)	1.0 (-7.06-4.57)	0.83 (-6.64-2.98)	1.0 (-2.66-1.49)
	De	44.2±0.2	44.5±0.7	43.6±0.5	42.2±0.8	1.0 (-2.83-2.08)	1.0 (-2.11-3.265)	0.14 (-0.75-4.69)	0.20 (-0.74-3.53)	**0.00 (0.32-4.36)**	1.0 (-2.75-4.65)
Ankle plantarflexion angle	**Wa**	2.2±0.7	**0.08±0.7***	2.42±1.1	**0.95±0.5***	0.44 (-6.89-2.33)	1.0 9-5.73-6.19)	0.09 (-6.92-0.62)	0.41 (-10.0-3.27)	1.0 (-3.78-2.04)	1.0 (-5.91-10.92)
	As	4.3±1.4	0.3±0.5	1.30±1.2	**4.6±0.9***	0.30 (-11.0-3.05)	0.68 (-10.5-4.36)	**0.04 (17.8-0.30)**	**0.02 (11.0—0.82)**	**0.01 (8.43-1.66)**	1.0 (-5.49-7.31)
	De	12.8±0.6	10.0±1.3	9.3±0.5	6.9±0.7	0.86 (-10.46-4.76)	**0.02 (6.69-.521)**	**0.02 (10.5-1.24)**	0.06 (-4.68-0.11)	0.70 (-10.4-4.37)	1.0 (-9.03-7.51)
ROM	**Wa**	23.7±1.5	21.7±0.7	23.3±1.7	25.9±2.0	0.12 (-0.5-4.2)	1.0 (-4.6-5.1)	0.61 (-7.96-3.13)	0.60 (-3.35-7.9)	**0.04 (0.157-8.3)**	0.8 (-2.67-3.12)
	As	31.9±2.0	27.3±0.6	28.8±0.9	24.1±0.8	0.69 (-6.52-15.6)	1.0 (-9.10-15.28)	**0.05 (-0.01-15.61)**	0.12 (-1.39-10.81)	0.15 (-1.25-7.68)	1.0 (-7.35-4.35)
	De	57.0±0.5	54.6±1.2	52.9±0.9	49.2±1.5	1.0 (-5.10-10.04)	0.05 (-0.08-8.44)	**0.01 (2.01-13.6)**	**0.02 (0.54-6.80)**	0.16 (-2.34-13.1)	1.0 (-7.06-10.47)

Table 4.13: Ankle angles frontal plane for the four conditions. Wa: walking, As: ascending, De: descending. **Bold indicates significance.**

variable		Mean ±SD				P value (CI 95%)					
		Shoe	OTS	Custom	KAFO	Shoe vs. OTS	Shoe vs. Custom	Shoe vs. KAFO	KAFO vs. Custom	KAFO vs. OTS	Custom vs. OTS
Ankle eversion angle	**Wa**	10.3±0.3	9.9±0.6	11.3±0.7	4.6±0.3	1.0 (-1.79-2.64)	1.0 (-4.37-2.87)	**0.0 (4.35-7.14)**	**0.00 (3.24-9.74)**	**0.00 (2.20-8.43)**	1.0 (-6.67-4.32)
	As	10.9±0.4	11.4±0.6	10.2±0.3	5.9±0.4	1.0 (-4.86-3.91)	1.0 (-2.68-4.10)	**0.02 (0.95-9.11)**	**0.00 (2.40-6.23)**	**0.02 (1.01-10.0)**	0.724 (-1.74-4.11)
	De	7.8±0.6	6.0±0.7	8.1±0.3	4.8±0.4	1.0 (-4.38-7.91)	1.0 (-3.70-3.12)	0.15 (-1.20-7.17)	**0.01 (1.05-5.49)**	1.0 (-2.45-4.89)	0.531 (-6.49-2.39)
Ankle inversion angle	**Wa**	0.4±0.5	2.0±1.4	1.7±0.4	1.2±0.2	1.0 (-6.14-9.23)	1.0 (-3.07-5.60)	1.0 (-1.76-3.39)	1.0 (-2.70-1.80)	1.0 (-7.29-5.84)	1.0 (-7.10-6.55)
	As	1.2±0.6	4.1±06	3.6±0.3	0.7±0.1	0.22 (-1.69 -7.25)	**0.00 (0.62-5.07)**	1.0 (-3.2-2.19)	**0.01 (4.31-1.84**	**0.04 (6.25-0.06)**	1.00 (-4.48-3.99)
	De	1.7±0.3	1.2±1.0	2.0±0.8	1.5±0.4	1.0 (-6.30-5.26)	1.0 (-3.77-4.40)	1.0 (-1.46-0.92)	1.0 (-5.00-3.83)	1.0 (-5.92-6.42)	1.0 (-7.43-9.09)

Chapter five: Discussion

This chapter will discuss the results for the intervention study and compare our results with previously published literature, followed by future directions for further study with a final limitations and conclusions of the thesis.

5.1. Discussion

5.1.1Background of discussion

Custom and off-the-shelf (OTS) knee valgus braces are one of the most commonly used conventional treatments for individuals with medial knee OA and previous results have shown that EKAM and KAAI can be reduced by knee valgus braces (Draper et al., 2000, Deie et al., 2013, Ramsey et al., 2007, Richards et al., 2005, Fantini Pagani et al., 2010b, Lindenfeld et al., 1997, Self et al., 2000, Fantini Pagani et al. 2012, Fantini Pagani et al., 2010a). This study was designed to provide evidence of the possibility of extending the conventional treatments options available for individuals with medial knee OA and severe knee varus deformity, by evaluation of the effect of a custom knee-ankle-foot orthosis (KAFO) on EKAM values and lower limb kinematics. A cosmetic KAFO was compared to a custom-made and OTS knee valgus brace which are commonly used in orthotic practice. To the author’s knowledge this is the first study which has examined the effects of a KAFO on EKAM values for an individual with a varus deformity during walking and stair climbing.

5.1.2 Summary of results

The KAFO was more effective than the custom or OTS knee valgus brace in reducing EKAM, KAAI, knee varus angle, and ankle eversion during walking and stair climbing. In addition, the KAFO improved knee and hip flexion angles and hip range of motion in the sagittal plane during walking on a level surface and during stair climbing. The KAFO also reduced knee range of motion in the sagittal plane compared to both knee valgus braces during walking and stair climbing, but not significantly.

The KAFO also significantly reduced ankle ROM and ankle plantarflexion compared to the shoe during stair ascent and descent. The OTS knee valgus brace reduced the knee varus angle more than the custom one. No significant differences were found between both knee valgus braces with regards to EKAM and KAAI. Both knee valgus braces insignificantly reduced knee range of motion, ankle plantarflexion and ankle ROM compared to the shoe.

5.1.3 Hypotheses

5.2.2.1 External knee adduction moment (EKAM).

Hypothesis one: A KAFO reduces EKAM more than custom and off-the-shelf knee valgus braces during walking and stair climbing.

Reducing the EKAM is one of the main aims for all interventions for medial knee OA to control the progression of osteoarthritis (Miyazaki et al., 2002). The results have shown that the KAFO significantly reduced the first peak of EKAM by 11.4% compared to the shoe during walking. However, neither of the knee valgus braces showed significant changes in EKAM first or second peaks during walking compared to the shoe. There was an insignificant difference in the second peak when using the KAFO compared to the shoe. A 12% reduction was found compared to the shoe during walking on a level surface.

No significant changes were seen when using either brace compared to the shoe. The custom knee valgus brace reduced the first EKAM peak by 4.2%. This is similar to that seen in previous studies where it has also been shown that both custom and OTS knee valgus braces do not reduced the EKAM significantly during walking compared to a baseline condition (Gaasbeek et al., 2007, Hewett et al., 1998, Pollo et al., 2002). This similarity in result is potentially related to the high varus angle in participants in both the previous and current studies, also this gives the indication that knee valgus brace are less effective to reduce EKAM for individuals with a severe knee varus deformity.

In previous studies, it was found that the UnloaderOne knee valgus brace reduced EKAM values by 5.5 % for individuals with medial knee OA during walking which was maintained over a period of 12 months (Deie et al., 2013). Also, a study by Toriyama et al., (2011), which used the same brace, found that using an OTS knee valgus braces reduced the first peak of EKAM significantly by 11%, but no changes in second peak compared to a no-brace condition during walking for individuals with medial knee OA were noted. Also, according to Moyer et al. (2013), an adjustable UnloaderOne OTS (an adjustable knee valgus angle between two to nine degrees) for individuals with medial knee OA with knee varus (6.6 ±3.3 degrees), reduced the first and second peaks of EKAM by 8% and 12.7% respectively during walking compared to a no brace condition. In contrast, our results show that both the UnloaderOne OTS and custom knee valgus braced did not reduce EKAM significantly. This dissimilarity in results could be due to different samples characteristics as we examined a participant without knee OA but still with a severe knee varus deformity of 10 degrees, and therefore a different valgus position (more valgus correction will reduce knee load more). In this current study, five degrees of valgus angulation was set, but previous studies have used adjustable knee valgus angulation. Furthermore, different periods of wearing a knee valgus brace (up to 12 months) have been used instead of a single test session in this current study.

When comparing the custom and OTS knee valgus braces together, the OTS knee valgus brace reduced EKAM and knee varus angle more effectively than the custom made knee valgus brace but not significantly. In contrast, in the study by Draganich et al., (2006), which utilised different types of OTS and custom knee valgus braces in the same study, found that the custom knee valgus brace reduced the first peak of EKAM during walking by 14.5% after immediate use, while the OTS knee valgus brace only reduced it by 3% compared to the baseline. This difference is mainly related to high anatomical knee varus angle in our sample (ten degrees) compared to the previous studies, different knee valgus braces, and the short length of the custom knee valgus brace in this current study compared to the OTS brace could also make OTS apply more correction force than the custom knee valgus brace.

Interlaced stairway climbing was the other activity which the participant undertook with the shoe, OTS, custom knee valgus brace, and the KAFO as test conditions. Interlaced stairway reliability was examined before the intervention study and proved that an interlaced stairway could be highly reliable when used to examine knee kinetics and knee kinematics with an SEM raised to 2.3 degrees. Furthermore, to our knowledge only one study has used stairs to examine interventions such as an insole (Alshawabka et al., 2014), plus no previous study has examined the effects of a KAFO on EKAM for varus individuals, and this study is only the second study that has investigated the effect of knee valgus braces during stair climbing [the previous study was undertaken by Al-Zahrani, (2014)].

The current study shows that the KAFO reduced first and second peaks by 7% and 10% respectively compared to the shoe during stair ascent and no significant changes were seen during stair descent. In addition, using custom and OTS knee valgus braces showed a non-significant reduction in the EKAM of 8.2% and 7% respectively during stair ascent. However, during stair descent the OTS and custom knee valgus braces increased the first peak of EKAM by 11.2% and 19.7% respectively. This is in agreement with the Al-Zahrani (2014) study which stated that a knee valgus brace did not reduce both peaks of EKAM significantly compared to the baseline after three months of treatment for individuals with knee OA.

