

**Exploring the Effects of a Non-mechanical
Knee Brace on Lower Limb Kinematics &
Kinetics in Healthy Individuals & its
Implications for Patients with
Osteoarthritis of the Knee**

by

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STUDENT DECLARATION

Concurrent registration for two or more academic awards:

I declare that while registered as a candidate for the research degree, I have not been a registered candidate or enrolled student for another award of the University or other academic or professional institution.

Material submitted for another award:

I declare that no material contained in the thesis has been used in any other submission for an academic award and is solely my own work.

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ABSTRACT

Background: Knee orthoses in the form of a brace for osteoarthritis (OA) are rarely recommended in clinical guidelines, but represents a possible treatment for patients not suited for surgery. Although effective biomechanically, mechanical braces can be unattractive to patients. Controlling symptomology by altering neuromuscular control with the use of non-mechanical (proprioceptive) knee braces could improve the treatment of OA.

Aim: The present thesis examines the effect of a proprioceptive knee brace on lower limb kinematics and kinetics in healthy participants and in participants with OA.

Methods: Thirteen healthy and three participants with OA aged 30 to 60 volunteered. Hip, knee and ankle biomechanics during walk and stepdown tasks with and without the Donjoy OA Reaction Web (DJO Global, USA, 2015) brace were examined using the calibrated anatomical systems technique (CAST). OA participants scored the effects of the brace using the Knee Osteoarthritis Outcome Score (KOOS) pre-testing and after four weeks of wear.

Results: During the braced walk task, at the knee there were reductions in sagittal angle ($p = 0.007$) and adduction at heel strike ($p = 0.004$), maximum internal rotation during stance ($p = 0.03$), peak flexion angular velocity during mid ($p = 0.003$) and terminal swing ($p = 0.021$). Both groups had a reduction of knee varum in stance ($p = 0.007$). At the hip, healthy participants had reductions in hip flexion at heel strike ($p = 0.016$) and weight acceptance ($p = 0.035$), while internal rotation increased ($p = 0.010$) and ankle inversion increased ($p = 0.011$). Mid-stance knee flexion moment reduced ($p = 0.006$) and peak hip flexion moment increased ($p = 0.004$) in healthy participants. During step descent, knee kinematics

demonstrated reductions in maximum internal rotation ($p = 0.005$), transverse range of movement ($p = 0.001$) and in transverse angular velocity ($p = 0.001$) in healthy participants. During braced stepdown, at the hip healthy participants showed a reduction in maximum internal rotation angular velocity ($p = 0.025$). Ankle inversion angle in healthy participants increased ($p = 0.049$), as did the maximum supination angular velocity ($p = 0.010$), while the maximum inversion angular velocity was reduced ($p=0.024$). Healthy participants had increased knee flexion moment at heel strike ($p = 0.019$). The OA group had reductions in knee varum at heel strike, adduction angular velocity during weight acceptance and terminal stance during the braced walk task. During braced stepdown in OA cases, the knee maximum internal rotation angular velocity was reduced and maximum pronation angular velocity at the ankle reduced. All OA participants improved their KOOS at four weeks across all tested parameters; with reductions of 85.5% in pain, 57.6% in symptomology, 81.2% in activities of daily living, 255.2% for sports and recreation and 127.7% for quality of life scores. 84.6% of healthy and all OA participants gave positive feedback on wearability of the brace.

Conclusion: Positive kinematic and kinetic changes in multiple planes are achieved with proprioceptive bracing alongside improved patient outcome. These changes occur not only at the knee but at other weight bearing joints. This study supports the concept of neuromuscular reinforcement and re-education through proprioceptive bracing as an alternative to mechanical correction. Future studies should couple brace design and action with the clinical grade of OA.

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ABBREVIATIONS

| | |
|------------|--|
| ADL: | Activity of Daily Living |
| ANOVA: | Analysis of Variance |
| CNS: | Central Nervous System |
| EKAM: | External knee adduction moment |
| EMG: | Electromyography |
| GRF: | Ground Reaction Force |
| KAAI: | Knee adduction angular impulse |
| KAM: | Knee Adduction Moment |
| KL Score: | Kellgren Lawrence Osteoarthritis Score |
| KOOS: | Knee Injury and Osteoarthritis Outcome Score |
| MSK: | Musculoskeletal |
| NSAID's: | Non-steroidal Anti-inflammatory Drugs |
| OA: | Osteoarthritis |
| PFP | Patellofemoral Pain Syndrome |
| PIS: | Participant Information Sheet |
| PNS: | Peripheral Nervous System |
| PROMS: | Patient Reported Outcome Measures |
| QOL: | Quality of Life |
| ROM: | Range of movement |
| STEMH: | Science, Technology, Engineering, Medicine & Health Ethics Committee |
| UCLAN: | University of Central Lancashire |
| UK | United Kingdom |
| USA | United States of America |
| VAS Score: | Visual Analog Pain Scale |
| WOMAC: | Western Ontario and McMaster Universities Osteoarthritis Score |

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THESIS LAYOUT

- Chapter 1 Introductory chapter which discusses the rationale and justification for the pursuit of the subject matter.
- Chapter 2 Literature review of the current data pertaining to the subject matter. An overview of the burden of OA and detailed review of the evidence relating to the use of orthoses for the management of the disease.
- Chapter 3 The objectives of this work and the hypothesis formulated at its inception.
- Chapter 4 Materials and methods used to collect and process biomechanical and non-biomechanical data.
- Chapter 5 The resultant kinetic and kinematic data with and without the use of the prototype knee brace in both healthy participants and OA case studies.
- Chapter 6 A detailed discussion of the biomechanical and non-biomechanical data results obtained from this study in both tested conditions and groups. A link to prior and future research is made.
- Chapter 7 Conclusions and the closing argument of the study, along with acknowledgement of study limitations and recommendations for future research.
- Chapter 8 References, cross references and footnotes
- Chapter 9 Appendix of supporting documentation

CHAPTER 1: INTRODUCTION

1.1 Background & Rational





1.1.1 The Importance & Clinical Challenges of Osteoarthritis:

Osteoarthritis (OA) is an irreversible breakdown of cartilage and underlying bone and represents the leading cause of musculoskeletal (MSK) disease, affecting 20% of people over the age of 60 (Bennemann et al., 2007). It results in progressive morbidity (Dieppe & Lohmander, 2005; Luyten et al., 2012) and is considered the 11th leading cause of disability globally (Vos et al., 2012). The lower limb is frequently involved, with debilitating disease most commonly involving the knee and hip (Davies-Tuck et al., 2008; Srikanth et al., 2005; Stone, 2008). The knee joint is an articulation formed by the femur, tibia and patella and is divided into three key compartments. The normal mechanics of the lower limb result in a varus or adduction moment throughout stance phase of gait (Pollo et al., 2002; Richards, 2008); meaning most of the joint load travels through the medial compartment (Prodromos, Andriacchi, & Galante, 1985) which is the most commonly affected by OA, followed by the lateral and patellofemoral compartments (Moen, Laskin, & Puri, 2011). Patients with knee OA have a deterioration in spatiotemporal parameters of gait, a reduction in peak range of movement and poor limb control strategies (Al-Zahrani & Bakheit, 2002; Gok, Ergin, & Yavuzer, 2002; Hicks-Little et al., 2011; Kaufman et al., 2001). There is an attempt to reduce force travelling through the afflicted joint space by changing gait characteristics. The limitation of knee flexion during swing (Gyory, Chao, & Stauffer, 1976; Messier et al., 1992) and stance (Hinman et al., 2002b) are examples of this; others include compensatory changes at the hip and ankle, such as increasing toe out gait or foot progression angle (Wang et al.,

1990). Although these adaptive changes can be effective at altering symptomology by offloading the afflicted knee compartment, they may in fact increase the risk of, or accelerate the progression of OA at other ipsilateral or contralateral weight bearing joints (McMahon., Block. et al 2003, Shakoor., Hurwitz. et al, 2003) further complicating disease management.

Current treatment modalities are subject to multiple international guidelines which all focus on managing symptoms conservatively with the aim of delaying surgery. These may include strategies aimed at preventing deterioration in symptoms, for example where the patient is educated on life style and physical activity (Beckwee et al., 2013; Nelson et al., 2014; Wallis & Taylor, 2011) and pharmacological management in the form of anti-inflammatories, enteral and parenteral analgesia as well as joint lubricants (Kon et al., 2012; McAlindon et al., 2014b). Surgery is the final step and ranges from arthroscopy to arthroplasty (Frizziero et al., 2005; Katz, 2006; Ronn et al., 2011). The effectiveness of non-surgical treatments varies between patients but is related to the grade of OA (*table 1, page 10, chapter 1, section 1.1*) which ranges from a low-grade disease (Kellgren Lawrence (KL) grade 1) consisting of only symptomatic change, to moderate grade disease (KL 2-3) where symptoms worsen and are accompanied by radiographic changes, to high grade OA (KL 4) which consists of marked symptomology as well as radiographic and gross anatomical changes (Kellgren & Lawrence.,1957).

Table 1: Kellgren Lawrence Grading for Knee OA

| | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
|--------------|---|---|--|---|
| Radiographic |  |  |  |  |
| Ost | Inconclusive | Minor | Marked | Marked / Large |
| JSN | Not Present | Minor | Moderate | Severe / SCS |
| GA | Intact | Intact | Bony Deformity | Bony / External Deformity |

Note: classic view is an anteroposterior weight bearing radiograph of both knees. Gross anatomy (GA), Joint space narrowing (JSN), osteophytic change (Ost), Subchondral Sclerosis (SCS). Source1.

The disease is progressive in the majority of sufferers, meaning in many patients there is a “point of no return” where non-surgical management fails and definitive operative correction is required. In the knee, this is usually in the form of arthroplasty which may be a partial joint replacement where the compartment afflicted by OA is replaced leaving the remaining native joint in situ. More commonly however, a total joint replacement is performed for pan articular involvement. The effects of arthroplasty surgery on local anatomy are permanent and include tissue loss and destruction, altered function of local tissues through metallosis (build-up of metal debris) and altered mechanical function; however, the longevity of a prosthesis is finite (Gioe et al., 2007; Keeney et al., 2011; Pakos, Paschos, & Xenakis, 2014). The aim is therefore to delay the need for such an intervention through conservative management options and avoid arthroplasty in younger patients. The dilemma is that current surgical options are not coupled to the changing demographics of an ageing population, meaning many patients exhaust all non-surgical options rapidly but remain at the lower limits

¹ Images courtesy of Radiopaedia.org, ID: 27042 / 29722.

of age for definitive surgical management. London et al (2013) termed this the OA treatment gap which consist of patients unsuitable for replacement procedures given the low longevity of implants in the young and the likely need for revision procedures once the implant has worn down with time. The longevity, also termed the survivorship of artificial joints is coupled to the mechanical demand of the patient with older, less active individuals having longer survivorships than young physically active patients (Gioe et al., 2007; Keeney et al., 2011; Pakos, Paschos, & Xenakis, 2014). Artificial joints currently have a maximum survivorship of about 30 years (Makela et al., 2014; Siqueira et al., 2015) meaning younger patients will need at least one revision in a lifetime. In addition to the risks of potentially devastating complications, replacement procedures are technically challenging and inevitably result in poor gait characteristics, inferior biomechanics and an increased risk of joint degeneration in both ipsilateral and contralateral weight bearing joints (Alnahdi, Zeni, & Snyder-Mackler, 2011). Revision replacements have the same disadvantages in addition to a technically challenging and less favourable anatomical environment.

1.1.2 Mechanical & Non-mechanical (Proprioceptive) Bracing:

Given the above difficulties, there is a need for non-surgical bridging treatments that aim to delay surgery for as long as possible to reduce the risk of revisions. These may take the form of innovations in recognised or existing management options such as targeted drug delivery with nanotechnology (Hamidi et al., 2013), or could be in the form of newer approaches to the disease such as acupuncture (Leopold et al., 2003; Manyanga et al., 2014). Orthoses are one form of non-surgical treatment which could offer a means of bridging this gap. The most common orthoses used for knee OA are braces but these are varied in their design and

reported outcomes (Beaudreuil et al., 2009; Dessery et al., 2014; Moyer et al., 2015; Ramsey & Russell, 2009; Richards et al., 2005).

Recently knee braces have been broadly classified as either mechanical, which alter movement through a three point rigid fixation, or non-mechanical, otherwise known as proprioceptive (Moyer et al., 2015; Richards et al., 2005; Selfe et al., 2011). The mechanical form of bracing is the historical approach of using a brace to counteract deleterious mechanics about the knee by applying an external mechanical force. The most common example of this is the valgising knee brace which counteracts the knee adduction moment that strongly correlates with the development of medial compartment OA (Moyer et al., 2014b). These braces have been extensively researched with strong evidence backing their mechanical effect; however, this data is highly heterogeneous meaning these braces do not always feature in current management guidelines (Bruyere et al., 2014; Chinese Orthopaedic Association, 2010; Fernandes et al., 2013; Hochberg et al., 2012; NICE, 2014; RACGP, 2009; Yates et al., 2014). In addition, such braces can be custom manufactured (Dessery et al., 2014; Laroche et al., 2014; Ramsey, Briem et al., 2007) adding to the overall lack of consensus on their use in patient care. Mechanical braces have also been less favoured by patients given their association with discomfort from the pressure applied to achieve a three-point fixation and cutaneous changes such as skin irritation (Squyer et al., 2013).

The newer concept of proprioceptive bracing is now under investigation and if proven effective may avoid excessive costs and may improve patient adherence. Proprioception is the awareness of position and movement and is crucial for limb control and injury prevention (Proske & Gandevia, 2012). OA is related to altered proprioception which may develop because of the disease (Lund, Juul-Kristensen et al., 2008; Shanahan, Wrigley et al., 2014) or

may be involved in its pathogenesis (Tsauo, Cheng et al., 2008). A proprioceptive brace abandons the three-point fixation mechanism and focuses on heightening sensory feedback from around the joint and therefore altering neuromuscular control. Provisional data on externally applied devices such as tape, sleeves and braces has shown evidence of improved symptomology with their use (Duman et al., 2012; Ju, Park, & Kim, 2015; Tunay, Baltaci, & Atay, 2010). There is some debate in the current literature as to what constitutes a brace and what is in fact a sleeve, but some of these devices have been shown to alter biomechanics (Doslikova, 2015; Hanzlikova et al., 2016).

1.1.3 Rationale:

Although research into proprioceptive braces is in its early stages, there are several key areas missing from the current literature. Firstly, previous studies have focused on biomechanical analysis of the knee joint and have not examined secondary effects of a proprioceptive knee brace at other lower limb joints. This is important to investigate given that knee OA results in adaptive changes at the hip and ankle in an attempt to counteract deleterious mechanics such as an increasing medial joint load, which may in turn pose an increased risk of degenerative change in these joints. (Asay, Mundermann, & Andriacchi, 2009; Kaufman et al., 2001; Tanaka et al., 2008). Secondly, the majority of the published literature on knee bracing focuses on sagittal and coronal plane biomechanical parameters and very few have examined changes in the transverse plane (Dessery et al., 2014; Gaasbeek et al., 2007; Laroche et al., 2014). Of the studies that have examined changes in the transverse plane, most have examined healthy participants and have found conflicting results (Selfe et al., 2008; Selfe et al., 2011; Hanzlikova et al., 2016). To the authors knowledge no other studies

have examined these effects during activities of daily living in individuals with medial compartment OA. Subjective information on patient opinion regarding the wearability or aesthetics of braces is also lacking in current data but could be of great importance in increasing patient adherence. This study examines the effects of a non-mechanical or proprioceptive knee brace; namely the OA Reaction Web knee brace (DJO Global, USA, 2015), on lower limb biomechanics in healthy participants and participants with moderate grade osteoarthritis (OA) of the knee.

CHAPTER 2: LITERATURE REVIEW

2.1 Understanding Osteoarthritis & its Significance

Frequently in medicine the clinician is forced to manage diseases which are of an elusive pathogenesis. Such diseases have prolonged periods of treatment which do not always culminate in cure and thus the aim of the clinician is to improve or maintain function and quality of life. OA is one such disease which is progressive and incurable, often requiring surgery to achieve these goals.

2.1.1 Epidemiology:

OA is age related, affecting 20% of people over the age of 60 (Bennemann et al., 2007) versus only 3% of under 25's (Lawrence et al., 1998). It is estimated that world population will increase by 2.7 billion within 35 years; with average life expectancy rising to 64 (Bongaarts, 2009). Most of this growth will occur in less developed nations (Bongaarts, 2009) with Asia experiencing a possible three-fold rise in over 65's (Kinsella & He, 2009). Rates of radiologically confirmed OA range from 5% in those under 34 to 52% in those aged over 75 (March & Bagga, 2004). Clinically evident OA in the form of arthralgia is more common, occurring in 5% of people 26 years of age and 17% of those 45 and over (Felson et al., 1988). In the young, repetitive use trauma and obesity are common etiological factors which are projected to rise (Felson, 2004; Goulston et al., 2011). All this indicates a 40% increase in rates of OA by as early as 2025 (Fransen et al., 2011; London, Miller, & Block, 2011).

2.1.2 Costs:

OA is the fourth and eighth most common cause of disability in women and men respectively (Vad et al., 2002). Its related disability rates have increased by over 60% in the two decades from 1990 and current trends indicate it will be the 4th leading cause of disability globally by 2020 (Vos et al., 2012). Most primary care patients presenting with MSK pathology have OA (London et al., 2013; Margham, 2011) and the disease is allocated the majority of MSK funds (Yates et al., 2014). Despite the ongoing debate as to the efficacy of various treatment modalities, MSK associated health care costs range from approximately 10 to 21% of gross domestic product in industrialised nations and include indirect (work disability, domestic and transportation) and direct (drug treatments, minor and major surgery, rehabilitation and physiotherapy) financial costs (Bruyere et al., 2014; Hiligsmann et al., 2014; London et al., 2011; Puig-Junoy & Ruiz Zamora, 2015; Ruchlin, Elkin, & Paget, 1997). OA is incurable therefore costs represent losses to both the individual and to the wider health sector. Knee OA is the most common form (March & Bagga, 2004; Nunez et al., 2008; Racine & Aaron, 2013), however the data is unclear on costs for specific joints and absolute figures are reported differently; ranging from \$19.3 billion per annum in 11 industrialised nations (Bitton, 2009; Chen et al., 2012) to \$128 billion per annum globally (London et al., 2013). Although the cost effectiveness ratio of current conservative treatment is poor (Pinto et al., 2012), evidence indicates OA patients spend >\$4000 per year on such treatments equating to over \$14 billion per annum in the USA (Badley, 1995; Bitton, 2009; Boyers et al., 2013; Chen et al., 2012; Crawford, Miller, & Block, 2013; Gillette & Tarricone, 2003; Hiligsmann et al., 2014; Losina et al., 2009; Murphy & Helmick, 2012; Pinto et al., 2012; Ruchlin et al., 1997; Segal et al., 2004; Stan, Orban, & Orban, 2015; Woolf & Pfleger, 2003). The end stage treatment for OA is replacement arthroplasty (Murphy & Helmick, 2012), which has

limitations in that it is expensive and sub-optimal for the young, physically active patient (Badley, 1995; Bitton, 2009; Boyers et al., 2013; Chen et al., 2012; Crawford et al., 2013; Gillette & Tarricone, 2003; Hiligsmann et al., 2014; Losina et al., 2009; Murphy & Helmick, 2012; Pinto et al., 2012; Ruchlin et al., 1997; Segal et al., 2004; Stan et al., 2015; Woolf & Pfleger, 2003).

Not all cost is in capital however; Busija et al (2013) classified the personal cost of OA on patients into physical and psychosocial distress, deconditioning and inactivity, loss of productivity and financial hardship. The functional capacity, social activity, socioeconomic and relationship status as well as perceived body image and emotional state are all worse in OA than in other arthropathies (Carr, 1999; Wilkie & Pransky, 2012). A survey of 197 patients conducted by Neville et al (1999), found that the leading concerns of patients were disease chronicity and progression (80%), future disability (70-80%), loss of independence, burdening family and financial concerns. Movement limitation are present in 80% of OA patients (Ma, Chan, & Carruthers, 2014), 25-69% struggle with activities of daily living (ADL) and 14-73% of these require assistance performing such tasks (Ma et al., 2014; Neville et al., 1999).

2.1.3 Pathogenesis:

OA has a pan-articular pathogenesis; involving bone, cartilage, the surrounding synovium (Dieppe & Lohmander, 2005; Krasnokutsky et al., 2008; Racine & Aaron, 2013) and an interplay of metabolic and catabolic pathways (Heijink et al., 2012; Sharma et al., 2013; Teichtahl, Wluka, & Cicuttini, 2003). Whether these pathways result from, or cause OA is debated (Knoop et al., 2011; Rice, McNair, & Lewis, 2011); however a resultant cyclical degenerative process ensues, culminating in connective tissue destruction and aberrant muscle, neuronal and proprioceptive tissue function (Cucchiari, Madry, & Terwilliger, 2014; Racine & Aaron, 2013; Teichtahl et al., 2003), all of which are intimately involved in the behaviour of the joint. Various etiological factors ranging from genetic predisposition to lifestyle and trauma classify OA as a complex multi-factorial disease (Felson, 2004; Loughlin, 2005). Primary OA is idiopathic, likely due to the natural senescence of the cartilage; while secondary OA develops as a result of an initiating factor such as septic arthritis or trauma (Aigner et al., 2004; Bennemann et al., 2007; Felson et al., 2000; Felson, 2004).

2.2 Proprioception & Neuromuscular Control

2.2.1 OA & Proprioception:

Proprioception is an awareness of movement and position; consisting of two entities; static joint position sense and dynamic awareness of joint movement (kinaesthesia) (Proske & Gandevia, 2012). Proprioceptive ability results from intra (nerve endings, Golgi receptors, articular mechanoreceptors), inter (Pacinian corpuscles, Ruffini endings) and extra-articular (equilibrioception, muscle spindles, Golgi tendon organs) structures generating feedback on load, angular velocity and direction of movement (Bottoni et al., 2013; Riemann & Lephart, 2002). This afferent information is transferred consciously (posterior column-medial lemniscus pathway) and subconsciously (dorsal and ventral spinocerebellar tracts) to the central nervous system and regionally via somatic reflexes (Brandt, 2004; Sanchez-Ramirez et al., 2013; Wolf, Cameron, & Owens, 2011; Zazulak et al., 2007). By restricting excessive or deleterious movement and providing stabilisation, proprioception is vital for coordination of joint function and injury prevention (Knoop et al., 2011).

Age, trauma, gender and localised or diffuse pathology may alter proprioception (Knoop et al., 2011; Lephart, Pincivero, & Rozzi, 1998; Pai et al., 1997; Petrella, Lattanzio, & Nelson, 1997; Sharma & Pai, 1997; Zazulak et al., 2007). Abnormal proprioception is related to diffuse (Lund et al., 2008) or focal (Shanahan et al., 2014) joint failure including damage to, or loss of intra and periarticular tissue. These include neuromuscular coordination, capsular and or ligamentous damage, thickening and laxity, as well as chondral and osseous dysfunction (Brandt, 2004; Laskowski, Newcomer-Aney, & Smith, 2000; Ozer Kaya, Duzgun, & Baltaci, 2014; Wolf et al., 2011), however, how these factors relate to OA has not

been fully investigated (Bayramoglu, Toprak, & Sozay, 2007). A generalised deficiency in proprioception, would implicate it in the initial development and ultimate progression of OA, as evidenced by some OA patients having proprioceptive deficiency in unrelated joints (Tsauo, Cheng, & Yang, 2008). Additional evidence also links the severity of proprioceptive deficits to disease grade (Knoop et al., 2011). Other studies have found that alterations in proprioceptive feedback may not be connected to pain severity or the extent of disability but may in fact be independent (Bennell et al., 2003; de Oliveira et al., 2014).

Newer OA management strategies with a possible proprioceptive role have been shown to significantly improve OA symptomology and function regardless of disease severity (Duman et al., 2012; Ju et al., 2015; Tunay et al., 2010). A study by Lin et al (2009) compared proprioceptive training, strength training and no training in patients with OA and found pain, function and proprioceptive ability significantly improved with intervention. A large scale meta-analysis by Smith et al (2012) confirmed this and noted that proprioceptive exercise could be used in the management of OA and was significantly efficacious ($p < 0.02$) especially in the first 8 weeks of use. Overall evidence appears to favour muscle strengthening including weight and resistance training especially of the quadriceps, which may retrain or regain neuromuscular control, as a management strategy across all grades of OA (Farrokhi et al., 2013; McQuade & de Oliveira, 2011; Reeves & Bowling, 2011; Wu & Tuan, 2005). McQuade et al (2011) examined the effects of a 3 day, 8 week programme on OA patients and found no change in co-contraction and selected kinematic/kinetic parameters, but did note significant improvements in symptomology. Ferreira et al (2015) confirmed this in their review which found limited biomechanical change from exercise programmes despite improvements in symptoms.

2.2.2 Orthoses & Proprioception:

The application of non-mechanical supportive devices around osteoarthritic knees has been shown to improve functionality (Birmingham et al., 1998; Brouwer et al., 2005; Bryk et al., 2011; Chuang et al., 2007; Collins et al., 2014; Pajareya, Chadchavalpanichaya, & Timdang, 2003; Schween, Gehring, & Gollhofer, 2015). Such changes cannot be attributed to the limited mechanical support provided from taping or a sleeve; which supports the idea that improving proprioception may aid in the conservative management of OA. Some evidence demonstrates improvements in proprioception with the use orthoses in diseased joint and in healthy subjects (Birmingham et al., 1998; Kaminski & Perrin, 1996). OA patients have been shown to self-manage with bandages which subjectively reduce pain and may provide a subconscious emotional reassurance from falling (Hassan, Mockett, & Doherty, 2002). Manipulation of proprioception is now another strategy in disease management (Duman et al., 2012; Segal et al., 2010; Smith et al., 2012; Tunay et al., 2010). It has been suggested that enhancing cutaneous stimulation using braces, sleeves and taping techniques may aid in knee control and therefore prevent further injury or alter disease symptomology (Lephart et al., 1998; Selfe et al., 2011). Some studies have shown that the use of knee sleeves and braces improve performance, postural sway and proprioceptive acuity (Birmingham et al., 2001; Collins et al., 2011; Hassan, Mockett, & Doherty, 2001; Hassan et al., 2002). Several methods of improving proprioception in diseased or at risk knees exist and have been investigated with the aim of lowering joint load (Beaudreuil et al., 2009; Collins et al., 2011; Vad et al., 2002) and include exercise/muscle strengthening, somatosensory re-education and sensory support through the use externally applied devices.

No studies were found that examined the effects of a predominantly proprioceptive brace on gait parameters, however some studies have considered the effects of orthotics devices on knee proprioception and indicated that a beneficial relationship exists (Chuang et al., 2007; Collins et al., 2014; Divine & Hewett, 2005; Pajareya et al., 2003). It has been suggested that the mechanism underlying this relationship is an alteration in the cutaneous component of proprioception or a mechanical restriction of the weight applied by the brace (Jones et al., 2013). Richards et al (2005) proposed that the changes in gait seen with the use of a valgising knee brace could be due to either proprioception or a placebo effect experienced by the wearer resulting in a mental or psychological reassurance of stability.

Few studies address the potentially advantageous effects of a predominantly proprioceptive device on knee biomechanics. One such study by Selfe et al (2008) which compared a brace to patellar taping in healthy subjects, found that neutral patellar taping produced torsional or transverse plane changes even though no directing force was applied. They suggested that improvement in knee control came from sensorimotor stimuli which could be proportionately related to the relative area of cutaneous stimulation (McNair, Stanley, & Strauss, 1996; Selfe et al., 2008). However, the relationship of brace design to superficial cutaneous (predominantly via mechanoreceptors) and deeper inter/intraarticular (via muscle spindles, tendon organs and nerve endings etc) proprioception is likely complex. A study by Hassan et al (2002) found that a loosely applied bandage improved proprioception while a tightly applied elastic bandage did not. They postulated that this could be because a looser bandage provided recurrent stimuli to cutaneous receptors thereby avoiding the desensitisation seen when receptors are exposed to a uniform, more constant pressure or stimulation (Hassan et al., 2002). The effects of bracing on proprioception may also be influenced by the stage of gait and the angle or direction of movement. Bottoni et al (2013) examined the effects of

prophylactic knee bracing and sleeves in a group of 20 healthy sports students. They found that changes in proprioception were heavily influenced by the angle and direction at the knee and that no significant difference in proprioception was noted with or without the orthoses (Bottoni et al., 2013). In another study, Marchini et al (2014) elaborated on this by comparing old and new generation knee and ankle orthoses at different knee and ankle positions. They found that there were no detectable differences in joint position sense between new and old generation devices regardless of position but that there was an obvious improvement in kinaesthesia with newer generation devices especially in the flexed knee. On the contrary however, the effects of a prophylactic brace on uninjured rugby players caused a statistically significant improvement in proprioceptive performance; assessed by comparing balance and control with and without a brace (Kruger, Coetsee, & Davies, 2004).

2.3 OA Management Strategies

2.3.1 The Treatment Gap:

The number of patients who fall within the OA treatment gap (defined as those who are unsuitable for replacement surgery given their younger age / quality of life, and therefore face a prolonged period of failing conservative management (London et al., 2013)) is projected to rise in line with forecast demographic changes. Bridging of this gap will therefore be of significant clinical importance.

OA is incurable and results in progressive restriction of daily activity (Dieppe & Lohmander, 2005; Luyten et al., 2012) and current management is aimed at preventing disability.

Treatment options are divided into three overlapping principles and are employed for OA of any joint not only the knee. Secondary or tertiary prevention strategies are attempted first; where the patient is educated in disease management through weight loss, exercise and physical/occupational therapy. Orthotics in the form of braces and insoles belong to this group of interventions (Beckwee et al., 2013; Nelson et al., 2014; Wallis & Taylor, 2011).

The second consists of systemic or intra-articular pharmacological management, including steroids, various analgesics and viscosupplementation (Kon et al., 2012; McAlindon et al., 2014b). The final group consists of surgery, which may include arthroscopic procedures, arthrodesis, osteotomy and arthroplasty (Frizziero et al., 2005; Katz, 2006; Ronn et al., 2011).

These options are tailored to the individual patient and to the stage of disease at presentation.

Their effectiveness has been subject to continuous deliberation within the medical community and many healthcare organisations in various countries have attempted to streamline and simplify the options available for clinical use (*Table 2, page 25, chapter*

2.3.1). The concept of proprioceptive intervention does not currently feature in these guidelines.

Table 2: Current International Guidelines on Orthotic Management of OA

| Guidance | Bracing | Sleeve | Insoles |
|-----------------|-----------------|-----------------|-----------------|
| NICE | Adjunct | NA | Adjunct |
| AAOS | Undecided | Undecided | Undecided |
| ACR | Undecided | Undecided | Recommended |
| EULAR | NA | NA | Not recommended |
| OARSI | Recommended | Recommended | Recommended |
| SMOH | Recommended | Recommended | Recommended |
| RACGP | Not recommended | Not recommended | Not recommended |

National Institute for Health and Clinical Excellence (NICE) (NICE, 2014), American Association of Orthopaedic Surgeons (AAOS, 2013), American College of Rheumatology (ACR) (Hochberg et al., 2012), European League Against Rheumatism (Fernandes et al., 2013), The Royal Australian College of General Practitioners (RACGP) (RACGP, 2009), Singapore Ministry of Health (SMOH) (SMOH 2007), OA Research Society International (OARSI) (McAlindon et al., 2014a).

2.3.2 Surgical Strategies:

Surgery for OA of any joint varies from diagnostic or minor arthroscopic procedures to total destruction of the joint or arthrodesis (Frizziero et al., 2005; Gomoll, Filardo, Almqvist et al., 2012; Gomoll, Filardo, de Girolamo et al., 2012). Minor surgery is a bridging measure to arthroplasty in those patients within the treatment gap. Arthroscopy is used for various procedures such as debridement and micro-fracture (Frizziero et al., 2005). Corrective tibial osteotomies are used in patients with significantly malaligned knees or unicompartmental OA in young patients (Price, Beard, & Thienpont, 2013; Amendola & Bonasia, 2010; Brouwer et al., 2007). Arthroplasty is the last resort in patients with advanced OA and those unresponsive to non-surgical management (Ahmad et al., 2015). Total joint replacement has been shown to improve pain, quality of life and functionality (Ahmad et al., 2015; Liddle, Pegg, & Pandit, 2013). In addition to being physiologically challenging, TKR surgery always carries risks and major complications can be life, limb or prosthesis threatening with

devastating results. Even with success, up to 12% of patients will need to have a revision procedure within 10 years due to loosening or eventual failure of the prosthesis (Siqueira et al., 2015). Other novel or occasionally, experimental surgical options have been discussed but not researched (Amanatullah et al., 2012; Segal, Buckwalter, & Amendola, 2006). Given the risks associated to surgical management, there is a current focus on prolonging the use of conservative management prior to attempts at surgery.

2.3.3 Non-surgical Strategies:

Some non-surgical treatment methods for OA are new and under investigated, including intra-articular injections of platelet rich plasma and growth factors (Khoshbin et al., 2013; Laudy et al., 2015), thermotherapy (Brosseau et al., 2003), acupuncture (Manyanga et al., 2014), electrotherapy (Zeng et al., 2015) and ultrasound therapy (Nieminen et al., 2014); and as such do not currently feature in any credible medical guidance. Other conservative methods are well researched and include the following:

Weight Loss & Physical Activity:

Weight loss, physiotherapy and exercise are the main preventative strategies for knee OA and are recommended in global guidelines (AAOS, 2013; Hochberg et al., 2012; NICE, 2014; RACGP, 2009). Weight loss reduces the load traveling through the joint, improving functionality, quality of life and emotional wellbeing (Farrokhi et al., 2013; Nelson et al., 2014; Reeves & Bowling, 2011; Segal et al., 2004; Wu & Tuan, 2005). Self-management via tailored activity programmes also feature in current guidance (Farrokhi et al., 2013; Nelson et al., 2014; Reeves & Bowling, 2011; Yates et al., 2014). Low impact aerobic exercises,

aquatic and resistance training have been recommended and found to improve both pain and disability (AAOS, 2013; Fernandes et al., 2013; NICE, 2014). Muscle strengthening exercises, especially closed chain exercises are the only intervention in this group that have been proven beneficial in improving proprioception (Beard et al., 1994; Fitzgerald, 1997; Lin et al., 2007).

Pharmacological Treatment:

Paracetamol (acetaminophen), Non-steroidal Anti-inflammatory Drugs (NSAID), steroids and variable strength opioids are used for analgesia in OA (AAOS, 2013; Fernandes et al., 2013; NICE, 2014). The intra-articular steroid injection is common practice but exact indications are debated and differ internationally. NICE in the United Kingdom (UK) and the ACR in the USA suggest the use of such injections as a final bridging measure in patients unresponsive to conservative options (AAOS, 2013; Hochberg et al., 2012). Although effective in alleviating pain with few side effects, the effects of such injections rarely last more than 3 months and the number of injections is finite (Bannuru et al., 2009; Chao et al., 2010; Rodriguez-Merchan, 2013). Hyaluronic acid (HA) is another injectable used and is a naturally occurring substance of connective tissue, especially abundant in synovial fluid which is involved in joint homeostasis, lubrication and shock absorption (Namiki, Toyoshima, & Morisaki, 1982; Reid, 2013; Wen, 2000). The efficacy of HA is debated and the evidence available is inconsistent (Aggarwal & Sempowski, 2004; Arrich et al., 2005; Fernandez Lopez & Ruano-Ravina, 2006; Wen, 2000).

2.4 Externally Applied Devices

2.4.1 Taping:

The application of adhesive tape (elastic cotton strip with an acrylic) around the knee has varied indications, ranging from “knee support” to patella traction taping and rarely OA. The data here is also heterogenous but taping can be neutral (applied to the skin without the aim of exerting a force on the joint) or mechanical (applied with the aim of altering soft tissue movement over the joint). In a study of medial patella taping in 87 patients with knee OA who were followed up at three and six weeks; it was found that pain with and without movement was significantly reduced in the treated group (Hinman et al., 2003). A systematic review by Warden et al (2008) looked at the role of patella orthoses including taping in the management of chronic knee pain. Six of the ten studies investigated immediate effects while the rest looked at short term benefits, defined as 3 to 12 weeks (Warden et al., 2008). They found significant reductions in pain with taping versus no tape and placebo. Medially directed tape also improved pain in OA patients, but crucially the authors found that placebo taping (taping without a mechanical objective) also significantly improved pain scores based on 6 studies with over 190 participants (Warden et al., 2008). Another review by Richette et al (2008) looked at five studies examining the effects of therapeutic patella taping on knee OA and found that therapeutic taping reduced pain during normal gait and aggravating activities, with the effects lasting up to 3 weeks after tape removal, which indicates some degree of proprioceptive retraining. These effects were better than non-mechanical active taping and no taping which could indicate a combined proprioceptive and mechanical effect (Richette et al., 2008). A recent randomised double blinded study of medially directed versus neutral taping also confirmed the improvements in symptomology with neural taping (Kocyigit et al., 2015).