In contrast to our results, a custom knee valgus brace has been shown to reduce the average peak of EKAM significantly during one stair stepping compared to baseline and an OTS knee valgus brace. The OTS knee valgus brace did not reduce it significantly compared to baseline (Draganich et al., 2006). However, this dissimilarity could be due to the different type, the design of knee valgus braces, and the degree of valgus correction used, since the previous study used bilateral upright knee valgus braces with bilateral polycentric knee joints and the valgus load applied was adjustable. In this current study four degrees of knee valgus angulation (which is the standard design for Ossur knee valgus braces) was applied with the knee valgus brace with a single upright and single hinge joint was used. Moreover, one step was used in the previous study to evaluate knee load, but three steps were used in this current study to evaluate the knee load during one complete gait cycle. Also, it has been suggested that a knee valgus brace may not reduce EKAM significantly during stair climbing due to the high knee varus moment during stair climbing compared to walking on level (Al-Zahrani, 2014).

The measure of total loading during stance phase, the KAAI, was reduced significantly when wearing the KAFO when compared to the shoe condition by 26.2% during stair ascent only; however, the KAFO insignificantly reduced KAAI by 18.4% and 4.6% during walking and descent respectively compared to the shoe. This means that using a KAFO reduced both EKAM and the duration of the applied force on the medial knee compartment. Using the custom knee valgus brace and its OTS variant did not significantly reduce the value of the KAAI during walking (it was reduced by 7.8% by the custom one) or stair ascent, but the custom knee valgus brace did however increase KAAI during stair descent by 10.4% compared to the shoe. This result is similar to the Al-Zahrani (2014) study as knee valgus braces insignificantly reduced KAAI values after three months compared to the shoe during walking and interlaced stairs way climbing for individuals with medial knee OA.

In contrast to our result, Jones et al., (2013) found that an OTS knee valgus brace reduced KAAI by 16.1% compared to baseline during walking activities. Furthermore, KAAI has also been shown to be reduced by 29% and 15% according to Fantini Pagani et al. (2010a) after using a four degree knee valgus brace and a flexible knee brace respectively. Similarly, it reduced when using four-degrees valgus braces by 14% during walking on a level surface (Fantini Pagani et al. 2012) and 18% with using 4 degrees for healthy group compared to walking without brace (Fantini Pagani et al., 2010b) and by 0.5% after using UnloaderOne OTS compared to walking without a brace (Moyer et al., 2013). This variation could be due to dissimilar knee braces types, and different sample characteristics. In the study by Fantini Pagani et al. (2012) a long knee valgus brace was used and participants had mild knee varus alignment (mean 2.1±1.2), but in the study by Fantini Pagani et al. (2010b) sixteen males with 8 degrees (±4 SD) of varus participated. In this current study the participant had ten degrees of varus and both the Ossur knee valgus braces used are shorter than the one which was used in the previous studies.

When comparing the KAFO and the knee valgus braces, the KAFO reduced the first peak of EKAM by 15% and 12.6% and reduced second peak by 9.5% and 12.3 % (significantly) in comparison to the OTS and custom knee valgus braces during walking. During stair ascent, KAFO reduced second peak of EKAM by 9% and 14.5% significantly compared to custom and OTS knee valgus brace respectively. During stair descent, KAFO reduced first peak of EKAM by 16.4% and 10% in comparison to custom and OTS knee valgus braces respectively. Also, KAAI is reduced by KAFO significantly compared to OTS and custom knee valgus brace during walking and stair climbing. This difference between KAFO and knee valgus braces could be due to KAFO design which can apply four point pressure over thigh, knee, and shank to correct the tibia alignment, keep tibia in vertical position, and maintain the end of tibia and foot part in the neutral position. This design could be able to shift the GRF more laterally and the knee joint centre more medially, thereby reducing EKAM. Although, knee valgus brace applied three points pressure likewise, the taller length of KAFO compared to knee valgus braces (Table 4.1) helps to apply more force correction by KAFO than knee valgus braces and apply more control on tibia position and foot alignment.

Even though reducing the EKAM is main aim for orthoses, the sagittal plane knee moment, especially in areas of knee flexion such as stairs has to be examined because a high knee flexion moment is correlated with increased knee pain and increased compression on the medial compartment for knee OA (Walter et al. 2010). However, it has been suggested that a high knee flexion moment only increases knee load during high flexion activities (Trepczynski et al., 2014). Our results show that the knee flexion moment was increased after using the KAFO and both knee braces during walking and stair climbing but this was not statistically significant. Also, using the OTS knee valgus brace for one year does not change the knee flexion moment significantly (Hewett et al., 1998).

Also, any change in GRF due to alteration in walking speed could change the EKAM (Mündermann et al., 2004). To eliminate the effects of speed variation on the vertical GRF, the speed was controlled during this current test by a metronome. Therefore, no significant changes in vertical GRF were found during walking and stair climbing between the test conditions (Table 4.2).

In summary, the KAFO reduced EKAM and KAAI more effectively than both knee valgus braces during walking and stair climbing without changing knee flexion moments. We hypothesised that this could be due to KAFO design which applies four points of pressure to correct knee alignment and its length cover more area to apply more correction force over a more extensive area on the thigh and leg. No previous study has examined effects of a KAFO on EKAM and KAAI for an individual with knee varus. Also, both knee valgus braces did not reduce EKAM and KAAI significantly compared to some previous studies which could be due to different knee valgus brace, degree of valgus position (2-9 degrees), short period of treatment in current study, high varus deformity in our sample, small sample size, and the short length of custom knee brace compared to the OTS.

Therefore, this hypothesis was accepted as the KAFO significantly reduced EKAM and KAAI compared to the shoe and both knee valgus braces during walking and stair climbing.

5.2.2.2 Lower limb kinematics

Hypothesis two: A KAFO would improve knee and hip ROMs more than either of the valgus knee braces during walking and stair climbing.

Knee joint malalignment due to medial knee OA can affect the knee and hip joint in both sagittal and frontal planes. It was suggested that a KAFO would improve knee and hip ROM more than both valgus knee braces. Improvement in knee flexion and knee ROM are also important for individuals with medial knee OA because it has been shown that individuals with medial knee OA have reduced knee flexion than controls and 6 degrees less knee flexion at initial contact (IC); (Landry et al., 2007, Mündermann et al., 2008a). Another purpose of using orthoses such as KAFOs and knee valgus braces is to increase the knee flexion angle at initial contact and mid swing, and increase overall sagittal plane knee ROM. This study has demonstrated that the maximum knee flexion angle at initial contact is significantly increased by wearing a KAFO by 8.6 degrees during walking, but no significant changes in knee flexion at mid swing were noted.

However, it reduced knee ROM significantly (up to 10 degrees) compared to the shoe during walking. Also, using OTS and custom knee valgus braces significantly increased knee flexion at IC during walking by 3.5 and 5.3 degrees respectively and insignificantly reduced knee ROM by 8.2 and 7.9 degrees respectively when compared to the shoe during walking. Also, during stair climbing, the KAFO and knee valgus braces also increased knee flexion at IC, but reduced knee flexion at mid-swing and knee ROM, but not statistically differently between them.

As a result, the KAFO was superior in increasing knee flexion at IC and this result is mainly related to the use of an offset knee joint which is used in KAFO design. This type of joint started the movement from a position of 6 degrees more flexion at IC. The reduced knee flexion at mid-swing may be associated with the weight of KAFO and the knee valgus braces could restrict knee flexion at mid-swing because of the tight straps around knee in the knee valgus braces.

However, previous studies have found no significant differences in knee ROM during walking and one stair stepping (Draganich et al., 2006) nor during interlaced stairway climbing (Al-Zahrani, 2014). In contrast, previous studies have found that using a knee valgus brace reduces knee flexion at mid swing, and total knee ROM during walking (Gasbeek et al., 2007, Jones et al., 2013). This result could be due to light weight of knee valgus brace with single upright and hinge joint instead of a double.

A high knee varus angle constitutes a high risk for medial knee OA subjects (Sharma et al., 2001), and it is suggested that reducing knee varus deformity reduces EKAM and thereby knee load (Fantini Pagani et al., 2010b, Landry et al., 2007). Also, a high knee varus angle is capable of increasing knee load by 100% (Johnson et al., 1980); therefore, it is important to reduce the knee varus angle using knee OA orthoses. This present study found that the knee adduction angle was significantly decreased when using the KAFO by 8.2 degrees during walking on a level surface compared to the shoe. Also, the custom and OTS knee valgus braces reduced it significantly by 5.2 degrees and 5.8 degrees respectively during walking compared to the shoe, but with no significant difference between them during walking. In previous studies, using a custom knee valgus brace significantly reduced knee varus during walking which is similarly to the studies by Draganich et al., (2006) and Matsuno et al., (1997). Also, our study found that using the OTS knee valgus brace was more effective than a custom knee brace in reducing the knee varus angle which is contrary to the studies by Draganich et al., (2006) and Toriyama et al., (2011). This variation could be due to different sample characteristics; for example previous studies have evaluated individuals with moderate and severe knee OA, while in the existing study the participant did not suffer from knee OA but had a knee varus deformity.

During stair climbing, the KAFO reduced the knee varus angle by 12 and 6 degrees during stair ascent and descent respectively compared to the shoe. Both knee valgus braces insignificantly reduced it during stair climbing up to 3 degrees which is similar to Al-Zahrani (2014) study. When we compared the KAFO with the knee valgus braces, the results showed that the KAFO reduced knee varus angle by up to 15 and 6.8 degrees compared to the custom knee valgus brace and up to 12.4 and 3.5 degrees compared to OTS knee valgus brace during stair ascent and descent respectively. The efficiency of a KAFO in reducing a knee varus angle is mainly related to the offset joint. This type of artificial knee joint is able to correct knee deformity in the frontal plane (knee valgus/varus) by up to 75mm (Johnson et al., 2004), also the length of the KAFO is able to apply more force over a more extensive tissue area than knee valgus braces, so would theoretically correct more deformity, and it is therefore assumed that the custom fit of the KAFO on the limb has an important role in correcting the knee varus deformity and reducing EKAM efficiently. When comparing both knee valgus braces together, the OTS was slightly superior to the custom made knee valgus brace and reduced knee varus more. However, custom made knee valgus braces fit better, but the one used in this study was shorter than the OTS and has a similar mass (Table 4.1). These differences could make the OTS more able to apply increased forces over the proximal and distal segments around the knee joint and control the knee rotation since the OTS used for the participant in this study was also a good fit over the affected knee.

With regards to hip flexion and extension angles, Briem and Snyder-Mackler (2009) demonstrated that hip flexion and hip ROM is reduced and hip extension is increased for individuals with knee OA. As a result, it would be advantageous for an orthosis to produce improved hip ROM for individuals with medial knee OA. In this current study, the KAFO increased hip range of motion during walking and stair ascent, while neither of the knee braces altered hip range of motion. This may have been due to the offset joint included in the design of the KAFO which shifts the GRF more posterior to the knee and more anterior to hip joint to generate knee and hip flexion. In addition, during taking the negative cast for the participant, the lower extremity was fixed with the knee and hip in a slightly flexion position as it is functional position for both joints. Custom knee and OTS knee valgus braces have not been shown previously to alter hip ROM significantly (Taghi Karimi et al., (2012) and Toriyama et al., (2011). However, hip ROM was reduced by the knee valgus brace during walking, but no changes were seen during stair ascent and descent (Al-Zahrani, 2014), which is suggested to be related to the tight strap around the thigh segment which restricted hip extension at mid swing.