They looked at 41 patients with OA who were allocated equally into treatment versus non-treatment groups and assessed at baseline and 12 days. The researchers found that the Lequesne index score of functional assessment was significantly improved for both groups. They also noted significant improvements in nocturnal and functional pain but this was greater for sham taping. The Nottingham Health Profile Score which measures quality of life demonstrated a noteworthy improvement in pain for both conditions; however, although sham taping had more significant improvements overall, physical activity scores were poor. Another randomised control trial by Cho et al (2015), contradicted these results. They found that taping had a significant effect on improving pain, range of movement (ROM) and proprioception while placebo taping did not. Likewise, in a randomised study, Anandkumar et al (2014) looked at the effects of kinesio taping on muscle torque in grade ≤ 2 OA patients both with and without applied tension. Here 40 patients were divided into tension and non-tension taping groups. Patients treated with tensioned tape had improvements in peak quadriceps muscle torque, stair climbing ability and pain scores while those treated with placebo taping did not. The effects of taping on neuromuscular control and improvements in symptomology are also unclear. In their review of eight studies involving electromyographic testing, Leibbrandt et al (2015) concluded that the original form of taping (termed McConnell taping after the original author), exhibited little supporting evidence for its use. Similarly, in their assessment of 12 randomised control trials, Parreira Pdo et al (2014) concluded that kinesio taping was no more beneficial than placebo tape. A coincidental review published by Barton et al (2014) looked specifically at biomechanical, symptomatic and electromyographic effects of patella taping on patellofemoral pain and found that “individualised” taping methods were the best for producing significant clinical results. In practical terms due to the heterogeneity of evidence, conclusions as to the efficacy of such taping either alone or in combination with other treatments, how long their effects last and what the optimal duration

of treatment may be, cannot currently be made (Callaghan et al., 2015; Rixe et al., 2013; Warden et al., 2008).

2.4.2 Knee Sleeves:

Knee sleeves are compression bandages without a rigid support structure such as a metallic or plastic frame. Such sleeves have been shown to reduce pain and improve activities of daily living (Bryk et al., 2011; Mazzuca et al., 2004; Pajareya et al., 2003). Schween et al (2015) studied the effects of a knee sleeve on 18 patients with medial joint knee OA (KL grade 1-4) and found that knee adduction angle (KAA) at heel strike, peak KAA, first peak knee adduction moment (KAM) were all significantly reduced. However, these findings did not correlate with changes in pain and crucially, stability (Schween et al., 2015). A biomechanical and muscle co-contraction study compared various combinations of a sleeve, stochastic electrical resonance and non-intervention in 52 patients with grade 1-3 knee OA (Collins et al., 2011). They found that the heel strike transient peak and knee flexion were both significantly reduced with the sleeve in isolation and with the sleeve in conjugation with electrical stimulation when compared to un-sleeved conditions. The authors concluded that this effect could be attributed to proprioceptive feedback. Three further follow on studies by the same authors explored the effects of neoprene sleeves on proprioception and postural control. The first found that joint position sense was greatly improved with the use of a sleeve with or without electrical stimulation (Collins et al., 2011b). The second study, assessed the effects of a neoprene sleeve on postural control using similar methods (Collins et al., 2012), however no differences were found between the three conditions tested. This contrasts with other studies that have found statistically significant improvements in control during both static and dynamic tests in OA patients when wearing neoprene knee sleeves.

Chuang et al (2007) examined the effects of an elastic knee sleeve on 50 patients with knee OA and found that balance scores greatly improved when wearing the device. The study by Collins et al (2014) assessed kinematics and kinetics of knee movement when wearing a neoprene sleeve. Although no change was noted in the KAM they found an increased knee flexion angle and decreased flexion moment immediately post heel strike when using a neoprene sleeve with or without stimulation (Collins et al., 2014). A recent study by Sinclair et al (2016) examined the effects of a knee sleeve in 20 patients with patellofemoral pain (PFP) syndrome while they performed athletic movement tasks. This study noted significant improvement in KOOS at 2 weeks of wear and marked reduction in the KAM and biomechanical parameters (Sinclair et al., 2016).

2.5 Bracing

Knee braces, typically a combination of metallic, foam, elastic and non-elastic material are amongst the most common MSK medical devices and are varied in their design, function, intended use and clinical outcomes (Beaudreuil et al., 2009; Dessery et al., 2014; Moyer et al., 2015; Ramsey & Russell, 2009; Richards et al., 2005). Knee braces have recently been classified into two broad groups (Moyer et al., 2015; Richards et al., 2005; Selfe et al., 2011). Mechanical braces, which provide support or control in one or more planes of movement through rigid fixation, the most common of which is the valgus unloading (valgising) brace. These braces forcibly correct altered anatomy and restore aberrant movement (Gaasbeek et al., 2007; Komistek et al., 1999; Pollo et al., 2002; Toriyama et al., 2011). This is achieved by means of a three point fixation system, which increases the compartmental intercondylar distance, reducing the moment arm and subsequent ground reaction force traveling through the medial knee joint (Pollo et al., 2002; Richards et al., 2005) thereby reducing the KAM during gait and the overall compartmental load (Gaasbeek et al., 2007; Komistek et al., 1999; Pollo et al., 2002; Toriyama et al., 2011). These braces attempt to restore “physiological” knee alignment, redistribute load and counteract KAM, as well as stabilise the joint via direct mechanical support and improve neuromuscular control (Briem & Ramsey, 2013; Pollo & Jackson, 2006; Ramsey & Russell, 2009). The other group are the non-mechanical braces which reinforce proprioceptive feedback resulting in better control.

OA is panarticular and therefore adversely affects proprioception and neuromuscular control (Knoop et al., 2011; Lephart et al., 1998; Lund et al., 2008; Zazulak et al., 2007). Studies have found that proprioceptive reinforcement can improve symptomology and abnormalities in knee function (Bennell, Hinman, & Metcalf, 2004; Collins et al., 2014; Duman et al., 2012; Ju et al., 2015; Kaminski & Perrin, 1996; Knoop et al., 2012; Sanchez-Ramirez et al., 2013).

Proprioceptive knee braces are those which lack the classic three-point fixation system but retain a rigid or realigning unit, an example of which is the OA Reaction Web Brace used within this study.

2.5.1 Patient Adherence:

Factors likely to influence patient behaviour are the wearability of the brace, its efficacy and cost (Squyer et al., 2013). It is known for example that the mechanical advantage to correct alignment increases with the size of the brace but patient adherence generally diminishes as size increases (Richards, 2008). Despite the documented improvements in PROMS (Patient Reported Outcome Measures, i.e. perceived outcomes following an intervention), there is unwillingness amongst patients to wear knee braces for prolonged periods (Squyer et al., 2013). Only 58 % of patients were found to be wearing a tested brace at 1 year and of those that stop using the brace, 64% did so within the first three months (Brouwer et al., 2006). Key reasons for lack of compliance were skin irritation, bad fit and lack of improvements in symptomology (Squyer et al., 2013). The literature predominantly looks at the immediate and short term effects (weeks) of such braces (Gaasbeek et al., 2007; Pagani et al., 2010; Toriyama et al., 2011) and although some studies have found long term improvements in gait and PROMS at 6 months, the period of time required for brace acclimatization is unknown and it is difficult to gauge the optimum period of wear for changes in gait and neuromuscular adaptation (Ebert et al., 2014; Richards et al., 2005). Discrete orthosis such as wedged insoles are a more attractive option to patients (Jones et al., 2013), however factors playing a key role in the wearability of a brace are not fully understood. They may include perceived social stigma of the brace, bulkiness resulting in restricted movement, practicality and or discomfort, especially with larger braces (Dessery et

al., 2014; Jones et al., 2013; Moyer et al., 2015). This could be particularly pertinent for valgising knee braces where employing a three-point fixation system invariably leads to increase pressure on anatomical structures to achieve proper fixation and distraction (Kutzner et al., 2011). Studies have found that eight degrees of correction may be the upper limit of tolerability for comfort (Kutzner et al., 2011) but this is far from conclusive and more research is needed to identify optimum angle to load ratio (Brouwer et al., 2006; Kutzner et al., 2011; Pollo et al., 2002). The OA Reaction Web brace is a new generation of brace which tries to counteract these issues. With its amalgamation of elastic, fabric, rubber and minimal metallic components, it may have the potential to significantly improve usability and quality of life and making it better suited to bridging young, active patients within the treatment gap.

2.5.2 Patient Reported Outcomes Measures:

Improvements in PROMs are demonstrated across a wide variety of ranking and scoring systems including the Japanese Orthopaedic Association Score (JOA), Hospital for specialist surgery score (HSS), Visual Analogue Score (VAS), Lower-Extremity Activity Scale (LEAS), Knee Society Score (KSS), The Western Ontario and McMaster Universities Arthritis Index (WOMAC) and the Knee injury and Osteoarthritis Outcome Score (KOOS) (Divine & Hewett, 2005; Gaasbeek et al., 2007; Hewett et al., 1998; Lindenfeld, Hewett, & Andriacchi, 1997; Moyer et al., 2014a; Pollo, 1998; Richards et al., 2005). Pain has been shown to improve in the majority of cases with anywhere from 80 to 95% of participants reporting such results (Brouwer et al., 2006; Dennis et al., 2006; Katsuragawa, Fukui, & Nakamura, 1999; Komistek et al., 1999; Matsuno, Kadowaki, & Tsuji, 1997) and analgesic use has been shown to decrease (Arazpour et al., 2013; Brouwer et al., 2006; Fu et al., 2015). Improvements in pain occur even when mechanical realignment has not taken place, again

indicating a role for proprioception (Brouwer et al., 2006). Patients who are 20% over their ideal body weight are less likely to achieve pain relief (Dennis et al., 2006) possibly due to a mechanical overload of the brace. The VAS is the most frequently reported scoring system and has been shown to improve in multiple brace conditions and study protocols (Arazpour et al., 2013; Della Croce et al., 2013; Dessery et al., 2014; Gaasbeek et al., 2007; Johnson et al., 2013; Ornetti et al., 2015; Pollo et al., 2002; Richards et al., 2005; Schmalz et al., 2010; van Raaij et al., 2010). VAS scores appear to show better improvements with bracing when compared to insoles (Arazpour et al., 2013; Schmalz et al., 2010) despite worsening biomechanics (Fu et al., 2015) and testing periods of 6 weeks to 1 year (Fu et al., 2015; Ornetti et al., 2015). The JOA and HSS scores have demonstrated significant improvements with the use of bracing, especially at long term follow up of 12 months (Brouwer et al., 2006; Katsuragawa et al., 1999; Matsuno et al., 1997; Richards et al., 2005). WOMAC and KOOS have been used for scoring in recent publications. WOMAC scores have shown better results with insoles when compared to bracing, however this could be due to factors related to adherence (Lamberg et al., 2015). Of the two studies that used KOOS both showed improvements in both the short and long term (Ornetti et al., 2015; Ramsey et al., 2007).

Not all the literature is conclusive however. Some have found improvements in VAS scoring but no improvement in HSS (Richards et al., 2005). Crucially other studies have found that neutral bracing led to significant improvements in KOOS while only 4 degrees of valgus bracing produced KOOS scores worse than no intervention at all (Ramsey et al., 2007) indicating that non-mechanical factors may be responsible for the improved symptomology. The mechanisms by which bracing improves PROMs is the subject of multiple theories, ranging from a direct alteration of biomechanics resulting in decreased load in the afflicted compartment (Dessery et al., 2014; Jones et al., 2013), mechanical stability and

psychosomatic reassurance (Richards et al., 2005) or possibly a placebo type effect (Wu, Ng, & Mak, 2001). However, these theories individually do not explain why similar beneficial results are seen independent of brace design or intended use (Dessery et al., 2014; Gaasbeek et al., 2007). Valgising knee braces may be slightly more efficacious at producing such results, their analgesic effects may stem from their ability to reduce the KAM by up to 8% (Fantini Pagani, Hinrichs, & Brüggemann, 2012; Jones et al., 2013), thus shifting the centre of maximum load away from areas of heightened nociception (Pollo et al., 2002). Proprioception may heighten sensory cutaneous and subcutaneous input which aids motor control and may create a sense of stability and reassurance which counteract the natural tendency to protect or off load the joint (Brouwer et al., 2006).

2.5.3 Gait Parameters:

Spatiotemporal & Clinical Changes Seen in OA:

OA causes an age proportional slowing of gait secondary to a reduction in walking velocity, widening of steps, diminished joint range of movement, shortening of stride length and reduction in cadence (Al-Zahrani & Bakheit, 2002; Gok et al., 2002; Hicks-Little et al., 2011; Kaufman et al., 2001; Andriacchi et al., 1977; Baliunas et al., 2002; Brinkmann & Perry, 1985; Messier et al., 2005). Secondary gait changes, such as exaggerated trunk movement and shifting of weight to the uninvolved limb, occur in an attempt to alleviate pain. Anatomical changes (malalignment of and incongruity of the joint, capsular changes), stiffness associated with the disease (Henriksen et al., 2006; Kiss, 2011; Steultjens, Dekker, & Bijlsma, 2001), changes in muscle function and disuse sarcopenia as well as diminished proprioceptive feedback (Marks, Quinney, & Wessel, 1993; Reid et al., 2015; Sharma & Pai, 1997) contribute to these changes. Gait abnormalities are noticeable even in moderate OA with

milder symptomology and without notable changes on radiography (Heiden, Lloyd, & Ackland, 2009; Hubley-Kozey et al., 2006). A study by Tas et al (2014) looked at spatiotemporal changes in 80 patients with varying degrees of knee OA. No differences were found when comparing controls to patients with grade 1 and 2 OA, however patients with grade 3 OA demonstrated a reduction in cadence, gait velocity, stride and step length. These patients also had an increase in both single and double support time as well as an increase in stride time (Tas et al., 2014).

Effects of Orthoses on Spatiotemporal Parameters:

Data on spatiotemporal changes with bracing is inconclusive. Some reports have shown that bracing leads to a more symmetrical gait in both stance and swing (Draper et al., 2000), less antalgia and increased velocity (Draper et al., 2000; Fantini Pagani, Potthast, & Brüggemann, 2010; Laroche et al., 2014). These changes are seen even with neutral bracing (Draper et al., 2000; Fantini Pagani et al., 2010; Laroche et al., 2014) which implies a possible proprioceptive mechanism for these changes. Improvements in cadence, step length and walking speed have been observed both immediately following application and with prolonged knee brace use at 5 to 6 weeks (Arazpour et al., 2013; Johnson et al., 2013; Jones et al., 2013; Laroche et al., 2014; Schmalz et al., 2010; Toriyama et al., 2011). A reduction in stance and double support time immediately with the brace and without the brace at week 5 has also been observed (Laroche et al., 2014). The step and stride length appear to be shorter with the use of a brace independent of self-selected walking speed (Gaasbeek et al., 2007) and overall alignment of gait (Moyer et al., 2015). Contradictory evidence exists with some findings showing no change in walking speed and other gait parameters (Kutzner et al., 2011; Pollo et al., 2002; Riskowski, 2010). Even fewer have found a worsening of parameters

including shorter step length and reduced gait velocity (Dessery et al., 2014; Gaasbeek et al., 2007).

There is limited evidence to support the role of proprioception in improving spatiotemporal parameters. Previous work which tested 12 patients with medial joint OA in a hinged, non-valgising and later a valgising brace, found patients were more willing to push off with the limb while wearing the valgising brace which translated into an increase in the ground reaction force at take-off and greater propulsion (Richards et al., 2005). The neutral brace did not display these effects.

2.5.4 Bracing & Biomechanics:

Biomechanical Changes in OA:

Compartmentalisation is a classic feature of knee OA (Felson et al., 2000; Hurwitz, Sharma, & Andriacchi, 1999; Sharma et al., 2001). The medial compartment is the most commonly involved, with the lateral and patellofemoral compartments rarely individually affected (Moen et al., 2011). In addition to the varus moment seen at heel impact, there is normally an external varus or adduction moment throughout stance (Pollo et al., 2002; Richards, 2008); this shifts the centre of pressure medially, results in an inherent asymmetric load with approximately 70% traveling through the medial compartment (Prodromos et al., 1985). Biomechanical analysis of individuals with knee OA has shown that the ratio of lateral to medial joint load is approximately 40 to 60 % respectively (Goh, Bose, & Khoo, 1993; Johnson, Leitzl, & Waugh, 1980). This rises to ~100% in favour of the medial space with a varus tibio-femoral mechanical angle (Johnson et al., 1980). The resultant change in knee biomechanics can be global or regional depending on the anatomical plane studied (Teichtahl et al., 2003). There is a reduction in load within the medial compartment, a prolongation of varus during stance and a prolongation of valgus during the swing phase of gait (Gok et al., 2002), but little change is noted on sagittal versus coronal plane analysis when comparing compartmental knee OA (Childs et al., 2004).

Coronal knee angle refers to the mechanical axis of the limb in the frontal plane and is classically described in terms of varus (medial space OA) and valgus (lateral space OA) angulation. The external knee adduction moment (EKAM) is an indirect indicator of medial joint load (Baliunas et al., 2002). While in stance the centre of maximum weight is shifted

medially in the knee and an increase in valgus angulation of only 5% will lead to a 20% increase force traveling through the medial compartment (Sharma et al., 2001). These joint forces are exaggerated depending on the task and are three times higher during walking and up to six times higher when undertaking a step (Al-Zahrani & Bakheit, 2002). The relationship of knee alignment to knee OA is another positive feedback loop in which malalignment leads to increase segmental force traversing the joint; this in turn leads to further breakdown of cartilage & subchondral bone attrition culminating in the further eradication of joint space, worsening malalignment and further shifting of the mechanical axis to the medial or lateral side (depending on the afflicted compartment) (Harrington, 1983; Johnson et al., 1980). Indeed, patients with moderate to high grade OA have been shown to have a 50% increase in their KAM as compared to healthy controls (Kim et al., 2004) and the severity of valgus or varus malalignment may be directly proportional to onset speed and/or progression of OA. A study by Sharma et al (2001) for example found that a varus/valgus malalignment of over 5 degrees lead to marked functional deterioration in only 18 months.

The KAM has a rotatory component in the transverse plane and may therefore be reduced by an external rotation of the limb, i.e. producing a toe out gait (Wang et al., 1990). Increasing the foot progression angle, defined as the angle between the axis of the foot and the axial plane in the direction of gait (Laroche et al., 2014), results in reduction of the KAM by the transfer of load to the medial aspect of the foot (Dessery et al., 2014). Similarly, an increase in external hip rotation is also a compensatory gait mechanisms (Andrews et al., 1996). Through the manipulation of rotation, one may shift the vertical axis of the ground reaction force backwards and medially towards the centre of the knee which counteracts the lock-down mechanism resulting in a reduction in KAM and therefore a reduction in the knee lever

arm (Andrews et al., 1996; Guo, Axe, & Manal, 2007; Jenkyn et al., 2008; Krohn, 2005; Lynn & Costigan, 2008; Simic et al., 2011).

Patients with OA have a reduction in their peak knee motion by as much as 6 degrees with their peak extension moment reduced as compared to healthy individuals (Kaufman et al., 2001). They are known to have greater knee flexion at heel strike and during early stance (Heiden et al., 2009) but reduced flexion during the swing phase (Gyory et al., 1976; Messier et al., 1992). These mechanisms are a strategy to limit the compressive forces acting across the knee. Limitation of knee flexion during mid and late stance is an effort by the sufferer to reduce joint load and therefore pain but it results in failure to cushion the joint on impact and results increased GRF (Hinman et al., 2002b). This increase in vertical ground reaction force indicates a failure of shock absorption and a predisposition to disease progression (Lawrence et al., 1998).

Bracing & Biomechanics:

The following review of biomechanical changes with the use of knee bracing has been divided into several subcategories (coronal kinematics and kinetics, sagittal kinematics and kinetics, transverse kinematics and kinetics, and finally step negotiation) as this is how result data is displayed later in this document.

Coronal Kinematics:

An increase in condylar separation, reduction in varus angle and a reduction in angular impulse are considered beneficial or protective due to their counteraction of the EKAM. Studies that have examined coronal kinematics show improvements in the knee adduction angular impulse and knee adduction angle. Dennis et al (2006) looked at the effects of several off the shelf knee OA braces in patients with advanced medial joint OA, while they walked on a treadmill. They analysed changes in intercondylar (tibio-femoral) separation distance at three key stages of gait (heel strike, mid-stance and toe off) and found that the condylar separation angle was increased mostly at heel strike for most braces. The Bledsoe thruster off-loading (Bledsoe Brace systems, USA) brace was the most effective with a condylar separation angle mean increase of 1.6 – 2 degrees at heel strike and 1.6-1.9 degrees at mid stance ($p = 0.015$) in the majority of test subjects (Dennis et al., 2006). Similarly, the study Komistek et al (1999) noted that 2.2 degrees change in angle in over 2/3 of participants. There was no change with neutral or placebo bracing, which would indicate failure of proprioception in altering biomechanics (Komistek et al., 1999). However, the effects of a brace on 16 healthy participants in neutral, 4 degrees and 8 degrees of valgus present. The external knee adduction angular impulse (KAAI) decreased in all three braced conditions indicating the involvement of non-mechanical strategies including proprioception in achieving such results (Fantini Pagani et al., 2010). Another study by Fantini Pagani and co researchers in 2012 examined the effects of an unloading brace in ten subjects with a mean age of 57.5y, and grade 2-3 OA. Again, patients were tested at neutral, 4 degrees and 8 degrees of applied valgus, resulting in a significant reduction of KAAI with all three testing conditions. This study also examined the effects of a 4-degree lateral wedge insoles which also showed significant changes; however, the effects of the brace were greater which adds

further weight to the concept of proprioceptive input (Fantini Pagani et al., 2012). A further study by Jones et al in 2013 confirmed these results by comparing the effects of the OA Adjuster brace, (DJO, Vista, USA) brace fixed at 6 degrees' valgus to those of an in-shoe wedge (Jones et al., 2013). Participants had grade 2-3 OA and were followed up for several weeks. The researchers found that KAAI was reduced over 16% with insoles but only by 8.6% with brace use. However, they also found that bracing decreased knee varus angle ($p < 0.001$) more so than insoles. A further study found that such reductions in KAAI were present at 2 weeks and with long term follow up at 2 months (Lamberg, Streb et al., 2015).

The association of KAAI to KAA is not clear as not all studies are conclusive. Some research has looked at the effects of a brace over 5 weeks in patients with moderate OA and found that KAA was not significantly reduced (Laroche et al., 2014). Fu et al (2015) found that varus angle significantly reduced at heel strike to mid stance but no such change was noted for the remainder of the cycle. A further study by Duivenvoorden et al (2015) investigated the effects of a valgus knee brace in 38 patients with mild OA and found that KAA improved at 6 weeks with brace use while there was an increase in KAAI and lever arm.

Coronal Kinetics:

Most studies indicate significant improvements in coronal kinetics (Della Croce et al., 2013; Fantini Pagani et al., 2012; Gaasbeek et al., 2007; Laroche et al., 2014; Pagani et al., 2010), while others indicate no change with bracing (Anderson et al., 2003; Ebert et al., 2014) and even fewer demonstrate worsening of the KAM with bracing (Duivenvoorden, Brouwer et al., 2015).

Through bracing the KAM is counteracted with the application of a valgus or external abduction moment that reduces the inclination or lever arm of the ground reaction force resulting in an alteration in the area of maximum compartmental load (Fantini Pagani et al., 2010; Pagani et al., 2010; Reeves & Bowling, 2011). Multiple studies have shown statistically significant reduction in KAM with the use of bracing, with a reported 10 to 22% reduction in KAM (Fantini Pagani et al., 2012; Jones et al., 2013; Kutzner et al., 2011; Laroche et al., 2014). Jones et al (2013) compared lateral wedge insoles and valgus knee braces in 28 patients with medial gonarthrosis (knee OA) for two weeks. They found that both had a statistically significant effect; with bracing reducing early external KAM by 7%. Toriyama et al examined the effects of bracing on 10 patients with medial joint OA and found that bracing reduced early KAM by 11% but no such effect was noted during mid and terminal KAM. These changes can be manipulated or influenced by the very nature of the brace (Toriyama et al., 2011). For example, brace rigidity or fixation has been found to play a significant role; where greater tension applied to the brace results in a greater correction to KAM (Moyer et al., 2015; Pagani et al., 2010; Schmalz et al., 2010; van Raaij et al., 2010).

The studies by Fantini Pagani et al in 2010 and 2012 found that bracing significantly improves knee joint kinetics. They first looked at 11 patients with medial joint OA and found significant reductions in second peak EKAM in both valgus settings and neutral (Fantini Pagani et al., 2010). Their following study looked at 10 patients with medial joint OA and found similar results of decreasing second peak KAM in all three tested conditions. They noted KAM was proportionally reduced for 4 and 8 degrees of valgus (Fantini Pagani et al., 2012). This proportional reduction in KAM was confirmed by Kutzner et al (2011) in their study. They studied two braces and found significant differences in braced and non-braced conditions, the amount of valgus correction and between the two braces. The MOSGenu

brace reduced both peaks of medial force in proportion to the amount of valgus correction; while the results were less pronounced for the GenuOrtho brace. The study by Fu et al (2015) also confirms that mean and peak KAM can be reduced with bracing. It was discovered that bracing reduce the KAM by 14 -19 % with a set valgus angle of 4 to 8 degrees respectively; however, they noted that pain and discomfort significantly increased with an increased set angle which could lead to poor compliance (Kutzner et al., 2011). They confirmed that without the use of an unloading brace over 70% of axial load travelled through the medial compartment during the first peak of KAM and over 60% during the second peak. Overall valgising knee braces appear to be more effective at decreasing the second peak of KAM (Dessery et al., 2014; Kutzner et al., 2011; Toriyama et al., 2011).

The brace design is one of the main factors influencing the level of correction. Some braces are manufactured with a mechanism allowing the user to set the valgus angle; and the degree of correction achieved by any given brace appears to be heavily dependent on this initial set angle rather than of the strap tension or non-metallic materials attaching the brace to the limb (Dessery et al., 2014; Gaasbeek et al., 2007). The optimal “balanced angle”, where the set angle and correction lead to a balance in gait and symptomology without causing adverse events to the patient, remains unclear from the current literature. Finding this ideal set angle is also made difficult by the fact that there appears to also be a relationship with between the initial joint angle and degree of correction achievable via bracing. Gaasbeek et al (2007) studied the effects of an unloading brace over a 6 week period and concluded that changes in varus moment were significant and directly proportional to the degree of initial varus malalignment, indicating that a greater initial joint deformity lead to a greater correction in varus.

Corrections in coronal plane kinematics may not always be the result of mechanical correction. Dessery et al (2014) looked at the effects of 3 braces, one of which was a placebo mechanical brace without valgising properties. Although of the valgising braces did reduced KAM impulse and second peak KAM the placebo brace also had significant effects. It reduced KAM by 8.5% which could be attributed to the proprioceptive properties of the brace rather than mechanical correction (Dessery et al., 2014). Not all studies showed improvements however. Studying patients with medial joint OA, Anderson et al measured knee pressures in vivo and found no improvements with any of the four braces examined (Anderson et al., 2003). Similarly, Ebert et al (2014) found no changes in peak or mean KAM in any of the test conditions. Duivenvoorden et al (2015) found that peak KAM increased with the braced conditions as did the mean KAM at one month follow up.

Sagittal Kinematics:

Biomechanical changes in the sagittal plane with bracing are inconsistently reported with some studies showing a decrease (Matsuno, Kadowaki et al., 1997; Gaasbeek, Groen et al., 2007; Jones, Nester et al., 2013), no change (Arazpour, Bani et al., 2013; Ramsey, Briem et al., 2007; Schmalz, Knopf et al., 2010) or an increase sagittal plane movement (Johnson et al., 2013).

Reduction in stride length is often expressed as a reduction in knee extension at terminal stance and could be due to the mechanical hindrance caused by the brace leading to a greater torsional misalignment (Gaasbeek et al., 2007). Early studies demonstrated that long term use of a knee brace has been shown to reduce the knee angle by 1.5 degrees at 12 months on average ($p < 0.05$) (Matsuno et al., 1997). Such changes have been noted at up to 2 months' post intervention (Lamberg et al., 2015).

In the study by Richards et al (2005) which looked at the effects of 2 braces (one valgising and the other neutral) in 12 patients with medial joint OA over 6 months of wear; knee flexion at heel strike, loading at mid-stance and swing were all decreased. This was statistically significant in the valgising brace however the neutral brace also demonstrated changes indicating a possible role for proprioceptive bracing (Richards et al., 2005). Despite these changes angular knee velocity did not change in the three conditions assessed as compared to the contralateral or unaffected side.

Some studies contradict brace induced sagittal plane alterations. Looking at the effects of a valgus knee brace on grade 1 to 4 OA, a recent study found that vertical loading and braking force were decreased in the non-braced conditions and that sagittal plane range of movement was not altered by bracing (Schmalz et al., 2010). This study confirmed the results of a study by Ramsey et al (2007), who looked at the effects of a custom brace on medial joint OA patients. They found that peak knee flexion was unchanged in both when comparing braced and unbraced conditions. This study also indicated the amount of valgus correction was related to the amount of extrusion at the knee (Ramsey et al., 2007).

Studies which looked at the effects of both bracing and in-shoe orthoses also reported changes in ROM with a reduced knee flexion during swing (Arazpour et al., 2013; Jones et al., 2013). Insoles were found to have greater improvements in ROM possibly because of mechanical hindrance by the brace (Arazpour et al., 2013). A study by examining the effects of a valgising knee brace on medial OA patients with a varus deformity of 5.1 degrees, found that sagittal movements reduced with use of the brace ($p = 0.02$) (Gaasbeek et al., 2007). Similarly, the effects of a mechanical brace in healthy subjects and OA controls, found that

total knee ROM decreased which translated into a beneficial decrease of knee angle at heel strike (Johnson et al., 2013).

Sagittal Kinetics:

It has been shown that posterior vertical load, propulsive force and loading force are significantly better with bracing, however, valgising (or mechanical) bracing have greater effects (Richards et al., 2005). Some studies contradict brace induced sagittal plane alterations. In the study by Schmalz et al (2010) it was found that vertical loading and braking force were decreased in the non-braced conditions and that the maximum flexion moment increased with the brace, however this was not statistically significant. A study of an unnamed brace by Riskowski et al (2010) found that peak extensor and flexor moment were altered by bracing as was the rate of loading and angle before and at initial contact. It was noted that these effects may last beyond brace removal. In a study of patients with moderate to severe medial joint OA, peak extension moment at the knee increased with bracing and changes were noted in the contralateral knee which showed an increased maximum extension moment (Toriyama et al., 2011).

Transverse Kinematics & Kinetics:

Biomechanical changes in the transverse plane at the knee are rarely reported in the current literature and most data focuses on transverse changes at the hip or knee. Dessery et al (2014) looked at the effects of a custom made valgising, external rotation brace in 24 patients with mild to moderate OA of the medial joint space. The study discovered that there was a greater external rotation at the knee and a subsequent reduction in load throughout the stance phase

(Dessery et al., 2014). This occurred without compensatory mechanisms such as a change in foot progression angle. Manipulation of rotation is also believed to play an important role in improving PROMS, especially pain. It is hypothesised that inducing and external rotation to counteract the KAM realigned the patellar-femoral joint thus contributing to a reduction in pain (Dessery et al., 2014). The VER brace (Orthoconcept Inc. Laval, QC, Canada) not only had an intrinsic external rotation mechanism, but was also custom built while the other brace was not. They found that both braces increased ankle external rotation while only the VER brace increased external rotation at the knee and reduced it at the hip. In the study by Laroche et al which also examined a custom brace no such alteration in knee rotation was noted (Laroche et al., 2014), and found that knee bracing significantly reduced the push off foot progression angle at initial and short term follow up. Such results were not found in the study by Gaasbeek and colleagues, who found no significant change in the progression angle of the foot (Gaasbeek et al., 2007).

Step Negotiation in OA & the Effects of Orthosis:

The step-down task is a single limb activity, taking the total weight of the individual it is heavy dependent on intact musculotendinous, osseo-ligamentous, chondral and proprioceptive mechanisms. Most of the published data pertains to stair descent rather than Step down task which looks at the period from fully loading on the ipsilateral limb to contralateral foot strike. Descent from height is more biomechanically demanding than ascent or walking (Liikavainio et al., 2007). In addition to a six-fold increase in joint loads (Kaufman et al., 2001), the knee is pushed to the extremes of ROM and torso muscles are unable to aid quadriceps function as they do in ascent (Hinman et al., 2002b). This is

expressed clinically by the fact that most OA associated falls and their related morbidity and mortality occurs during stair descent (Dore et al., 2015; Svanstrom, 1974).

In his thesis, Al-Zahrani (2014) provided an overview of stair descent gait. Like walking, step descent consists of both a stance and a swing phase (McFadyen & Winter, 1988; Riener, Rabuffetti, & Frigo, 2002; Zachazewski, Riley, & Krebs, 1993). Stance phase consists of a two double support periods and one single limb support period. Stance during stair descent has three phases;

- . *First phase*: there is weight acceptance which encompasses the period of toe down to heel down and allows weight transferred to the ipsilateral side (McFadyen & Winter, 1988; Zachazewski et al., 1993).
- . *Second phase*: is forward continuance' where the torso and leg come forward and the ankle continues its dorsiflexion (McFadyen & Winter, 1988).
- . *Third phase*: is controlled lowering (Riener et al., 2002) where maximum knee flexion and maximum ankle dorsiflexion are reached (Zachazewski et al., 1993) and the contralateral foot strike occurs (Andriacchi et al., 1980).

The swing phase consists of a pull through phase and foot positioning phase. Swing starts with an extended leg with the hip in slight flexion, the knee extended and the ankle plantar flexed, ready for loading. Eccentric muscle contraction is the predominant control mechanism in this phase of descent (Andriacchi et al., 1980; McFadyen & Winter, 1988). While flexed, the knee is unstable and this instability is amplified by the acceleration of forward and downward movement in the centre of mass, which results from the external flexion moment secondary to gravity (Selfe et al., 2008; Tata et al., 1983). These moments are counteracted by autonomic and reflex mechanisms, strongly associated with proprioception and culminate

in an eccentric contraction or an internal extension moment of the quadriceps (Santello, 2005; Selfe et al., 2008).

Patients with knee OA have a decrease in sagittal ROM during all phases of stair gait (Hicks-Little, Whatling 2007). Older adults are at higher risk of OA and people within this demographic exhibit greater movements in the transverse and coronal plane (Buckley, Jones, & Johnson, 2010), they have less knee flexion and produce greater muscle activity than younger adults (Saywell, Taylor, & Boocock, 2012) indicating an age related decay in control strategy. A study by Hicks-Little which compared healthy individuals and OA patients in step down and step up tests found that the OA group had decreased total gait velocity, less single support and stride length and greater step width (Hicks-Little et al., 2011). Patients with OA demonstrate greater KAM, greater adduction angle, greater loading and GRF as well as a smaller peak flexion at touch down as compared to healthy participants (Hicks-Little et al., 2011; Hinman et al., 2005; Liikavainio et al., 2007). There is also evidence to suggest that these findings may worsen as the grade of OA increases (Lessi et al., 2012). There is an attempt to counteract these changes endogenously, through alterations in foot progression angle (Bechard et al., 2012), trunk sway (Hunt et al., 2008; Simic et al., 2011; Simic et al., 2012; Tanaka et al., 2008) and notable changes in hip kinematics (Hicks-Little et al., 2011). In patients with, OA knee flexion, extension moment and power are reduced when compared to health subjects (Igawa & Katsuhira, 2014) and the KAM is much increased during step negotiation in patients with OA, especially during stair descent (Guo et al., 2007). Such gait adaptations occur even in low grade and painless OA where the greatest vertical force and loading rates are significantly higher during descent (Liikavainio et al., 2007). Not all studies have found such results. Lessi et al for example concluded that patients with early stage OA have little biomechanical change plane when compared to health controls (Lessi et al., 2012).

Few studies have investigated the effects of bracing on the biomechanics of step negotiation and data is therefore limited. The study by Kutzner et al (2011) found that when ascending stairs peak force occurred during contralateral toe off and stair contact showing over 63% axial load was transferred in the first peak and > 50% in the second peak of ascent, however there was a significant redistribution of load with bracing. During stair descent, peak forces occurred during contralateral toe off and immediately before contralateral contact. Again, bracing significantly lateralised the axial force traveling through the joint (Kutzner et al., 2011). The effects were largely attributed to mechanical correction and were higher with increasing valgising angle. In her 2010 study Fantini Pagani et al examined the time required for stair negotiation with and without a valgising brace. The researchers found that bracing significantly reduced the time required for such an activity.

Evidence that supports the role of proprioception in altering step mechanics comes from studies done on patellofemoral pain. Selfe et al (2008) considered the effects of patella bracing and taping in healthy Participants during step descent. Maximum knee coronal plane angle and maximum coronal plane moment and rotational moments were all reduced by both modalities; however, the brace resulted in greater reductions. In a similar study carried out by Selfe et al which looked at step down biomechanics with various treatment modalities for patellofemoral pain syndrome (Selfe et al., 2011); neutral patellar taping was found to have significantly reduced maximum coronal knee angle, while bracing significantly reduced the transverse plane ROM. The researchers found that a net improvement in limb control occurred with bracing and postulated this could also be due to proprioceptive input. In a recent study by Doslikova et al the kinematic and kinetic effects of the Bioskin Q knee brace (Össur, Iceland) which lacks the rigid three-point fixation system and could therefore be

considered predominantly proprioceptive (Doslikova, 2015). They examined patients with patellofemoral joint OA and found that such bracing significantly reduced sagittal plane total ROM and maximum flexion angle but no significant changes were noted for other biomechanical measures. They noted that the brace significantly reduced the minimum knee flexion angle and peak extension moment during stance. The study by Al-Zahrani looked at the effects of a valgising knee brace alone and in combination with in shoe orthosis at immediate and prolonged use of 3 months. Reduction in loading was noted with both interventions but was more noticeable during combination treatment (Al-Zahrani, 2014). Hanzlikova et al examined the effects of a proprioceptive knee brace similar in design to the OA reaction web brace in 12 healthy subjects while they performed a slow step descent among other athletic tasks (Hanzlikova et al., 2016). Their results demonstrated significant differences in sagittal, coronal and transverse plane angles and angular velocity. Other than for transverse plane angular velocity most of the results were insignificant during the slow step-down task when comparing braced and non-braced conditions. Notable changes during step descent have also been noted in patients with injuries to key proprioceptive structures within the knee. Roy et al (2016) looked at the effects of medial tension taping, tension free taping in ten patients with isolated meniscal injuries and found significant increases in maximum and minimum sagittal plane angles and a decrease in the transverse plane when taping was applied.