For hip adduction/abduction angle and moment, it has been suggested that knee OA is associated with a high hip abduction angle and low hip adduction moment due to the lateral bending compensatory gait during early stance. This is used as a strategy to reduce EKAM (Briem and Snyder-Mackler, 2009), but unfortunately this compensation could increase back pain and the incidence of hip OA in the future (Mündermann et al. 2008a, Toriyama et al., 2011). Therefore, it is necessary to control the hip abduction angle and increase the hip adduction moment, and thereby prevent hip lateral bending.

Using the KAFO reduced hip abduction, increased hip adduction angle, and also increased hip adduction moment during walking and stair climbing more than both knee valgus braces. This means that the KAFO did not produce an increase in pelvic tilt or lateral bending to reduce the EKAM, but it reduced EKAM by controlling the tibia and foot alignments. However, no significant changes in hip adduction/abduction angles were seen after using the knee valgus braces, but both of them reduced the second peak of the hip adduction moment. In contrast to our results, hip adduction angle is reduced by 2.5 degrees with a custom knee valgus brace according to Toriyama et al., (2011) due to a reduction in the hip adduction moment and an increase in hip bending to the swing phase side as a compensation to reduce EKAM. This supports the biomechanical theory that the knee valgus brace can reduce EKAM by shifting the centre of mass more laterally and closer to the centre of the knee. This difference could be due to the fact that subjects with bilateral knee OA participated in the Toriyama (2011) study.

For the ankle joint, the KAFO reduced ankle ROM significantly, but no changes in ankle ROM were demonstrated when using either knee valgus braces during walking or stair climbing. However, according to the study by Al-Zahrani (2014), no significant changes in ankle ROM were found during walking and stair descent, but it was significantly reduced during stair ascent which could be due to the tight straps that limited shank movement and thereby ankle joint motion.

For ankle inversion/eversion, the KAFO was superior in reducing ankle eversion than the knee valgus braces; however, both knee valgus braces increased ankle eversion compared to the shoe. Similarly, ankle eversion angles and moments were not significantly reduced during walking with a 4 degree knee valgus brace according to the studies by Fantini Pagani et al. (2012) and Hewett et al., (1998). However, the orthosis used was an 8 degree knee valgus brace (Fantini Pagani et al. 2012); this dissimilarly in result is clearly related to the different varus angle in the brace knee valgus angle which was used in this study (4 degrees) and the one which was used in the previous study (8 degrees).

In conclusion, this hypothesis is partially accepted since the KAFO significantly increased knee flexion at IC, and increased hip flexion and hip ROM more than both knee valgus braces during walking and stair climbing; however, using the KAFO insignificantly reduced knee ROM more than both knee valgus braces during walking and stair climbing.

Since the knee joint is one of the most affected joints by osteoarthritis, a variety of orthoses are recommended as conservative treatments to correct the knee deformity, reduce pain, improve the activity level, and thereby hope to delay the inevitable knee replacement. The primary anatomical deviation in medial knee OA is a varus deformity which results in a higher EKAM. Therefore, conservative orthotic interventions such as footwear, lateral wedges and knee valgus braces are used to examine their effect on these parameters. However, these previous interventions have some limitations such as changing ankle alignment, not being very effective to reduce EKAM, they reduce knee flexion in mid swing, increase hip lateral bending, have tight straps in knee valgus brace which causes swelling, and they may feel uncomfortable for extended use. Therefore, the feasibility of a KAFO was examined in order to find a new conservative treatment for severe knee varus and medial knee OA individuals. Thus, this study demonstrates that the KAFO reduced EKAM, KAAI, knee varus angle, improved hip ROM, and reduced hip lateral bending more effectively than knee valgus braces.

5.3. Limitations

The current study has some limitations such as small sample size and the subject used having a knee varus deformity without complaining from pain or knee OA or any previous injury. As a result, one of the future plans is to increase the sample size to include medial compartment knee OA participants in a future investigation. Another limitation of this study is that it evaluated the immediate effects of KAFO and knee braces on the primary outcome measures. A longitudinal study could be helpful to examine the long term effects of using KAFO on the knee load and OA progression. Furthermore, because of that reason it is difficult to know if these orthoses would reduce pain and improve activity levels. Also, using a simple ankle joint limits ankle joint movement and a free mechanical ankle joint will be used in future even though it will increase KAFO weight and cost.

Besides that, it is important to examine if using a custom KAFO is acceptable to be used for long periods or not and the associated side effects. Nevertheless, the design of KAFO used in this study is considered as being lightweight compared to other designs, and the absence of straps around knee joint gives it a more comfortable feeling when flexing the knee particularly when using stairs and it is able to provide an intimate fit as it was custom made. Nevertheless, its cost will be more than an OTS knee valgus brace but still it does not cost as much as some types of knee valgus braces which contain air champers. The author's experience found that this design of KAFO is already used and recommended for individuals with very severe knee OA in some countries who wish to avoid undergoing total knee replacement surgery and have not previously found any benefit of using knee valgus braces; however, the long term effect of using a long brace needs to be investigated. In contrast, the limitations of using knee valgus braces have already been reported, such as poor fit (especially the OTS knee valgus brace), skin irritation, discomfort when flexing the knee due to knee strap impingement (Stamenović et al., 2008), discontinuation of use (Squyer et al., 2013). In addition, some designs are bulky, heavy, and are not acceptable for long term use, and some individuals have complained from swelling and thrombosis after 6 months of use (Giori, 2004).

With regards to the biomechanical testing, markers artifacts due to skin movements could be one of the limitations during walking and stair climbing, but because of the use of dynamic tracking markers (clusters) and a good shoe fit with a tight lace, the artifacts would have been reduced. For static alignment capturing, two static alignments were captured before the participant started walking and the shoe size was the only variable which had changed. The rest of the markers were still in the correct position during the two static alignments and their location was marked and checked. In addition, off-the-shelf knee valgus braces may not offer an intimate fit for some individuals as they are not custom made, but the one which was used in this study was an adequate fit for the participant.

The ten minute washout period between treatments may not have been long enough but it was thought to be acceptable because using braces inflict immediate biomechanical changes in knee angles and load, and it is suggested that the knee biomechanics returns to the original position and alignment immediately once the braces are removed (Draganich et al., (2006). Finally, the staircase which was used in this study contained only three steps; therefore, the contra lateral side was not evaluated. Having a staircase with more than three steps could be helpful to evaluate the both sides and give information about the effects of a KAFO on both the affected and non-affected side.

5.2. Future work

This pilot study evaluated a new modified type of KAFO which could be a possible conservative treatment for medial knee OA in the future. Therefore, the next phase would be to evaluate the device in a sample of medial knee OA subjects and appraising if this design incorporating a free ankle joint could help to reduce EKAM, KAAI, and knee varus angle during walking and negotiating stairs. Also, a free mechanical ankle joint could be added to the KAFO design instead of a plastic one to add more ankle motion freedom and add more plantarflexion freedom during stair climbing. Further assessments of pain and activity levels, muscles activity, energy consumption, and quality of life enhancement could be examined in the future study after using the device for an extended period such as for between six and twelve months.

5.4. Conclusion

After taking into account the study limitations, this study is the first study to evaluate the effect of a modified KAFO for knee varus individuals during walking and stair climbing. The data from this pilot study supports use of a modified KAFO to reduce EKAM, KAAI, and knee varus angle during walking and stair climbing and also giving improved hip and knee range of motion. However, the limitation of the ankle range of motion is something which needs addressing before embarking on a follow-up study. Therefore, the data supports that wearing a KAFO can significantly reduce EKAM and knee varus deformity and it could be one of the future interventions for individuals with medial compartment knee OA who have a varus aligned knee joint especially if current treatment (knee valgus braces for example) are not restrictive or corrective enough.

Chapter 6: Appendices

Appendix 6 (A): Research Governance & Ethics Committee approval letter.

University of Salford
MANCHESTER

Research, Innovation and Academic Engagement Ethical Approval Panel

College of Health & Social Care
AD 101 Allerton Building
University of Salford
M6 6PU

T +44(0)161 295 7016
r.shuttleworth@salford.ac.uk

www.salford.ac.uk/

28 February 2014

Dear Huda,

RE: ETHICS APPLICATION HSCR13/81 – The effectiveness of a knee ankle foot orthosis (KAFO) and a knee brace on the knee load for knee varus individuals (KAFO study)

Based on the information you provided, I am pleased to inform you that application HSCR13/81 has now been approved. The Chair has asked me to pass on her thanks to you for submitting such detailed revisions.

If there are any changes to the project and/ or its methodology, please inform the Panel as soon as possible.

Yours sincerely,

Rachel Shuttleworth

Rachel Shuttleworth
College Support Officer (R&I)

Appendix 6 (B): Demographic and examination sheet.

Demographic collection sheet (KAFO study):

Participant's ID.: .... **Gender: Male / Female.**

Age:... **Height (M):........................**

Mass (Kg):... **Knee varus degree: ....**

KAFO: left / right. **Knee joint type:..................**

Any comments:

....

....

....

....

Appendix 6 (C): The study poster.

University of Salford MANCHESTER

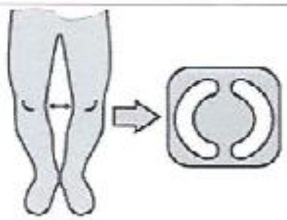
Have you been told that you have bow legs (knee varus) ?

If so, we are seeking healthy volunteers aged 20 -60 years to take a part in the following trial " The Effectiveness of a Knee Ankle Foot orthosis (KAFO) and a valgus knee brace on knee loading in individuals with knee varus (bow leg). This study aims to collect walking and stair data with a new treatment for knee alignment deformity.

If you are interested to take part and feel that your knee has outward alignment like in figure 1, please contact the principal investigator **Huda Alfatafta**, *PO43 Brain Blatchford Building, University of Salford, M6 6PU.* ***E-mail (h.h.al-fatafta@edu.salford.ac.uk)*** *for further information.*

The study will take part in the Podiatry lab, Allerton Building, University of Salford, M6 6PU where we will examine your knee, and if eligible, we will examine your walking and stair climbing when wearing a custom made knee-Ankle-foot orthosis (Figure2) and valgus knee braces (figure3).

We appreciate your help :)



Knee varus (figure 1)

KAFO (figure 2)

Knee brace (figure 3)

Appendix 6 (D): Consent Form.

Principal investigator: Huda Alfatafta.

INFORMED CONSENT FORM

Study title: The effect of a knee ankle foot orthosis on lower limb kinematics and kinetics in an individual with varus knee alignment (KAFO study).

Please initial

Each box

1. I confirm that I have read and understand the participant information sheet dated **(V 1.1 Dated 22.1.2014)** for the above study and have had the opportunity to ask any questions. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and without my medical care or legal rights being affected. ☐

3. Should I withdraw I understand that the data acquired from my participation may still be used unless I specify otherwise in writing. ☐

4. I agree for the research team to keep my details on record for future research they are performing in conation related to osteoarthritis and I am happy to be contacted to discuss potential participation in the study. ☐

5. I understand that the information about me and the data generated from the study is to be kept and may be used in future studies. ☐

6. I agree to take part in the above study. ☐

Name of Participant	Date	Signature
Name of person taking consent (If different from Researcher)	Date	Signature
Researcher	Date	Signature

1 copy for participant; 1 for researcher to be kept with study file

Appendix 6 (E): Abbreviations.

AC	Ascending Cycle
ACL	Anterior Cruciate Ligament
AMTI	Advanced Mechanical Technology Incorporation
ANOVA	Analysis Of Variance
AS	Ascending
ASIS	Anterior Superior Iliac Spine
BMI	Body Mass Index
CAST	Calibration Anatomical System Technique
CP	Center of Pressure
CVs	Coefficients of Variations
De	Descending
DC	Descending Cycle
DIP	Distal Interphalangeal
EKAM	External Knee Adduction Moment
IC	Initial Contact
ICC	Intraclass Correlation Coefficients
KAAI	Knee Adduction Angular Impulse
KAFO	Knee Ankle Foot Orthosis
KL	Kellgren and Lawrence
LLL	Lower limb length
MCL	Medial Collateral Ligament
MTP	Metatarsophalangeal
NSAIDs	Non-Steroidal Anti-Inflammatory Drugs
OA	Osteoarthritis
OTS	Off The Shelf
PIP	Proximal Interphalangeal
QTM	Qualisys Track Manger

R	Correlation Coefficient
RMSD	Root Mean Square Deviation
ROM	Range Of Motion
SD	Standard of Deviation
SEM	Standard Error of Measurement
TKR	Total Knee Replacements
VAS	Visual Analogue Scale
VGRF	Vertical Ground Reaction Force
WA	Walking
WHO	World Health Organisation
WOMAC	Western Ontario and McMaster Universities Osteoarthritis Index

References

1. Abdallah, A. A., & Radwan, A. Y. (2011). Biomechanical changes accompanying unilateral and bilateral use of laterally wedged insoles with medial arch supports in patients with medial knee osteoarthritis. *Clinical Biomechanics*, *26*(7), 783-789.

2. Ahlbäck, S. (1968). Osteoarthrosis of the knee. A radiographic investigation. *Acta radiologica: diagnosis*, Suppl-277.

3. 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*, *29*(6), 650-6.

4. Altman, R. D. (1991a, June). Classification of disease: osteoarthritis. In*Seminars in arthritis and rheumatism* (Vol. 20, No. 6, pp. 40-47). WB Saunders.

5. Altman, R., Alarcon, G., Appelrouth, D., Bloch, D., Borenstein, D., Brandt, K., ... & Wolfe, F. (1990). The American College of Rheumatology criteria for the classification and reporting of osteoarthritis of the hand. *Arthritis & Rheumatism*, *33*(11), 1601-1610.

6. Altman, R., Alarcon, G., Appelrouth, D., Bloch, D., Borenstein, D., Brandt, K., ... & Wolfe, F. (1991b). The American College of Rheumatology criteria for the classification and reporting of osteoarthritis of the hip. *Arthritis & Rheumatism*, *34*(5), 505-514.

7. Altman, R., Asch, E., Bloch, D., Bole, G., Borenstein, D., Brandt, K., Christy, W., Cooke, T. D., Greenwald, R. , Hochberg, M. (1986). Development of criteria for the classification and reporting of osteoarthritis: Classification of osteoarthritis of the knee. *Arthritis & Rheumatism*, *29*(8), 1039-1049.

8. Al-Zahrani, K.S., & Bakheit, A.M. (2002). A study of gait characteristic of patients with chronic osteoarthritis of the knee. *Disabil Rehabil.*, *24*, 275-280.

9. Al-Zahrani, Y. (2014). Effectiveness of a valgus knee brace on biomechanical and clinical outcomes during walking and stair climbing in individuals with knee osteoarthritis. PhD thesis. University of Salford. Available at: http://usir.salford.ac.uk/32833/1/Yousef_Al-zahrani_Thesis_%28Sep-2014%29.pdf

10. 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). *American Journal of Epidemiology*, *128*(1), 179-189.

11. Andriacchi, T.P. (1994). Dynamics of knee malalignment. *Orthop Clin North Am*, *25*(3), 395-403.

12. 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.

13. Andriacchi, T. P., Briant, P. L., Bevill, S. L., & Koo, S. (2006). Rotational changes at the knee after ACL injury cause cartilage thinning. *Clinical orthopaedics and related research*, *442*, 39-44.

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. Angst, F., Aeschlimann, A., Steiner, W., & Stucki, G. (2001). Responsiveness of the WOMAC osteoarthritis index as compared to the SF-36 in patients with osteoarthritis of the legs undergoing a comprehensive rehabilitation intervention. *Annals of the rheumatic diseases*, *60*(9), 834-840.

17. Arazpour, M., Bani, M. A., Maleki, M., Ghomshe, F. T., Kashani, R. V., & Hutchins, S. W. (2013). Comparison of the efficacy of laterally wedged insoles and bespoke unloader knee orthoses in treating medial compartment knee osteoarthritis. *Prosthetics and Orthotics International, 37*(1), 50-57.

18. Arokoski, J. P. A., Jurvelin, J. S., Väätäinen, U., & Helminen, H. J. (2000). Normal and pathological adaptations of articular cartilage to joint loading. *Scandinavian journal of medicine & science in sports, 10*(4), 186-198.

19. Arthritis care (2004) OA nation. www.Arthritiscare.Org.Uk.

20. Arthritis research UK (2013). http://www.arthritisresearchuk.org.

21. Astephen, J. L., Deluzio, K. J., Caldwell, G. E., & Dunbar, M. J. (2008a). 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.

22. Astephen, J. L., Deluzio, K. J., Caldwell, G. E., Dunbar, M. J., & Hubley-Kozey, C. L. (2008b). Gait and neuromuscular pattern changes are associated with differences in knee osteoarthritis severity levels. *Journal of Biomechanics, 41*(4), 868-876.

23. Baker, K., Goggins, J., Xie, H., Szumowski, K., LaValley, M., Hunter, D.J., Felson, D.T. (2007). A randomized crossover trial of a wedged insole for treatment of knee osteoarthritis. *Arthritis Rheum, 56*(4):1198-203.

24. Baker, K., Xu, L., & Zhang, Y. (2005). Quadriceps weakness and its relationship to tibiofemoral and patellofemoral knee osteoarthritis in Chinese. *Br J Sports Med*, *39*, 50-51.

25. Baker, R. (2013). Gait graphs for beginners. http://wwrichard.net/2013/11/08/gait-graphs-for-beginners/.

26. 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 presented in subjected with knee osteoarthritis. *Osteaoarthritis Cartalidge*, *10*, 573-579.

27. Bashaw, R. T., & Tingstad, E. M. (2005). Rehabilitation of the osteoarthritic patient: focus on the knee. *Clinics in sports medicine*, *24*(1), 101-131.

28. Beaupre, G., Stevens, S., Carter, D. (2000). Mechanobiology in the development, maintenance, and degeneration of articular cartilage. *Journal of Rehabilitation Research and Development*, *37*(2), 145—151.

29. Benjamin, A., & Trickey, E. L. (1969). Double osteotomy for the painful knee in rheumatoid arthritis and osteoarthritis. *J Bone Joint Surg Br*, *51*(4), 694-699.

30. Bennell, K., Bowles, K. A., Payne, C., Cicuttini, F., Osborne, R., Harris, A., & Hinman, R. (2007). Effects of laterally wedged insoles on symptoms and disease progression in medial knee osteoarthritis: a protocol for a randomised, double-blind, placebo controlled trial. *BMC musculoskeletal disorders*, *8*(1), 96.

31. Bennell, K.L, Bowles, K.A, Payne, C., Cicuttini, F., Williamson, E., Forbes, A., Hanna, F., Davies-Tuck, M., Harris A., Hinman, R.S. (2011a). Lateral wedge insoles for medial knee osteoarthritis: 12 month randomised controlled trial. *BMJ*. *18*, 342.

32. Bennell, K. L., Bowles, K. A., Wang, Y., Cicuttini, F., Davies-Tuck, M., & Hinman, R. S. (2011b). 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.

33. Bennell, K. L., Kean, C. O., Wrigley, T. V., & Hinman, R. S. (2013). Effects of a modified shoe on knee load in people with and those without knee osteoarthritis. *Arthritis & heumatism*, *65*(3), 701-709.

34. Bennell, K. L., Hinman, R. S., Metcalf, B. R., Buchbinder, R., McConnell, J., McColl, G., ... & Crossley, K. M. (2005). Efficacy of physiotherapy management of knee joint osteoarthritis: a randomised, double blind, placebo controlled trial. *Annals of the Rheumatic Diseases*, *64*(6), 906-912.

35. Bennell, K. L., Hunt, M. A., Wrigley, T. V., Hunter, D. J., McManus, F. J., Hodges, P. W., & Hinman, R. S. (2010). Hip strengthening reduces symptoms but not knee load in people with medial knee osteoarthritis and varus malalignment: a randomised controlled trial. *Osteoarthritis and Cartilage, 18*(5), 621-628.

36. Bergland A, Jarnlo GB, Laake K. (2003). Predictors of falls in the elderly by location. *Aging Clin Exp Res, 15*(1), 43–50.

37. Billings, A., Scott, D. F., Camargo, M. P., & Hofmann, A. A. (2000). High Tibial Osteotomy with a Calibrated Osteotomy Guide, Rigid Internal Fixation, and Early Motion. Long-Term Follow-up. *The Journal of Bone & Joint Surgery*, *82*(1), 70-9.

38. Bolen, J., Schieb, L., Hootman, J. M., Helmick, C. G., Theis, K., Murphy, L. B., & Langmaid, G. (2010). Peer Reviewed: Differences in the Prevalence and Impact of Arthritis Among Racial/Ethnic Groups in the United States, National Health Interview Survey, 2002, 2003, and 2006. *Preventing chronic disease, 7*(3), 10_0035a.

39. Bowker, P. (1993). The biomechanics of orthoses. Biomechanical Basis of Orthotic Management. Oxford, England: Butterworth-Heinemann

40. Brater, D. C. (1988). Clinical pharmacology of NSAIDs. *The Journal of Clinical Pharmacology*, *28*(6), 518-523.

41. Brehm, M. A., Beelen, A., Doorenbosch, C. A., Harlaar, J., & Nollet, F. (2007). Effect of carbon-composite knee-ankle-foot orthoses on walking efficiency and gait in former polio patients. *Journal of Rehabilitation Medicine*, *39*(8), 651-657.

42. Briem, K., & Snyder-Mackler, L. (2009). Proximal gait adaptations in medial knee OA. *Journal of Orthopaedic Research*, *27*(1), 78-83.

43. Brooks, P., & Hochberg, M. (2001). Outcome measures and classification criteria for the rheumatic diseases. A compilation of data from OMERACT (Outcome Measures for Arthritis Clinical Trials), ILAR (International League of Associations for Rheumatology), regional leagues and other groups.*Rheumatology*, *40*(8), 896-906.