Not all studies indicate improvements in biomechanics or symptomology from the application of such proprioceptive modalities. Mason et al examined the effects of patellar taping and muscle strengthening treatments in patients with PFP syndrome (Mason, Keays, & Newcombe, 2011). They found that pain and quadriceps length both significantly improved with infrapatellar taping, however these improvements were not found during step

negotiation. What relation these such changes have on neuromuscular control is poorly defined. A study of a protonic knee brace in healthy young adults under various degrees of resistance, examined changes in quadriceps EMG behaviour (Earl, Piazza, & Hertel, 2004), finding the quadriceps exhibited less activity during the medium and high setting during descent and postulated this was due to unloading of the muscle.

CHAPTER 3: AIMS & HYPOTHESIS

The current literature pertaining to bracing in OA provides strong evidence for the beneficial effects of bracing on patient reported outcomes and changes in biomechanical parameters mostly in the sagittal, coronal and very rarely in the transverse plane. Most of the data examines the effects of bracing during walk and rarely during step down task which correspond to the most common and challenging activities of daily living. The clear majority of data relates to mechanical bracing and examines a wide range of OA grades and rarely healthy participants.

3.1 Aims

This study aims to investigate the effects of a non-mechanical knee brace on multiplane kinematic and kinetic variables of the lower limb. Biomechanical analysis will take place during walking at a self-selected comfortable speed and slow step down in healthy participants and participants with OA.

The effects of the brace on patient reported outcomes in participants with OA before and after four weeks of wear will be assessed via the Knee Injury and Osteoarthritis Outcome Score (KOOS). Subjective opinions regarding the wearability of the brace will be collected from both groups of participants via verbal feedback.

3.2 Hypothesis

3.2.1 Experimental Hypothesis:

There will be a statistically significant change in lower limb kinematic and kinetic variables in all tested planes which will indicate improvements in limb control when using the brace. At the knee, there will be a reduction in coronal and transverse angles and angular velocities. There will be an increase in sagittal plane range of movement in the OA group but a decrease in sagittal plane range of movement in the healthy group. This will be observed during both tasks. Similar reductions in hip and ankle kinematics will also be noted but will be more marked in the OA group and will indicate loss of protective gait characteristics such as toe out gait. Multi plane kinetics will also show significant reductions load, but especially the coronal plane during both tasks. Given the deterioration in proprioceptive feedback of osteoarthritic knees, the hypothesis is that there will be more noticeable changes in both kinematic and kinetic variables in the OA group. There will also be marked improvements in PROMS as reported across all subsections of KOOS at four weeks of wear and that overall feelings to the brace will be favourable.

3.2.2 Null Hypothesis:

There will be a statistically insignificant change in lower limb kinematic and kinetic with the use of the brace in both healthy participants and individuals with knee OA. This will be the case for walk and stepdown task. There will be no change or a possible deterioration in PROMS as assessed by KOOS at four weeks.

CHAPTER 4: MATERIALS & METHODS

4.1 Recruitment & Inclusion Criteria

The University of Central Lancashire (UCLAN) Science, Technology, Engineering, Medicine and Health (STEMH) ethics committee approved this study (*appendix chapter 9.1 page 165 and 9.2 page 177; application numbers are STEMH 235 & 356*) which was conducted in accordance with the Declaration of Helsinki (Seoul 2008). The tested brace was provided by the manufacturer (DJO, Donjoy Global, USA); participants with OA were allowed to keep the brace following completion of the study. All participants received a participant information sheet (PIS) immediately prior to testing (*appendix chapter 9.6, page 192 and chapter 9.7 page 194*) and were required to sign a consent form on arrival at the testing facility (*appendix chapter 9.3, page 188 and chapter 9.4 page 189*).

4.1.1 Participants:

Healthy participants were recruited from the staff and student body of UCLAN.

Advertisement for the study took the form of posters (*appendix chapter 9.5, page 191*) and an open email invitation posted to staff and student university webpages. Potential healthy participants were also recruited via the snowballing effect of the study. To be eligible, participants needed to be able to walk without the use of an aid for the duration of the testing period, have no history of lower limb OA, trauma or surgery and be aged between 30 to 60 years.

Participants with OA aged between 30 and 60 years self-volunteered for this study. To be eligible participants needed to be able to walk without the use of an aid for the duration of the testing period, have a history of grade 2-3 knee OA on the Kellgren-Lawrence scale, have no history of major trauma or surgery to the lower limbs.

4.2 Materials

4.2.1 Intervention:

The brace used was the Donjoy OA Reaction Web knee brace, 2015 (*Figure 1, page 59, chapter 4.2.1*) (OA Reaction Web (USA 2015), DJO Global). Correct sizing was determined by measuring thigh circumference 6 inches above the middle of the patella in line with the manufacturer's guidance (*Table 3, page 60, chapter 4.2.1*). Once fitted participants were permitted to adjust the fit of the brace until firm and comfortable. Subjective feedback on brace fit and comfort were collected at the end of the testing session.



Figure 1: OA Reaction Web (USA 2015), DJO Global on right knee demonstrating anterior (A), lateral (B) and posterior (C) aspects of the brace with its various components namely the under sleeve (S), Silicone (R), fabric/Velcro (F) and metallic lateral component (M).

Table 3: Brace size and methods used for measurement.

| Brace Size | Thigh Circumference |
|-------------------|----------------------------|
| Extra Small | 13 – 15.5” (33 – 39 cm) |
| Small | 15.5 – 18.5” (39 – 47 cm) |
| Medium | 18.5 – 21” (47 – 53 cm) |
| Large | 21 – 23.5” (53 – 60 cm) |
| Extra Large | 23.5 – 26.5” (60 – 67 cm) |

Thigh circumference was measured 6 inches above the middle of the patella as per manufacturer’s guidance.

4.2.2 Kinematic Instruments:

The 3D motion capture system used for this study was a 10 camera, Oqus 3+ series camera system (Qualisys Track Manager Software (QTM), Qualisys medical, Gothenburg, Sweden (*Figure 2, page 61, chapter 4.2.3*). This highly accurate, infra-red motion system captures visible information from retro-reflective markers applied to the participant’s body. A double umbrella camera configuration was used to collect the kinematic data (*Figure 3, page 61, chapter 4.2.3*). Each camera was checked prior to testing to ensure adequate positioning to allow frame capture. This was done by ensuring all static retro-reflective markers placed within the test space floor were visible to each camera during the calibration process data (*Figure 3, page 61, chapter 4.2.3*).

4.2.3 Kinetic Instruments:

Kinetic data was collected using four ground embedded piezoelectric force platforms (BP600400 Advanced Mechanical Technology, Inc (AMTI), USA). Force plates measured 60cm by 40cm, and kinetic data was collected at 1000Hz. For step down analysis a 10cm step was used (*Figure 4, page 61, chapter 4.2.3*).



Figure 2: Motion analysis camera. Image source ²



Figure 3: Double umbrella camera setup.

² Image origin www.qualisys.com/cameras, accessed 12/2016

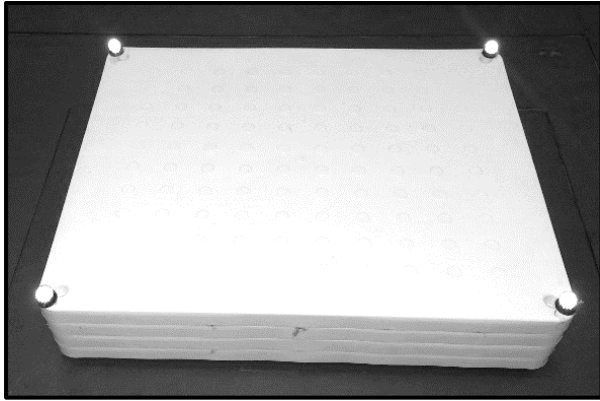


Figure 4: 10cm step used for step down task

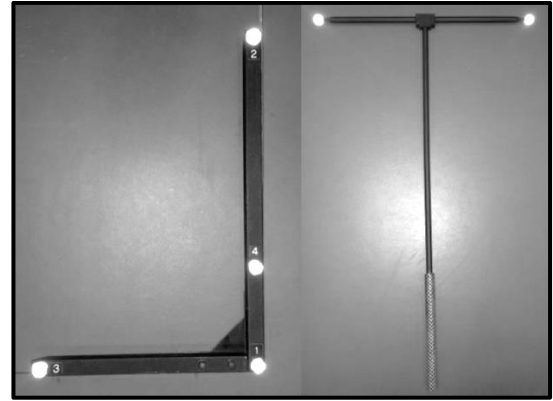


Figure 5: Static (L) frame & dynamic (T) calibration wand.

4.2.4 Calibration:

An area of 8 x 1.5 metres was calibrated (*Figure 3, page 61, chapter 4.2.3*). To match camera position to the anatomical axis represented by the global coordinate system, calibration of the QTM system must be performed. During this process, L (static) and T (dynamic) frame markers are placed within the capture area (*Figure 5, page 61, chapter 4.2.3*). If any camera did not “see” a marker, its position and/or setting would be adjusted until satisfactory image was obtained. The position of these markers is then coupled or matched to the anatomical axis. To match the position of each camera relative to the others and relative to the position of the wand and L-frame (Triggs et al., 2000), the data points collected during calibration undergo a bundle adjustment in the form of a non-linear transformation technique intrinsic to QTM. The error associated with each camera is dependent on T-wand length. For the 750.5mm wand, a minimum <0.5mm of residuals or error from each camera was used. The calibration process was repeated and camera settings were adjusted until this figure was obtained.

Before data collection the camera system was calibrated. This was achieved with the use of static and dynamic referencing frames (*Figure 5, page 61, chapter 4.2.3*). The static frame

defines the global coordinate system (GCS) while the dynamic calibration wand defines the observational zone visible to the motion capture system (Richards et al., 2008). The static L-shaped frame was used as a reference to define the GCS by being placed on the piezoelectric force platform with one limb paralleled to the X axis and another paralleled to the Y (where the X axis is sagittal, Y is coronal, and Z is the transverse plane of movement). With the L frame, still in place and referencing the GCS, the T shaped wand is moved in a non-linear fashion in all planes of movement for 30 seconds to define the motion capture space of the ten cameras relative to the global coordinate system and to provide dynamic calibration (Richards et al., 2008). The T-wand movement must encompass the entire motion capture space visible to all cameras and must be of sufficient variation to ensure accurate calibration (Richards et al., 2008).

Kinetic data was generated by performing inverse dynamics on the force platform ground reaction force and on the kinematic data obtained from modelling (Winter, Patla, & Frank, 1990). Inverse dynamics is the process of obtaining moment data by reverse analysis of kinematic data from limb segments in addition to force platform data and provides information on the orientation and magnitude of force acting on a joint. It is possible to ascertain which muscles are acting around the joint by analysing moment data in graphical or table form, where for example a flexor may have a positive value and an extensor will be negative (Richards et al., 2008).

4.2.5 Anatomical Modelling:

Three-dimensional marker position is identified by using the two-dimensional infrared image captured from each camera to calculate marker position relative to the global coordinate

system. To enable three-dimensional tracking, the Calibrated Anatomical System Technique (CAST) (Cappozzo et al., 1995) was used to model body segments and joint centres in six degrees of freedom (linear freedom (vertical, medial-lateral, anterior-posterior), rotational freedom (sagittal, coronal, transverse)). For the CAST system to build an anatomical coordinate system for each segment, a bony reference frame based on anatomical markers must be defined and coupled to the tracking cluster of each segment. This is achieved by capturing a static calibration frame immediately following mark-up, while the participant stands in the centre of the capture area in an anatomical position. The marker sets used for CAST consisted of the pelvis which was defined proximally by left and right anterior superior iliac spines (ASIS) and distally by posterior superior iliac spines (PSIS); the thigh defined proximally by greater trochanter and hip joint centre and distally by the medial and lateral femoral condyles; the shank defined proximally by the medial and lateral femoral condyles and distally by the medial and lateral malleoli; and the foot defined proximally by the medial and lateral malleoli and distally by the 1st and 5th metatarsal heads.

The body segments and joint centres modelled in six degrees of freedom using CAST include static and dynamic markers. Anatomical (static frame) markers are 9mm retroreflective markers which reference joint centres and are attached to both malleoli, medial and lateral knee and greater trochanter to allow comparison of relative movement in an anatomical frame and modelling of a skeletal representation of the participant during recording (*Figure 6, page 65 and Figure 7, page 65, chapter 4.2.5*). The markers were attached to bony landmarks using hypo-allergic double sided tape. Dynamic tracking markers consisted of pelvic markers (one for each ASIS and PSIS) and marker clusters. Clusters are groups of four 9mm retro-reflective markers on a rigid thermoplastic plate represent the body segments (thigh and shank) and are used to define a rigid body within 6 degrees of freedom (*Figure 6, page 654,*

chapter 4.2.5). These were attached to the femoral and tibial segments using flexifoam straps. Where garments would cause a potential obstruction of the markers they were held securely out of place with the use of adhesive tape (Hypafix). A minimum of three markers are needed to define a segment (Cappozzo et al., 2005). The hip joint centre is calculated based on regression equations as defined by Bell (Bell, Pedersen, & Brand, 1990). During static capture the participant is asked to stand fully on the force platform where his/her weight is recorded.

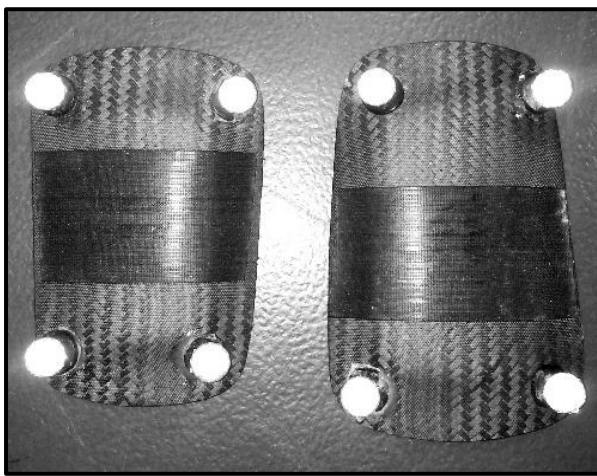


Figure 6: Shank (left) & thigh (right) clusters used for the creation of the anatomical coordinate system.



Figure 7: CAST Marker setup & corresponding image on Qualysis.

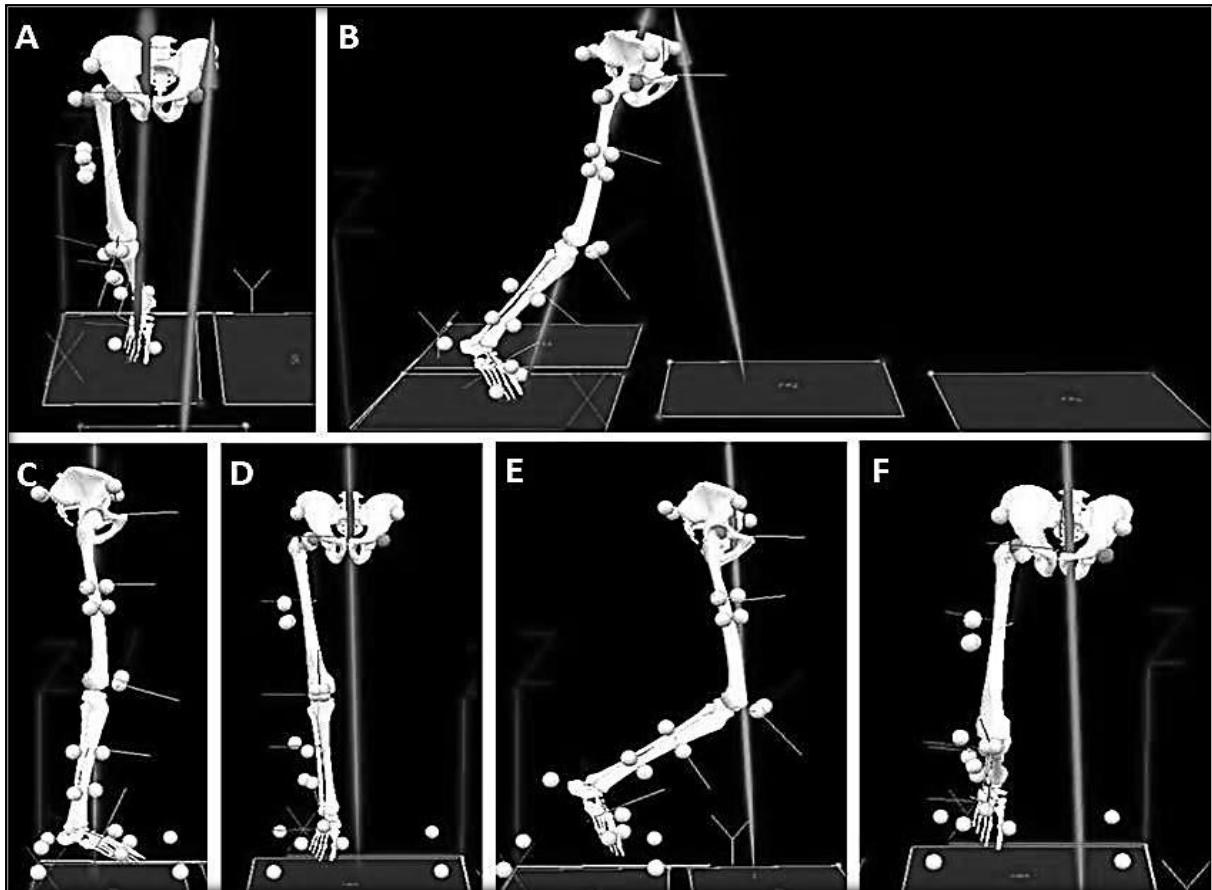


Figure 8: Images as they appear on V3D (C-Motion Inc, Rockville, MD, USA) at various stages of testing; walking task (A & B), stationary on 10cm step (C & D) and during step down (E & F).

4.2.6 Other relevant equipment:

A Leicester Height Measure was used to confirm participant height. Footwear used was standardised (*Figure 9, page 66, chapter 4.2.6*) and participants were asked to state their shoe size and confirm correct fit once the shoes were donned.



Figure 9: Dr Comfort, Wisconsin, USA, Spirit Plus Shoes were available in multiple sizes.
Figure shows size 8 UK.

4.3 Test Protocol

Data collection took place at the movement analysis laboratory, Brook Building, UCLAN. Participants contacted the research team via email to express their interest. They were subsequently emailed the PIS prior to deciding to participate. On arrival at the laboratory participants were once again given the PIS and the opportunity to ask questions. Participants were then asked to sign the consent form following which height was collected and participants with OA were asked to fill in the first KOOS questionnaire (*Figure 10, page 68, chapter 4.3 and appendix chapter 9.8 page 196*). All participants wore shorts which needed to be above the level of the mid-thigh to allow accurate marker placement. Standardized footwear was worn for the testing session, sizing of which was confirmed by asking the participant to state their shoe size (*Figure 9, page 66, chapter 4.2.6*). The tested limb was the limb which the participant deemed dominant in the healthy group and the symptomatic limb for participants with OA. The anatomical frame was captured prior to donning the brace. The researcher performed fitting of the knee brace as per the manufacturers guidance; however, participants could readjust the tightness of the brace to be form yet comfortable. To allow for marker placement the brace was applied without the use of the undersleeve however all participants with OA were provided with the undersleeve for the intervention. All participants performed two movement tasks under the two conditions of braced and unbraced. The order of the task performed and conditions was randomized.

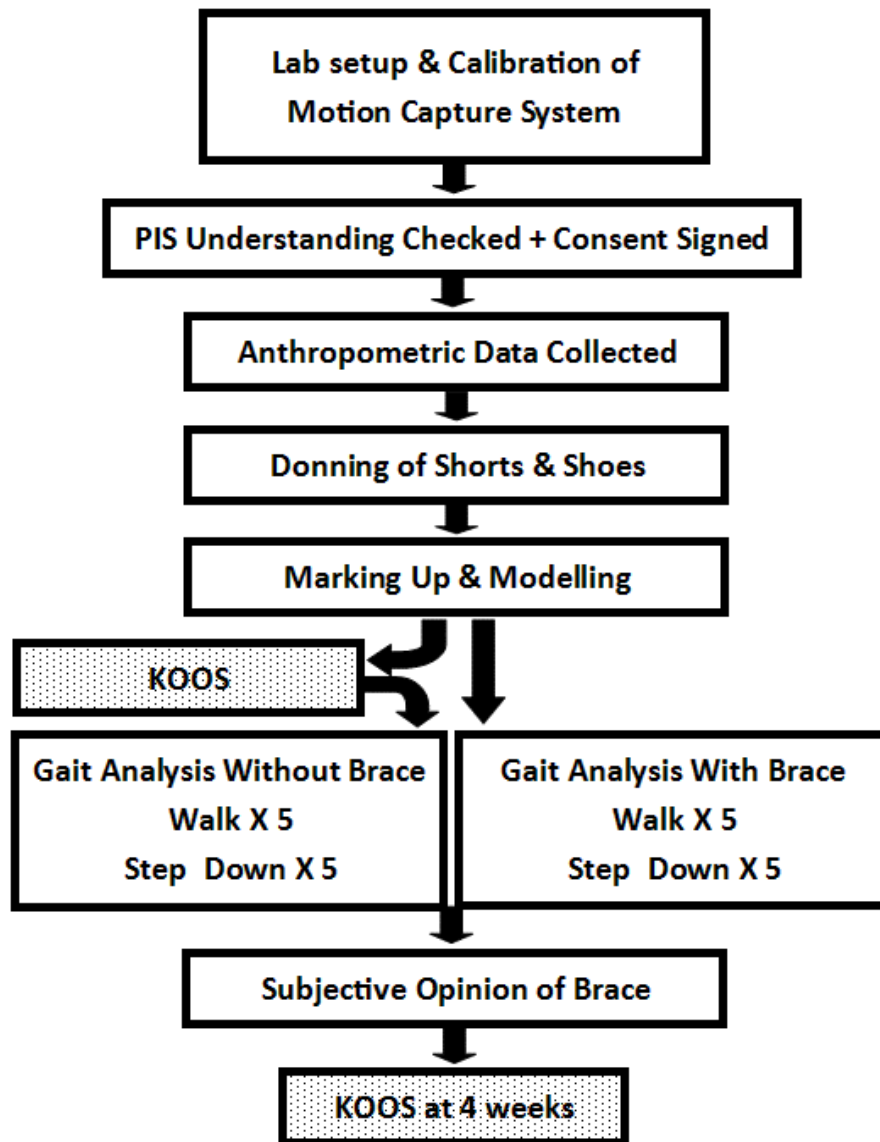


Figure 10: Study Protocol.

Shaded areas indicate steps taken only for OA participants.
Participant Information Sheet PIS, Knee injury and OA Outcome Score KOOS.
walk and stepdown tasks both braced and non-braced were randomised.

4.3.1 Walking Task:

At the start of each trial participants were instructed to walk at a comfortable pace while the research team observed for a force platform strike with the dominant (or affected) limb. A minimum of 5 trials were performed for both test conditions.

4.3.2 Controlled Step-down Task:

Participants were instructed to cross their arms across the chest and slowly dismount a 10cm step using their non-dominant (non-tested) limb first ending with a heel strike onto the force platform. A minimum of 5 successful step-down trials were performed for both test conditions.

4.3.3 Patient Reported Outcome Measures:

Clinical Outcome:

Prior to data collection participants with OA were asked to complete a KOOS questionnaire (appendix chapter 9.8, page 196). This was repeated electronically or by phone at 4 weeks. KOOS was developed as an extension of WOMAC. It examines acute and chronic changes in mechanical symptoms, pain, activities of daily living, sport and recreational activity and overall quality of life.

Subjective questions:

Following successful completion of the walk and step-down tasks, participants with and without OA were asked to give their subjective opinion regarding the wearability of the brace and any perceived change in comfort, stability and movement caused by the device.

4.4 Data Analysis

4.4.1 Modelling & Analysis:

For kinematics during step down task, the start was unilateral limb stance while the end point was force platform heel strike with the contralateral limb (*Figure 8, page 65, chapter 4.2.5*).

The start and end points for the walk task kinematic data was heel strike to ipsilateral heel strike while for kinetic data collection the start and end points were force plate heel strike to consecutive force plate toe off. The events for kinetic data collection during the walk task were a full contact heel strike onto the force platform and toe off from the same force platform. This was ensured by asking the participant to alter their start point accordingly until a successful sequence was archived. A secondary quality check process occurred during the period of identifying the event points on Visual 3D, C-Motion Inc, Rockville, MD, USA (V3D); where endplates that did not have a successful event sequence, trials were disregarded and not used for data analysis. A minimum of three successful trails was required for data analysis.

Successful task trials were captured using QTM, where anomalies in the marker trajectories were corrected. Following QTM processing all trials were exported as C3D file formats into the V3D where further analysis occurred and the static calibration trial was used to create a dynamic model. The filter used was a low pass, Butterworth fourth-order, zero-lag filter with a 12Hz cut off frequency (Sinclair, Taylor, & Hobbs, 2013). The movement patterns of the various anatomical markers and segments were used by this software to quantify kinematics such as joint angles and velocities between the start and end points identified as heel strike to heel strike (one stride). Numerical and visual representation of data in the form of

preliminary graphs were extracted for the hip, knee and ankle in three planes of movement namely sagittal (flexion / extension), coronal (abduction / adduction) and transverse (internal / external rotation). For reporting, kinematic data was normalized to body weight (Nm/Kg).

4.4.2 Statistics:

Mean and standard deviations were used to describe all outcome variables including kinetic and kinematic data in both participant groups and for both tasks; as well as basic anthropometric data including height, weight and age of participants. KOOS data is described as percentage change (www.koos.nu). Descriptive statistics were analysed on Microsoft Excel.

Paired t-tests were used to analyse differences with and without the brace. To avoid type 1 error the α (alpha) value was set to 0.05. V3D variables were organised with Microsoft Excel and statistical analysis was carried out in SPSS (IBM analytics, Version 22). A check for normality of the data was not undertaken as the paired t-test was used to test means of random samples.

4.4.3 Sample Size & Power Calculation:

Given the exploratory nature of the study and reliance upon participant volunteering, it was not necessary to complete a power calculation. A figure of 13 participants was the minimum number chosen based on previous research which concluded with statistically significant results after examining similar numbers (Richards, Sanchez-Ballester et al., 2005; Selfe, Thewlis et al., 2011).

CHAPTER 5: RESULTS

5.1 Introduction

A total of 13 healthy participants aged between 30 and 60 years (age of 42 ± 12 years of age) with an average height of 178cm (± 16.5 cm) and weight of 81kg (± 17 kg) volunteered for the study. Of these 6 were male and 7 were female. Three participants with OA aged between 30 and 60 years took part in the study.

5.2 Walk Task Kinematic Data

5.2.1 The Knee:

Sagittal Plane Angles:

Paired t-tests showed significant difference ($p = 0.007$) in sagittal knee angle at heel strike in healthy participants when wearing the brace (*Table 4, page 73, chapter 5.2.1*). This represented an increase in knee flexion at heel strike when wearing the brace.

Coronal Plane Angles:

Statistically significant changes were noted in coronal knee angle in both groups (*Table 4, page 73, chapter 5.2.1*). In participants with OA this included a decrease in the varum at heel strike ($p = 0.002$) (*Figure 12, page 74, chapter 5.2.1*); while in the healthy group, there was a decrease of adduction at heel strike from a mean of 0.6 without the brace to -1.0 with the brace ($p = 0.004$) (*Figure 11, page 74, chapter 5.2.1*). There was also a significant reduction of knee varum throughout the stance phase ($p = 0.007$) (*Table 4, page 73, chapter 5.2.1*). No

other significant changes were noted in coronal knee angulation for the remaining phases of gait.

Transverse Plane Angles:

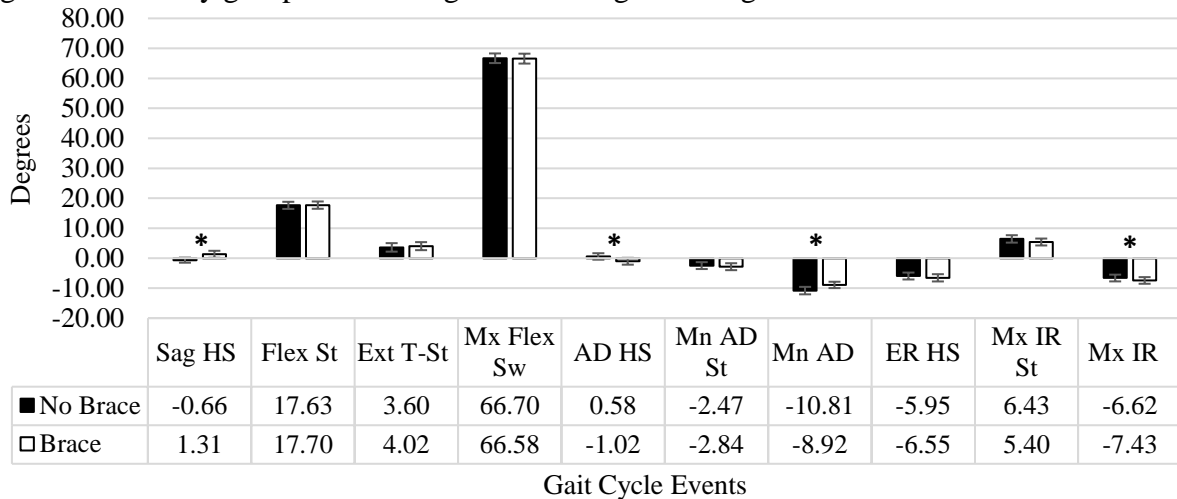
The paired t-test demonstrated significant differences in the maximum internal rotation during stance phase in the healthy participant group (Table 4, page 73, chapter 5.2.1). This reduced from a mean of 6.4 degrees without the brace to a mean of 5.4 degrees with the brace (Figure 11, page 74, chapter 5.2.1).

Table 4: Walk task angular change for the knee

| <i>Angular Change (°)</i> | Healthy Participants | | | | OA Participants | | | |
|----------------------------|-----------------------------|-------------|-------------|----------------|------------------------|-------------|-------------|----------------|
| | <i>MD</i> | <i>L-CI</i> | <i>U-CI</i> | <i>P value</i> | <i>MD</i> | <i>L-CI</i> | <i>U-CI</i> | <i>P value</i> |
| <i>Sagittal HS</i> | -1.97 | -3.30 | -0.64 | 0.007* | -0.32 | -7.46 | 6.81 | 0.863 |
| <i>Flexion St</i> | -0.08 | -0.97 | 0.82 | 0.858 | 2.06 | -2.09 | 6.21 | 0.166 |
| <i>Extension T-St</i> | -0.42 | -1.42 | 0.59 | 0.382 | 2.33 | -1.20 | 5.86 | 0.105 |
| <i>Max Flexion Swing</i> | 0.12 | -0.44 | 0.68 | 0.649 | -0.53 | -6.00 | 4.94 | 0.717 |
| <i>Adduction HS</i> | 1.60 | 0.62 | 2.57 | 0.004* | -1.01 | -1.20 | -0.82 | 0.002* |
| <i>Min Adduction St</i> | 0.37 | -0.45 | 1.19 | 0.348 | -1.77 | -4.37 | 0.82 | 0.099 |
| <i>Min Adduction</i> | -1.90 | -3.17 | -0.62 | 0.007* | -3.81 | -10.39 | 2.77 | 0.130 |
| <i>Ext Rotation HS</i> | 0.60 | -0.73 | 1.93 | 0.343 | 1.22 | -6.78 | 9.21 | 0.580 |
| <i>Max Int Rotation St</i> | 1.03 | 0.12 | 1.95 | 0.030* | 3.41 | -6.78 | 13.60 | 0.287 |
| <i>Max Int Rotation</i> | 0.81 | -0.48 | 2.10 | 0.198 | 1.67 | -4.37 | 7.72 | 0.356 |

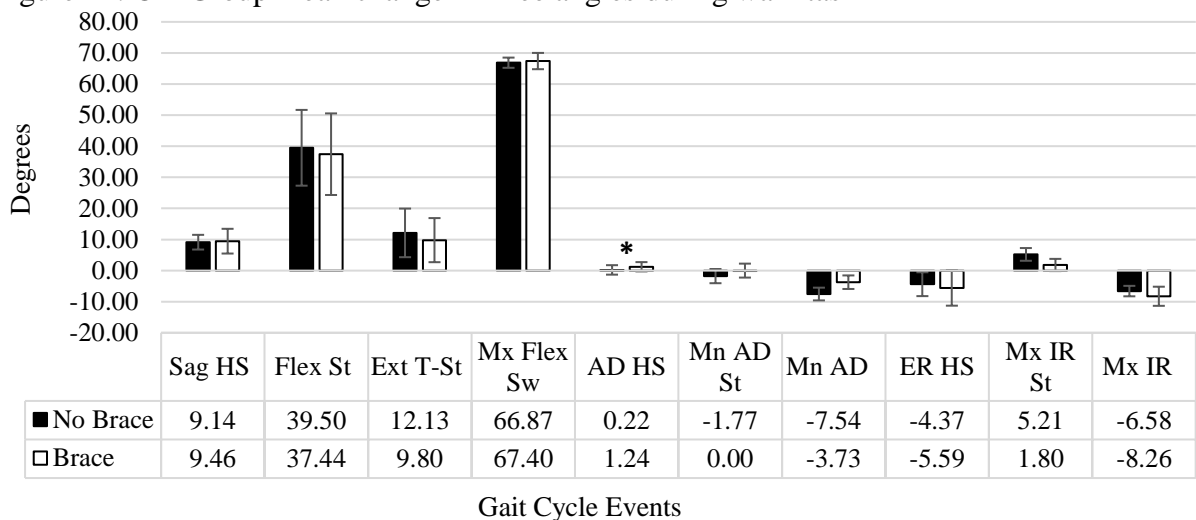
Angular change in degrees (°), Mean Difference (MD), Lower (L-CI) and Upper (U-CI) Confidence intervals, Heel Strike (HS), Stance Phase (St), Terminal Stance (T-St), Maximum (Max), Minimum (Min), Significant results are marked with bold font and an asterisk (*).

Figure 11: Healthy group mean change in knee angles during walk task



Sagittal angle at heel strike (Sag HS), flexion during stance (Flex St), extension at terminal stance (Ext T-St), maximum flexion during swing (Mx Flex Sw), adduction at heel strike (AD HS), minimum adduction during stance (Mn AD St), minimum adduction (Mn AD), external rotation at heel strike (ER HS), maximum internal rotation during stance (Mx IR St), maximum internal rotation (Mx IR). Significant differences marked with an asterisk (*).

Figure 12: OA Group mean change in knee angles during walk task



Sagittal angle at heel strike (Sag HS), flexion during stance (Flex St), extension at terminal stance (Ext T-St), maximum flexion during swing (Mx Flex Sw), adduction at heel strike (AD HS), minimum adduction during stance (Mn AD St), minimum adduction (Mn AD), external rotation at heel strike (ER HS), maximum internal rotation during stance (Mx IR St), maximum internal rotation (Mx IR). Significant differences marked with an asterisk (*).

Sagittal Plane Angular Velocity:

Significant changes in the peak flexion angular velocity during swing phase were noted in the healthy participants ($p = 0.003$) (Table 5, page 75, chapter 5.2.1). These decreased from

231.8 degrees per second (deg/s) free of the brace to 198.8 deg/s with the brace (*Figure 13, page 76, chapter 5.2.1*). No other changes of significance were noted in the sagittal plane in both tested groups. Knee angular velocity at the end of swing phase went from a mean of -451.6 without the brace to -434.8 with the brace ($p = 0.021$) (*Table 5, page 75, chapter 5.2.1*), indicating an increase in extension angular velocity of 6.8 deg/s with the brace (*Figure 13, page 76, chapter 5.2.1*).

Coronal Plane Angular Velocity:

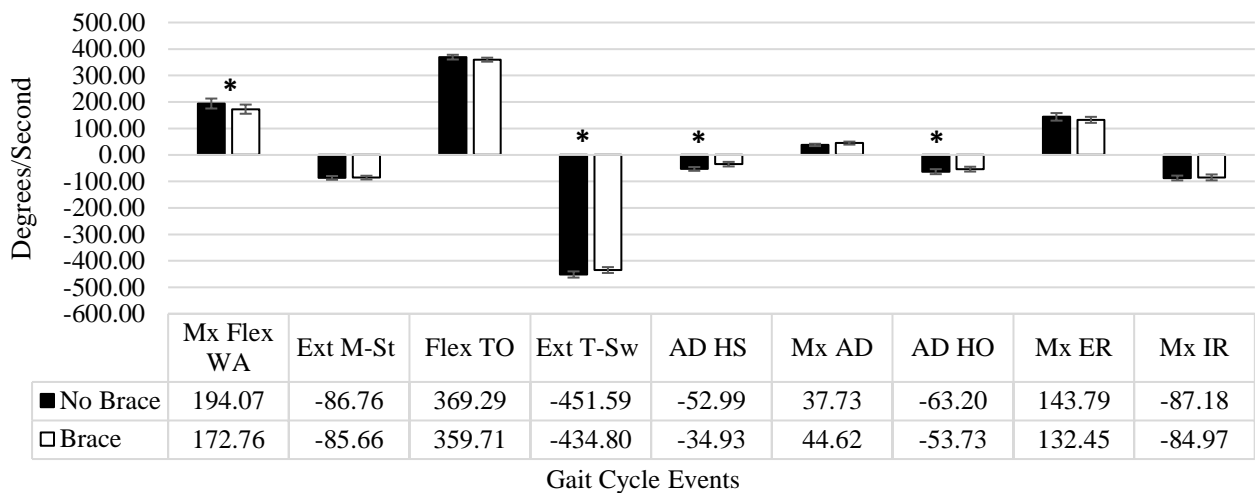
Healthy participants showed significant change in adduction angular velocity during the period of weight acceptance following heel strike ($p < 0.001$); which reduced from a mean of -28.4 deg/s free of the brace to -19.5 deg/s when braced (*Figure 13, page 76, chapter 5.2.1*). This corresponds to a 9 deg/s decrease (*Figure 13, page 76, chapter 5.2.1*) in the knee adduction angular velocity. Similar significant reductions were noted at terminal stance ($p = 0.004$) (*Table 5, page 75, chapter 5.2.1*). There were no changes seen in the participants with OA (*Table 5, page 75 and Figure 14, page 76, chapter 5.2.1*).