44. Bruton, A., Conway, J. H., & Holgate, S. T. (2000). Reliability: what is it, and how is it measured?. *Physiotherapy*, *86*(2), 94-99.

45. Buckwalter, J.A., Saltzman, C., Brown, T. (2004). The impact of osteoarthritis: implications for research. *Clin Orthop Rel Res., 427(Suppl),* S6–S15.

46. Carter, D.R., Beaupré ,G.S., Wong ,M., Smith, R.L., Andriacchi, T.P., Schurman, D.J. (2004). The mechanobiology of articular cartilage development and degeneration. *Clin Orthop Relat Res, (427 Suppl),* S69-77.

47. Cappozzo, A., Catani, F., Della Croce, U., & Leardini, A. (1995). Position and orientation in space of bones during movement: anatomical frame definition and determination. *Clinical Biomechanics*, *10*(4), 171-178.

48. 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.

49. Chang, A., Hayes, K., Dunlop, D., Hurwitz, D., Song, J., Cahue, S., & Sharma, L. (2004). Thrust during ambulation and the progression of knee osteoarthritis. *Arthritis & Rheumatism*, *50*(12), 3897-3903.

50. Chang, C.B., Yoo, J.H., Koh, I.J., Kang, Y.G., Seong, S.C., & Kim, T.K. (2010). Key factors in determining surgical timing of total knee arthroplasty in osteoarthritic patients: age, radiographic severity, and symptomatic severity. *J.Orthop. Traumatol*, *11* (1), 21-27.

51. Chinn, S. (1991). Statistics in respiratory medicine. 2. Repeatability and method comparison. *Thorax*, *46*(6), 454-456.

52. Cooke, T. D. V., Scudamore, A., & Greer, W. (2003). Varus knee osteoarthritis: whence the varus?. *Journal of rheumatology, 30*(12), 2521-2523.

53. 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.

54. Costa, R. A., Oliveira, L. M. D., Watanabe, S. H., Jones, A., & Natour, J. (2010). Isokinetic assessment of the hip muscles in patients with osteoarthritis of the knee. *Clinics*, *65*(12), 1253-9.

55. D'Ambrosia, R.D. (2005). Epidemiology of osteoarthritis. *Orthopedics, 28(2 Suppl)*, s201–205.

56. Davies, A. P., Calder, D. A., Marshall, T., & Glasgow, M. M. S. (1999). Plain radiography in the degenerate knee A CASE FOR CHANGE. *Journal of Bone & Joint Surgery, British Volume*, *81*(4), 632-635.

57. Davies-Tuck, M. L., Wluka, A. E., Teichtahl, A. J., Martel-Pelletier, J., Pelletier, J. P., Jones, G., ... & Cicuttini, F. M. (2008). Association between meniscal tears and the peak external knee adduction moment and foot rotation during level walking in postmenopausal women without knee osteoarthritis: a cross-sectional study. *Arthritis Research and Therapy*, *10*(3), R58.

58. Dawson, J., Linsell, L., Zondervan, K., Rose, P., Randall, T., Carr, A., & Fitzpatrick, R. (2004). Epidemiology of hip and knee pain and its impact on overall health status in older adults. *Rheumatology*, *43*(4), 497-504.

59. Dayal, N., Chang, A., Dunlop, D., Hayes, K., Chang, R., Cahue, S., ... & Sharma, L. (2005). The natural history of anteroposterior laxity and its role in knee osteoarthritis progression. *Arthritis & Rheumatism*, *52*(8), 2343-2349.

60. 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*, 6.

61. Della Croce, U., & Bonato, P. (2007). A novel design for an instrumented stairway. *Journal of biomechanics*, *40*(3), 702-704

62. Dempster, W. T. (1955). *Space Requirements of the Seated Operator: Geometric, Kinematic, and Mechanical Aspects of the Body with Special Reference to Limbs*. NTIS.

63. DeVita, P., & Hortobagyi, T. (2000). Age causes a redistribution of joint torques and powers during gait. *Journal of applied physiology*, *88*(5), 1804-1811.

64. Dhawan, A., Mather III, R. C., Karas, V., Ellman, M. B., Young, B. B., Bach Jr, B. R., & Cole, B. J. (2014). An Epidemiologic Analysis of Clinical Practice Guidelines for Non-Arthroplasty Treatment of Osteoarthritis of the Knee. *Arthroscopy: The Journal of Arthroscopic & Related Surgery*, *30*(1), 65-71.

65. Dieppe, P., Lohmander, L., (2005). Pathogenesis and management of pain in osteoarthritis. *Lancet, 365 (9463)*, 965-73.

66. 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. *J Rheumatol, 33*(11), 2271–9.

67. Divine, J. G., & Hewett, T. E. (2005). Valgus bracing for degenerative knee osteoarthritis: relieving pain, improving gait, and increasing activity. *The Physician and sports medicine*, *33*(2), 40-46.

68. D'Lima, D.D., Fregly, B.J., Patil, S., Steklov, N., Colwell, C.W. (2012). Knee joint forces: prediction, measurement, and significance. *Proc Inst Mech Eng H, 226*(22), 95-102.

69. 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.

70. Draper, E., Cable, J., Sanchez-Ballester, J., Hunt, N., Robinson, J., & Strachan, R. (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.

71. Dreinhöfer, K. E., Dieppe, P., Stürmer, T., Gröber-Grätz, D., Flören, M., Günther, K. P., ... & Brenner, H. (2006). Indications for total hip replacement: comparison of assessments of orthopaedic surgeons and referring physicians. *Annals of the rheumatic diseases*, *65*(10), 1346-1350.

72. Duncan, R.C., Hay, E.M., Saklatvala, J., et al. (2006). Prevalence of radiographic osteoarthritis – it all depends on your point of view. *Rheumatology, 45*(6), 757–60.

73. Eckstein, F., Faber S., M¨uhlbauer R., Hohe J., Englmeier K., Reiser M., Putz R. (2002). Functional adaptation of human joints to mechanical stimuli. *Osteoarthritis Cartilage, 10,* 44–50.

74. Emrani, P. S., Katz, J. N., Kessler, C. L., Reichmann, W. M., Wright, E. A., McAlindon, T. E., & Losina, E. (2008). Joint space narrowing and Kellgren–Lawrence progression in knee osteoarthritis: an analytic literature synthesis.*Osteoarthritis and Cartilage*, *16*(8), 873-882.

75. Erhart-Hledik, J. C., Elspas, B., Giori, N. J., & Andriacchi, T. P. (2012). Effect of variable-stiffness walking shoes on knee adduction moment, pain, and function in subjects with medial compartment knee osteoarthritis after 1 year. *Journal of Orthopaedic Research*, *30*(4), 514-521.

76. Erhart, J. C., Mündermann, A., Elspas, B., Giori, N. J., & Andriacchi, T. P. (2008). A variable-stiffness shoe lowers the knee adduction moment in subjects with symptoms of medial compartment knee osteoarthritis. *Journal of biomechanics, 41*(12), 2720-2725.

77. Erhart, J. C., Mündermann, A., Elspas, B., Giori, N. J., & Andriacchi, T. P. (2010). Changes in knee adduction moment, pain, and functionality with a variable-stiffness walking shoe after 6 months. *Journal of Orthopaedic Research*, *28*(7), 873-879.

78. Fallah Yakhdani, H. R., Bafghi, H. A., Meijer, O. G., Bruijn, S. M., Dikkenberg, N. V. D., Stibbe, A. B., ... & van Dieën, J. H. (2010). Stability and variability of knee kinematics during gait in knee osteoarthritis before and after replacement surgery. *Clinical biomechanics*, *25*(3), 230-236.

79. Fantini Pagani, C. H., Böhle, C., Potthast, W., & Brüggemann, G. P. (2010a). Short-term effects of a dedicated knee orthosis on knee adduction moment, pain, and function in patients with osteoarthritis. *Archives of physical medicine and rehabilitation*, *91*(12), 1936-1941.

80. Fantini Pagani, C. H., Hinrichs, M., & Brüggemann, G. P. (2012). Kinetic and kinematic changes with the use of knee valgus brace and lateral wedge insoles in patients with medial knee osteoarthritis. *Journal of Orthopaedic Research, 30*(7), 1125-1132.

81. Fantini Pagani, C. H., Potthast, W., & Brüggemann, G. P. (2010b). 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.

82. Felson, D.T., Lawrence, R.C., Dieppe P.A., et al. (2000). Osteoarthritis: new insights. Part 1: the disease and its risk factors. *Ann Intern Med. 133*(8), 635-46.

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 Rheum, 30*(8), 914– 918.

84. Felson, D. T., Nevitt, M. C., Zhang, Y., Aliabadi, P., Baumer, B., Gale, D., ... & Xu, L. (2002). High prevalence of lateral knee osteoarthritis in Beijing Chinese compared to Framingham Caucasian subjects. *Arthritis & Rheumatism*, *46*(5), 1217-1222.

85. 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.

86. Fitzgerald, G. K., Piva, S. R., & Irrgang, J. J. (2004). Reports of joint instability in knee osteoarthritis: its prevalence and relationship to physical function. *Arthritis Care & Research*, *51*(6), 941-946.

87. Flegal, K. M., Graubard, B. I., Williamson, D. F., & Gail, M. H. (2005). Excess deaths associated with underweight, overweight, and obesity. *JAMA: the journal of the American Medical Association*, *293*(15), 1861-1867.

88. Fleiss, J. L. (1986). The Design and Analysis of Clinical Experiments. New York, NY: Wiley.

89. 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.

90. Giori, NJ. (2004). Load-shifting brace treatment for osteoarthritis of the knee: a minimum 2 1/2-year follow-up study. *J Rehabil Res*, *41*(2), 187–93.

91. 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.

92. Gombatto, S. P., Collins, D. R., Sahrmann, S. A., Engsberg, J. R., & Van Dillen, L. R. (2007). Patterns of lumbar region movement during trunk lateral bending in 2 subgroups of people with low back pain. *Physical Therapy*, *87*(4), 441-454.

93. Goldin, R., McAdam, L., Louie, J., Gold, R., Bluestone, R. (1976). Clinical and radiological survey of the incidence of osteoarthrosis among obese patients. *Annals of the rheumatic diseases*, *35*(4), 349-353.

94. Griffin, M. R., Piper, J. M., Daugherty, J. R., Snowden, M., & Ray, W. A. (1991). Nonsteroidal anti-inflammatory drug use and increased risk for peptic ulcer disease in elderly persons. *Annals of Internal Medicine, 114*(4), 257-263.

95. Griffin, T. M., & Guilak, F. (2005). The role of mechanical loading in the onset and progression of osteoarthritis. *Exercise and sport sciences reviews*, *33*(4), 195-200.

96. Grood, E. S., & Suntay, W. J. (1983). A joint coordinate system for the clinical description of three-dimensional motions: application to the knee. *Journal of biomechanical engineering*, *105*(2), 136-144.

97. Guccione, A. A., Felson, D. T., Anderson, J. J., Anthony, J. M., Zhang, Y., Wilson, P. W., ... & Kannel, W. B. (1994). The effects of specific medical conditions on the functional limitations of elders in the Framingham Study.*American Journal of Public Health*, *84*(3), 351-358.