Table 5: Walk task change in angular velocity for the knee

| <i>Angular Velocity</i> (deg/s) | Healthy Participants | | | | OA Participants | | | |
|------------------------------------|-----------------------------|-------------|-------------|----------------|------------------------|-------------|-------------|----------------|
| | <i>MD</i> | <i>L-CI</i> | <i>U-CI</i> | <i>P value</i> | <i>MD</i> | <i>L-CI</i> | <i>U-CI</i> | <i>P value</i> |
| <i>Peak Flexion WA</i> | 21.31 | 8.60 | 34.03 | 0.003* | 33.08 | -80.40 | 146.55 | 0.337 |
| <i>Extension M-St</i> | -1.09 | -9.90 | 7.71 | 0.791 | -1.41 | -23.97 | 21.14 | 0.813 |
| <i>Flexion Toe Off</i> | 9.58 | -0.27 | 19.43 | 0.056 | 2.65 | -37.76 | 43.05 | 0.804 |
| <i>Extension T-swing</i> | -16.79 | -30.53 | -3.05 | 0.021* | -13.45 | -208.11 | 181.22 | 0.794 |
| <i>Adduction HS</i> | -18.06 | -25.04 | -11.07 | 0.000* | -8.87 | -35.56 | 17.81 | 0.289 |
| <i>Max Adduction</i> | -6.89 | -15.96 | 2.18 | 0.124 | -2.61 | -15.72 | 10.50 | 0.482 |
| <i>Adduction Heel Off</i> | -9.47 | -15.19 | -3.76 | 0.004* | -0.45 | -38.84 | 37.94 | 0.964 |
| <i>Max Ext Rot</i> | 11.34 | -12.70 | 35.38 | 0.324 | 8.12 | -28.44 | 44.68 | 0.440 |
| <i>Max Int Rot</i> | -2.21 | -16.33 | 11.90 | 0.739 | -19.78 | -119.34 | 79.79 | 0.483 |

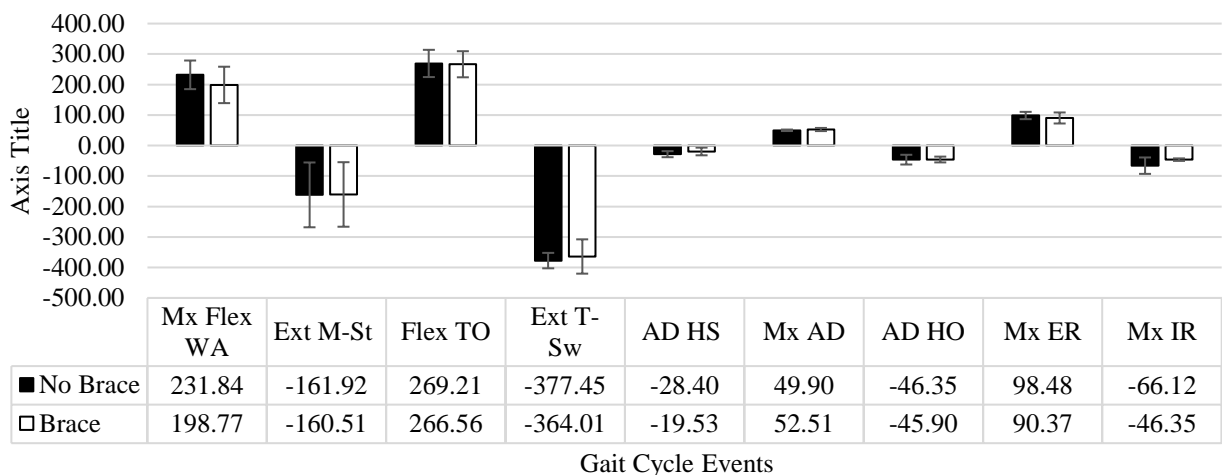
Angular Velocity in degrees per second (deg/s), Mean Difference (MD), Lower (L-CI) and Upper (U-CI) Confidence intervals (CI), P Value of Significance (P), Heel Strike (HS), Stance Phase (St), Maximum (Max), Minimum (Min), Weight Acceptance (WA), Significant results are marked with an asterisk (*)

Figure 13: Healthy group mean change in knee angular velocity during walk task



Peak flexion at weight acceptance or early stance (Mx Flex WA), extension at mid-stance (Ext M-St), flexion at toe off (Flex TO), extension at terminal swing (Ext T-Sw), Adduction at heel strike (AD HS), maximum adduction (Mx AD), adduction at terminal stance or heel off (AD HO), maximum external rotation (Mx ER), maximum internal rotation (Mx IR). Significant differences marked with an asterisk (*). Degrees/Second

Figure 14: OA group mean change in knee angular velocity during walk task



Peak flexion at weight acceptance or early stance (Mx Flex WA), extension at mid-stance (Ext M-St), flexion at toe off (Flex TO), extension at terminal swing (Ext T-Sw), Adduction at heel strike (AD HS), maximum adduction (Mx AD), adduction at terminal stance or heel off (AD HO), maximum external rotation (Mx ER), maximum internal rotation (Mx IR).

5.2.2 The Hip:

Sagittal Plane Angles:

In healthy participant's hip flexion at heel strike went from a mean of 26.9 degrees without the brace to 29.0 with the brace ($p = 0.016$) (Table 6, page 77, chapter 5.2.2). This indicates a

2.1 degree change in hip flexion angle (Figure 15, page 78, chapter 5.2.2). Hip flexion during the period of weight acceptance also changes significantly ($p = 0.035$) reducing from a mean of 27.6 without the brace to 29.2 with the brace (Figure 15, page 78, chapter 5.2.2). Such changes were not noted in the participants with OA (Figure 16, page 78, chapter 5.2.2).

Transverse Plane Angles:

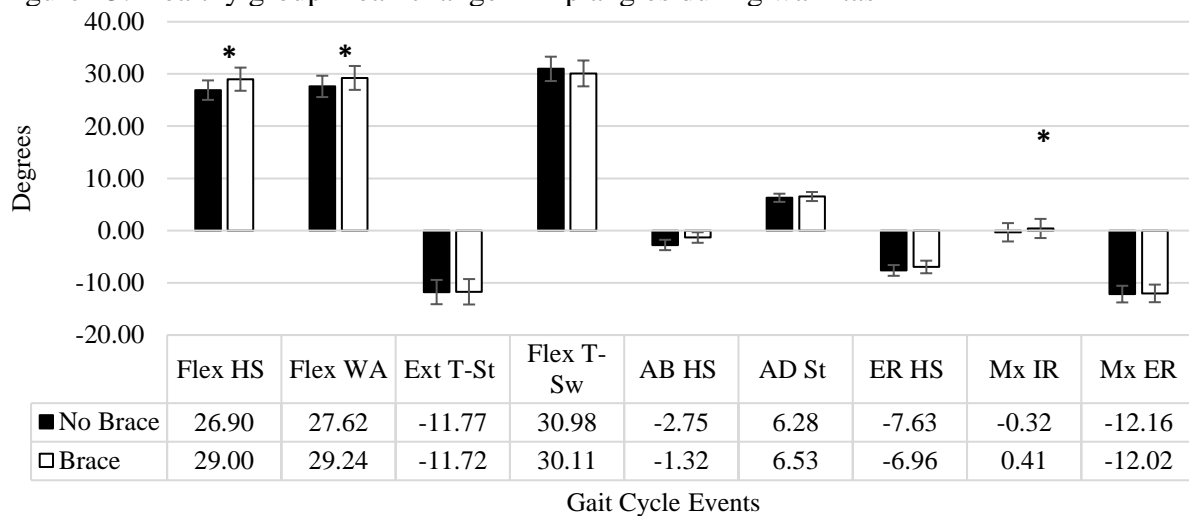
The internal rotation at the hip in healthy participants increased significantly ($p = 0.010$) when wearing the brace (Table 6, page 77, chapter 5.2.2). These changes were not noted in participants with OA.

Table 6: Walk task angular change for the hip

| Angular Change (°) | Healthy Participants | | | | OA Participants | | | |
|--------------------|----------------------|-------|-------|---------------|-----------------|--------|-------|---------|
| | MD | L-CI | U-CI | P value | MD | L-CI | U-CI | P value |
| Flexion HS | 2.10 | 0.47 | 3.73 | 0.016* | -12.92 | -74.71 | 48.87 | 0.463 |
| Flexion WA | 1.62 | 0.13 | 3.11 | 0.035* | -8.93 | -46.86 | 29.00 | 0.418 |
| Extension T-St | 0.05 | -1.13 | 1.24 | 0.924 | -9.15 | -47.50 | 29.20 | 0.413 |
| Flexion T-Swing | -0.87 | -2.45 | 0.71 | 0.253 | -15.99 | -97.55 | 65.57 | 0.488 |
| Abduction HS | -1.43 | -2.92 | 0.07 | 0.060 | 0.46 | -2.34 | 3.27 | 0.551 |
| Adduction St | -0.24 | -1.10 | 0.61 | 0.546 | 0.87 | -2.36 | 4.10 | 0.367 |
| External Rot HS | -0.66 | -1.75 | 0.42 | 0.208 | -0.42 | -8.15 | 7.30 | 0.835 |
| Max Int Rotation | -0.73 | -1.26 | -0.21 | 0.010* | -0.94 | -2.59 | 0.71 | 0.133 |
| Max Ext Rotation | -0.14 | -0.91 | 0.64 | 0.715 | -1.76 | -8.02 | 4.51 | 0.351 |

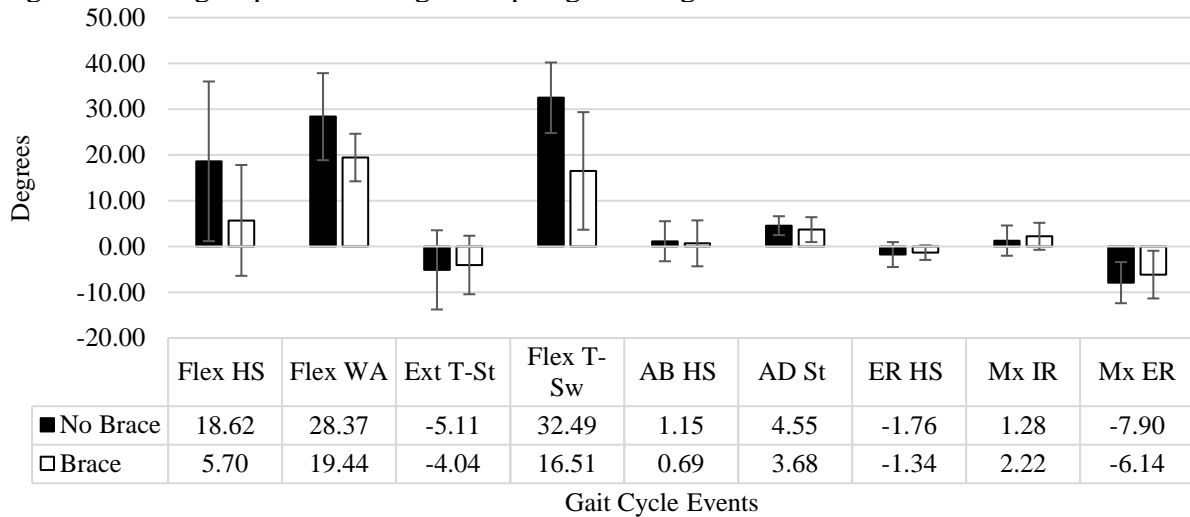
Angular change in degrees (°), Mean Difference (MD), Lower (L-CI) and Upper (U-CI) Confidence intervals, P Value of Significance (P), Heel Strike (HS), Stance Phase (St), Maximum (Max), Minimum (Min).

Figure 15: Healthy group mean change in hip angles during walk task



Flexion at heel strike (Flex HS), flexion at weight acceptance or early stance (Flex WA), extension a terminal stance (Ext T-St), flexion at terminal swing (Flex T-Sw), abduction at heel strike (AB HS), adduction during stance (AD St), external rotation at heel strike (ER HS), maximum internal rotation (Mx IR), maximum external rotation (Mx ER). Significant differences marked with an asterisk (*).

Figure 16: OA group mean change in hip angle during walk task



Flexion at heel strike (Flex HS), Flexion at weight acceptance or early stance (Flex WA), extension at terminal stance (Ext T-St), flexion at terminal swing (Flex T-Sw), abduction at heel strike (AB HS), adduction during stance (AD St), external rotation at heel strike (ER HS), maximum internal rotation (Mx IR), maximum external rotation (Mx ER).

Sagittal, Coronal & Transverse Plane Angular Velocity:

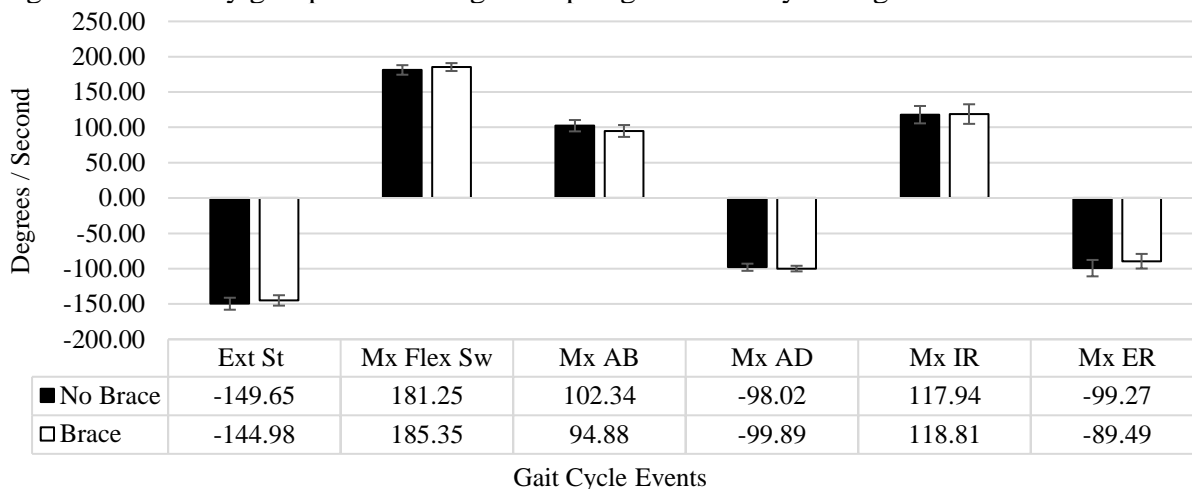
There were no significant changes in hip angular velocity for both groups of participants in all planes of movement (Table 7, page 78, Figure 17, page 79 and Figure 18, page 79, chapter 5.2.2).

Table 7: Walk task change in angular velocity for the hip

| Angular Velocity (deg/s) | Healthy Participants | | | | OA Participants | | | |
|-----------------------------|----------------------|--------|-------|---------|-----------------|---------|--------|---------|
| | MD | L-CI | U-CI | P value | MD | L-CI | U-CI | P value |
| Extension St | 4.67 | -4.67 | 14.01 | 0.297 | 34.58 | -107.17 | 176.33 | 0.404 |
| Max Flexion Swing | 4.10 | -2.15 | 10.35 | 0.178 | -23.11 | -152.82 | 106.61 | 0.524 |
| Max Abduction | 7.46 | -3.33 | 18.25 | 0.158 | 18.19 | -123.97 | 160.34 | 0.637 |
| Max Adduction | 1.88 | -6.74 | 10.50 | 0.643 | -30.23 | -166.64 | 106.17 | 0.441 |
| Max Int Rotation | -0.88 | -11.65 | 9.89 | 0.862 | 38.49 | -139.07 | 216.06 | 0.449 |
| Max Ext Rotation | -9.78 | -31.12 | 11.56 | 0.338 | -39.92 | -172.88 | 93.05 | 0.326 |

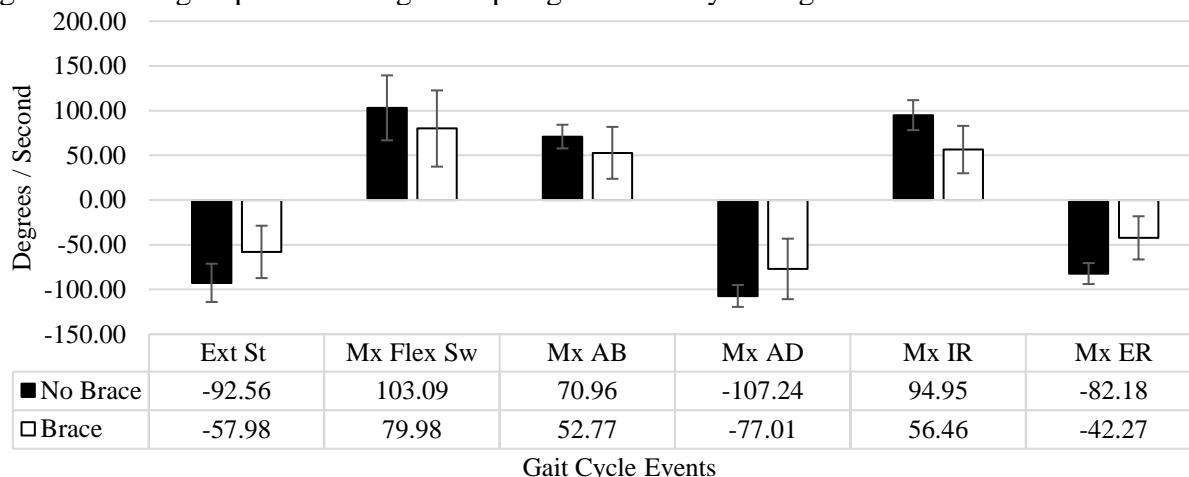
Angular velocity in degrees per second (deg/s), Mean Difference (MD), Lower (L-CI) and Upper (U-CI) confidence intervals, P Value of Significance (P), Stance Phase (St), Maximum (Max), Minimum (Min).

Figure 17: Healthy group mean change in hip angular velocity during walk task



Extension during stance (Ext St), maximum flexion during swing (Mx Flex Sw), maximum abduction (Mx AB), maximum adduction (Mx AD), maximum internal rotation (Mx IR), maximum external rotation (Mx ER).

Figure 18: OA group mean change in hip angular velocity during walk task



Extension during stance (Ext St), maximum flexion during swing (Mx Flex Sw), maximum abduction (Mx AB), maximum adduction (Mx AD), maximum internal rotation (Mx IR), maximum external rotation (Mx ER).

5.2.3 The Ankle:

Coronal Plane Angles:

Significant changes ($p = 0.011$) in inversion angle at the ankle were noted in the healthy group (Table 8, page 80, chapter 5.2.3). This increased by approximately 1.4 degrees when

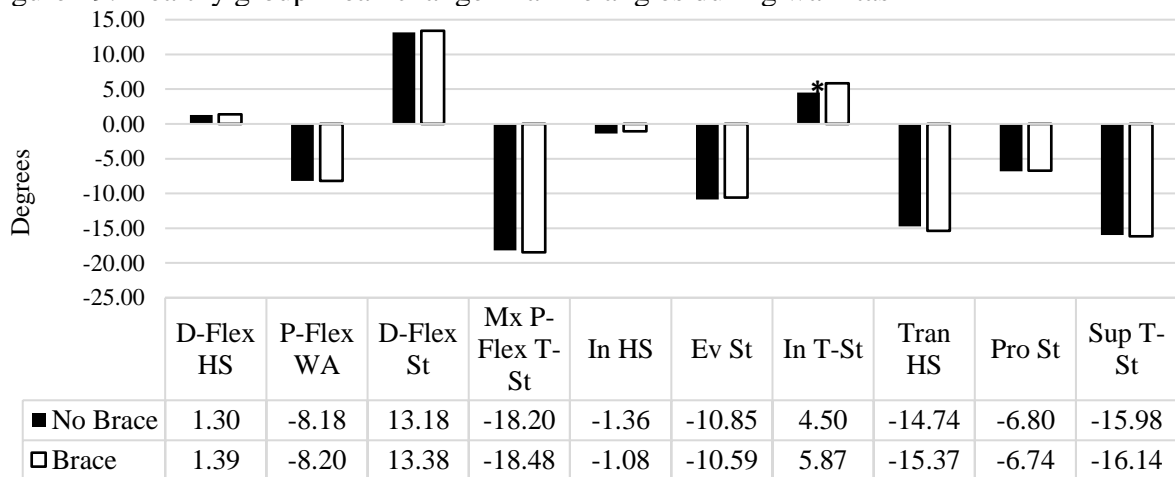
wearing the brace (Figure 19, page 80, chapter 5.2.3). Such changes were not found in participants with OA (Figure 20, page 81, chapter 5.2.3).

Table 8: Walk task angular change for the ankle
Angular Change (°)

| | Healthy Participants | | | | OA Participants | | | |
|-------------------------|----------------------|-------|-------|---------------|-----------------|---------|--------|---------|
| | MD | L-CI | U-CI | P value | MD | L-CI | U-CI | P value |
| Dorsiflexion HS | 0.09 | -0.73 | 0.90 | 0.825 | 4.86 | -4.67 | 14.39 | 0.159 |
| Plantar Flexion WA | -0.02 | -0.41 | 0.36 | 0.900 | -56.22 | -304.34 | 191.10 | 0.432 |
| Dorsiflexion St | 0.20 | -0.14 | 0.54 | 0.225 | 55.85 | -172.94 | 284.65 | 0.404 |
| Max plantarflexion T-St | -0.36 | -1.37 | 0.66 | 0.459 | -69.18 | -375.62 | 237.26 | 0.434 |
| Inversion HS | -0.28 | -1.28 | 0.72 | 0.555 | 26.79 | -84.40 | 137.98 | 0.409 |
| Eversion St | -0.26 | -0.87 | 0.35 | 0.374 | 25.60 | -76.97 | 128.16 | 0.395 |
| Inversion T-St | -1.37 | -2.38 | -0.37 | 0.011* | -10.89 | -62.43 | 40.65 | 0.459 |
| Transverse HS | 0.64 | -0.33 | 1.61 | 0.178 | 6.82 | -34.04 | 47.68 | 0.547 |
| Pronation St | -0.06 | -0.57 | 0.45 | 0.790 | -25.23 | -122.44 | 71.99 | 0.380 |
| Supination T-St | 0.16 | -0.61 | 0.92 | 0.664 | 14.58 | -53.75 | 82.92 | 0.455 |

Angular change in degrees (°), Mean Difference (MD), Lower (L-CI) and Upper (U-CI) Confidence intervals, P Value of Significance (P), Heel Strike HS, Stance Phase (St), Terminal Stance (T-St), Maximum (Max), Minimum (Min).

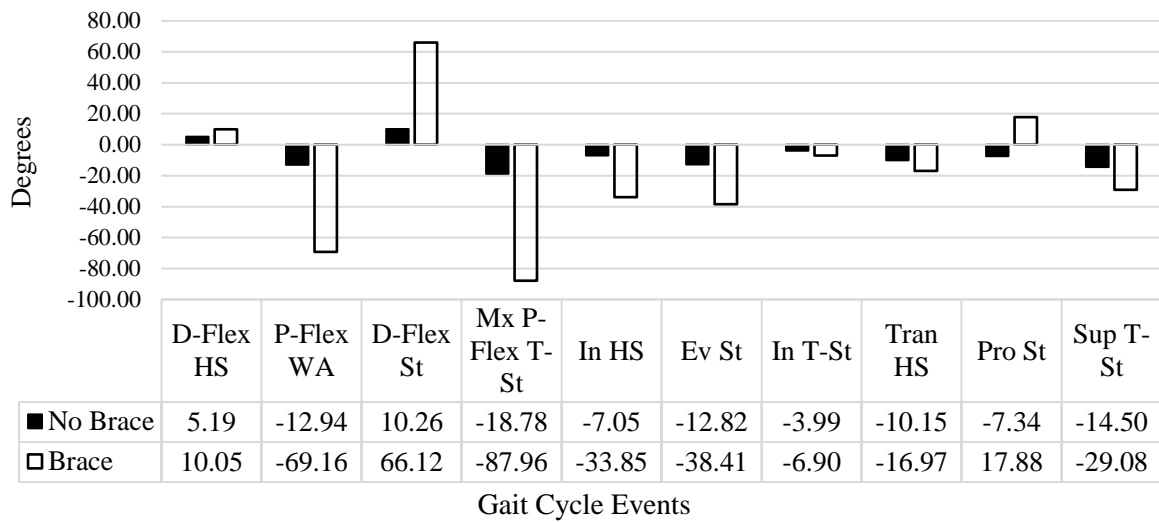
Figure 19: Healthy group mean change in ankle angles during walk task



Gait Cycle Events

Dorsiflexion at heel strike (D-Flex HS), plantar flexion during weight acceptance or early stance (P-Flex WA), dorsiflexion during stance (D-Flex St), maximum plantarflexion at terminal or late stance (Mx P-Flex T-St), inversion at heel strike (In HS), eversion during stance (Ev St), inversion at terminal stance (Ev T-St), Transverse angle at heel strike heel strike (Tran HS), pronation during stance (Pro St), supination at terminal stance (Sup T-St). Significant differences marked with an asterisk (*).

Figure 20: OA group mean change in ankle angles during walk task



Dorsiflexion at heel strike (D-Flex HS), plantar flexion during weight acceptance or early stance (P-Flex WA), dorsiflexion during stance (D-Flex St), maximum plantarflexion at terminal or late stance (Mx P-Flex T-St), inversion at heel strike (In HS), eversion during stance (Ev St), inversion at terminal stance (Ev T-St), Transverse angle at heel strike heel strike (Tran HS), pronation during stance (Pro St), supination at terminal stance (Sup T-St).

5.3 Walk Task Kinetic Data

5.3.1 The Knee:

Sagittal Plane Moments:

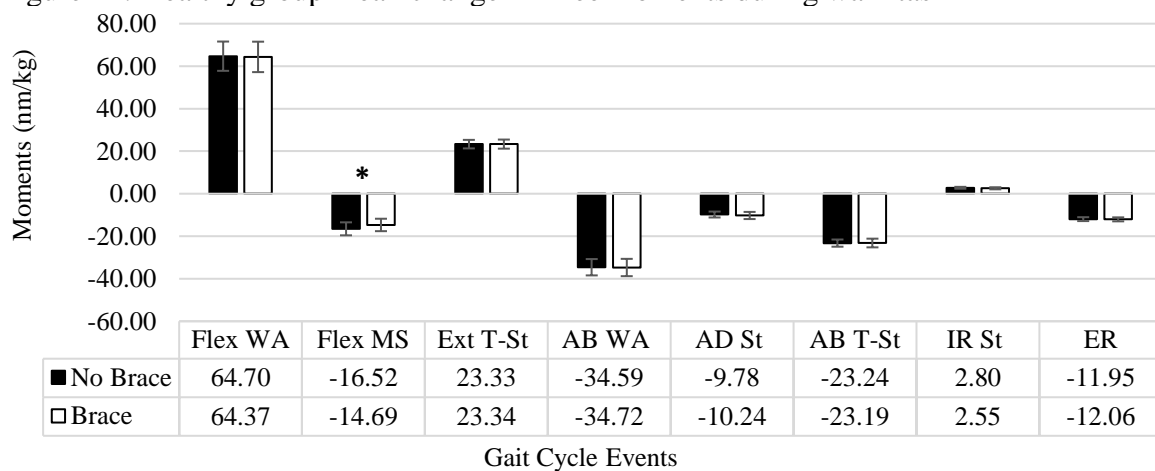
A significant reduction ($p = 0.006$) in flexion moment at mid-stance was found with the use of the brace in the healthy group (Table 9, page 82, chapter 5.3.1). This reduced by 1.82 Nm/Kg on average (Figure 21, page 82, chapter 5.3.1). Such changes were not found in participants with OA (Figure 22, page 83, chapter 5.3.1).

Table 9: Walk task kinetic change for the knee

| Moments (Nm/Kg) | Healthy Participants | | | | OA Participants | | | |
|-----------------|----------------------|-------|-------|---------------|-----------------|--------|-------|---------|
| | MD | L-CI | U-CI | P value | MD | L-CI | U-CI | P value |
| Flexion WA | 0.33 | -1.81 | 2.47 | 0.743 | 1.89 | -7.71 | 11.49 | 0.486 |
| Flexion Mid St | -1.82 | -3.01 | -0.64 | 0.006* | 3.14 | -8.41 | 14.68 | 0.363 |
| Ext T-St | -0.01 | -1.51 | 1.48 | 0.984 | 2.67 | -4.97 | 10.31 | 0.271 |
| Abduction WA | 0.13 | -1.58 | 1.84 | 0.869 | 0.40 | -7.16 | 7.96 | 0.841 |
| Adduction St | 0.46 | -0.85 | 1.77 | 0.461 | 0.36 | -1.04 | 1.75 | 0.385 |
| Abduction T-St | -0.05 | -1.97 | 1.87 | 0.959 | -3.55 | -25.02 | 17.92 | 0.551 |
| Int Rotation St | 0.24 | -0.31 | 0.80 | 0.354 | -0.43 | -1.71 | 0.84 | 0.283 |
| Ext Rotation | 0.11 | -0.50 | 0.72 | 0.698 | 2.73 | -5.14 | 10.60 | 0.274 |

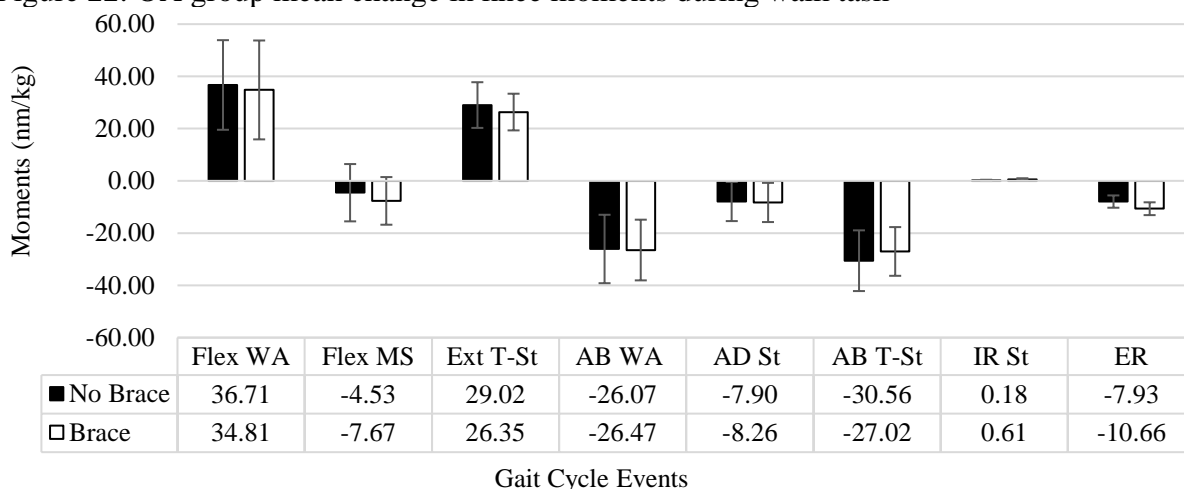
Moments in nanometres per kilogramme (Nm/Kg) normalised to body weight, Mean Difference (MD), Lower (L-CI) and Upper (U-CI) Confidence intervals, P Value of Significance (P), Stance Phase (St), Maximum (Max), Minimum (Min).

Figure 21: Healthy group mean change in knee moments during walk task



Flexion during early stance or weight acceptance (Flex WA), flexion at mid-stance (Flex MS), extension at terminal stance (Ext T-St), abduction at early stance or weight acceptance (AB WA), adduction during stance (AD St), abduction at terminal stance (AB T-St), internal rotation during stance (IR St), external rotation (ER). Significant differences marked with an asterisk (*).

Figure 22: OA group mean change in knee moments during walk task



Flexion during early stance or weight acceptance (Flex WA), flexion at mid-stance (Flex MS), extension at terminal stance (Ext T-St), abduction at early stance or weight acceptance (AB WA), adduction during stance (AD St), abduction at terminal stance (AB T-St), internal rotation during stance (IR St), external rotation (ER).

5.3.2 The Hip:

Sagittal Plane Moments:

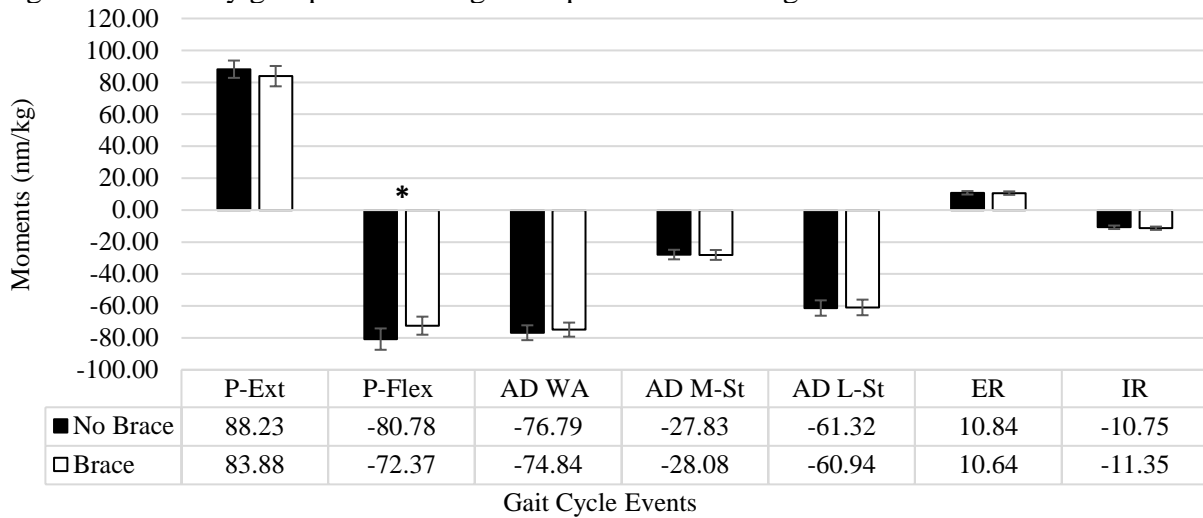
In healthy participants, peak flexion moment at the hip increased by 8.4 Nm/Kg when using the brace (Figure 23, page 84, chapter 5.3.2). This was statistically significant with $p = 0.004$ (Table 10, page 83, chapter 5.3.2). These changes were not found in participants with OA (Figure 24, page 84, chapter 5.3.2).

Table 10: Walk task kinetic change for the hip

| Moments (Nm/Kg) | Healthy Participants | | | | OA Participants | | | |
|-----------------|----------------------|--------|-------|---------------|-----------------|---------|--------|---------|
| | MD | L-CI | U-CI | P value | MD | L-CI | U-CI | P value |
| Peak Extension | 4.35 | -0.24 | 8.94 | 0.061 | 30.85 | -103.07 | 164.77 | 0.426 |
| Peak Flexion | -8.41 | -13.55 | -3.27 | 0.004* | 23.59 | -42.43 | 89.61 | 0.264 |
| Adduction WA | -1.95 | -4.06 | 0.16 | 0.067 | -2.67 | -30.10 | 24.76 | 0.716 |
| Adduction M-St | 0.25 | -2.51 | 3.01 | 0.847 | -1.83 | -18.41 | 14.75 | 0.682 |
| Adduction L-St | -0.38 | -3.00 | 2.24 | 0.758 | -11.93 | -31.89 | 8.03 | 0.124 |
| Ext Rotation | 0.20 | -0.95 | 1.33 | 0.719 | 2.33 | -5.28 | 9.94 | 0.319 |
| Int Rotation | 0.60 | -0.57 | 1.77 | 0.289 | 3.36 | -2.65 | 9.37 | 0.138 |

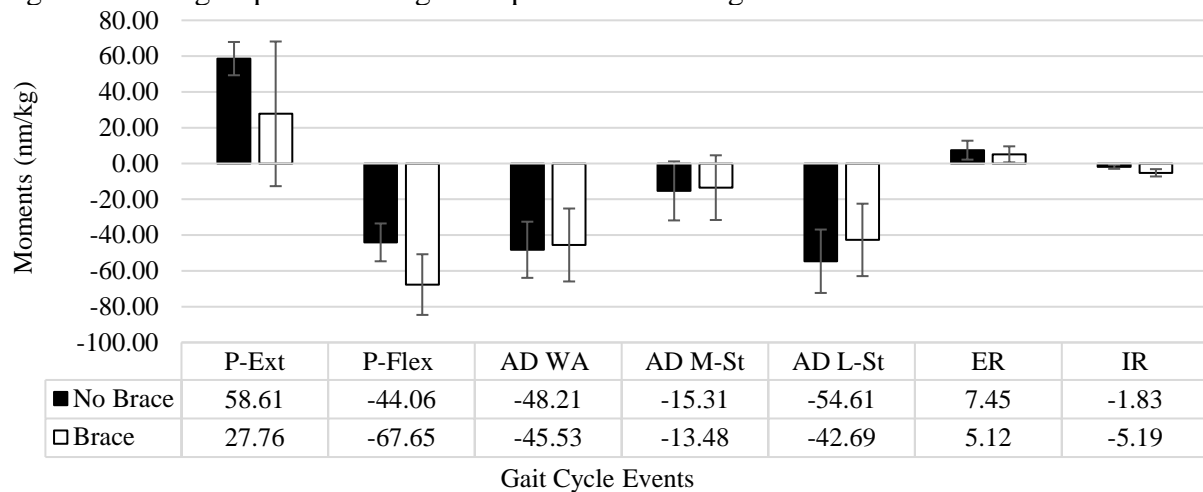
Moments in nanometres per kilogramme (Nm/Kg) normalised to body weight, Mean Difference (MD), Lower (L-CI) and Upper (U-CI) Confidence intervals, P Value of Significance P, Stance Phase (St), Maximum (Max), Minimum (Min). Significant results are marked with an asterisk (*).