98. Guillemin, F., Rat, A.C., Mazieres, B., Pouchot, J., Fautre,l B., Euller-Ziegler, L., Fardellone, P., Morvan, J., Roux, C.H., Verrouil, E., Saraux, A., Coste, J. 3000 Osteoarthritis group. (2011).Prevalence of symptomatic hip and knee osteoarthritis: a two-phase population-based survey. *Osteoarthritis Cartilage*, *19*(11), 1314-22.

99. 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.

100. Haim, A., Rozen, N., Dekel, S., Halperin, N., & Wolf, A. (2008). Control of knee coronal plane moment via modulation of centre of pressure: a prospective gait analysis study. *Journal of biomechanics*, *41*(14), 3010-3016.

101. Hamel, K. A., & Cavanagh, P. R. (2004). Stair performance in people aged 75 and older. *Journal of the American Geriatrics Society*, *52*(4), 563-567.

102. Haq, I., Murphy, E., Darce, J. (2003). Osteoarthritis. *Postgrad Med J, 79* (933), 377-383.

103. Hayashi, D., Englund, M., Roemer, F. W., Niu, J., Sharma, L., Felson, D. T., ... & Guermazi, A. (2012). Knee malalignment is associated with an increased risk for incident and enlarging bone marrow lesions in the more loaded compartments: the MOST study. *Osteoarthritis and Cartilage*, *20*(11), 1227-1233.

104. Hebert, J. S., & Liggins, A. B. (2005). Gait evaluation of an automatic stance-control knee orthosis in a patient with postpoliomyelitis. *Archives of physical medicine and rehabilitation*, *86*(8), 1676-1680.

105. 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.

106. Hicks-Little, C. A., Peindl, R. D., Fehring, T. K., Odum, S. M., Hubbard, T. J., & Cordova, M. L. (2012). Temporal-Spatial Gait Adaptations during Stair Ascent and Descent in Patients With Knee Osteoarthritis. *The Journal of Arthroplasty*, *27*(6), 1183-1189.

107. 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.

108. Hinman, R. S., Bowles, K. A., Payne, C., & Bennell, K. L. (2008). Effect of length on laterally-wedged insoles in knee osteoarthritis. *Arthritis Care & Research*, *59*(1), 144-147.

109. Hinman, R. S., Crossley, K. M., McConnell, J., & Bennell, K. L. (2003). Efficacy of knee tape in the management of osteoarthritis of the knee: blinded randomised controlled trial. *Bmj*, *327*(7407), 135.

110. Hunt, M.A., Hinman, R.S., Metcalf, B.R., Lim, B.W., Wrigley, T.V., Bowles, K.A., Kemp, G., Bennell, K.L. (2010). Quadriceps strength is not related to gait impact loading in knee osteoarthritis. *Knee, 17*(4), 296-302.

111. Hunter, D.J., McDougall, J.J., Keefe, F.J. (2008). The symptoms of osteoarthritis and the genesis of pain. *Rheum Dis Clin North Am*, *34*(3), 623-43

112. Hurwitz, D.E., Ryals, A.R., Block, J.A., Sharma, L., Schnitzer, T.J., & Andriacchi, T.P. (2000). Knee pain and joint loading in subjects with oasteoarthritis of the knee. *J Orthop Res.*, *18*, 572-579.

113. Hurwitz, D. E., Hulet, C. H., Andriacchi, T. P., Rosenberg, A. G., & Galante, J. O. (1997). Gait compensations in patients with osteoarthritis of the hip and their relationship to pain and passive hip motion. Journal *of orthopaedic research, 15*(4), 629-635.

114. 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.

115. Jacobson, L. T. (1996). Definitions of osteoarthritis in the knee and hand.*Annals of the rheumatic diseases*, *55*(9), 656.

116. Järvenpää, J., Kettunen, J., Kröger, H., & Miettinen, H. (2010). Obesity may impair the early outcome of total knee arthroplasty. *Scandinavian journal of surgery: SJS: official organ for the Finnish Surgical Society and the Scandinavian Surgical Society*, *99*(1), 45.

117. Jenkyna, T., Hunta, M., Jonesa, I., Giffina, J., Birmingham, T. (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*, 276–283.

118. Jevsevar, D. S., Riley, P. O., Hodge, W. A., & Krebs, D. E. (1993). Knee kinematics and kinetics during locomotor activities of daily living in subjects with knee arthroplasty and in healthy control subjects. *Physical Therapy*, *73*(4), 229-239.

119. Johnson, F., Leitl, S., & Waugh, W. (1980). The distribution of load across the knee. A comparison of static and dynamic measurements. *Journal of Bone & Joint Surgery, British Volume, 62*(3), 346-349.

120. Johnson, G. R., Ferrarin, M., Harrington, M., Hermens, H., Jonkers, I., Mak, P., & Stallard, J. (2004). Performance specification for lower limb orthotic devices. *Clinical Biomechanics*, *19*(7), 711-718.

121. Jones, R. K., Chapman, G. J., Parkes, M. J., Forsythe, L., & Felson, D. T. (2014). Foot and ankle biomechanics play a role in biomechanical response to lateral wedge insoles. *Journal of Foot and Ankle Research, 7*(Suppl 1), A39.

122. 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 knee valgus braces and lateral wedged insoles in patients with knee osteoarthritis. *Gait & Posture*.37 (3), 368-72.

123. Jordan, K., Arden, N., Do herty, M., Bannwarth, B., Bijlsma, J., Dieppe P., et al., (2003). Standing Committee for International Clinical Studies Including Therapeutic Trials ESCISIT: EULAR Recommendations 2003: an evidence based approach to the management of knee osteoarthritis: Report of a Task Force of the Standing Committee for International Clinical Studies Including Therapeutic Trials (ESCISIT). *Ann Rheum Dis, 62*(12), 1145-1155.

124. Julin, J., Jämsen, E., Puolakka, T., Konttinen, Y. T., & Moilanen, T. (2010). Younger age increases the risk of early prosthesis failure following primary total knee replacement for osteoarthritis: a follow-up study of 32,019 total knee replacements in the Finnish arthroplasty register. *Acta orthopaedica*, *81*(4), 413-419.

125. Kakihana, W., Akai, M., Nakazawa, K., Takashima,T., Naito,K., Torii,S. (2005). Effects of laterally wedge insole on knee and subtalar joint moments. *Arch Phys Med Rehabil, 86*(7):1465-71.

126. Kakihana, W., Akai, M., Yamasaki, N., Takashima, T., & Nakazawa, K. (2004). Changes of joint moments in the gait of normal subjects wearing laterally wedged insoles. *American journal of physical medicine & rehabilitation*, *83*(4), 273-278.

127. 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.

128. 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.

129. Kellgren, J. H., Jeffrey, M. R., & Ball, J. (1963). Atlas of standard radiographs of arthritis. Vol II. The epidemiology of chronic rheumatism. *Oxford Blackwell Scientific*.

130. Kellgren, J., Lawrence, J. (1958), Osteoarthritis and disk generation in an urban population. *Annals of Rheumatic disease*, *17*(4), 388-397.

131. Kellgren, J., Lawrence, J. (1957). Radiological assessment of osteo-arthrosis. *Ann Rheum Dis*, *16*(4), 494-502.

132. Kellgren, J. H., & Lawrence, J. S. (1952). Rheumatism in miners. Part II: X-ray study. *British Journal of Industrial Medicine*, *9*(3), 197.

133. Kerrigan, D. C., Johansson, J. L., Bryant, M. G., Boxer, J. A., Della Croce, U., & Riley, P. O. (2005). Moderate-heeled shoes and knee joint torques relevant to the development and progression of knee osteoarthritis. *Archives of physical medicine and rehabilitation*, *86*(5), 871-875.

134. 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.

135. Kerrigan, D. C, Todd, M. K, Riley, P. O. (1998). Knee osteoarthritis and high-heeled shoes. *Lancet*, *351* (9113), 1399–401.

136.Kijowski, R., Blankenbaker, D., Stanton P., Fine, J., De Smet, A. (2006). Arthroscopic validation of radiographic grading scales of osteoarthritis of the tibiofemoral joint. *AJR Am J Roentgenol*, *187*(3), 794-9.

137. King, L., Birmingham, T., Kean, C., Jones, I., Bryant, D., & Giffin, J. R. (2008). Resistance training for medial compartment knee osteoarthritis and malalignment. *Medicine and Science in Sports and Exercise*, *40*(8), 1376.

138. Kirkley, A., Birmingham, T. B., Litchfield, R. B., Giffin, J. R., Willits, K. R., Wong, C. J., ... & Fowler, P. J. (2008). A randomized trial of arthroscopic surgery for osteoarthritis of the knee. *New England Journal of Medicine*, *359*(11), 1097-1107.

139. Ko, S. U., Ling, S. M., Schreiber, C., Nesbitt, M., & Ferrucci, L. (2011). Gait patterns during different walking conditions in older adults with and without knee osteoarthritis—Results from the Baltimore Longitudinal Study of Aging. *Gait & posture*, *33*(2), 205-210.

140. Koca, B., Öz, B., Ölmez, N., & Memiş, A. (2009). Effect of lateral wedge shoe insoles on pain and function in patients with knee osteoarthritis. *Türk Fiz Tıp Rehab Derg*, *55*, 158-62.

141. Kowalk, D. L., Duncan, J. A., & Vaughan, C. L. (1996). Abduction-adduction moments at the knee during stair ascent and descent. *Journal of biomechanics*, *29*(3), 383-388.

142. 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.

143. Lane, N. E., Gore, L. R., Cummings, S. R., Hochberg, M. C., Scott, J. C., Williams, E. N., & Nevitt, M. C. (1999). Serum vitamin D levels and incident changes of radiographic hip osteoarthritis: a longitudinal study. *Arthritis & Rheumatism*, *42*(5), 854-860.

144. Lawrence, R.C., Helmick, C.G., Arnett, F.C., Deyo, R.A., Felson, D.T., Giannini, E.H., et al. (1998). Estimates of the prevalence of arthritis and selected musculoskeletal disorders in the United States. *Arthritis & Rheumatism, 41*(5), 778–799.

145. Leitner, M., Schmid, S., Hilfiker, R., & Radlinger, L. (2011). Test–retest reliability of vertical ground reaction forces during stair climbing in the elderly population. *Gait & Posture*, *34*(3), 421-425.

146. Leufkens, H. G., Ameling, C. B., Hekster, Y. A., & Bakker, A. (1990). Utilization patterns of non-steroidal anti-inflammatory drugs in an open Dutch population. *Pharmaceutisch Weekblad*, *12*(3), 97-103.

147. 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.

148. Linley, H. S., Sled, E. A., Culham, E. G., & Deluzio, K. J. (2010). A biomechanical analysis of trunk and pelvis motion during gait in subjects with knee osteoarthritis compared to control subjects. *Clinical Biomechanics, 25*(10), 1003-1010.

149. Lippert, L. (2006). Knee (4rd edition*). Clinical Kinesiology and Anatomy (pp.* 251-258). Philadelphia: FA.Davis.

150. Liu, K., Lao, L., Asami, T., Itoh, Y., & Watanabe, H. (1998). Clinical care of osteoarthritic knee with knee orthoses. *Fukuoka igaku zasshi= Hukuoka acta medica*, *89*(10), 298.