Figure 23: Healthy group mean change in hip moments during walk task



Peak extension (P-Ext), peak flexion (P-Flex), adduction at earl stance or weight acceptance (AD WA), adduction at mid stance (AD M-St), adduction at late or terminal stance (Ad L-St), external rotation (ER), internal rotation (IR). Significant differences marked with an asterisk (*).

Figure 24: OA group mean change in hip moments during walk task



Peak extension (P-Ext), peak flexion (P-Flex), adduction at earl stance or weight acceptance (AD WA), adduction at mid stance (AD M-St), adduction at late or terminal stance (Ad L-St), external rotation (ER), internal rotation (IR).

5.3.3 The Ankle:

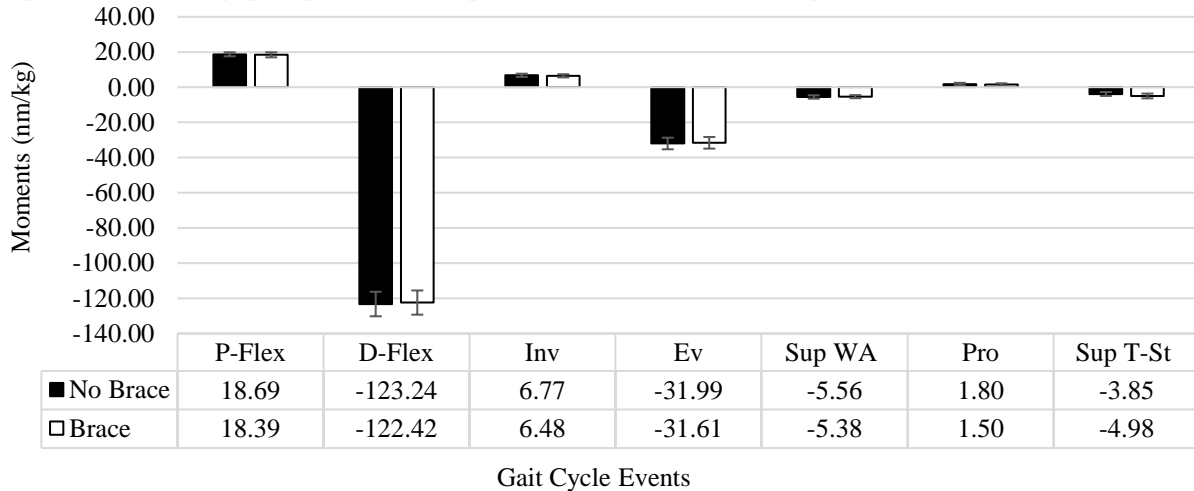
There were no changes in moments at the ankle in any plane for both groups of participants (Table 11, page 85, Figure 25, page 85, and Figure 26, page 85, chapter 5.3.3).

Table 11: Walk task kinetic change for the ankle

| <i>Moments (Nm/Kg)</i> | Healthy Participants | | | | OA Participants | | | |
|------------------------|-----------------------------|-------------|-------------|----------------|------------------------|-------------|-------------|----------------|
| | <i>MD</i> | <i>L-CI</i> | <i>U-CI</i> | <i>P value</i> | <i>MD</i> | <i>L-CI</i> | <i>U-CI</i> | <i>P value</i> |
| <i>Plantarflexion</i> | 0.30 | -0.95 | 1.55 | 0.612 | -19.52 | -112.54 | 73.49 | 0.462 |
| <i>Dorsiflexion</i> | -0.82 | -2.18 | 0.53 | 0.211 | -8.89 | -85.10 | 67.32 | 0.666 |
| <i>Inversion</i> | 0.29 | -0.23 | 0.81 | 0.244 | -2.81 | -10.30 | 4.67 | 0.247 |
| <i>Eversion</i> | -0.38 | -1.15 | 0.39 | 0.304 | 0.28 | -18.77 | 19.33 | 0.955 |
| <i>Supination WA</i> | -0.19 | -0.84 | 0.46 | 0.545 | 2.35 | -17.08 | 21.78 | 0.654 |
| <i>Pronation</i> | 0.29 | -0.44 | 1.03 | 0.399 | 0.94 | -6.74 | 8.61 | 0.652 |
| <i>Supination T-St</i> | 1.13 | -0.36 | 2.63 | 0.124 | 5.94 | -18.90 | 30.78 | 0.412 |

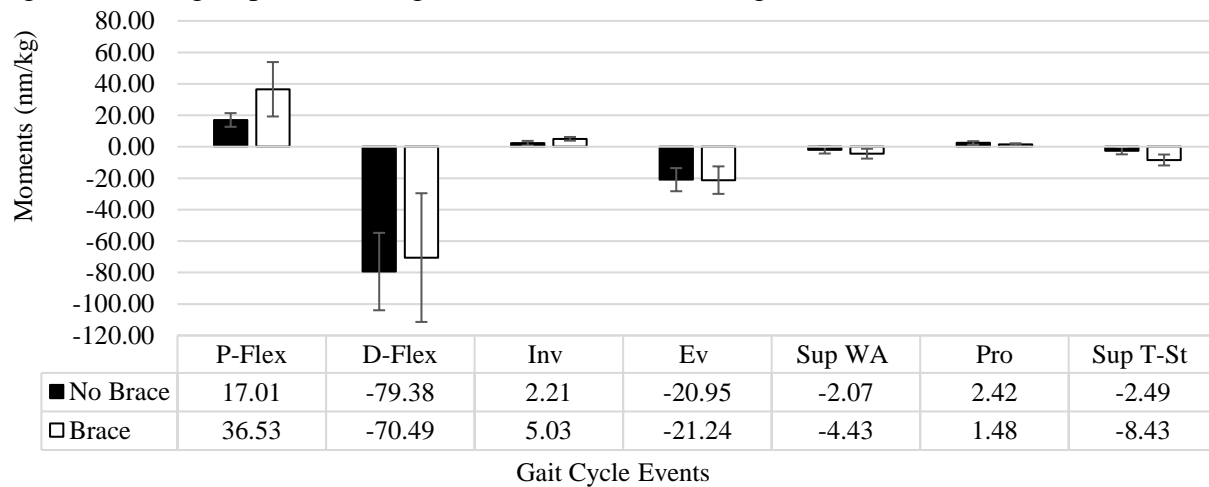
Moments in nanometres per kilogramme (Nm/Kg) normalised to body weight, Mean Difference (MD), Lower (L-CI) and Upper (U-CI) Confidence intervals, P Value of Significance (P), Stance Phase (St), Maximum (Max), Minimum (Min).

Figure 25: Healthy group mean change in ankle moments during walk task



Plantarflexion (P-Flex), dorsiflexion (D-Flex), inversion (In), eversion (Ev), supination at early stance or weight acceptance (Sup WA), pronation (Pro), supination at terminal stance (Sup T-St).

Figure 26: OA group mean change in ankle moments during walk task



Plantarflexion (P-Flex), dorsiflexion (D-Flex), inversion (In), eversion (Ev), supination at early stance or weight acceptance (Sup WA), pronation (Pro), supination at terminal stance (Sup T-St).

5.4 Step Down Task Kinematic Data

5.4.1 The Knee:

Transverse Plane Angles:

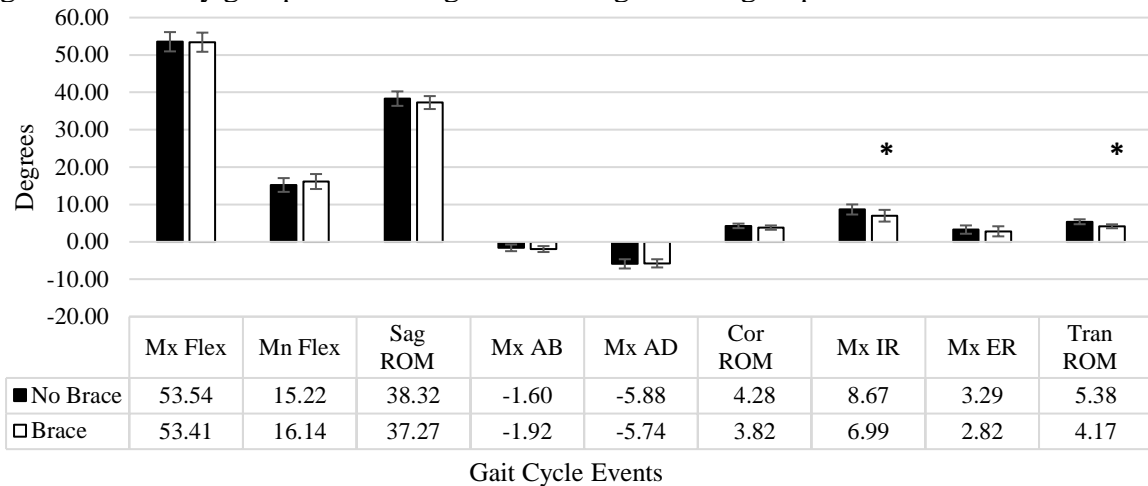
The maximum internal rotation at the knee in healthy participants was reduced by a mean of 1.7 degrees when using the brace (*Figure 27, page 87, chapter 5.4.1*). This was statistically significant ($p = 0.005$) (*Table 12, page 86, chapter 5.4.1*). Such a change was noted experienced by participants with OA (*Figure 28, page 87, chapter 5.4.1*). Changes in the total range of movement with the use of a brace in healthy participants were also significant ($p = 0.001$) (*Table 12, page 86, chapter 5.4.1*). This reduced from mean of 5.4 to a mean of 4.2 degrees when using the brace (*Figure 27, page 87, chapter 5.4.1*).

Table 12: Step down task angular change for the knee

| <i>Angular Change (°)</i> | Healthy Participants | | | | OA Participants | | | |
|---------------------------|-----------------------------|-------------|-------------|----------------|------------------------|-------------|-------------|----------------|
| | <i>MD</i> | <i>L-CI</i> | <i>U-CI</i> | <i>P value</i> | <i>MD</i> | <i>L-CI</i> | <i>U-CI</i> | <i>P value</i> |
| <i>Max Flexion</i> | 0.12 | -1.99 | 2.24 | 0.901 | 1.94 | -4.72 | 8.60 | 0.336 |
| <i>Min Flexion</i> | -0.93 | -3.04 | 1.19 | 0.358 | -0.05 | -1.99 | 1.89 | 0.924 |
| <i>Sagittal ROM</i> | 1.05 | -0.70 | 2.80 | 0.215 | 1.99 | -4.39 | 8.37 | 0.311 |
| <i>Max Abduction</i> | 0.32 | -0.39 | 1.03 | 0.347 | -1.58 | -3.42 | 0.26 | 0.066 |
| <i>Max Adduction</i> | -0.14 | -1.26 | 0.98 | 0.790 | -2.20 | -6.40 | 2.00 | 0.153 |
| <i>Coronal ROM</i> | 0.46 | -0.82 | 1.74 | 0.450 | 0.63 | -2.12 | 3.37 | 0.430 |
| <i>Max Int Rot</i> | 1.68 | 0.63 | 2.73 | 0.005* | 2.63 | -6.41 | 11.67 | 0.337 |
| <i>Max Ext Rot</i> | 0.46 | -0.71 | 1.65 | 0.407 | 1.22 | -6.04 | 8.47 | 0.546 |
| <i>Transverse ROM</i> | 1.21 | 0.65 | 1.78 | 0.001* | 1.42 | -0.99 | 3.82 | 0.127 |

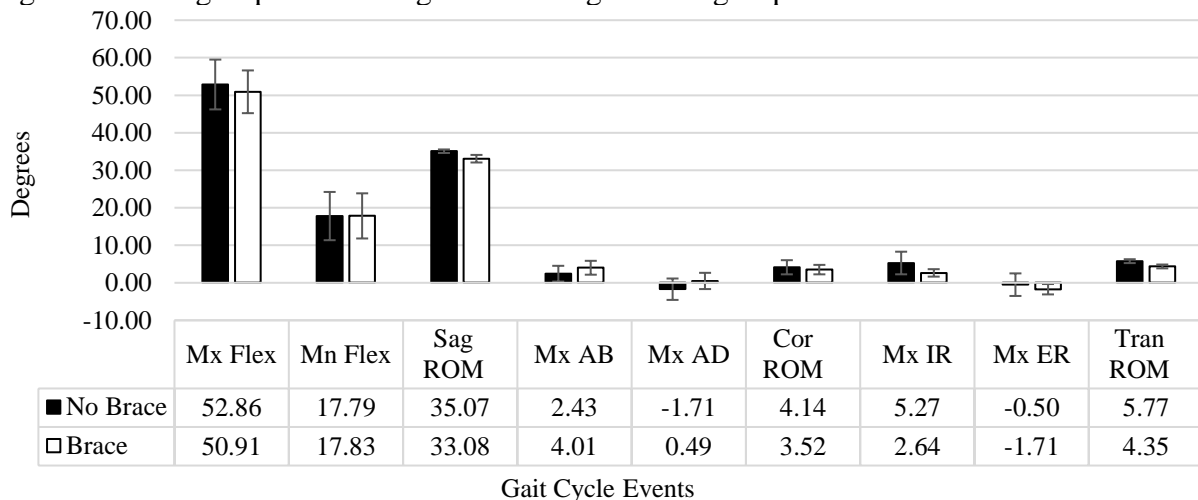
Angular change in degrees (°), Range of Movement ROM, Mean Difference (MD), Lower (L-CI) and Upper (U-CI) Confidence intervals, P Value of Significance (P), Stance Phase (St), Maximum (Max), Minimum (Min), Significant results are marked with an asterisk (*).

Figure 27: Healthy group mean change in knee angles during step task



Maximum flexion (Mx Flex), minimum flexion (Mn Flex), sagittal range of movement (Sag ROM), maximum abduction (Mx AB), maximum adduction (Mx AD), coronal range of movement (Cor ROM), maximum internal rotation (Mx IR), maximum external rotation (Mx ER), transverse range of movement (Tran ROM). Significant differences marked with an asterisk (*).

Figure 28: OA group mean change in knee angles during step task



Maximum flexion (Mx Flex), minimum flexion (Mn Flex), sagittal range of movement (Sag ROM), maximum abduction (Mx AB), maximum adduction (Mx AD), coronal range of movement (Cor ROM), maximum internal rotation (Mx IR), maximum external rotation (Mx ER), transverse range of movement (Tran ROM).

Transverse Plane Angular Velocity:

Significant reductions in angular velocity for transverse range of movement were noted (Table 13, page 88, chapter 5.4.1). This reduced from a mean of 48.8 deg/s without the brace to 42.1 deg/s when using the brace (p = 0.001) (Figure 29, page 88 chapter 5.4.1). There were also significant changes in maximum internal and external rotation angular velocities at

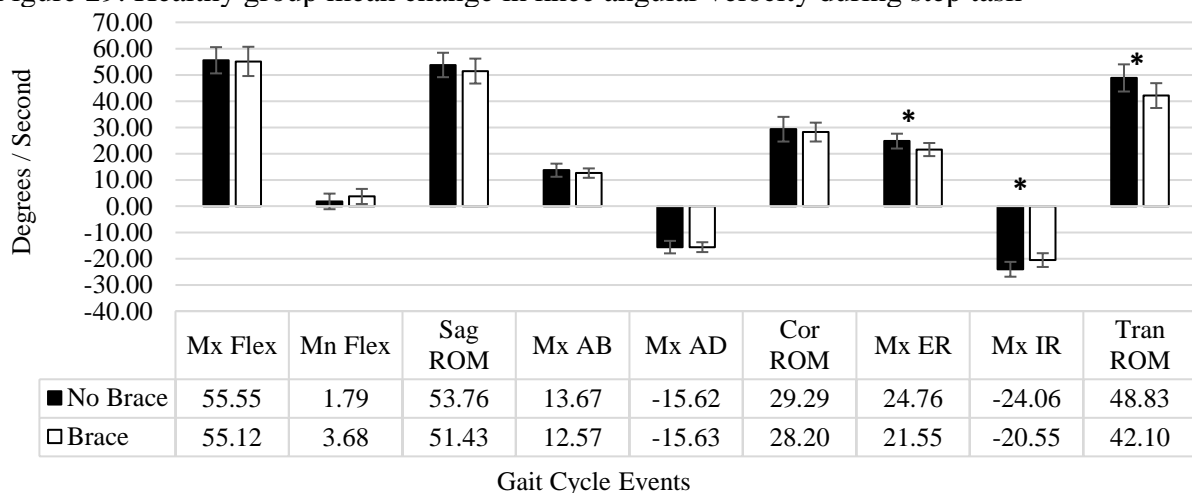
the knee for both healthy participants and participants with OA (Table 13, page 88, chapter 5.4.1). In the healthy group, maximum internal rotation angular velocity was reduced from a mean of 24.8 deg/s without the brace to 21.5 deg/s ($p = 0.006$) (Figure 29, page 88, chapter 5.4.1). In participants with OA, there was a reciprocal drop from a mean of 32.1 deg/s without to 24.5 deg/s with the brace ($p = 0.039$) (Figure 30, page 89, chapter 5.4.1). The maximum external rotation angular velocity was also reduced by 3.6 deg/s when wearing the brace (Figure 30, page 89, chapter 5.4.1).

Table 13: Step down task change in angular velocity for the knee

| Angular Velocity (deg/s) | Healthy Participants | | | | OA Participants | | | |
|-----------------------------|----------------------|-------|-------|---------------|-----------------|--------|-------|---------------|
| | MD | L-CI | U-CI | P value | MD | L-CI | U-CI | P value |
| Max Flexion | 0.44 | -3.87 | 4.74 | 0.830 | -11.03 | -47.20 | 25.14 | 0.320 |
| Min Flexion | -1.89 | -5.82 | 2.03 | 0.314 | -7.24 | -20.54 | 6.05 | 0.144 |
| Sagittal ROM | 2.33 | -3.83 | 8.49 | 0.426 | -3.79 | -48.27 | 40.69 | 0.749 |
| Max Abduction | 1.10 | -2.64 | 4.83 | 0.533 | 4.32 | -1.23 | 9.87 | 0.079 |
| Max Adduction | 0.01 | -2.55 | 2.56 | 0.995 | 1.19 | -15.76 | 18.13 | 0.791 |
| Coronal ROM | 1.09 | -4.52 | 6.71 | 0.679 | 3.13 | -9.21 | 15.47 | 0.389 |
| Max Ext Rotation | 3.21 | 1.12 | 5.31 | 0.006* | 7.62 | 0.95 | 14.30 | 0.039* |
| Max Int Rotation | -3.51 | -6.77 | -0.25 | 0.037* | -3.13 | -10.48 | 4.22 | 0.208 |
| Transverse ROM | 6.72 | 3.22 | 10.22 | 0.001* | 10.76 | -3.18 | 24.69 | 0.080 |

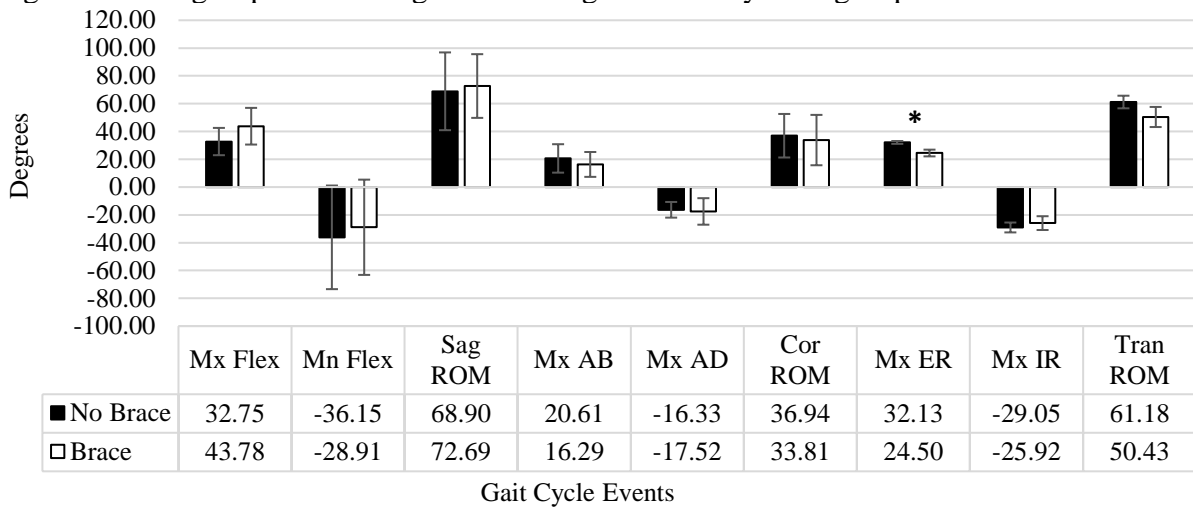
Angular velocity in degrees per second (deg/s), Range of Movement ROM, Mean Difference (MD), Lower (L-CI) and Upper (U-CI) Confidence intervals, P Value of Significance (P), Stance Phase (St), Maximum (Max), Minimum (Min). Significant results are marked with an asterisk (*).

Figure 29: Healthy group mean change in knee angular velocity during step task



Maximum flexion (Mx Flex), minimum flexion (Mn Flex), sagittal range of movement (Sag ROM), maximum abduction (Mx AB), maximum adduction (Mx AD), coronal range of movement (Cor ROM), maximum internal rotation (Mx IR), maximum external rotation (Mx ER), transverse range of movement (Tran ROM). Significant differences marked with an asterisk (*).

Figure 30: OA group mean change in knee angular velocity during step task



Maximum flexion (Mx Flex), minimum flexion (Mn Flex), sagittal range of movement (Sag ROM), maximum abduction (Mx AB), maximum adduction (Mx AD), coronal range of movement (Cor ROM), maximum internal rotation (Mx IR), maximum external rotation (Mx ER), transverse range of movement (Tran ROM). Significant differences marked with an asterisk (*).

5.4.2 The Hip:

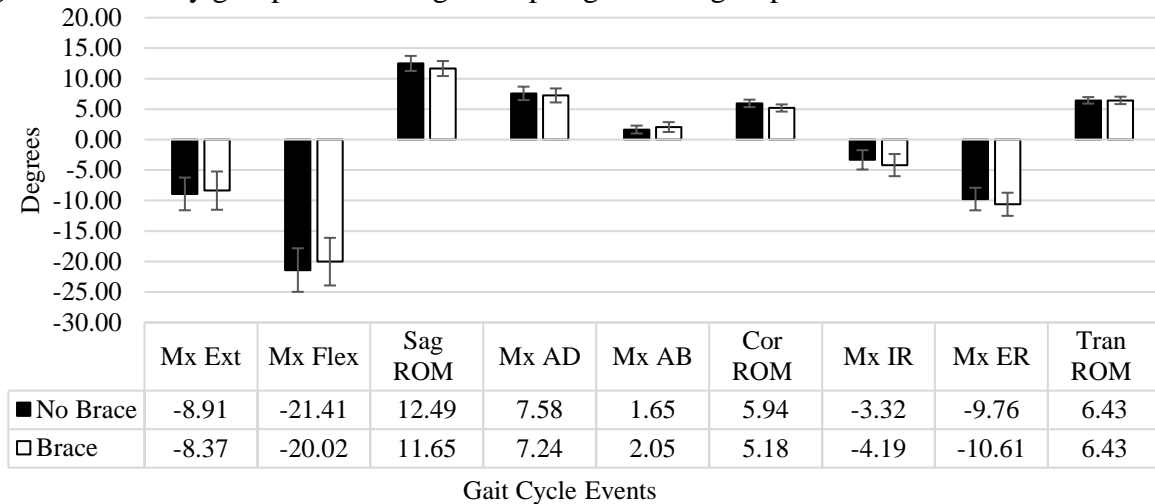
There were no changes in hip angles in any plane with the use of the brace for both groups of participants (Table 14, page 89, Figure 31, page 90 and Figure 32 page 90).

Table 14: Step down task angular change for the hip

| Angular Change (°) | Healthy Participants | | | | OA Participants | | | |
|--------------------|----------------------|-------|------|---------|-----------------|-------|------|---------|
| | MD | L-CI | U-CI | P value | MD | L-CI | U-CI | P value |
| Max Extension | -0.54 | -2.32 | 1.24 | 0.520 | -0.08 | -2.88 | 2.71 | 0.908 |
| Max Flexion | -1.38 | -3.53 | 0.76 | 0.186 | -0.07 | -5.91 | 5.77 | 0.963 |
| Sagittal ROM | 0.84 | -0.60 | 2.29 | 0.229 | -0.01 | -6.11 | 6.08 | 0.993 |
| Max Adduction | 0.34 | -0.52 | 1.21 | 0.403 | -0.03 | -0.44 | 0.39 | 0.787 |
| Max Abduction | -0.41 | -1.05 | 0.23 | 0.187 | -1.39 | -5.73 | 2.95 | 0.302 |
| Coronal ROM | 0.75 | -0.09 | 1.60 | 0.076 | 1.36 | -2.89 | 5.61 | 0.303 |
| Max Int Rotation | 0.87 | -0.48 | 2.21 | 0.186 | -0.58 | -3.62 | 2.47 | 0.502 |
| Max Ext Rotation | 0.86 | -0.55 | 2.26 | 0.207 | -2.34 | -6.93 | 2.25 | 0.160 |
| Transverse ROM | 0.01 | -0.86 | 0.87 | 0.989 | 1.76 | -1.01 | 4.53 | 0.111 |

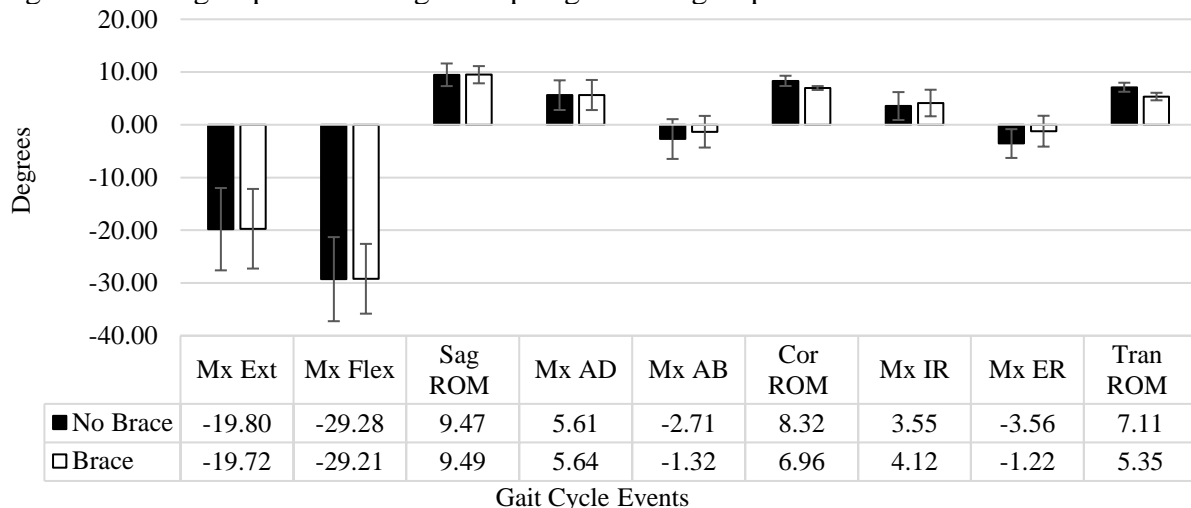
Angular change in degrees (°), Range of Movement (ROM), Mean Difference (MD), Lower (L-CI) and Upper (U-CI) Confidence intervals, P Value of Significance (P), Stance Phase (St), Maximum (Max), Minimum (Min).

Figure 31: Healthy group mean change in hip angles during step task



Maximum extension (Mx Ext), maximum flexion (Mx Flex), sagittal range of movement (Sag ROM), maximum adduction (Mx AD), maximum abduction (Mx AB), coronal range of movement (Cor ROM), maximum internal rotation (Mx IR), maximum external rotation (Mx ER), transverse range of movement (Tran ROM).

Figure 32: OA group mean change in hip angles during step task



Maximum extension (Mx Ext), maximum flexion (Mx Flex), sagittal range of movement (Sag ROM), maximum adduction (Mx AD), maximum abduction (Mx AB), coronal range of movement (Cor ROM), maximum internal rotation (Mx IR), maximum external rotation (Mx ER), transverse range of movement (Tran ROM).

Transverse Plane Angular Velocity:

Maximum internal rotation angular velocity at the hip in healthy participants was significantly reduced ($p = 0.025$) (Table 15, page 91, chapter 5.4.2) from a mean of 32.2

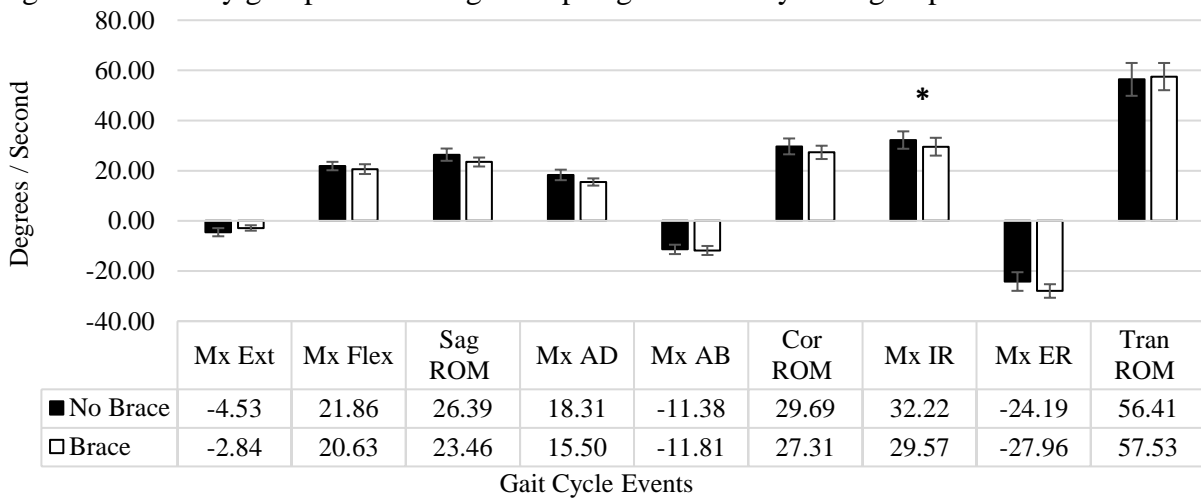
deg/s without the brace to 29.6 deg/s with it (Figure 33, page 91, chapter 5.4.2). Such changes were not seen in participants with OA (Figure 34, page 92, chapter 5.4.2).

Table 15: Step down task change in angular velocity for the hip

| Angular Velocity (deg/s) | Healthy Participants | | | | OA Participants | | | |
|-----------------------------|----------------------|-------|------|---------------|-----------------|--------|-------|---------|
| | MD | L-CI | U-CI | P value | MD | L-CI | U-CI | P value |
| Max Extension | 1.69 | -0.56 | 3.94 | 0.127 | -1.77 | -18.00 | 14.45 | 0.685 |
| Max Flexion | -1.23 | -3.74 | 1.27 | 0.304 | 5.38 | -14.47 | 25.24 | 0.364 |
| Sagittal ROM | 2.92 | -1.21 | 7.06 | 0.149 | -7.15 | -41.95 | 27.64 | 0.470 |
| Max Adduction | 2.82 | -0.17 | 5.81 | 0.063 | 3.85 | -1.72 | 9.42 | 0.097 |
| Max Abduction | 0.43 | -3.00 | 3.86 | 0.789 | -4.16 | -11.92 | 3.62 | 0.148 |
| Coronal ROM | 2.39 | -3.34 | 8.12 | 0.382 | 8.01 | -3.82 | 19.84 | 0.100 |
| Max Int Rotation | 2.65 | 0.40 | 4.90 | 0.025* | 7.63 | -12.07 | 27.34 | 0.238 |
| Max Ext Rotation | 3.77 | -0.70 | 8.25 | 0.091 | -4.43 | -22.93 | 14.08 | 0.411 |
| Transverse ROM | -1.12 | -6.02 | 3.78 | 0.627 | 12.06 | -22.77 | 46.88 | 0.275 |

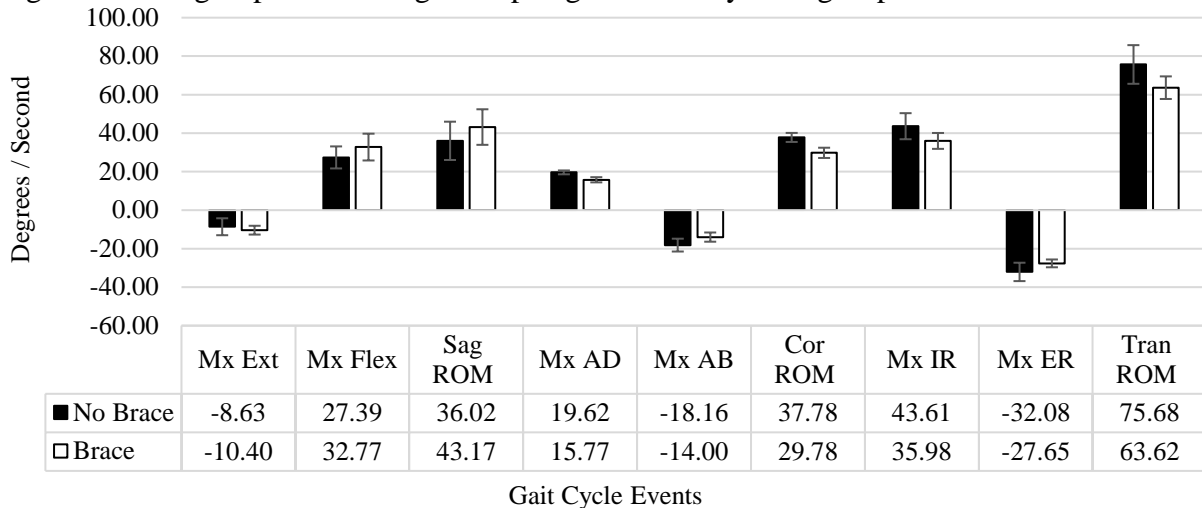
Angular velocity in degrees per second (deg/s), Range of Movement (ROM), Mean Difference (MD), Lower (L-CI) and Upper (U-CI) Confidence intervals, P Value of Significance (P), Maximum (Max), Minimum (Min).

Figure 33: Healthy group mean change in hip angular velocity during step task



Maximum extension (Mx Ext), maximum flexion (Mx Flex), sagittal range of movement (Sag ROM), maximum adduction (Mx AD), maximum abduction (Mx AB), coronal range of movement (Cor ROM), maximum internal rotation (Mx IR), maximum external rotation (Mx ER), transverse range of movement (Tran ROM). Significant differences marked with an asterisk (*).

Figure 34: OA group mean change in hip angular velocity during step task



Maximum extension (Mx Ext), maximum flexion (Mx Flex), sagittal range of movement (Sag ROM), maximum adduction (Mx AD), maximum abduction (Mx AB), coronal range of movement (Cor ROM), maximum internal rotation (Mx IR), maximum external rotation (Mx ER), transverse range of movement (Tran ROM).

5.4.3 The Ankle:

Coronal Plane Angles:

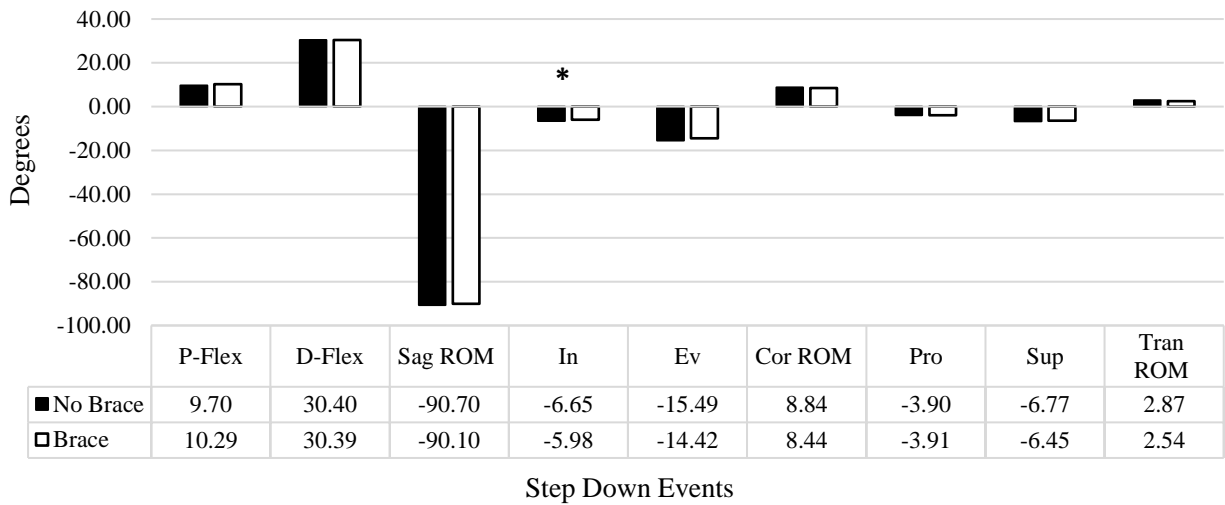
Significant changes were also seen in ankle inversion in healthy participants (Table 16, page 92, chapter 5.4.3). This went to a mean of -5.98 degrees with the brace ($p = 0.049$) from a mean of -6.65 without (Figure 35, page 93, chapter 5.4.3). Such changes were not found in participants with OA (Figure 36, page 93, chapter 5.4.3).

Table 16: Step down task angular change for the ankle

| Angular Change (°) | Healthy Participants | | | | OA Participants | | | |
|--------------------|----------------------|-------|------|---------------|-----------------|-------|------|---------|
| | MD | L-CI | U-CI | P value | MD | L-CI | U-CI | P value |
| Plantarflexion | 0.58 | -0.01 | 1.18 | 0.055 | 1.24 | -4.21 | 6.70 | 0.430 |
| Dorsiflexion | -0.01 | -0.75 | 0.72 | 0.968 | 1.73 | -2.07 | 5.54 | 0.189 |
| Sagittal ROM | 0.60 | -0.37 | 1.57 | 0.205 | -0.49 | -2.53 | 1.55 | 0.409 |
| Inversion | -1.07 | -2.15 | 0.00 | 0.049* | -0.97 | -5.71 | 3.77 | 0.471 |
| Eversion | -0.67 | -2.10 | 0.76 | 0.326 | 1.38 | -6.82 | 9.58 | 0.544 |
| Coronal ROM | 0.40 | -0.75 | 1.56 | 0.463 | 2.35 | -2.30 | 7.00 | 0.161 |
| Pronation | 0.01 | -0.45 | 0.48 | 0.947 | -1.59 | -8.69 | 5.51 | 0.437 |
| Supination | -0.32 | -0.94 | 0.30 | 0.285 | -2.37 | -8.67 | 3.92 | 0.246 |
| Transverse ROM | 0.33 | -0.19 | 0.86 | 0.189 | 0.78 | -2.91 | 4.48 | 0.457 |

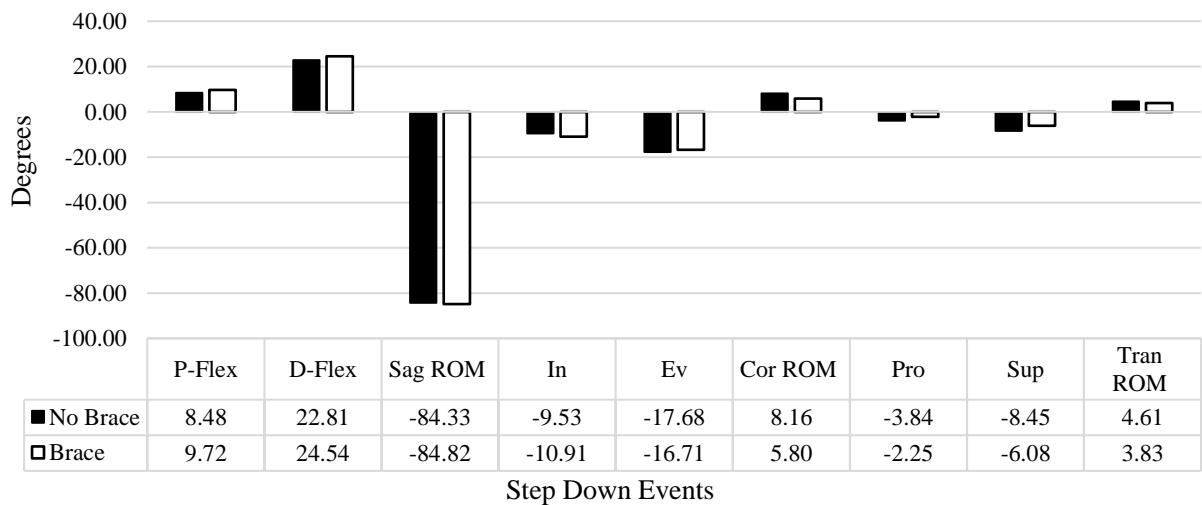
Angular change in degrees (°), Range of Movement (ROM), Mean Difference (MD), Lower (L-CI) and Upper (U-CI) Confidence intervals, P Value of Significance (P), Stance Phase (St), Maximum (Max), Minimum (Min).

Figure 35: Healthy group mean change in ankle angles during step task



Plantarflexion (P-Flex), dorsiflexion (D-Flex), sagittal range of movement (Sag ROM), inversion (In), eversion (Ev), coronal range of movement (Cor ROM), pronation (Pro), supination (Sup), transverse range of movement (Tran ROM). Significant differences marked with an asterisk (*).

Figure 36: OA group mean change in ankle angles during step task



Plantarflexion (P-Flex), dorsiflexion (D-Flex), sagittal range of movement (Sag ROM), inversion (In), eversion (Ev), coronal range of movement (Cor ROM), pronation (Pro), supination (Sup), transverse range of movement (Tran ROM).

Coronal Plane Angular Velocity:

Maximum inversion angular velocity changes significantly with the use of the brace (*Table 17, page 94, chapter 5.4.3*). This reduced by 2.5 deg/s ($p = 0.024$) when wearing the brace in

the healthy participants (Figure 37, page 95 chapter 5.4.3). This was not seen in participants with OA (Figure 38, page 95, chapter 5.4.3).

Transverse Plane Angular Velocity:

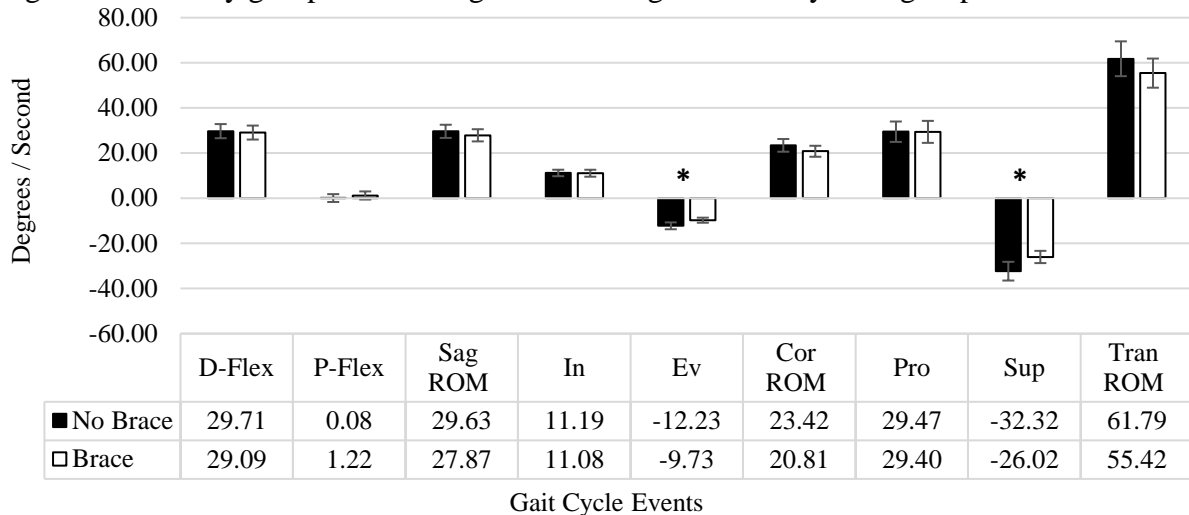
Statistically significant changes in the transverse angular velocities were noted in both healthy participants and participants with OA (Table 17, page 94, chapter 5.4.3). In healthy participants the maximum supination angular velocity increased by 6.3 deg/s when wearing the brace (p = 0.010) (Figure 37, page 95 chapter 5.4.3); while in participants with OA, maximum angular velocity during pronation reduced by 11.9 deg/s when wearing the brace (p = 0.042) (Figure 38, page 95, chapter 5.4.3).

Table 17: Step down task change in angular velocity for the ankle

| <i>Angular Velocity</i> | Healthy Participants | | | | OA Participants | | | |
|-------------------------|-----------------------------|-------------|-------------|----------------|------------------------|-------------|-------------|----------------|
| | <i>MD</i> | <i>L-CI</i> | <i>U-CI</i> | <i>P value</i> | <i>MD</i> | <i>L-CI</i> | <i>U-CI</i> | <i>P value</i> |
| <i>Dorsiflexion</i> | 0.62 | -2.20 | 3.45 | 0.639 | 2.14 | -3.83 | 8.11 | 0.263 |
| <i>Plantarflexion</i> | -1.14 | -2.70 | 0.43 | 0.139 | -13.25 | -44.91 | 18.42 | 0.214 |
| <i>Sagittal ROM</i> | 1.76 | -1.94 | 5.47 | 0.320 | 15.38 | -10.58 | 41.35 | 0.126 |
| <i>Inversion</i> | 0.12 | -1.95 | 2.18 | 0.903 | 1.07 | -16.58 | 18.73 | 0.818 |
| <i>Eversion</i> | -2.50 | -4.60 | -0.40 | 0.024* | -3.64 | -20.00 | 12.72 | 0.440 |
| <i>Coronal ROM</i> | 2.61 | -1.24 | 6.47 | 0.165 | 4.71 | -7.48 | 16.89 | 0.238 |
| <i>Pronation</i> | 0.07 | -4.81 | 4.96 | 0.975 | 11.85 | 1.01 | 22.70 | 0.042* |
| <i>Supination</i> | -6.29 | -10.81 | -1.78 | 0.010* | -6.65 | -34.27 | 20.98 | 0.409 |
| <i>Transverse ROM</i> | 6.37 | -1.64 | 14.37 | 0.109 | 18.50 | -15.12 | 52.12 | 0.142 |

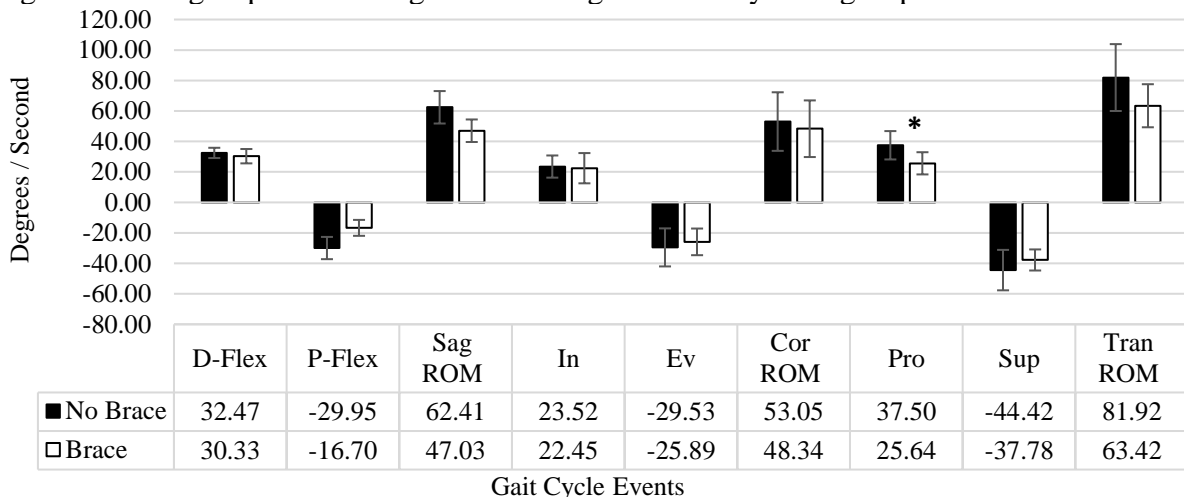
Angular velocity in degrees per second (deg/s), Range of Movement (ROM), Mean Difference (MD), Lower (L-CI) and Upper (U-CI) Confidence intervals, P Value of Significance (P), Stance Phase (St), Maximum (Max), Minimum (Min).

Figure 37: Healthy group mean change in ankle angular velocity during step task



Plantarflexion (P-Flex), dorsiflexion (D-Flex), sagittal range of movement (Sag ROM), inversion (In), eversion (Ev), coronal range of movement (Cor ROM), pronation (Pro), supination (Sup), transverse range of movement (Tran ROM). Significant differences marked with an asterisk (*).

Figure 38: OA group mean change in ankle angular velocity during step task



Plantarflexion (P-Flex), dorsiflexion (D-Flex), sagittal range of movement (Sag ROM), inversion (In), eversion (Ev), coronal range of movement (Cor ROM), pronation (Pro), supination (Sup), transverse range of movement (Tran ROM). Significant differences marked with an asterisk (*). Degrees Second

5.5 Step Down Task Kinetic Data

5.5.1 The Knee:

Sagittal Plane Moments:

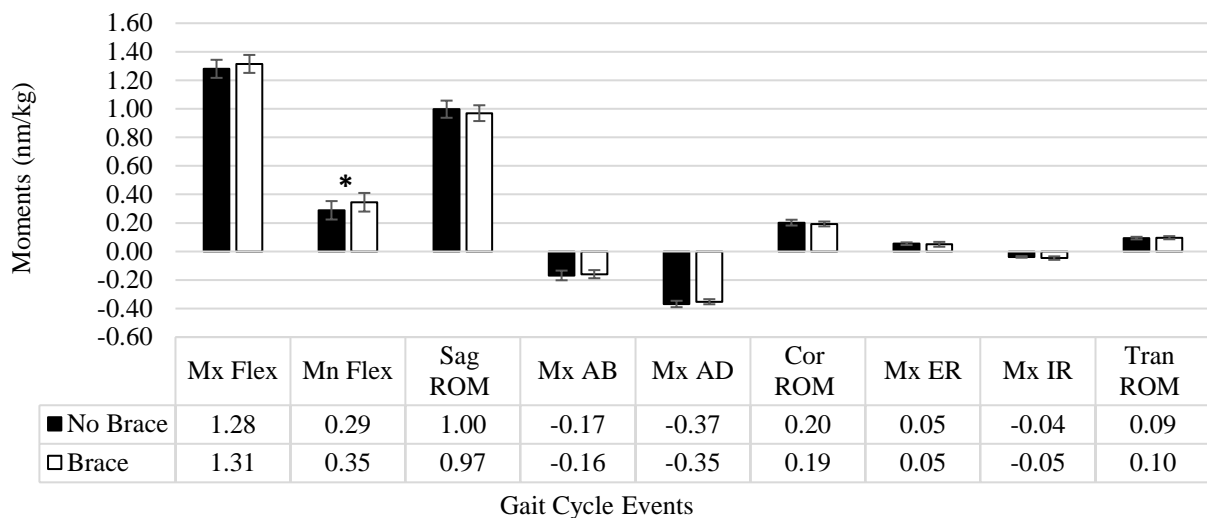
In the healthy participant group, there was a significant increase in the flexion moment at heel strike when wearing the brace (*Table 18, page 96, chapter 5.5.1*). This went from a mean of 0.29 Nm/Kg without a brace, to 0.35 Nm/Kg with the brace ($p = 0.019$) (*Figure 39, page 97, chapter 5.5.1*). No changes in sagittal knee kinetics were noted in participants with OA (*Figure 40, page 97, chapter 5.5.1*).

Table 18: Step down task kinetic change for the knee

| <i>Moments (Nm/Kg)</i> | Healthy Participants | | | | OA Participants | | | |
|-------------------------|-----------------------------|-------------|-------------|----------------|------------------------|-------------|-------------|----------------|
| | <i>MD</i> | <i>L-CI</i> | <i>U-CI</i> | <i>P value</i> | <i>MD</i> | <i>L-CI</i> | <i>U-CI</i> | <i>P value</i> |
| <i>Max Flexion</i> | -0.03 | -0.10 | 0.03 | 0.268 | -0.04 | -0.17 | 0.10 | 0.349 |
| <i>Min Flexion</i> | -0.06 | -0.10 | -0.01 | 0.019* | -0.05 | -0.18 | 0.09 | 0.277 |
| <i>Sagittal ROM</i> | 0.03 | -0.02 | 0.08 | 0.244 | 0.01 | -0.08 | 0.10 | 0.761 |
| <i>Max Abduction</i> | -0.01 | -0.03 | 0.01 | 0.410 | 0.01 | -0.07 | 0.09 | 0.603 |
| <i>Max Adduction</i> | -0.02 | -0.04 | 0.01 | 0.162 | -0.02 | -0.17 | 0.13 | 0.638 |
| <i>Coronal ROM</i> | 0.01 | -0.01 | 0.03 | 0.286 | 0.03 | -0.05 | 0.12 | 0.263 |
| <i>Max Ext Rotation</i> | 0.00 | -0.02 | 0.03 | 0.677 | 0.01 | -0.03 | 0.04 | 0.456 |
| <i>Max Int Rotation</i> | 0.01 | -0.01 | 0.03 | 0.400 | 0.00 | -0.04 | 0.05 | 0.677 |
| <i>Transverse ROM</i> | 0.00 | -0.01 | 0.00 | 0.362 | 0.00 | 0.00 | 0.01 | 0.228 |

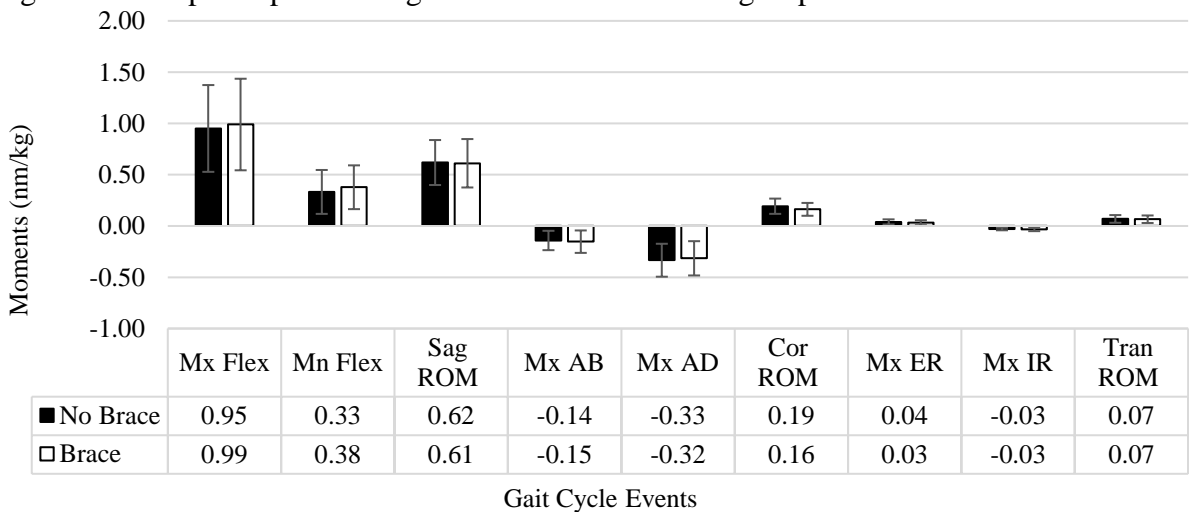
Moments in nanometres per kilogramme (Nm/Kg) normalised to body weight, Range of Movement (ROM), Mean Difference (MD), Lower (L-CI) and Upper (U-CI) Confidence intervals, P Value of Significance (P), Stance Phase (St), Maximum (Max), Minimum (Min).

Figure 39: Healthy participants change in knee moments during step task



Maximum flexion (Mx Flex), minimum flexion (Mn Flex), sagittal range of movement (Sag ROM), maximum abduction (Mx AB), maximum adduction (Mx AD), coronal range of movement (Cor ROM), maximum internal rotation (Mx IR), maximum external rotation (Mx ER), transverse range of movement (Tran ROM). Significant differences marked with an asterisk (*).

Figure 40: OA participants change in knee moments during step task



Maximum flexion (Mx Flex), minimum flexion (Mn Flex), sagittal range of movement (Sag ROM), maximum abduction (Mx AB), maximum adduction (Mx AD), coronal range of movement (Cor ROM), maximum internal rotation (Mx IR), maximum external rotation (Mx ER), transverse range of movement (Tran ROM).

5.5.2 The Hip:

Sagittal Plane Moments:

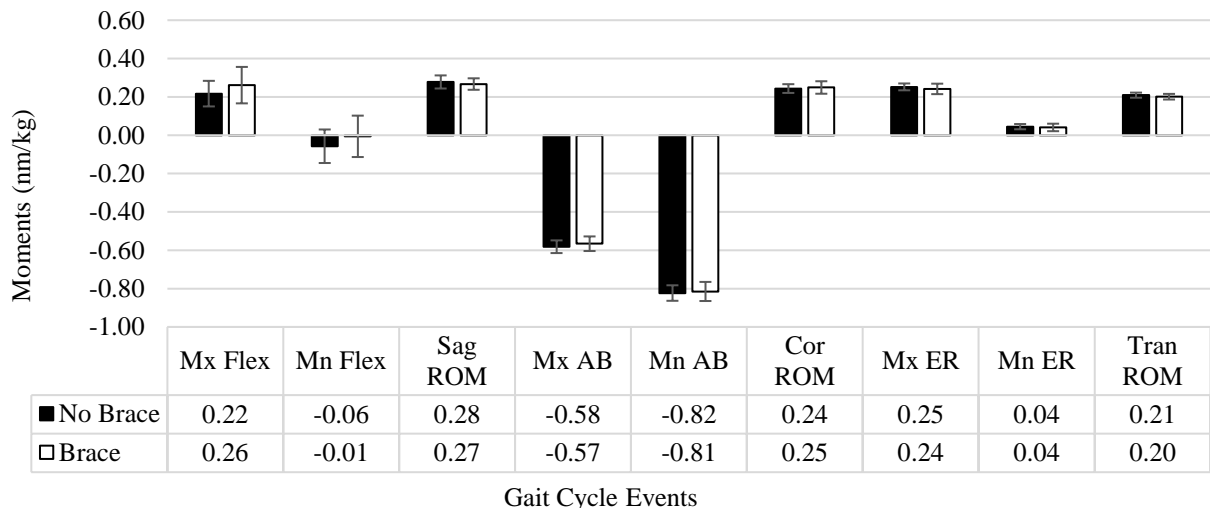
No changes of significance (Table 19, page 98, chapter 5.5.2) were noted in hip kinetics in both healthy participants (Figure 41, page 98, chapter 5.5.2) and participants with OA (Figure 42, page 99, chapter 5.5.2) during the stepdown task.

Table 19: Step down task kinetic change for the hip

| <i>Moments (Nm/Kg)</i> | Healthy Participants | | | | OA Participants | | | |
|-------------------------|-----------------------------|-------------|-------------|----------------|------------------------|-------------|-------------|----------------|
| | <i>MD</i> | <i>L-CI</i> | <i>U-CI</i> | <i>P value</i> | <i>MD</i> | <i>L-CI</i> | <i>U-CI</i> | <i>P value</i> |
| <i>Max Flexion</i> | -0.04 | -0.13 | 0.04 | 0.28 | -0.02 | -0.13 | 0.09 | 0.519 |
| <i>Min Flexion</i> | -0.05 | -0.13 | 0.02 | 0.15 | -0.11 | -0.23 | 0.01 | 0.056 |
| <i>Sagittal ROM</i> | 0.01 | -0.03 | 0.05 | 0.528 | 0.09 | -0.07 | 0.25 | 0.134 |
| <i>Max Abduction</i> | -0.02 | -0.05 | 0.02 | 0.366 | 0.01 | -0.10 | 0.11 | 0.783 |
| <i>Min Abduction</i> | -0.01 | -0.05 | 0.03 | 0.673 | -0.01 | -0.05 | 0.02 | 0.242 |
| <i>Coronal ROM</i> | -0.01 | -0.05 | 0.04 | 0.788 | 0.02 | -0.10 | 0.14 | 0.514 |
| <i>Max Ext Rotation</i> | 0.01 | -0.02 | 0.05 | 0.521 | 0.02 | -0.04 | 0.09 | 0.268 |
| <i>Min Ext Rotation</i> | 0.00 | -0.02 | 0.03 | 0.752 | 0.02 | -0.04 | 0.07 | 0.306 |
| <i>Transverse ROM</i> | 0.01 | -0.01 | 0.02 | 0.311 | 0.01 | -0.01 | 0.02 | 0.207 |

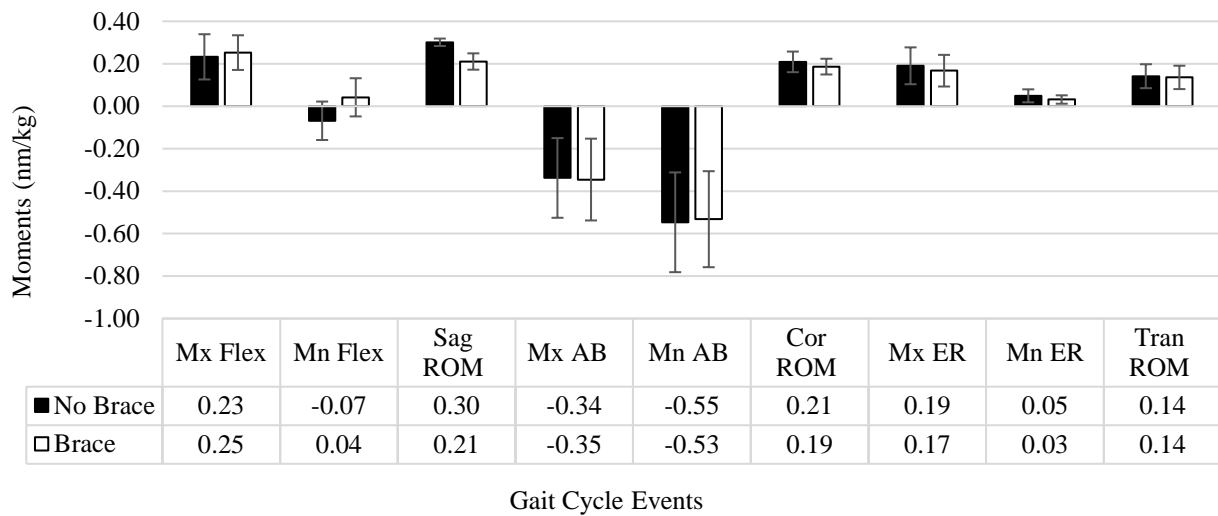
Moments in nanometres per kilogramme (Nm/Kg) normalised to body weight, Range of Movement (ROM), Mean Difference (MD), Lower (L-CI) and Upper (U-CI) Confidence intervals, P Value of Significance (P), Stance Phase (St), Maximum (Max), Minimum (Min).

Figure 41: Healthy participants change in hip moments during step task



Maximum flexion (Mx Flex), minimum flexion (Mn Flex), sagittal range of movement (Sag ROM), maximum abduction (Mx AB), minimum abduction (Mn AB), coronal range of movement (Cor ROM), maximum external rotation (Mx ER), minimum external rotation (Mn ER), transverse range of movement (Tran ROM).

Figure 42: OA participants change in hip moments during step task



Maximum flexion (Mx Flex), minimum flexion (Mn Flex), sagittal range of movement (Sag ROM), maximum abduction (Mx AB), minimum abduction (Mn AB), coronal range of movement (Cor ROM), maximum external rotation (Mx ER), minimum external rotation (Mn ER), transverse range of movement (Tran ROM).

5.5.3 The Ankle:

Sagittal, Coronal & Transverse Plane Moments:

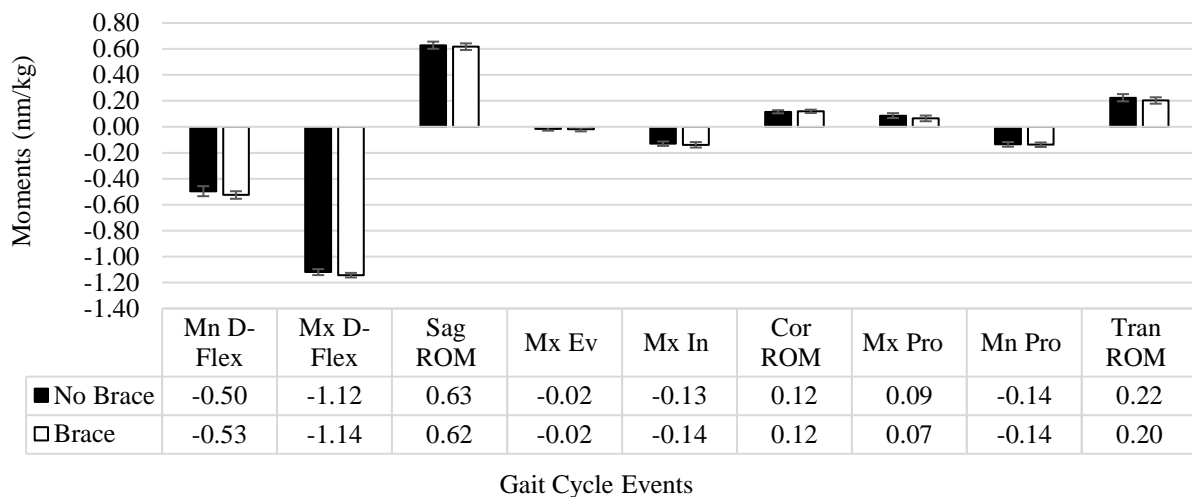
There were no changes in moments at the ankle for both participant groups in any plane based on the paired t-test (*Table 20, page 99, chapter 5.5.3*) and on analysis of mean data (*Figure 43, page 100 and Figure 44, page 100, chapter 5.5.3*).

Table 20: Step down task kinetic change for the ankle

| <i>Moments (Nm/Kg)</i> | Healthy Participants | | | | OA Participants | | | |
|-------------------------|-----------------------------|-------------|-------------|----------------|------------------------|-------------|-------------|----------------|
| | <i>MD</i> | <i>L-CI</i> | <i>U-CI</i> | <i>P value</i> | <i>MD</i> | <i>L-CI</i> | <i>U-CI</i> | <i>P value</i> |
| <i>Min Dorsiflexion</i> | 0.03 | -0.01 | 0.07 | 0.144 | -0.03 | -0.08 | 0.03 | 0.181 |
| <i>Max Dorsiflexion</i> | 0.02 | -0.01 | 0.06 | 0.147 | -0.05 | -0.17 | 0.07 | 0.227 |
| <i>Sagittal ROM</i> | 0.01 | -0.04 | 0.06 | 0.624 | 0.02 | -0.08 | 0.12 | 0.426 |
| <i>Max Eversion</i> | 0.00 | -0.02 | 0.03 | 0.685 | 0.01 | -0.03 | 0.04 | 0.398 |
| <i>Max Inversion</i> | 0.01 | -0.02 | 0.04 | 0.524 | -0.01 | -0.03 | 0.02 | 0.341 |
| <i>Coronal ROM</i> | 0.00 | -0.02 | 0.01 | 0.564 | 0.02 | -0.01 | 0.04 | 0.133 |
| <i>Max Pronation</i> | 0.02 | -0.01 | 0.05 | 0.119 | 0.00 | -0.02 | 0.02 | 0.986 |
| <i>Min Pronation</i> | 0.00 | -0.02 | 0.03 | 0.821 | -0.01 | -0.04 | 0.03 | 0.417 |
| <i>Transverse ROM</i> | 0.02 | -0.01 | 0.05 | 0.133 | 0.01 | -0.03 | 0.05 | 0.483 |

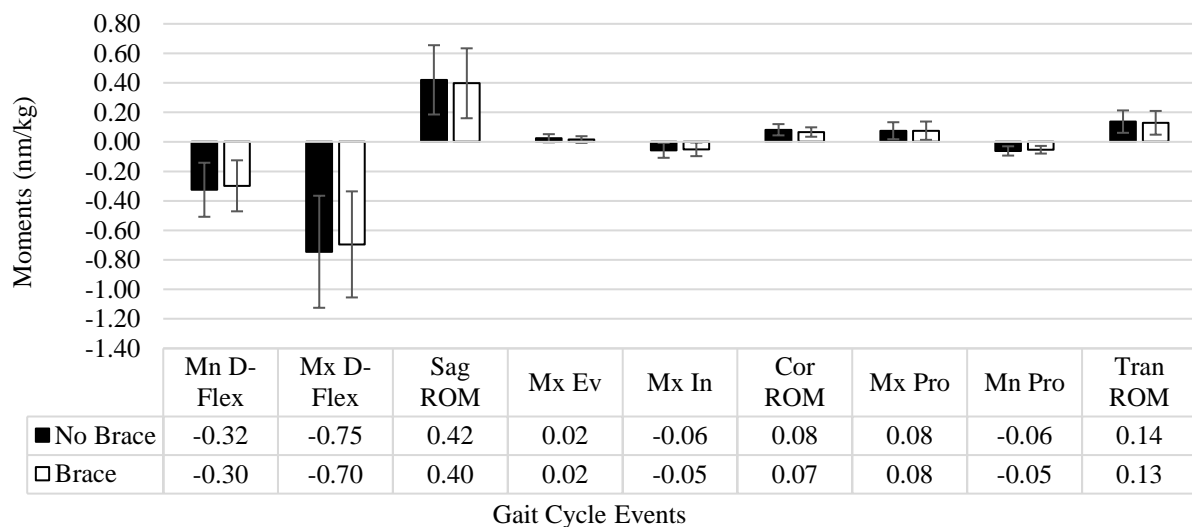
Moments in nanometres per kilogramme (Nm/Kg) normalised to body weight, Range of Movement (ROM), Mean Difference (MD), Lower (L-CI) and Upper (U-CI) Confidence intervals, P Value of Significance (P), Stance Phase (St), Maximum (Max), Minimum (Min).

Figure 43: Healthy participants change in ankle moments during step task



Minimum dorsiflexion (Mn D-Flex), maximum dorsiflexion (Mn D-Flex), sagittal range of movement (Sag ROM), maximum eversion (Mx Ev), maximum inversion (Mx In), coronal range of movement (Cor ROM), maximum pronation (Mx Pro), minimum pronation (Mn Pro), transverse range of movement (Tran ROM).

Figure 44: OA participants change in ankle moments during step task



Minimum dorsiflexion (Mn D-Flex), maximum dorsiflexion (Mn D-Flex), sagittal range of movement (Sag ROM), maximum eversion (Mx Ev), maximum inversion (Mx In), coronal range of movement (Cor ROM), maximum pronation (Mx Pro), minimum pronation (Mn Pro), transverse range of movement (Tran ROM).

5.6 Subjective Opinion of the Brace

Most (84.6%) of healthy and all of the participants with OA gave positive subjective feedback regarding the design and wearability of the brace. Recurrent comments included the low profile of the device, the “stabilising/supporting” qualities and comfort. Negative comments from participants with OA included sensation of pressure over the lateral aspect of the knee joint applied by the valgising unit (N = 2).

5.7 Patient Reported Outcomes Measures

All OA participants demonstrated improvements in KOOS scores at four weeks.

Improvements as demonstrated by an increase in KOOS score occurred across all tested parameters with brace use (*Table 21, page 101, chapter 5.7*) and were on average 85.5% in pain score, 57.6% in symptomology score, 81.2% in activities of daily living, 255.2% for sports and recreation and 127.7% for quality of life.

Table 21: KOOS questionnaire results for participants with OA

| Case | Pain | Sym | ADL | S/R | QOL |
|-----------------|-------------|------------|------------|------------|------------|
| <i>P1-Pre</i> | 55.555 | 71.428 | 67.647 | 35 | 25 |
| <i>Post</i> | 83.333 | 89.286 | 88.235 | 65 | 50 |
| <i>% change</i> | 50 | 25 | 30.4 | 85.7 | 100 |
| <i>P2-Pre</i> | 27.778 | 32.143 | 29.412 | 5 | 12.5 |
| <i>Post</i> | 50 | 50 | 73.529 | 25 | 18.75 |
| <i>% change</i> | 80 | 55.5 | 149.9 | 400 | 50 |
| <i>P3-Pre</i> | 41.667 | 46.428 | 60.294 | 25 | 18.75 |
| <i>Post</i> | 94.444 | 89.286 | 98.529 | 95 | 62.5 |
| <i>% change</i> | 126.6 | 92.3 | 63.4 | 280 | 233.3 |

Knee injury and Osteoarthritis Outcome Score (KOOS), Activities of Daily Living (ADL), Sports and Recreation (S/R), Quality of Life (QOL), Symptoms (Sym), Patient (P).

CHAPTER 6: DISCUSSION

6.1 Introduction

This study achieved its aims of investigating the effects of a non-mechanical (or proprioceptive) knee brace on multiplane kinematic and kinetic variables of the lower limb during walk and stepdown task. It confirmed the experimental hypothesis in some of the tested parameters. There were statistically significant changes in lower limb kinematic and kinetic variables in all tested planes.

6.1.1 Biomechanics:

Neuromuscular control of gait can be ascertained by examining the range and velocity of angular change in multiple planes of movement. In general, a reduction in total range of movement when an identical task is performed is an indication of better control. A reduction in angular velocity also indicates better control but must be analysed in the context of better analgesia.