151. Manninen, P., Riihimäki, H., Heliövaara, M., & Suomalainen, O. (2001). Physical exercise and risk of severe knee osteoarthritis requiring arthroplasty. *Rheumatology*, *40*(4), 432-437.

152. 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.

153. McAlindon, T. E., Felson, D. T., Zhang, Y., Hannan, M. T., Aliabadi, P., Weissman, B., ... & Jacques, P. (1996a). 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.

154. McAlindon, T. E., Jacques, P., Zhang, Y., Hannan, M. T., Aliabadi, P., Weissman, B., ... & Felson, D. T. (1996b). Do antioxidant micronutrients protect against the development and progression of knee osteoarthritis?. *Arthritis & Rheumatism*, *39*(4), 648-656.

155. McAlindon, T. E., Snow, S., Cooper, C., & Dieppe, P. A. (1992). Radiographic patterns of osteoarthritis of the knee joint in the community: the importance of the patellofemoral joint. *Annals of the rheumatic diseases*, *51*(7), 844-849.

156. McFadyen, B. J., & Winter, D. A. (1988). An integrated biomechanical analysis of normal stair ascent and descent. *Journal of biomechanics*, *21*(9), 733-744.

157. Mcneill, T., Warwick, D., Andersson, G., & Schultz, A. (1980). Trunk strengths in attempted flexion, extension, and lateral bending in healthy subjects and patients with low-back disorders. *Spine*, *5*(6), 529-538.

158. Meng, X. L., Zhang, Z. Q., Sun, S. Y., Wu, J. K., & Wong, W. C. (2012). Biomechanical model-based displacement estimation in micro-sensor motion capture. *Measurement Science and Technology*, *23*(5), 055101.

159. Messier, S. P., Loeser, R. F., Miller, G. D., Morgan, T. M., Rejeski, W. J., Sevick, M. A., ... & Williamson, J. D. (2004). Exercise and dietary weight loss in overweight and obese older adults with knee osteoarthritis: the Arthritis, Diet, and Activity Promotion Trial. *Arthritis & Rheumatism*, *50*(5), 1501-1510.

160. Mills, O. S., & Hull, M. L. (1991). Rotational flexibility of the human knee due to varus/valgus and axial moments in vivo. *Journal of biomechanics*, *24*(8), 673-690.

161. 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. *Ann Rheum Dis*, *61*, 617–622.

162. Moreland, J. R., Bassett, L. & Hanker, G. 1987. Radiographic analysis of the axial alignment of the lower extremity. *The Journal of Bone and Joint Surgery, 69 (5),* 745-749.

163. Morrison, J.B., 1969. Function of the knee joint in various activities. *Biomedical Engineering*, *4*(12), 473–580.

164. Moyer, R. F., Birmingham, T. B., Dombroski, C. E., Walsh, R. F., Leitch, K. M., Jenkyn, T. R., & Giffin, J. R. (2013). 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*, *94*(1), 103-112.

165. Mündermann, A., Asay, J. L., Mündermann, L., & Andriacchi, T. P. (2008a). Implications of increased medio-lateral trunk sway for ambulatory mechanics.*Journal of biomechanics*, *41*(1), 165-170.

166. Mündermann, A., Dyrby, C. O., & Andriacchi, T. P. (2008b). A comparison of measuring mechanical axis alignment using three-dimensional position capture with skin markers and radiographic measurements in patients with bilateral medial compartment knee osteoarthritis. *The Knee*, *15*(6), 480-485.

167. 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.

168. Mündermann, A., Dyrby, C. O., D'Lima, D. D., Colwell, C. W., & Andriacchi, T. P. (2008c). In vivo knee loading characteristics during activities of daily living as measured by an instrumented total knee replacement. *Journal of Orthopaedic Research*, *26*(9), 1167-1172.

169. 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 Rheum, 50*(4), 1172-8.

170. Murphy, L., Schwartz, T. A., Helmick, C. G., Renner, J. B., Tudor, G., Koch, G., ... & Jordan, J. M. (2008). Lifetime risk of symptomatic knee osteoarthritis. *Arthritis Care & Research*, *59*(9), 1207-1213.

171. Nagura, T., Dyrby, C. O., Alexander, E. J., & Andriacchi, T. P. (2002). Mechanical loads at the knee joint during deep flexion. *Journal of Orthopaedic Research, 20*(4), 881-886.

172. National Collaborating Centre for Chronic Conditions (Grande Bretagne). (2008). Osteoarthritis: National clinical guideline for care and management in adults. Royal College of Physicians. London.

173. Nevitt, M. C., Cummings, S. R., Lane, N. E., Hochberg, M. C., Scott, J. C., Pressman, A. R., ... & Cauley, J. A. (1996). Association of estrogen replacement therapy with the risk of osteoarthritis of the hip in elderly white women. *Archives of Internal Medicine*, *156*(18), 2073.

174. Nicholas, H.Y., Paul, K.C., Hamid, N.H. (2010). The effect of the frontal plane tibiofemoral angle and varus knee moment on the contact stress and strain at the knee cartilage. *Journal of Applied Biomechanics, 26,* 432-443.

175. Nietert, M., (1975). *Untersuchungen zur Kinematik des menschlichen Kniegelenks im Hinblick auf ihre Approximation in der Prothetik*. Dissertation, Berlin.

176. Novak, A. C., Reid, S. M., Costigan, P. A., & Brouwer, B. (2010). Stair negotiation alters stability in older adults. *Lower Extremity Review*, *2*(10), 47-51.

177. Noyes, F. R., Schipplein, O. D., Andriacchi, T. P., Saddemi, S. R., & Weise, M. (1992). The anterior cruciate ligament-deficient knee with varus alignment An analysis of gait adaptations and dynamic joint loadings. *The American journal of sports medicine*, *20*(6), 707-716.

178. Nussbaumer, S., Leunig, M., Glatthorn, J. F., Stauffacher, S., Gerber, H., & Maffiuletti, N. A. (2010). Validity and test-retest reliability of manual goniometers for measuring passive hip range of motion in femoroacetabular impingement patients. *BMC musculoskeletal disorders*, *11*(1), 194.

179. Oliveria, S. A., Felson, D. T., Reed, J. I., Cirillo, P. A. & Walker, A. M. (1995). Incidence of symptomatic hand, hip, and knee osteoarthritis among patients in a health maintenance organization. *Arthritis & Rheumatism, 38*(8), 1134-1141.

180. 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.

181. Parkes, M., Maricar, N., Lunt, M., LaValley M., Jones, R., Segal N., Takahashi-Narita, K., Felson, D. (2013). Lateral Wedge Insoles as a Conservative Treatment for Pain in Patients With Medial Knee Osteoarthritis A Meta-analysis. *JAMA, 310*(7):722-730.

182. Peat, G., Thomas, E., Duncan, R., Wood, L., Hay, E., & Croft, P. (2006). Clinical classification criteria for knee osteoarthritis: performance in the general population and primary care. *Annals of the rheumatic diseases, 65*(10), 1363-1367.

183. Perneger, T. V. (1998). What's wrong with Bonferroni adjustments. *BMJ: British Medical Journal*, *316*(7139), 1236.

184. Perry, J. (1992). Gait analysis: Normal and pathological function, SLACK incorporated. *Journal of Pediatric Orthopaedics, 12*, 815.

185. Petersson, I. F., Jacobsson, L. T. (2002). Osteoarthritis of the peripheral joints. *Best Practice & Research Clinical Rheumatology*, *16*(5), 741-760.

186. Pincus, T., Koch, G. G., Sokka, T., Lefkowith, J., Wolfe, F., Jordan, J. M., ... & Fort, J. (2001). A randomized, double-blind, crossover clinical trial of diclofenac plus misoprostol versus acetaminophen in patients with osteoarthritis of the hip or knee. *Arthritis & Rheumatism, 44*(7), 1587-1598.

187. Pinto, R. Z., Souza, T. R., Trede, R. G., Kirkwood, R. N., Figueiredo, E. M., & Fonseca, S. T. (2008). Bilateral and unilateral increases in calcaneal eversion affect pelvic alignment in standing position. *Manual therapy*, *13*(6), 513-519.

188. 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.

189. 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.

190. 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.

191. 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.

192. Redford, J. B., Basmajian, J. V., & Trautman, P. (1995). *Orthotics: clinical practice and rehabilitation technology*. Churchill Livingstone.

193. Reginster, J. Y. (2002). The prevalence and burden of arthritis. *Rheumatology*, *41*(suppl 1), 3-6.

194. Reid, D., Kennedy, N., Smith, M. A., Nicoll, J., Brown, N., Tothill, P., & Nuki, G. (1986).Bone loss in rheumatoid arthritis and primary generalized osteoarthrosis: effects of corticosteroids, suppressiveantirheumatic drugs and calcium supplements. *Rheumatology*, *25*(3), 253-259.

195. 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.

196. Richette, P., Poitou, C., Garnero, P., Vicaut, E., Bouillot, J. L., Lacorte, J. M., ... & Chevalier, X. (2011). Benefits of massive weight loss on symptoms, systemic inflammation and cartilage turnover in obese patients with knee osteoarthritis. *Annals of the rheumatic diseases*, *70*(1), 139-144.

197. Richmond, J., Hunter, D., Irrgang, J., Jones, M. H., Levy, B., Marx, R., ... & McGowan, R. (2009). Treatment of osteoarthritis of the knee (nonarthroplasty).*Journal of the American Academy of Orthopaedic Surgeons*, *17*(9), 591-600.

198. Richy, F., Bruyère, O., Ethgen, O., Rabenda, V., Bouvenot, G., Audran, M., ... & Reginster, J. Y. (2004). Time dependent risk of gastrointestinal complications induced by non-steroidal anti-inflammatory drug use: a consensus statement using a meta-analytic approach. *Annals of the rheumatic diseases*, *63*(7), 759-766.

199. Roos, E. M. (2005). Joint injury causes knee osteoarthritis in young adults. *Current opinion in rheumatology*, *17*(2), 195-200.

200. Robbins, S. M., & Maly, M. R. (2009). The effect of gait speed on the knee adduction moment depends on waveform summary measures. *Gait & posture*, *30*(4), 543-546.

201. Roos, H., Laurén, M., Adalberth, T., Roos, E. M., Jonsson, K., & Lohmander, L. S. (1998). Knee osteoarthritis after meniscectomy: prevalence of radiographic changes after twenty-one years, compared to matched controls. *Arthritis & Rheumatism*, *41*(4), 687-693.

202. Ryu, J. H., Lee, A., Huh, M. S., Chu, J., Kim, K., Kim, B. S., ... & Youn, I. (2012). Measurement of mmp activity in synovial fluid in cases of osteoarthritis and acute inflammatory conditions of the knee joints using a fluorogenic peptide probe-immobilized diagnostic kit. *Theranostics*, *2*(2), 198.

203. Sasaki, K., & Neptune, R. R. (2010). Individual muscle contributions to the axial knee joint contact force during normal walking. *Journal of biomechanics*, *43*(14), 2780-2784.

204. 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.