This study confirms that lower limb biomechanics can be improved by altering proprioception and neuromuscular control with the use of a proprioceptive knee brace. The results demonstrate improved control in all planes at the knee but also an alteration of control strategies around the hip and ankle. Significant biomechanical changes during gait included a reduction in sagittal knee angle at heel strike and peak knee flexion angular velocity with the use of the brace (*Table 4, page 73, chapter 5.2.1*). These results are in keeping with previous research that examined mechanical bracing (Matsuno, Kadowaki et al., 1997; Gaasbeek,

Groen et al., 2007; Jones, Nester et al., 2013). A reduction in both knee angle and angular velocity was noted by Jones et al in their study of a mechanical brace which analysed 28 patients with medial joint OA (Jones et al., 2013). The present study also demonstrated a reduction in knee flexion velocity with a reciprocal increase in knee extension angular velocity in the braced condition. No studies were identified that examined these parameters with the use of a knee brace. The coronal knee angle in healthy participants and participants with OA significantly decreased when wearing the brace (*Table 4, page 73, chapter 5.2.1*). Similar reductions were noted in knee adduction angular velocity during weight acceptance or the early part of stance when wearing the brace. Previous studies have noted that coronal kinematic variables decrease with the use of mechanical braces set in neutral (i.e. not set to valgus of 4, 8 or greater degrees) (Fantini Pagani et al., 2010; Fantini Pagani et al., 2012; Jones et al., 2013). This would indicate a strong proprioceptive mechanism for such change rather than a mechanically fixating or restrictive function. Maximum internal rotation at the knee during stance phase also reduced with the tested brace which is of importance as previous research looking at knee OA bracing has rarely examined changes in the transverse plane. Other studies of mechanical bracing also failed to identify compensatory change in other lower limb joints (Gaasbeek et al., 2007; Laroche et al., 2014). This contrasts with the results of this study which note significant changes at these joints despite no mechanically rotational component to the tested device. A reduction of hip flexion at heel strike and during weight acceptance was noted in the healthy participants (*Table 6, page 77, chapter 5.2.2*). Internal rotation at the hip also increased with the use of the brace as did ankle inversion (*Table 8, page 80, chapter 5.2.3*). The OA reaction brace achieved these significant alterations without mechanical support and confirms the findings of Dessery et al who examined customised mechanical braces (Dessery et al., 2014) and found similar results. Significant changes in kinetics were noted at the hip and knee in healthy participants. These

included reductions of the knee flexion moment at mid-stance and peak flexion moment at the hip during walking in healthy participants (*Table 9, page 82, chapter 5.3.1 and Table 10, page 83, chapter 5.3.2*). These findings appear to reinforce former studies that state significant changes occur in the sagittal plane during normal gait without mechanical input (Richards et al., 2005; Riskowski, 2010).

Important changes that occurred during stepdown task were also noted, including reductions in maximum knee internal rotation, transverse range of movement and transverse angular velocity with the use of the brace (*Table 12, page 86, chapter 5.4.1*). These results confirm the findings of previous research which examined proprioceptive device and found significant changes in transverse plane kinematics (Selfe et al., 2008; Selfe et al., 2011). The maximum internal rotation angular velocity was reduced in both groups at the knee (*Table 13, page 88, chapter 5.4.1*). A recent study by Hanzlíková et al is the only one to examine the effects of a similar brace in three planes of movement (Hanzlikova et al., 2016).

Although overall tasks were very different to those examined in the present study, the slow step-down task did not demonstrate significant changes in transverse velocities. This could be related to brace design or the young age of the participants in their study. Interestingly, this study found no changes coronal plane kinematics which is not in agreement with other reports (Hanzlikova et al., 2016; Selfe et al., 2011). Previous studies have noted significant changes in the sagittal plane kinematics at the knee (Doslikova, 2015) but no changes in other planes during step negotiation with the use of proprioceptive knee bracing. Similarly, to the present study, no changes were noted in sagittal kinematics; however healthy participants showed an increase in the knee flexion moment at heel strike during stepdown. No former studies were identified that examined three lower limb joints during stepdown; however, the present study indicates kinematic variables at the hip and ankle were inconclusive with

regards to improved control. Healthy participants had significant reductions in maximum hip internal rotation angular velocity, maximum ankle plantar flexion and maximum ankle inversion angular velocity; however, there was an increase in ankle inversion and maximum supination angular velocity. Similarly, participants with OA had an increase in the hip flexion moment at heel strike but a reduction in maximum pronation angular velocity.

Other near significant results were seen in the sagittal plane angular velocity at the ankle and during walk task, sagittal plane angular velocity at the knee during walking and sagittal plane angular change at the hip in participants with OA during step-down. The knee flexion angular velocity at toe off in the healthy group showed near statistically significant change with the use of the brace. This slowed from a mean of 369.29 deg/s without the brace to 359.71 deg/s (*Figure 13, page 76, chapter 5.2.1*) when wearing it ($p = 0.056$). Although this could indicate better control at the knee, the reduction could be related to the restrictive nature of the device or the extension spring load in the lateral unit of the brace. Participants with OA demonstrated a near significant increase in the minimum hip flexion during the stepdown task ($p = 0.056$) (*Figure 41, page 98, chapter 5.5.2*). This corresponded to a more pronounced angle of hip flexion at the start of the stepdown task which could represent better control of the lower limb when fully loading on the arthritic limb. Healthy participants showed near significant results in ankle plantar flexion during the stepdown task ($p = 0.055$). (*Figure 35, page 93, chapter 5.4.3*).

6.1.2 Subjective Opinions & KOOS:

The results of this study highlight the importance of the wearability of an orthosis with regards to adherence to its utilisation by patients. Overall participants with OA had a favourable opinion of the brace design; with the low profile and wearability of the braces being key factors in this study. It was also found that OA participants who had previously utilised orthoses were more likely to positively comment on the wearability of the device. Healthy participants also had a favourable opinion regarding comfort but were more likely to comment on the restriction in movement at the knee joint and the sensation of assisted extension produced by the brace. It is known that continued use of knee braces can be low among OA patients and previous publications have highlighted key reasons for this including skin irritation, bad fit and lack of improvements in symptomology (Squyer et al., 2013). Other key factors relating to brace use include perceived social stigma of the brace, bulkiness, practicality and or discomfort especially with larger braces (Dessery et al., 2014; Jones et al., 2013; Moyer et al., 2015). During the testing phase of the present study there were some negative comments from participants with OA which included sensation of pressure over the lateral aspect of the knee joint applied by the hinge unit. However, this could be related to the intentional abandonment of the undersleeve which should usually be worn underneath the brace, so that retroreflective markers could be attached. Participants with OA were given the undersleeve to use as per the manufacturer's intent and no participants repeated these comments at four weeks of follow up.

The issue of aesthetics to patients and improving rates of utilisation and adherence to the orthosis is arguably of great significance for bridging the OA treatment gap, but there is little data on the issue. Jones et al postulated that a discrete orthosis is more attractive to patients (Jones et al., 2013), however the current literature does not investigate this issue in detail. Current data also predominantly looks at the short term effects of bracing of on

average 4 to 6 weeks (Gaasbeek et al., 2007; Pagani et al., 2010; Toriyama et al., 2011); in addition, no studies were found which investigate the period of time required for brace acclimatization, long term use rates, purchase data of over the counter or generic devices and long term self-management with orthoses among OA patients. These factors may all play an important role in adherence to brace use which in turn may important date on symptomology and biomechanics over long periods of use. KOOS scores of OA participants showed significant improvements across all tested parameters. These finding agree with the current literature which notes significant improvements in PROMS across multiple scoring criteria and assessment tools (Divine & Hewett, 2005; Gaasbeek et al., 2007; Hewett et al., 1998; Lindenfeld et al., 1997; Moyer et al., 2014a; Pollo, 1998; Richards et al., 2005).

6.2 The Complexities of Proprioception

Altering neuromuscular control through reinforcement of proprioceptive feedback can lead to changes in biomechanics. Proprioception is intimately linked to movement and has been studied in terms of disease manifestations and management since the 1960's and 1970's (Bossom, 1974). Control of movement can be divided into four components, namely internal signalling or corollary discharge, external signalling in the form of efferent discharge to muscles, non-proprioceptive sensory input and proprioceptive feedback; not all of which have been studied in relation to OA. Internal signals termed corollary discharge are sister signals of the primary motor impulses to muscles, which travel from motor centres to other regions of the brain; i.e. are fully contained within the central nervous system (Sperry., 1950). They are involved in the interpretation of the results of movement and act as a substitute for proprioception when the speed of movement is greater than the time required to receive proprioceptive information (Sperry., 1950). Corollary discharge has not been studied in

relation to OA and it is difficult to speculate on its relationship to the disease. Efferent signalling to muscles is a key component of movement control. Discoordination, weakness and slow reaction times have all been associated with the increase risk of injury but few studies have related this component of movement to chronic disease, and it is unknown if this association occurs before or after disease manifestations (Bennell et al., 2004; Ramsey, Snyder-Mackler et al., 2007; Serrao et al., 2015; Thomas et al., 2010; van der Esch et al., 2014). Non-proprioceptive feedback can be broadly viewed as balance related, namely visual and inner ear senses, which are crucial in terms of limb positioning. Patients afflicted with OA are known to have abnormalities on posturography with balance senses removed (Hinman et al., 2002a; Taglietti et al., 2016). The above represents another feedback loop or continuum and these senses are directly related to proprioceptive feedback (Sziver et al., 2016). Few management strategies have been developed to combat this area in OA. Some studies have found that balance control exercises with an unstable base and quadriceps strengthening can improve postural control and therefore proprioception (Kim, Lee, & Lim., 2016); however, historical treatments such as Tai Chi may provide similar improvements in symptomology (Solloway et al., 2016). Pain is the most debilitating feature in OA and is the primary reason for secondary alterations in gait seen with the disease (Henriksen et al., 2006; Henriksen et al., 2010). Some OA patients are known to have heightened sensitivity to pain (Castagna et al., 2010) and such patients may have a worse clinical picture than patients of lower sensitivities. Higher level brain imaging studies have examined this in relation to fear conditioning and neuromuscular relearning (Kulkarni et al., 2007; Sehlmeier et al., 2009) but this is beyond the scope of this document.

Proprioceptive ability results from a complex regional and systemic interplay of intra, inter and extra-articular sensory components (Riemann, Lephart, 2002; Bottoni, Herten et al.,

2013; Wolf, Cameron et al., 2011; Sanchez-Ramirez, van der Leeden et al., 2013; Zazulak, Hewett et al., 2007; Brandt, 2004) and is closely related to OA. As a disease, OA results in focal and diffuse changes in the joint both of which may contribute to the altered proprioception noted with the disease (Lund, Juul-Kristensen et al., 2008; Shanahan, Wrigley et al., 2014). These changes are noted prior to any evidence of the disease and may be implicated in its development (Tsauo, Cheng et al., 2008). Treatments such as sensory training (Lin, Lin et al., 2009; Smith, King et al., 2012) and muscle re-education (Farrokhi, Voycheck et al., 2013; Reeves, Bowling, 2011; Wu, Tuan, 2005; McQuade, de Oliveira 2011) have been used to improve proprioception in some disease states but have not always been associated with a return to improved limb control (Ferreira, Robinson et al., 2015; Chang, Lee et al., 2014). The idea that the application of externally applied devices could achieve change in movement has developed over recent years with the concept of proprioceptive bracing. Few studies considered this in terms of disease management until the 2000's with the explosion in the number of research studies pertaining to bracing in MSK medicine and in particular OA. Previous research looked at the effects of externally applied devices such as taping methods, sleeves and braces on a variety of diseased states, but most did not speculate on the reasons underlying and connecting the changes in proprioception and neuromuscular control. Externally applied devices are likely to influence cutaneous and superficial subcutaneous components of proprioception but the mechanism by which this relates to symptom and movement control are poorly understood. There is strong evidence that sensory feedback from around the affected joint can be reinforced by externally applied devices with resultant improvements in symptomology (Divine & Hewett, 2005; Gaasbeek et al., 2007; Hewett et al., 1998; Lindenfeld et al., 1997; Moyer et al., 2014a; Pollo, 1998; Richards et al., 2005). However, the current literature examines the use of proprioceptive

braces predominantly aimed at patellofemoral pain syndrome (Selfe et al., 2011; Sinclair et al., 2016) and ACL injuries (Hanzlikova et al., 2016) but not OA.

Those that have examined OA arrive at some solid conclusions regarding the potential of such devices. It is clear for example that bracing improves PROMS, with the majority of studies highlighting clear improvements in pain scores, quality of life measures and various other response parameters. Improvements in biomechanics with the use of bracing is hypothesised to occur because of both mechanical and proprioceptive support (Collins, Blackburn et al., 2014; Brouwer, Jakma et al., 2005; Birmingham, Kramer et al., 1998; Chuang, Huang et al., 2007; Pajareya, Chadchavalpanichaya et al., 2003; Bryk, Jesus et al., 2011; Schween, Gehring et al., 2015). Mechanical correction and resultant changes in biomechanics are believed to be related to brace size and are proportional to the pre-set degrees of correction. This proportional change in kinetics and kinematics about the knee is confirmed by novel studies such as that by Kutzner et al (2011). They undertook an in vivo analysis of two braces (MOSGenu, Bauerfeind AG and the Genu Arthro, Otto Bock HealthCare) by inserting a telemeterized tibial component as part of a knee prosthesis to gather interarticular data and found significant differences in braced and non-braced conditions, the amount of valgus correction and between the two braces (Kutzner et al., 2011). The MOSGenu brace reduced both peaks of medial force in proportion to the amount of valgus correction; while the results were less pronounced for the GenuOrtho brace (Kutzner et al., 2011). The challenge is ascertaining how much of the return to optimal biomechanics is down to the influence of proprioception.

Such changes may be attributed to improved confidence, a reduction in kinesophobia, mental or psychological reassurance of stability, placebo type effect (Richards, Sanchez-Ballester et al., 2005) or a true proprioceptive and neuromuscular response (Tengman et al., 2014; Thijs et al., 2010). The evidence for an organic change in control secondary to proprioception is solid but has been obtained from studies which examine other non-mechanical devices such as sleeves (Hassan, Mockett et al., 2001; Hassan, Mockett et al., 2002; Birmingham, Kramer et al., 2001; Collins, Blackburn et al., 2011a). For example, the application of cutaneous stimuli in the form of taping around the knee results in changes in the regional neuronal response as well as changes within the central nervous system as noted on higher level neuronal imaging (Callaghan et al., 2012). The relationship of proprioceptive change to proprioceptive acuity and clinical/biomechanical change is investigated heterogeneously in the current data; with some studies examining changes by the detection of movement during passive joint position and others assessing active motion sense where an attempt is made at reproducing a given joint angle (Bottoni, Herten et al., 2013). There is debate as to which method is more accurate in detecting changes in proprioception as mechanoreceptors are more susceptible to changes in movement (Bottoni, Herten et al., 2013). The underlying mechanism by which bracing alters sensation is unknown but it has been suggested that there could be a response related to the mechanical restriction created by the brace which would suggest stimulation of deeper proprioceptive structures in and around the joint itself, or a response related to the weight applied by the brace (Jones, Nester et al., 2013). Deeper structures such as those within or immediately adjacent to the joint would be more difficult to examine but could play significant role in this regard. It is known for example that the menisci are highly proprioceptive structures (Karahan et al., 2010; Magyar, Knoll, & Kiss, 2012) and an increase in joint pressure as a result of wearing brace could influence feedback. Studies have examined such an increase in pressure in at other lower limb joints and noted

that improvements in proprioceptive acuity could be achieved, particularly when proprioceptive ability was already diminished (You, Granata, & Bunker, 2004). This then raises the question as to why lighter or mechanically inferior devices also have a significant effect. Others have postulated that repeated stimulation of sensory and mechanoreceptors resulting from a loosely applied device could be an underlying factor (Hassan, Mockett et al., 2002). This would not however explain the improvements seen with the use of taping which is adherent to the skin (Anandkumar et al., 2014; Cho et al., 2015; Hinman et al., 2003; Richette et al., 2008). However, some studies strengthen this concept. For example, Edin et al. undertook a study which noted that “confusing” the slowly adapting mechanoreceptors found in the skin by the application of a polydirectional stimulation such as that experienced with a brace could result in increased activation rates and thus heightened proprioception (Edin, 2001). Possible changes in the behaviour of proprioceptive mechanism in relation to limb movement and phases of gait have also been offered as contributing factors (Bottoni, Herten et al., 2013).

There is strong evidence that alterations in biomechanics resulting in a restoration of optimal gait or a protective gait strategy, can be achieved with the use of mechanical devices and other externally applied devices which lack a mechanical frame and are thus proprioceptive. Mechanical braces have been heavily studied and produce changes including an increase in the velocity of gait, cadence and larger stride length (Draper, Cable et al., 2000; Laroche, Morisset et al., 2014; Fantini Pagani, Potthast et al., 2010; Jones, Nester et al., 2013; Toriyama, Deie et al., 2011; Johnson, Starr et al., 2013). Mechanical braces are also effective at counteracting the EKAM and are known to reduce the varus angle and medial joint load (Fantini Pagani et al., 2010; Gaasbeek et al., 2007; Laroche et al., 2014; Pagani et al., 2010). The changes are far from conclusive however and even less clear when proprioceptive braces

are to be used. It is known that OA results in global alterations of movement at the trunk, hip and ankle (McMahon., Block. et al., 2003; Shakoor., Hurwitz. et al., 2003; Wang, Kuo et al., 1990), however few previous studies have examined the effects of a knee brace on secondary gait parameters at the hip, ankle or other areas such as the trunk. One such study was by Dessery et al who looked at the effects of a several braces including a custom brace with an external rotation function. They noted a reduction in internal rotation of the knee and ankle, as well as increased external rotation at the hip when examining the non-rotating brace while the rotating brace resulted in the opposite (Dessery, Belzile et al., 2014).

6.3 Future Research & Recommendations

6.3.1 Clinical Relevance:

Research into the effects of proprioceptive bracing is required clinically due to the poor rates of use seen with mechanical braces and is made urgent by the projected demographic changes of OA. Various treatments have been tried to bridge the treatment gap with little success. Simple measures such as community education initiatives and distribution of walking aids have been shown to improve emotional outlook and function (Busija et al., 2013) but such initiatives would likely be less attractive to young, active patients. Minor surgery in the form of arthroscopy may be an effective tool for diagnosis but not for treatment due to the progressive nature of the disease. As such there is great potential for bracing and other externally applied devices as an option for bridging this deficit. The results of this study show that proprioceptive bracing, which lacks focal points of pressure and the bulkiness of mechanical devices, can improve symptomology and mechanics. This indicates an inherent advantage of proprioceptive over mechanical braces as there is the possibility of abandoning factors that diminish patient utilisation such as pain and skin reaction (Squyer et al., 2013) and therefore improving adherence to the treatment while still preserving beneficial clinical changes. There is however a lack of consensus on the utilisation of orthoses for knee OA, which could in part be related to nomenclature. Although knee bracing has recently been classified into mechanical and proprioceptive in terms of mechanism of action, and while some have attempted to classify bracing in terms of design (Ramsey et al., 2007; Segal., 2012), an area of contention that emerges on reviewing current publications is what constitutes a brace.

The majority of investigated devices fall within the mechanical brace category which could be described as a joint spanning device containing a rigid framework which is continuous and provides a three point or rigid fixation mechanism. The current literature does not make the distinction, but mechanical braces can be split between those with a large lever and a small lever arm (*Figure 45, page 116, chapter 6.3.1*). It has not been examined previously but it could be hypothesised that braces with a larger lever arm have a greater mechanical effect, would be more likely to alter biomechanics at adjacent lower limb joints and could influence proprioception to a greater degree given their larger surface area. A further subcategory of mechanical brace exists which involves active components that generally function in the transverse plane (internal and external rotators) further adding to difficulties with correct labelling (Dessery, Belzile et al., 2014). In addition, some OA braces of various designs encompass or capture the patella via a large anterior perforation; which could alter overall patella alignment, tracking and the duration of contact at the patellofemoral joint (*Figure 45, page 116, chapter 6.3.1*). The result of this could be changes in mechanics as a result of altering the pull of the quadriceps, changes in neuromuscular control and changes in the clinical picture in patients with significant patellofemoral OA. The data on proprioceptive knee bracing is less clear especially in terms of what constitutes a brace. Some studies for example label knee sleeves as braces when no mechanical structure is involved in the makeup of the device (Sinclair et al., 2016; Vincent, 2016), while others are classed as simple sleeves despite the presence of rigid structures within the unit that may or may not exert a mechanical effect (Mortaza et al., 2012). Reasons for this lack of clarity could be that the field is at its infancy with regards to the widespread clinical use of bracing, or it could be that there is a lack of consistency with the nomenclature leading to a mislabelling of devices in the current published data. A firm classification system pertaining to knee orthoses which is more precise in its definition of externally applied devices and resultant research into each specific

category of device would help stem the confusion pertaining to knee bracing in the medical community and better usage rates.



Figure 45: Externally applied device used for the management of knee OA. Kinesio taping (A)³, Genustrain 7 Sleeve, Bauerfeind Ag, Germany (B)⁴, Reaction Web Brace, Donjoy Global USA (C)⁵, OA Reaction Web Brace, Donjoy Global USA (D)⁶, Unloader One Brace, Ossur, Iceland (E)⁷, Genu Arthro Brace, Otto bock, Germany (F)⁸.

In addition to difficulties with nomenclature, data pertaining to bracing is highly variable in terms of study design, disease state, participant selection, data representation and analysis.

Some studies involve healthy participants (Ebert et al., 2014; Fantini Pagani et al., 2010;

Larsen et al., 2013), others look at varied degrees of OA ranging from low grade and asymptomatic OA (Della Croce et al., 2013), moderate grade (Arazpour et al., 2013; Johnson et al., 2013; Jones et al., 2013), high grade OA (Ornetti et al., 2015) and the full spectrum of the disease (Duivenvoorden et al., 2015; Schmalz et al., 2010; van Raaij et al., 2010). Even fewer, highly experimental studies examine the biomechanical effects of bracing on cadavers (Engel et al., 2015) and artificial implanted joints (Kutzner, Kuther et al., 2011).

Heterogeneity also exists in the types of braces tested, some studies examine the effects of

³ mcdavidusa.com/product-type/sportmed/kinesiology-tape-athletic-tape, accessed 12/2016

⁴ otg-handel.de/downloads/produkte/bfd-bandagen.pdf, accessed 12/2016

⁵ djoglobal.com/products/donjoy/reaction-web-knee-brace, accessed 12/2016

⁶ djoglobal.com/our-brands/donjoy/oa-reaction, accessed 12/2016

⁷ ossur.com/oa-solutions/oa-products/oa-knee/custom-oa-braces/unloader-one-custom, accessed 12/2016

⁸ ottobock.com/media/local-media/sonstiges/klinische-forschung/genu-arthro-study-summaries.pdf, accessed 12/2016

custom made braces (Arazpour et al., 2013; Birmingham et al., 2001; Draper et al., 2000; Larsen et al., 2013; Pollo et al., 2002), while others examine over the counter or generic devices (Anderson et al., 2003; Brouwer et al., 2006; Dennis & Komistek, 1999; Katsuragawa et al., 1999; Komistek et al., 1999; Matsuno et al., 1997; Richards et al., 2005) but do not speculate on whether or not this variable influences mechanics. These variables make it extremely difficult for the clinician to arrive at a conclusion for or against bracing in knee OA and makes prescribing braces for OA patients difficult to justify. As a result, even though outcomes of previous studies into externally applied devices show significant changes in many parameters such as PROMS and spatiotemporal variables, they cannot be extrapolated as a whole to justify changes in clinical practice.

6.3.2 Coupling Disease to Device Subtype:

Another shortfall in the current literature is that no studies have attempted to match brace subset to disease state and a discussion is much needed on what type of externally applied device is better suited for the individual based on the clinical and radiographic severity of OA. An attempt at matching the devices to disease states is demonstrated in the table below (*Table 22, page 118, chapter 6.3.1*). It could be hypothesised that that simple proprioceptive devices such as taping and sleeves would be a means of prophylaxis against OA by heightening proprioceptive feedback which may be lacking or diminished in some individuals. This could be applied in combination with centralised proprioceptive retraining and targeted muscle strengthening exercises in high risk individuals. Proprioceptive bracing, which would need by definition to include some form of rigid framework but lacking a mechanically active or three-point fixative structure to be classed as a brace, could be a means of treating lower grade or less symptomatic OA. Although it has a rudimentary valgising component, the OA Reaction Web Brace lacks the classic three-point fixation or

rigid encompassing frame seen in more traditional unloading braces and is therefore predominately proprioceptive in nature (*Figure 46, page 118, chapter 6.3.1*). The lateral unit is also spring-loaded to extension meaning this brace could represent the future of proprioceptive devices which actively assist in movement based on a specific deficiency.



Figure 46: Lateral unit (*) of the Donjoy OA Reaction Web Brace

It would seem logical that larger devices which employ a mechanically active structure with or without the three-point fixation system, could be utilised in patients with higher grade OA anatomical changes, high BMI and in those patients on the natural decline to surgery. Future research in the form of larger, randomised trials should aim answer this question by comparing the various types of externally applied device to the clinical grade of disease with the aim of fostering a desire for wider clinical implementation.

Finally, it is important at this stage to consider the cautionary aspects of bracing both mechanical and proprioceptive. Although there is great potential for bracing to aid in bridging the treatment gap there is a risk that without proper coupling of brace subset to disease stage bracing may lead to a worsening of the disease. The long term consequences of improving spatiotemporal gait parameters and encouraging increased loading in patients with OA are

poorly understood in terms of how they might relate to disease progression. An increase in walking speed for example may imply a reduction in OA symptomology, however increased step length, cadence, and speed are all associated with increasing overall load through the joint (de David, Carpes, & Stefanyshyn, 2015; Schwameder, Lindenhofer, & Muller, 2005). Bracing can alter the axial load to the degree that an increase of as little as 5% in speed could lead to a 3% increase in joint load, which could be of great significance in the context of increased steps taken in daily life (Kutzner, Kuther et al., 2011). In addition to improving speed, bracing can lead to an increased push anterior propulsive or push off force (Richards, Sanchez-Ballester et al., 2005) which is also important to consider in terms of chronicity.

Table 22: Author's classification of externally applied devices and indications for use:

| Device | Mode of Action | Examples (studies) | Applications |
|---|---|---|---|
| Passive Tape | reinforcing proprioception | Neutral taping (9) | reconditioning, injury prevention |
| Active Tape | applied with uni or poly-directional force to alter movement and reinforce proprioception | Kinesiology tape (10) | reconditioning, injury prevention, early onset low grade OA in young/healthy |
| Passive Sleeve | joint spanning device which lacks any rigid framework | Neoprene sleeve (11) | reconditioning, injury prevention, early onset low grade OA in young/healthy and older but healthy age group. |
| Active Sleeve | joint spanning without rigid framework but with uni or polydirectional force and or restriction | Genustrain 7 brace (12) | reconditioning, injury prevention, early onset low grade OA in young/healthy and older but healthy age group. |
| Passive Proprioceptive Brace | joint spanning device containing a rigid framework or component but lacking a continuous frame or three-point fixation mechanism | NEOMESH brace (13) | Early / moderate OA |
| Active Proprioceptive braces | joint spanning device containing a rigid framework or component, lacking a continuous frame which contains intrinsic moving parts | Donjoy OA reaction web brace (examined in this study) | Early / moderate OA with known or suspected movement deficiency |
| Passive Mechanical Brace, Small Lever Arm | joint spanning device containing a rigid framework which is continuous and provides a three point or rigid fixation mechanism | Ossur unloader one brace (14) | Moderate / severe OA. |
| Passive Mechanical Brace, Large Lever Arm | joint spanning device containing a rigid framework which is continuous and provides a three point or rigid fixation mechanism. | Genu Arthro brace (15) | Moderate / severe OA other mechanical factors (structural or neuromotor disease) |
| Active Mechanical Braces | joint spanning device containing a rigid framework which is continuous and contains intrinsic moving parts. | VER brace (16) | Moderate / severe OA & other mechanical factors (structural or neuromotor disease, high BMI etc) |

Please note that these studies are not all biomechanical in nature and employ a variety of outcome criteria. Braces can be generic or custom made.

⁹ Generic, multiple companies (Hinman, Crossley et al. 2003)

¹⁰ Generic, multiple companies (Warden, Hinman et al. 2008; Richette, Sautreuil et al. 2008)

¹¹ Generic, multiple companies (Chuang, Huang et al. 2007)

¹² Bauerfeind Ag, Zeulenroda-Triebes, Germany (Schween, Gehring et al. 2015)

¹³ Tenortho srl, Biassono, Italy (Marchini, Lauermaun et al. 2014)

¹⁴ Reykjavik, Iceland (Toriyama, Deie et al. 2011)

¹⁵ Otto Bock, Duderstadt, Germany (Schmalz, Knopf et al. 2010; Kutzner, Kuther et al. 2011)

¹⁶ Orthoconcept Inc, Laval, Quebec, Canada (Dessery, Belzile et al. 2014)

6.3.3 Study Limitations:

There are several limitations to this study which warrant discussion. The subjective feedback received from participants regarding wearability of the brace was collected by word of mouth rather than by any objective method such as questionnaire use. There have been no other studies which examine the subjective opinion of bracing among participants and a standardised questionnaire could not be found. However, it would have been possible to fashion such a questionnaire to improve the validity of such data.

Equipment limitations include the stepdown block used for this study which was 10cm in height. A smaller step requires less neuromuscular control to execute than larger steps however, step size is arguably related to participant's height, where taller participants would find executing a 10cm step less demanding than participants who are shorter in stature. It would have been more accurate to couple the height of the step with participant height to create similar moment potential across the knee for all participants.

This study also lacks analysis of muscle function which is of profound importance in OA given that proprioception is coupled to neuromuscular control. Although the original study protocol sought to examine electromyographic data during both tasks, this was abandoned due to technical difficulties with instrumentation. Muscle "dysfunction" is one of the leading pathogenic factors in knee OA and its morbidity (Reid et al., 2015; van Baar et al., 1998). The relationship between muscle activity, strength and proprioception to disease pathogenesis has not been fully studied and further research is needed in this area. Nagai et al (2013)

examined knee joint stability by assessing kinematics, strength and proprioception in 50 healthy males and concluded that individuals with better preconception had greater strength and better kinematics (Nagai et al., 2013). Similarly, Van der Esch et al (2008) undertook a non-biomechanical study which examined similar knee joint control in 63 OA patients but found no association between muscle strength, proprioceptive acuity and joint control.

The quadriceps mechanism is the most important muscle group involved in knee joint function and stability (Childs et al., 2004; Fitzgerald et al., 2004; Hurley, Rees, & Newham, 1998). It is the quadriceps pre-activation potential that decelerates the limb and reduces the force of impact at heel strike thereby cushioning ambulation and reducing the risk of OA (Hinman et al., 2002b). Indeed, its weakness results in increased loads across the knee and may directly increase OA risk (Mikesky, Meyer, & Thompson, 2000). Altered proprioception has been linked to suboptimal muscle behaviours (Chang et al., 2014; Pai et al., 1997; Sharma et al., 1997). Joint control is heavily dependent on the ratio of medial to lateral and agonist to antagonist muscle activation or co-contraction (Ebert et al., 2014; Hinman et al., 2005; Sirin & Patla, 1987). Mills et al (2013) conducted a review neuromuscular alterations in knee OA and found increased lateral muscle co-contraction regardless of disease severity, laxity and malalignment. Sharma et al studied the relationship of quadriceps strength to OA progression in 200 patients, concluding that a strong quadriceps may only be protective with an intact tension compression matrix and normal alignment (Sharma et al., 2003). Proprioception is intimately involved when ligament laxity because of bone attrition and cartilage loss leads to loss of tension and subsequent compensatory muscle activation (Lewek, Rudolph, & Snyder-Mackler, 2004). Re-enforcing sensory feedback from around a joint and allowing an endogenous mechanism to lead mechanical change, could

mean that proprioceptive bracing offers a certain degree of protection from this form of deterioration and this should be investigated in future research.

A final critique of this study is the sample size as there were only 13 test subjects in the healthy group of participants. A power calculation was not performed at the beginning of this study due to its exploratory nature. Non-probability sampling methods were used as the most convenient method of participant recruitment was by obtaining a convenience sample of 13 participants from the university staff and student body, and via the snowballing effect of the study. Although a figure of 13 participants is low, previous research has concluded with statistically significant results after examining similar numbers (Richards, Sanchez-Ballester et al., 2005; Selfe, Thewlis et al., 2011).

CHAPTER 7: CONCLUSION

To conclude, this study investigated the effects of a proprioceptive knee brace in healthy participants and in participants with OA. The results confirm findings from previous research that PROMS can be significantly improved with the use of proprioceptive knee bracing and that the wearability of the brace is an important factor in brace design and patient utilisation. The results showed significant positive changes in kinematic and kinetic variables in healthy participants in the coronal, sagittal and transverse planes of movement at the knee which have a secondary effect on other weight bearing joints leading to altered strategies of limb control. Although the number of OA participants was small, changes at multiple joints were also found in this group indicating potential for the use of such devices in managing disease.

The review of current literature demonstrated lack of consensus on the utilisation of externally applied devices for the management of OA. Most studies pertaining to knee bracing involved mechanical bracing but were highly heterogeneous in study design and methodology, making it difficult for the clinician to implement in practice. The literature did not demonstrate any previous studies which examined a proprioceptive brace in patients with OA, however several studies have previously investigated non-mechanical bracing in patients with other disease processes and found significant results which correlated with improvements in symptomology and limb control.

In addition to further highlighting the importance of multiplane and multi-joint analysis in biomechanical studies, the present study has added to the growing body of evidence which supports the concept of neuromuscular reinforcement and re-education through proprioceptive bracing as an alternative to mechanical correction. This holds great potential

with regards to offering newer and more patient friendly treatment modalities for the management of OA given the rapidly changing demography. Future studies should aim to couple the mechanism of action of a brace with the clinical grade of OA which could improve consensus rates and eventually prescription rates among health care workers involved with treating patients suffering with the disease.

CHAPTER 8: REFERENCES

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CHAPTER 9: APPENDICES

9.1 Ethics Approval Form:



| |
|---|
| UNIVERSITY OF CENTRAL LANCASHIRE Ethics Committee Application Form |
|---|

PLEASE NOTE THAT ONLY ELECTRONIC SUBMISSION IS ACCEPTED

This application form is to be used to seek approval from one of the three University Ethics Committees (BAHSS; PSYSOC & STEMH). Where this document refers to ‘Ethics Committee’ this denotes BAHSS; PSYSOC & STEMH (see Appendix 1 for list of Schools associated with each ethics committee). These Ethics Committees deal with all staff and postgraduate research student project. Taught (undergraduate and MSc dissertation projects) will normally be dealt with via School process / committee.

If you are unsure whether your activity requires ethical approval please complete an UCLAN Ethics Checklist. If the proposed activity involves animals, you should not use this form. Please contact the Research Development and Support Team within Research & Innovation Office – roffice@UCLAN.ac.uk – for further details.

Please read the Guidance Notes before completing the form. Please provide all information requested and justify where appropriate. Use as much space as you need – the sections expand as you type. Click on box or circle to select relevant option (e.g. type or Yes/No) and click on ‘grey oblong shape’ to start typing for the free text entry questions. Each question on this form has instructions on how to answer that particular question. In addition links to relevant documents (e.g. templates, examples, etc.) and further guidelines are available in the Guidance Notes which can also be access from the question by clicking on appropriate question number. It is the applicant’s responsibility to ensure that an English translation of any supporting documentation is a faithful translation of the copy being used with participants.

Your application needs to be filled in electronically and emailed to roffice@UCLAN.ac.uk. Please insert in the subject line of your email the acronym of the committee that needs to deal with your application. Committee acronyms are BAHSS, PSYSOC or STEMH – see Appendix 1, at the back of this form, for list of Schools associated with each ethics committee.

PLEASE NOTE – ethical approval can be granted in **phases**. If you have a project that is likely to evolve, or has subsequent phases determined by initial results – you can apply for Phase One approval, and then come back for Phases Two, Three or even more as your research progresses.

If this application relates to an activity which has previously been approved by one of the UCLAN Ethics Committees, please supply the corresponding reference number(s) from your decision letter(s).

| |
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Section 1**DETAILS OF PROJECT****All applicants must complete Section**

| | | |
|--|--|---|
| 1.1 Project Type: | | |
| <input type="checkbox"/> Staff Research | <input checked="" type="checkbox"/> Master by Research | <input type="checkbox"/> Taught MSc/MA Research |
| <input checked="" type="checkbox"/> Commercial Project | <input type="checkbox"/> MPhil Research | <input type="checkbox"/> Undergrad Research |
| | <input type="checkbox"/> PhD Research | <input type="checkbox"/> Internship |
| | <input type="checkbox"/> Professional Doctorate | |
| 1.2 Principal Investigator: | | |
| Name | School | Email |
| Dr Ambreen Chohan | Sport, Tourism & the Outdoors (AHRC, SENS & CASES) | AChohan@UCLAN.ac.uk |
| 1.3 Other Researchers / Student: | | |
| Name | School | Email |
| Dr Tariq Kwaees | Sport, Tourism & The Outdoors (AHRU, SENS & CASES) | TAKwaees@UCLAN.ac.uk |
| Professor Jim Richards | Sport, Tourism & The Outdoors (AHRU, SENS & CASES) | JRichards@UCLAN.ac.uk |
| Gillian Rawlinson | Sport, Tourism & The Outdoors (AHRU, SENS & CASES) | gawlinson@UCLAN.ac.uk |
| 1.4 Project Title: | | |
| <i>Please provide your project title. If your project title has both a short and long title, please enter your short title here.</i> | | |
| Exploring the effects of a proprioceptive knee brace for osteoarthritis in healthy individuals. | | |
| 1.5 Anticipated Start Date: | | |
| 08/06/2015 | | |
| 1.6 Anticipated End Date: | | |
| 01/01/2016 | | |
| 1.7 Is this project in receipt of any external funding (including donations of samples, equipment etc.)? | | |
| <input checked="" type="radio"/> Yes <input type="radio"/> No | | |
| This project also forms part of the Research and Development contract with DJO. Findings of this data are publishable and constitute independent research. The company provide samples for testing however research is independent in nature. The research student is not in any way funded by the company. | | |
| 1.8 Project Description (in lay's terms) including the aim(s) and justification of the project (max 300 words) | | |
| <i>Give a brief summary of the background, purpose and the possible benefits of the investigation. This should include a statement on the academic rationale, context of the activity and justification for conducting the project.</i> | | |
| Modification of moments about joints is by far the most common method of direct orthotic management. Knee braces are varied and aimed to support and/or control the movement of one or more planes of movement of different joints. The use of knee orthoses to correct and to support moments about joints is one of the most common uses of direct orthotic management. The aims of knee valgus braces are to “unload the painful compartment, through bending moments applied proximally and distally to the knee joint, and reducing the varus deformity” (Pollo 1998). Several studies have been conducted into the use of valgus knee braces for medial compartment osteoarthritis (OA) and have reported that patients experience significant pain relief and an | | |

improvement in physical function (Hewett et al 1998, Kirkley et al 1999, Lindenfeld et al 1997, Matsumo et al 1997, Richards et al 2005) and also a reduction in medial compartment load (Pollo et al 2002, Richards 2006). Valgus OA braces may be grouped into two types, double sided and single sided, however some single sided braces have been shown to slip round the leg making them less effective (Richards et al 2005).