205. Sattari, S., & Ashraf, A. (2011). Comparison the Effect of 3 Point Valgus Stress Knee Support and Lateral Wedge Insoles in Medial Compartment Knee Osteoarthritis. *Iranian Red Crescent Medical Journal*, *13*(9), 624.

206. Sattin, R. W. (1992). Falls among older persons: a public health perspective. *Annual review of public health*, *13*(1), 489-508.

207. Self, B., Greenwald, R., & Pflaste, D. (2000). A biomechanical analysis of a medial unloading brace for osteoarthritis in the knee. *Arthritis Care & Research*, *13*(4), 191-197.

208. 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.

209. 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.

210. Shakoor, N., Lidtke, R. H., Sengupta, M., Fogg, L. F., & Block, J. A. (2008). Effects of specialized footwear on joint loads in osteoarthritis of the knee.*Arthritis Care & Research*, *59*(9), 1214-1220.

211. 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: the journal of the American Medical Association*, *286*(2), 188-195.

212. Shelburne, K., Torry M., Steadman J., Pandy, G. (2008). Effects of foot orthoses and valgus bracing on the knee adduction moment and medial joint load during gait. *Clinical Biomechanics*, *23*, 814–821.

213. Shimada, S., Kobayashi, S., Wada, M., Uchida, K., Sasaki, S., Kawahara, H., ... & Baba, H. (2006). Effects of disease severity on response to lateral wedged shoe insole for medial compartment knee osteoarthritis. *Archives of physical medicine and rehabilitation*, *87*(11), 1436-1441.

214. Shiomi, T. (1994). Effects of different patterns of stair climbing on physiological cost and motor efficiency. *Journal of human ergology*, *23*(2), 111-1120.

215. Shull, P. B., Shultz, R., Silder, A., Dragoo, J. L., Besier, T. F., Cutkosky, M. R., & Delp, S. L. (2013). Toe-in gait reduces the first peak knee adduction moment in patients with medial compartment knee osteoarthritis. *Journal of biomechanics*, *46*(1), 122-128.

216. Skou, S. T., Hojgaard, L., & Simonsen, O. H. (2013). Customized foot insoles have a positive effect on pain, function, and quality of life in patients with medial knee osteoarthritis. *Journal of the American Podiatric Medical Association*, *103*(1), 50-55.

217. Silva, M. P., & Ambrósio, J. A. C. (2002). Kinematic data consistency in the inverse dynamic analysis of biomechanical systems. *Multibody System Dynamics*, *8*(2), 219-239.

218. Simmonds, M. J., Kumar, S., & Lechelt, E. (1996). Psychosocial factors in disabling low back pain: causes or consequences?. *Disability & Rehabilitation*, *18*(4), 161-168.

219. 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.

220. Spector, T. D., Cicuttini, F., Baker, J., Loughlin, J., & Hart, D. (1996). Genetic influences on osteoarthritis in women: a twin study. *BMJ: British Medical Journal*, *312*(7036), 940-3.

221. Spector, T., Hart, D. (1992), How serious is knee osteoarthritis?. *Annals of Rheumatic disease*, *51*(10), 1105-1106.

222. Spector, T. D., Hart, D. J., & Doyle, D. V. (1994). Incidence and progression of osteoarthritis in women with unilateral knee disease in the general population: the effect of obesity. *Annals of the rheumatic diseases*, *53*(9), 565-568.

223. Squyer, E., Stamper, D. L., Hamilton, D. T., Sabin, J. A., & Leopold, S. S. (2013). Unloader knee braces for osteoarthritis: do patients actually wear them?. *Clinical Orthopaedics and Related Research*, *471*(6), 1982-1991.

224. Stacoff, A., Diezi, C., Luder, G., Stüssi, E., & Kramers-de Quervain, I. A. (2005). Ground reaction forces on stairs: effects of stair inclination and age. *Gait & Posture*, *21*(1), 24-38.

225. Stamenović, D., Kojić, M., Stojanović, B., & Hunter, D. (2008). A finite element analysis of an osteoarthritis knee brace. *Journal of the Serbian Society for Computational Mechanics/Vol*, *2*(2), 29-41.

226. Stauffer, R. N., Chao, E. Y., & Györy, A. N. (1977). Biomechanical gait analysis of the diseased knee joint. *Clinical orthopaedics and related research*, *126*, 246-255.

227. Stratford, P. W., & Goldsmith, C. H. (1997). Use of the standard error as a reliability index of interest: an applied example using elbow flexor strength data. *Physical therapy*, *77*(7), 745-750.

228. Svensson, W., & Holmberg, U. (2007). Stair gait classification from kinematic sensors. Available at: http://cdn.intechopen.com/pdfs-wm/575.pdf.

229. Swift, A. (2012). *A clinical study exploring hip and knee osteoarthritis pain transmission using cerebrospinal fluid*. Doctoral dissertation, University of Birmingham.

230. Taghi Karimi, M., Esrafilian, A., & Amiri, P. (2012). Design and Evaluation of a New Type of Knee Orthosis to Align the Mediolateral Angle of the Knee Joint with Osteoarthritis. *International Proceedings of Chemical, Biological & Environmental Engineering*, *34*. doi: 10.1155/2012/104927.

231. Takacs, J., Hunt, M.A. (2012). The effect of contralateral pelvic drop and trunk lean on frontal plane knee biomechanics during single limb standing. *J Biomech, 45*, 2791–6.

232. Taktak, D. M., & Bowker, P. (1995). Lightweight, modular knee-ankle-foot orthosis for Duchenne muscular dystrophy: design, development, and evaluation. *Archives of physical medicine and rehabilitation*, *76*(12), 1156-1162.

233. Tanaka, K., Miyashita, K., Urabe, Y., Ijiri, T., Takemoto, Y., Ishii, Y., & Ochi, M. (2008). Characteristics of trunk lean motion during walking in patients with symptomatic knee osteoarthritis. *The Knee*, *15*(2), 134-138.

234. Toda, Y., Tsukimura, N., & Segal, N. (2005). An optimal duration of daily wear for an insole with subtalar strapping in patients with varus deformity osteoarthritis of the knee. *Osteoarthritis and cartilage*, *13*(4), 353-360.

235. Thomas, P. A., Philipp, L. L., Eugene, J. A., Debra, E. H. (2000). Methods for evaluating the progression of osteoarthritis. *J Rehabil Res Dev*, *37*, 163 -170.

236. 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 to moderate medial knee osteoarthritis. *Arthritis & Rheumatism*, *54*(12), 3842-3849.

237. 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.

238. 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.

239. Trepczynski, A., Kutzner, I., Bergmann G., Taylor WR., Heller MO. Modular of the relation between external knee adduction moments and medial joint contact forces across subjects and activities. *Arthritis Rheumatol*, *66*(5), 1218-27.

240. Update, C. S. M. (1986). Non-steroidal anti-inflammatory drugs and serious gastrointestinal adverse reactions-1. *Br Med J*, *292*(614), 614.

241. Valente, G., Taddei, F., & Jonkers, I. (2013). Influence of weak hip abductor muscles on joint contact forces during normal walking: probabilistic modeling analysis. *Journal of biomechanics*, *46*, 2186-2193.

242. Van der Esch, M., Steultjens, M. P., Harlaar, J., van den Noort, J. C., Knol, D. L., & Dekker, J. (2011). Lateral Trunk Motion and Knee Pain in Osteoarthritis of the Knee: a cross-sectional study. *BMC musculoskeletal disorders*, *12*(1), 141.

243. Van Saase, J., Van Romunde, L., Cats, A., Vandenbroucke, J., & Valkenburg, H. (1989). Epidemiology of osteoarthritis: Zoetermeer survey. Comparison of radiological osteoarthritis in a Dutch population with that in 10 other populations. *Annals of the rheumatic diseases*, *48*(4), 271-280.

244. Walker, C. R. C., Myles, C., Nutton, R., & Rowe, P. (2001). Movement of the knee in osteoarthritis The Use Of Electrogoniometry to Assess Function.*Journal of Bone & Joint Surgery, British Volume*, *83*(2), 195-198.

245. Walter, J., 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.

246. Whatling, Gemma Marie, Jones, L., Holt, Catherine Avril and Evans, Samuel Lewin (2007). A study of stair climbing for patients with advanced knee osteoarthritis [Abstract]. *Gait & Posture* 26 (S1), S117. 10.1016/S0966-6362(07)80010-5.

247. WHO Scientific Group, (1992). “Rheumatic diseases,” Tech. Rep., WHO, Geneva, Switzerland.

248. Whiteside J., (2011). Improved Outcomes Using a New Free Motion KAFO for Treatment of Blounts Disease vs. Traditional Locked Knee Designs. Available from: http://www.anatomicalconceptsinc.com/sites/default/files/images/knee-ankle-foot-orthoses/KAFO%20blounts/White%20Paper-Treat%20Blounts%20Using%20Free%20Motion%20KAFO.pdf.

249. Williamson, J.D., Fried, L.P. (1996). Characterization of older adults who attribute functional decrements to “old age”. *J Am Geriatr Soc*, *44*(12):1429-1434.

250. Winby, C.R., Lloyd, D.G., Besier, T.F., Kirk, T.B. (2009). Muscle and external load contribution to knee joint contact loads during normal gait. *J Biomech, 42*(14), 2294–300.

251. Wright, J. M., Crockett, H. C., Slawski, D. P., Madsen, M. W., & Windsor, R. E. (2005). High tibial osteotomy. *Journal of the American Academy of Orthopaedic Surgeons*, *13*(4), 279-289.

252. Yakimovich, T., Lemaire, E. D., & Kofman, J. (2006). Preliminary kinematic evaluation of a new stance-control knee–ankle–foot orthosis. *Clinical Biomechanics*, *21*(10), 1081-1089.

253. Yu, B., Kienbacher, T., Growney, E. S., Johnson, M. E., & An, K. N. (1997a). Reproducibility of the kinematics and kinetics of the lower extremity during normal stair-climbing. Journal of orthopaedic research, 15(3), 348-352.

254. Yu, B., Stuart, M. J., Kienbacher, T., Growney, E. S., & An, K. N. (1997b). Valgus-varus motion of the knee in normal level walking and stair climbing. *Clinical Biomechanics*, *12*(5), 286-293.

255. 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.

256. Zeni, J. A., & Higginson, J. S. (2009). Differences in gait parameters between healthy subjects and persons with moderate and severe knee osteoarthritis: a result of altered walking speed?. *Clinical Biomechanics, 24*(4), 372-378.

257. Zeni, J. A., & Higginson, J. S. (2011). Knee osteoarthritis affects the distribution of joint moments during gait. *The Knee*, *18*(3), 156-159.

258. Zhang, Y., Hannan, M.T., Chaisson, C.E., McAlindon, T.E., Evans, S.R., Aliabadi, P., et al. (2000). Bone mineral density and risk of incident and progressive radiographic knee osteoarthritis in women: the Framingham Study. *J Rheumatol. 27 (4)*, 1032-7.

259. Zhang, Y., Niu, J., Kelly-Hayes, M., Chaisson, C.E., Aliabadi, P., Felson, D.T. (2002). Prevalence of symptomatic hand osteoarthritis and its impact on functional status among the elderly: The Framingham Study. *American Journal of Epidemiology*, *156*(11), 1021–1027.