Recent work by the team at UCLAN with Queens University in Kingston, Canada have discovered that the effect of such braces is not just mechanical but also proprioceptive. This study will investigate the effects of a new proprioceptive knee brace designed to offer a low profile conservative management tool for individuals with mild to moderate medial compartment OA, using a group of healthy participants.

1.9 Methodology Please be specific

Provide an outline of the proposed method, include details of sample numbers, source of samples, type of data collected, equipment required and any modifications thereof, etc.

See attached Protocol (Appendix 1)

1.10 Has the quality of the activity been assessed? (select all that apply)

- Independent external review
- Internal review (e.g. involving colleagues, academic supervisor, School Board)
- Through Research Degrees Sub-Committee (BAHSS, STEM or SWESH)
- None
- Other

If other please give details **RPA Approved March 2015**

1.11 Please provide details as to the storage and protection for your data for the next 5 years
– as per UCLAN requirements

Movement analysis data will be recorded on University computers. All data will be coded and no names will be able to be associated with any data recorded to ensure the confidentiality of the participants, and enable the researcher analysing the data to be blinded to the conditions. All data will be pooled as a population so that no individual's data is presented alone.

All hard copies of consent forms will be stored separately from any other data. These will be stored in a locked filing cabinet at all times, only the research team will have access to these. All electronic data will be stored for a minimum of 5 years following the completion of the study, after this it will be destroyed.

All movement data will be anonymous. Due to the nature of the system, no identifiable video footage is collected, subjects will be coded following the collection of the data all files will be encrypted.

1.12 How is it intended the results of the study will be reported and disseminated?
(select all that apply)

- Peer reviewed journal
- Internal report
- Conference presentation
- Other publication
- Written feedback to research participants
- Presentation to participants or relevant community groups
- Dissertation/Thesis
- Other

If other, please give details Independent report

| | |
|--|--|
| <p>1.13 Will the activity involve any external organisation for which separate and specific ethics clearance is required (e.g. NHS; school; any criminal justice agencies including the Police, Crown Prosecution Service, Prison Service, Probation Service or successor organisation)?</p> | |
| <p><input type="radio"/> Yes <input type="radio"/> No</p> | |
| <p>If Yes, please provided details of the external organisation / ethics committee and attached letter of approval NB – external ethical approval must be obtained before submitting to UCLAN ethics.</p> | |
| <p>n/a</p> | |
| <p>1.14 The nature of this project is most appropriately described as research involving:-(more than one may apply)</p> | |
| <p><input type="checkbox"/> Behavioural observation</p> <p><input type="checkbox"/> Self-report questionnaire(s)</p> <p><input type="checkbox"/> Interview(s)</p> <p><input type="checkbox"/> Qualitative methodologies (e.g. focus groups)</p> <p><input type="checkbox"/> Psychological experiments</p> <p><input type="checkbox"/> Epidemiological studies</p> <p><input type="checkbox"/> Data linkage studies</p> <p><input type="checkbox"/> Psychiatric or clinical psychology studies</p> <p><input type="checkbox"/> Human physiological investigation(s)</p> <p><input checked="" type="checkbox"/> Biomechanical devices(s)</p> <p><input type="checkbox"/> Human tissue</p> <p><input type="checkbox"/> Human genetic analysis</p> <p><input type="checkbox"/> A clinical trial of drug(s) or device(s)</p> <p><input type="checkbox"/> Lab-based experiment</p> <p><input type="checkbox"/> Archaeological excavation/fieldwork</p> <p><input type="checkbox"/> Re-analysis of archaeological finds/ancient artefacts</p> <p><input type="checkbox"/> Human remains analysis</p> <p><input type="checkbox"/> Other (please specific in the box below)</p> | |
| <p>If ‘Other’ please provide details</p> | |

Please read all the following questions carefully and if you respond ‘Yes’ then you should provide all relevant details and documentation (including risk assessments), and justify where appropriate.

Section 2: HUMAN PARTICIPANTS, DATA OR MATERIAL

| | |
|---|---|
| <p>2.1 Are you using human participants (including use of their data), tissues or remains?</p> <p>(please select the appropriate box)</p> | |
| <p><input checked="" type="checkbox"/> Participants [proceed to question 2.2]</p> <p><input type="checkbox"/> Data [proceed to question 2.20]</p> | <p>Click here for Q2.20</p> |

| | |
|--|---|
| <input type="checkbox"/> Tissues / Fluids / DNA Samples [proceed to question 2.20] <input type="checkbox"/> Remains [proceed to question 2.24] <input type="checkbox"/> No [proceed to Section 3] | Click here for Q2.24 Click here for Section 3 |
| 2.2 Will the participants be from any of the following groups: (tick as many as applicable) | |
| <input checked="" type="checkbox"/> Students or staff of this University <input type="checkbox"/> Children/legal minors (anyone under the age of 18 years) <input type="checkbox"/> Patients or clients of professionals <input type="checkbox"/> Those with learning disability <input type="checkbox"/> Those who are unconscious, severely ill, or have a terminal illness <input type="checkbox"/> Those in emergency situations <input type="checkbox"/> Those with mental illness (particularly if detained under Mental Health Legislation) <input type="checkbox"/> People with dementia <input type="checkbox"/> Prisoners <input type="checkbox"/> Young Offenders <input type="checkbox"/> Adults who are unable to consent for themselves <input type="checkbox"/> Any other person whose capacity to consent may be compromised <input type="checkbox"/> A member of an organisation where another individual may also need to give consent <input type="checkbox"/> Those who could be considered to have a particularly dependent relationship with the investigator, e.g. those in care homes, medical students <input type="checkbox"/> Other vulnerable groups (please list) | |
| 2.2a Justify their inclusion | |
| <i>Ethical approval covers all participants but particular attention must be given to vulnerable participants. Therefore you need to fully justify their inclusion and give details of extra steps taken to assure their protection. Where the 'Other vulnerable groups' box has been selected, please also describe/list.</i> | |
| Individuals with knee osteoarthritis are often provided with knee bracing, though proprioceptive bracing is a new emerging concept in osteoarthritis management. It is hence important for us to be able to see what biomechanical change occurs in healthy individuals, using the staff/student population. | |
| 2.2b Is a DBS – Disclosure and Barring Service (formerly CRB – Criminal Records Bureau) check required? | |
| <i>Certain activities and/or groups of individuals require DBS (formerly CRB) clearance.</i> | |
| <input type="radio"/> Yes <input checked="" type="radio"/> No | |
| If Yes, please advise status of DBS clearance (e.g. gained; in process; etc) | |
| n/a | |
| 2.3 Please indicate exactly how participants in the study will be (i) identified, (ii) approached and (iii) recruited? | |
| See appendix 2 | |
| 2.4 Will consent be sought from the participants and how will this be obtained? | |
| Written informed consent (Appendix 3) | |
| 2.5 What information will be provided at recruitment and briefing to ensure that consent is | |

| |
|---|
| informed? |
| N.B. if an information sheet is being used, please attach <i>Give details of any particular steps to provide information and justify where an information sheet is not being used.</i> |
| Participant information sheet (Appendix 4) |
| 2.6 How long will the participants have to decide whether to take part in the research? |
| <i>Indicate whether this is days or weeks and if less than 24 hours please justify.</i> |
| At least 24 hours. |
| 2.7 What arrangements have been made for participants who might not adequately understand verbal explanations or written information given in English, or who have special communication needs? |
| In this study we unfortunately do not have additional resources for translation, however we will consult international office and any University translation services where possible to widen participation as required. |
| 2.8 Payment or incentives: Do you propose to pay or reward participants? |
| <input type="radio"/> Yes <input type="radio"/> No NO |
| 2.9 Does the activity involve conducting a survey, interviews, questionnaire, observational study, experiment, focus group or other research protocol? |
| <input type="radio"/> Yes <input checked="" type="radio"/> No |
| If Yes, please provide details and attach copy of what you will be using <i>Give details of the specific procedures/activities being used and indicate where documentation (i.e. questionnaire or agendas) will be developed as part of the project. Also include what is the experience of those administering the procedures</i> |
| |
| 2.10 Will deception of the participant be necessary during the activity? |
| <input type="radio"/> Yes <input checked="" type="radio"/> No |
| If Yes, please provide justification <i>Gives details of the deception and explain why the deception is necessary.</i> |
| |
| 2.11 Does the activity (e.g. Art) aim to shock or offend? |
| <input type="radio"/> Yes <input checked="" type="radio"/> No |
| If yes, please explain <i>Give details, justify and what measures are in place to mitigate.</i> |
| |
| 2.12 Does your activity involve the potential imbalance of power/authority/status, particularly those which might compromise a participant giving informed consent? |
| <input type="radio"/> Yes <input checked="" type="radio"/> No |
| If Yes, please detail including how this will mitigated <i>Describe the relationship and the steps to be taken by the investigator to ensure that the participant's participation is purely voluntary and not influenced by the relationship in any way.</i> |
| |
| 2.13 Does the procedure involve any possible distress, discomfort or harm (or offense) to participants or researchers (including physical, social, emotional, psychological)? |
| <input type="radio"/> Yes <input checked="" type="radio"/> No |
| If Yes, please explain <i>Describe the potential for distress, discomfort, harm or offense for research participants as a result of their participation in your study and what measures are in place to protect the participants or researcher(s). Please consider all possible causes of distress carefully, including likely reaction to the subject matter, debriefing or participants.</i> |
| |

| |
|--|
| 2.14 Does the activity involve any information pertaining to illegal activities or materials or the disclosure thereof? |
| <input type="radio"/> Yes <input checked="" type="radio"/> No |
| If Yes, please detail <i>Describe involvement and explain what risk management procedures will be put in place.</i> |
| 2.15 What mechanism is there for participants to withdraw from the investigation and how is this communicated to the participants? |
| <i>Describe exactly how, and when, participants may withdraw if they change their minds about taking part including how participants know they have the right to withdraw.</i> |
| Please see PIS and consent form. (Appendix 3 and 4) |
| 2.16 What is the potential for benefit? |
| <i>Briefly describe the main benefits and contribution of the study. Include any immediate benefits to participants as well as the overall contribution to knowledge or practice (e.g. educational purposes only).</i> |
| There are no direct benefits to the participants in this initial exploration. However if positive changes in joint loading and muscle activity occur there may be possible advantages to patients with knee osteoarthritis as a result. |
| 2.17 What arrangements are in place to ensure participants receive any information that becomes available during the course of the activity that may be relevant to their continued participation? |
| <i>Describe how participants will be made aware of relevant information that was not available when they started.</i> |
| Participants will be informed of any changes, however there is only 1 data collection so it is expected that this is unlikely to occur. |
| 2.18 Debriefing, Support and/or Feedback to participants |
| <i>Describe any debriefing, support or feedback that participants will received following the study and when.</i> |
| None as part of the standard protocol of this study. |
| 2.19 Adverse / Unexpected Outcomes |
| <i>Please describe what measures you have in place in the event of any unexpected outcomes or adverse effects to participants arising from their involvement in the project</i> |
| Appropriate complaints procedures are addressed in the last section of the Participant information sheet (Appendix 4) |
| 2.20 Will the activity involve access to confidential information about people without their permission? |
| <input checked="" type="radio"/> Yes <input type="radio"/> No |
| If yes, please explain and justify. <i>State what information will be sought, from which organisations and the requirement for this information.</i> |
| 2.21 Does the activity involve human tissue? See Human Tissue Act (HTA) Supplementary list of Materials to check what is classified as human tissue. |
| <input type="radio"/> Yes <input checked="" type="radio"/> No |
| If no, please skip to question 2.22 If yes, please detail and answer questions 2.21a & 2.21b <i>Clearly state the source of the material (a tissue bank governed by its own HTA licence such as Brain Tumour North West, or purchased from overseas, etc.)</i> |
| 2.21a Will the human tissue be stored at UCLAN? |
| <input type="radio"/> Yes <input type="radio"/> No |

If yes, please state how long and in what form - cellular or acellular (DNA extracted)
Please note – if human tissue is only kept for the purpose of DNA extraction rendering it acellular the HTA storage regulations may not apply. If holding for DNA extraction, please state the length of time the tissue would be stored pre-extraction.

2.21b Is the human tissue being used for an activity listed as a ‘scheduled purpose’ under Schedule 1 Parts 1 and 2 of the Human Tissue Act 2004? (*click here to see list of HTA ‘scheduled purpose’ activities*)

Yes No

2.22 Confidentiality/Anonymity - Will the activity involve:

| | Yes | No |
|---|----------------------------------|----------------------------------|
| a. non-anonymisation of participants (i.e. researchers may or will know the identity of participants and be able to return responses)? | <input type="radio"/> | <input checked="" type="radio"/> |
| b. de-identified samples or data (i.e. a reversible process in which the identifiers are removed and replaced by a code. Those handling the data subsequently do so using the code. If necessary, it is possible to link the code to the original identifiers and identify the individual to whom the sample or information relates)? | <input checked="" type="radio"/> | <input type="radio"/> |
| c. participants having the consented option of being identified in any publication arising from the research? | <input type="radio"/> | <input checked="" type="radio"/> |
| d. the use of personal data (i.e. anything that may identify them – e.g. institutional role – see DP checklist for further guidance)? | <input type="radio"/> | <input type="radio"/> |

If yes to any proceed to question below

If no to all, please skip to question 2.24

2.23 Which of the following methods of assuring confidentiality of data will be implemented?
 (Please select all relevant options)

N.B. Please attach completed DP Checklist (*click here to see further DP advice*)

- data and codes and all identifying information to be kept in separate locked filing cabinets
 access to computer files to be available by password only
 other

If other, please describe method. **See DP Checklist attached**

2.24 Does the activity involve excavation and study of human remains?

Yes No

If yes, please give details

Discuss the provisions for examination of the remains and the management of any community/public concerns, legal requirement etc.

Section 3: BIOLOGICAL ORGANISMS/ENVIRONMENT

3.1 Does the activity involve microorganisms, genetic modification or collection of rare plants?

Yes No

If yes please provide further details below State the type and source of the samples to be used in the project and include compliance with relevant legislation.

If no please continue section 4

Section 4: HAZARDOUS SUBSTANCES

4.1 Does the activity involve any hazardous substances?

Yes No

| |
|--|
| <i>If yes please continue If no please continue to section 5</i> |
| 4.2 Does the activity involve igniting, exploding, heating or freezing substances? |
| <input type="radio"/> Yes <input checked="" type="radio"/> No |
| 4.3 Does the activity involve substances injurious to human or animal health or to the environment? |
| <input type="radio"/> Yes <input checked="" type="radio"/> No |
| 4.4 Are you using hazardous chemicals? |
| <input type="radio"/> Yes <input checked="" type="radio"/> No |
| <i>If Yes to any please attach all relevant COSHH (single substance OR multi/complex substance) and/or risk assessment forms N.B. Please address issues of quantity involved, disposal and potential interactions as well as a thorough evaluation of minimisation of risk</i> |
| Section 5: OTHER HAZARDS |
| 5.1 Does the activity relate to military equipment, weapons or the defence industry? |
| <input type="radio"/> Yes <input checked="" type="radio"/> No |
| <i>If yes please provide details and attach relevant permissions and risk assessments. Describe the hazard, clearly explaining the risks associated and specify how you will minimise these If no please continue</i> |
| 5.2 Does the activity relate to the excavation of modern battlefields, military installations etc? |
| <input type="radio"/> Yes <input checked="" type="radio"/> No |
| <i>If yes please provide details and attach relevant permissions and risk assessments. Discuss the provisions for examination and the management of any community/public concerns, legal requirement, associated risks, etc. If no please continue</i> |
| Section 6: FIELDWORK/TRAVEL |
| 6.1 Does the activity involve field work, lone working or travel to unfamiliar places? |
| <input type="radio"/> Yes <input checked="" type="radio"/> No |
| <i>If yes, answer the following questions If no, go to Section 7</i> |
| 6.2 Where will the activity be undertaken? |
| N.B. If your work involves field work or travel to unfamiliar places (e.g. outside the UK) please attach a risk assessment specific to that place <i>Give location(s) details (e.g. UCLAN campus only)</i> |
| BB021 Mvoement lab, UCLAN |
| 6.3 Does the activity involve lone working? |
| <input type="radio"/> Yes <input checked="" type="radio"/> No |
| <i>If yes please provide further details below and attach a completed risk assessment form Describe the lone working element, clearly explaining the risks associated and specify how you will minimise these</i> |
| |

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| 6.4 Does the activity involve children visiting from schools? |
| <input type="radio"/> Yes <input checked="" type="radio"/> No |
| If yes please provide further details below and attach a completed risk assessment form <i>Describe the nature of the visit, clearly explaining the risks associated and specify how you will minimise these</i> |
| |

Section 7: ETHICAL AND POLITICAL CONCERNS

| |
|--|
| 7.1 Are you aware of any potential ethical and/or Political concerns that may arise from either the conduct or dissemination of this activity (e.g. results of research being used for political gain by others; potential for liability to the University from your research)? |
|--|

| |
|---|
| <input type="radio"/> Yes <input checked="" type="radio"/> No |
|---|

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|---|
| <i>If yes please provide details below. If no please continue</i> |
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| 7.2 Are you aware of any ethical concerns about collaborator company / organisation (e.g. its product has a harmful effect on humans, animals or the environment; it has a record of supporting repressive regimes; does it have ethical practices for its workers and for the safe disposal of products)? |
|---|

| |
|---|
| <input type="radio"/> Yes <input checked="" type="radio"/> No |
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| <i>If yes please provide details below</i> |
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| <i>If no please continue</i> |
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| 7.3 Are there any other ethical issues which may arise with the proposed study and what steps will be taken to address these? |
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|---|
| <input type="radio"/> Yes <input checked="" type="radio"/> No |
|---|

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| <i>If yes please provide details below</i> |
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|------------------------------|
| <i>If no please continue</i> |
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Section 8: DECLARATION

This section needs to be signed by the Principal Investigator (PI), and the student where the study relates to a student project (for research student projects PI is Director of Studies and for Taught or Undergrad project the PI is the Supervisor). Electronic submission of the form is required to roffice@UCLAN.ac.uk. Where available insert electronic signature, if not a signed version of the submitted application form should be retained by the Principal Investigator.

| |
|----------------------------|
| Declaration of the: |
|----------------------------|

| |
|---|
| <input checked="" type="radio"/> Principal Investigator |
|---|

| |
|-----------|
| OR |
|-----------|

| |
|---|
| <input checked="" type="radio"/> Director of Studies/Supervisor and Student Investigators |
|---|


| |
|-------------------------------|
| (please check as appropriate) |
|-------------------------------|

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|---|
| <ul style="list-style-type: none"> The information in this form is accurate to the best of my knowledge and belief, and I take full responsibility for it. |
|---|

| |
|--|
| <ul style="list-style-type: none"> I have read and understand the University Ethical Principles for Teaching, Research, Knowledge Transfer, Consultancy and Related Activities. |
|--|

| |
|---|
| <ul style="list-style-type: none"> I undertake to abide by the ethical principles underlying the Declaration of Helsinki and the University Code of Conduct for Research, together with the codes of practice laid down by any relevant professional or learned society. |
|---|

| | |
|--|--|
| <ul style="list-style-type: none"> • If the activity is approved, I undertake to adhere to the study plan, the terms of the full application of which the Ethics Committee* has given a favourable opinion and any conditions of the Ethics Committee in giving its favourable opinion. | |
| <ul style="list-style-type: none"> • I undertake to seek an ethical opinion from the Ethics Committee before implementing substantial amendments to the study plan or to the terms of the full application of which the Ethics Committee has given a favourable opinion. | |
| <ul style="list-style-type: none"> • I understand that I am responsible for monitoring the research at all times. | |
| <ul style="list-style-type: none"> • If there are any serious adverse events, I understand that I am responsible for immediately stopping the research and alerting the Ethics Committee within 24 hours of the occurrence, via roffice@UCLAN.ac.uk. | |
| <ul style="list-style-type: none"> • I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to security and confidentiality of personal data. | |
| <ul style="list-style-type: none"> • I understand that research records/data may be subject to inspection for audit purposes if required in future. | |
| <ul style="list-style-type: none"> • I understand that personal data about me as a researcher in this application will be held by the University and that this will be managed according to the principles established in the Data Protection Act. | |
| <ul style="list-style-type: none"> • I understand that the information contained in this application, any supporting documentation and all correspondence with the Research Ethics Committee relating to the application, will be subject to the provisions of the Freedom of Information Acts. The information may be disclosed in response to requests made under the Acts except where statutory exemptions apply. | |
| <ul style="list-style-type: none"> • I understand that all conditions apply to any co-applicants and researchers involved in the study, and that it is my responsibility to ensure that they abide by them. | |
| <ul style="list-style-type: none"> • For Supervisors/Director of Studies: I understand my responsibilities as Supervisor/Director of Studies, and will ensure, to the best of my abilities, that the student investigator abides by the University's Policy on Research Ethics at all times. | |
| <ul style="list-style-type: none"> • For the Student Investigator: I understand my responsibilities to work within a set of safety, ethical and other guidelines as agreed in advance with my Supervisor/Director of Studies and understand that I must comply with the University's regulations and any other applicable code of ethics at all times. | |
| <input type="radio"/> Signature of Principal Investigator: or <input checked="" type="radio"/> Supervisor or Director of Studies: |  |
| Print Name: | |
| Date: | 05/06/2015 |
| Signature of Student Investigator: | Tariq Kwaees |
| Print Name: | Tariq Kwaees |
| Date: | 05/06/2015 |

Section 9: ACCOMPANYING DOCUMENTATION

Please indicate here what documentation you have included with your application:

- Proposal / protocol
- RDSC2 form – Application to Register for a Research Degree / Application for Research Programme Approval
- External ethics approval letter
- Letter of permission

* Ethics Committee refers to either BBAHSSS, PSYSOC or STEMH

- Participant consent form(s)
- Participant information sheet(s)
- Interview or observation schedule
- Questionnaire(s)
- Advert(s)
- Debrief sheet(s)
- DP checklist
- Risk Assessment
- COSHH
- Other

If 'Other' please list/describe

9.2 Ethics Approval Form (Case Studies):

UNIVERSITY OF CENTRAL LANCASHIRE

Ethics Committee Application Form

PLEASE NOTE THAT ONLY ELECTRONIC SUBMISSION IS ACCEPTED



This application form is to be used to seek approval from one of the three University Ethics Committees (BAHSS; PSYSOC & STEMH). Where this document refers to 'Ethics Committee' this denotes BAHSS; PSYSOC & STEMH (see [Appendix 1](#) for list of Schools associated with each ethics committee). These Ethics Committees deal with all staff and postgraduate research student project. Taught (undergraduate and MSc dissertation projects) will normally be dealt with via School process / committee.

If you are unsure whether your activity requires ethical approval please complete an [UCLan Ethics Checklist](#). If the proposed activity involves animals, you should not use this form. Please contact the Research Development and Support Team within Research & Innovation Office – roffice@uclan.ac.uk – for further details.

Please read the [Guidance Notes](#) before completing the form. Please provide all information requested and justify where appropriate. Use as much space as you need – the sections expand as you type. Click on box or circle to select relevant option (e.g. type or Yes/No) and click on 'grey oblong shape' to start typing for the free text entry questions. Each question on this form has instructions on how to answer that particular question. In addition links to relevant documents (e.g. templates, examples, etc.) and further guidelines are available in the Guidance Notes which can also be accessed from the question by clicking on appropriate question number. It is the applicant's responsibility to ensure that an English translation of any supporting documentation is a faithful translation of the copy being used with participants.

Your application needs to be filled in electronically and emailed to roffice@uclan.ac.uk. Please insert in the subject line of your email the acronym of the committee that needs to deal with your application. Committee acronyms are BAHSS, PSYSOC or STEMH – see [Appendix 1](#), at the back of this form, for list of Schools associated with each ethics committee.

PLEASE NOTE – ethical approval can be granted in **phases**. If you have a project that is likely to evolve, or has subsequent phases determined by initial results – you can apply for Phase One approval, and then come back for Phases Two, Three or even more as your research progresses.

If this application relates to an activity which has previously been approved by one of the UCLan Ethics Committees, please supply the corresponding reference number(s) from your decision letter(s).

STEMH 235

Section 1: DETAILS OF PROJECT

All applicants **must** complete Section 1

1.1 Project Type:

| | | |
|---|--|--|
| <input checked="" type="checkbox"/> Staff Research <input type="checkbox"/> Commercial Project | <input type="checkbox"/> Master by Research <input type="checkbox"/> MPhil Research <input type="checkbox"/> PhD Research <input type="checkbox"/> Professional Doctorate | <input type="checkbox"/> Taught MSc/MA Research <input type="checkbox"/> Undergrad Research |
|---|--|--|

1.2 Principal Investigator:

| Name | School | Email |
|-------------------|--|-----------------------|
| Prof Jim Richards | Sport, Tourism & the Outdoors (AHRC, SENS & CASES) | jrichards@uclan.ac.uk |

1.3 Other Researchers / Student:

| Name | School | Email |
|---|--|----------------------|
| Dr. Jessie Janssen | Sport, Tourism & The Outdoors (AHRU, SENS & CASES) | jjanssen@uclan.ac.uk |
| Dr. Ambreen Chohan | Sport, Tourism & The Outdoors (AHRU, SENS & CASES) | Achohan@uclan.ac.uk |
| Prof. James Selfe | Sport, Tourism & The Outdoors (AHRU, SENS & CASES) | Jselfe1@uclan.ac.uk |
| 1.4 Project Title: | | |
| <i>Please provide your project title. If your project title has both a short and long title, please enter your short title here.</i> | | |
| Clinical case study | | |
| 1.5 Anticipated Start Date: | | |
| 02/06/2014 | | |
| 1.6 Anticipated End Date: | | |
| 06/06/2019 | | |
| 1.7 Is this project in receipt of any external funding (including donations of samples, equipment etc.)? | | |
| <input type="radio"/> Yes <input checked="" type="radio"/> No | | |
| If Yes, please provide details of sources of the funding and what part it plays in the current proposal. | | |
| | | |
| 1.8 Project Description (in lay's terms) including the aim(s) and justification of the project (max 300 words) | | |
| <i>Give a brief summary of the background, purpose and the possible benefits of the investigation. This should include a statement on the academic rationale, context of the activity and justification for conducting the project.</i> | | |
| Through our work we regularly come across people with unique pathologies or movement patterns, who have found innovative ways of dealing with it. On the other hand innovative devices that could aid people with a deviation in their movement pattern also come to our attention. As the individual aspect is very important in these cases, a case study design excels at bringing an in-depth and unique insight into the underlying biomechanics of each participant. | | |
| 1.9 Methodology Please be specific | | |
| <i>Provide an outline of the proposed method, include details of sample numbers, source of samples, type of data collected, equipment required and any modifications thereof, etc.</i> | | |
| Participant: Participants with a deviation in his/her movement or participants willing to try out new devices to correct deviation of movement. Design: A case study design will be used to explore the movements and/or changes an innovative device can make to the movement of an individual. Each case study contains one person. There is no cap on how many single case studies will be conducted. Methods: After the patient has read the information sheet and has signed the consent form, he/she will change into shorts and/or t shirt (clothing can be provided at the Movement Analysis Laboratory). | | |
| The proposed tests will make use of either: 1) A highly accurate motion analysis system (Qualisys medical, Sweden) OR 2) A highly accurate motion analysis system (Qualisys medical, Sweden) in conjunction with force platform analysis and EMG (electromyography) (Delsys) OR 3) XSENS wireless motion capture system (Xsens Technologies B.V., Enschede, the Netherlands). No change of clothing is required for this option. (Separate information sheets and consent forms will be provided for each option) | | |
| Questionnaire data will be collected using the clinically validated- Knee Injury and Osteoarthritis Outcome score (KOOS, http://www.koos.nu/) before the testing session. Participants will complete a follow up KOOS assessment after trialling an intervention brace (DJO, UK) for 4 weeks. For the Qualisys measurement the participant will be marked up with reflective markers on double sided tape attached to the skin. The EMG preparation will consist of cleaning the skin with alcohol wipes and placing non-invasive EMG devices upon the skin of the participant. Then collection of the data can start. The participant will perform 3-5 repetitions of the particular movement (for example walking, running, step down). | | |

All data will be analysed using Visual 3D software. All data will be stored under the participant's code and date of assessment.

1.10 Has the quality of the activity been assessed? (select all that apply)

- Independent external review
- Internal review (e.g. involving colleagues, academic supervisor, School Board)
- Through Research Degrees Sub-Committee (BAHSS, STEM or SWESH)
- None
- Other

If other please give details

1.11 Please provide details as to the storage and protection for your data for the next 5 years

– as per UCLan requirements

Throughout the study all information collected will be kept strictly confidential and in accordance with the Data Protection Act (1998). All data will be coded using participant code and date of assessment. All identifying information will be stored on a password protected files on a University computer and deleted at the end of the study. The data will be kept for 5 years and will then be destroyed. All personal information will not be passed onto any third parties or external companies. All data will be stored separately to the consent forms. All questionnaires will be coded and kept separately to any consent forms.

1.12 How is it intended the results of the study will be reported and disseminated?

(select all that apply)

- Peer reviewed journal
- Internal report
- Conference presentation
- Other publication
- Written feedback to research participants
- Presentation to participants or relevant community groups
- Dissertation/Thesis
- Other

If other, please give details: independent report, a series of/single case studies may also be used by students within Masters research theses, however data collection will always involve atleast 1 member of the research team.

1.13 Will the activity involve any external organisation for which separate and specific ethics clearance is required (e.g. NHS; school; any criminal justice agencies including the Police, Crown Prosecution Service, Prison Service, Probation Service or successor organisation)?

Yes No

If Yes, please provided details of the external organisation / ethics committee and attached letter of approval NB – external ethical approval **must** be obtained before submitting to UCLan ethics.

1.14 The nature of this project is most appropriately described as research involving:-(more than one may apply)

- Behavioural observation
- Self-report questionnaire(s)
- Interview(s)

- Qualitative methodologies (e.g. focus groups)
- Psychological experiments
- Epidemiological studies
- Data linkage studies
- Psychiatric or clinical psychology studies
- Human physiological investigation(s)
- Biomechanical devices(s)
- Human tissue
- Human genetic analysis
- A clinical trial of drug(s) or device(s)
- Lab-based experiment
- Archaeological excavation/fieldwork
- Re-analysis of archaeological finds/ancient artefacts
- Human remains analysis
- Other (please specific in the box below)

If 'Other' please provide details

Please read all the following questions carefully and if you respond 'Yes' then you should provide all relevant details and documentation (including risk assessments), and justify where appropriate.

Section 2: HUMAN PARTICIPANTS, DATA OR MATERIAL

2.1 Are you using human participants (including use of their data), tissues or remains?

(please select the appropriate box)

- Participants [proceed to question 2.2]
- Data [proceed to question 2.20]
- Tissues / Fluids / DNA Samples [proceed to question 2.20]
- Remains [proceed to question 2.24]
- No [proceed to Section 3]

[Click here for Q2.20](#)

[Click here for Q2.24](#)

[Click here for Section 3](#)

2.2 Will the participants be from any of the following groups: (tick as many as applicable)

- Students or staff of this University
- Children/legal minors (anyone under the age of 18 years)
- Patients or clients of professionals
- Those with learning disability
- Those who are unconscious, severely ill, or have a terminal illness
- Those in emergency situations
- Those with mental illness (particularly if detained under Mental Health Legislation)
- People with dementia
- Prisoners
- Young Offenders

| |
|---|
| <input type="checkbox"/> Adults who are unable to consent for themselves <input type="checkbox"/> Any other person whose capacity to consent may be compromised <input type="checkbox"/> A member of an organisation where another individual may also need to give consent <input type="checkbox"/> Those who could be considered to have a particularly dependent relationship with the investigator, e.g. those in care homes, medical students <input type="checkbox"/> Other vulnerable groups (please list) |
| 2.2a Justify their inclusion |
| <i>Ethical approval covers all participants but particular attention must be given to vulnerable participants. Therefore you need to fully justify their inclusion and give details of extra steps taken to assure their protection. Where the 'Other vulnerable groups' box has been selected, please also describe/list.</i> |
| We are aiming to recruit participants over the age of 18 years with a deviation in their movement. These can be staff and students from UCLan or patients who have referred themselves to the Allied Health Profession Research Unit through our network. Any alternations in inclusion criteria will constitute an ethical amendment. |
| 2.2b Is a DBS – Disclosure and Barring Service (formerly CRB – Criminal Records Bureau) check required? |
| <i>Certain activities and/or groups of individuals require DBS (formerly CRB) clearance.</i> |
| <input type="radio"/> Yes <input checked="" type="radio"/> No |
| If Yes, please advise status of DBS clearance (e.g. gained; in process; etc) |
| All the staff working in the movement laboratory are DBS cleared. |
| 2.3 Please indicate exactly how participants in the study will be (i) identified, (ii) approached and (iii) recruited? |
| N.B if a recruitment advertisement is to be used, please attach <i>State how you will identify, approach and recruit participants including how you will ensure no coercion will be used in your recruitment.</i> |
| As these are case studies there are different pathways these participants can be identified, however generally participants identify themselves as potential participants and come to us to enquire if participation is possible. |
| 2.4 How exactly will consent be given? |
| N.B. if a written consent form is being used, please attach <i>Please specify what information you will provide in order that consent be informed, and whether consent will be given verbally or in writing. If consent is not to be obtained, please explain why not.</i> |
| Potential participants will be given an information sheet explaining the process of the study (see attached) and the process of opting out of the study. After people have read the information sheet and have asked questions, they will be asked to sign a consent form. |
| 2.5 What information will be provided at recruitment and briefing to ensure that consent is informed? |
| N.B. if an information sheet is being used, please attach <i>Give details of any particular steps to provide information and justify where an information sheet is not being used.</i> |
| An information sheet will be provided appropriate to data collection method. |
| 2.6 How long will the participants have to decide whether to take part in the research? |
| <i>Indicate whether this is days or weeks and if less than 24 hours please justify.</i> |
| This will generally be 1-2 days, but can be longer if needed. |
| 2.7 What arrangements have been made for participants who might not adequately understand verbal explanations or written information given in English, or who have special communication needs? |
| <i>Gives details of what arrangements have been made (e.g. translation, use of interpreters, etc).</i> |
| In this study we have not got additional resources for translation, however we will consult international office and any University translation services where possible to widen participation as required. |
| 2.8 Payment or incentives: Do you propose to pay or reward participants? |
| <input type="radio"/> Yes <input checked="" type="radio"/> No |

| |
|---|
| If Yes, please provided details |
| 2.9 Does the activity involve conducting a survey, interviews, questionnaire, observational study, experiment, focus group or other research protocol? |
| <input checked="" type="radio"/> Yes <input type="radio"/> No |
| If Yes, please provide details and attach copy of what you will be using <i>Give details of the specific procedures/activities being used and indicate where documentation (i.e. questionnaire or agendas) will be developed as part of the project. Also include what is the experience of those administering the procedures</i> |
| The focus of these case studies is of a biomechanical nature. The proposed tests will make use of a highly accurate motion analysis system (Qualisys medical, Sweden) in conjunction with force platform analysis and electromyography (EMG) (Delsys). |
| 2.10 Will deception of the participant be necessary during the activity? |
| <input type="radio"/> Yes <input checked="" type="radio"/> No |
| If Yes, please provide justification <i>Gives details of the deception and explain why the deception is necessary.</i> |
| 2.11 Does the activity (e.g. Art) aim to shock or offend? |
| <input type="radio"/> Yes <input checked="" type="radio"/> No |
| If yes, please explain <i>Give details, justify and what measures are in place to mitigate.</i> |
| 2.12 Does your activity involve the potential imbalance of power/authority/status, particularly those which might compromise a participant giving informed consent? |
| <input type="radio"/> Yes <input checked="" type="radio"/> No |
| If Yes, please detail including how this will mitigated <i>Describe the relationship and the steps to be taken by the investigator to ensure that the participant's participation is purely voluntary and not influenced by the relationship in any way.</i> |
| 2.13 Does the procedure involve <u>any</u> possible distress, discomfort or harm (or offense) to participants or researchers (including physical, social, emotional, psychological)? |
| <input checked="" type="radio"/> Yes <input type="radio"/> No |
| If Yes, please explain <i>Describe the potential for distress, discomfort, harm or offense for research participants as a result of their participation in your study and what measures are in place to protect the participants or researcher(s). Please consider all possible causes of distress carefully, including likely reaction to the subject matter, debriefing or participants.</i> |
| Any test being conducted is in line with clinical guidance. However activities used in this study should not exceed daily activity levels. |
| 2.14 Does the activity involve any information pertaining to illegal activities or materials or the disclosure thereof? |
| <input type="radio"/> Yes <input checked="" type="radio"/> No |
| If Yes, please detail <i>Describe involvement and explain what risk management procedures will be put in place.</i> |
| 2.15 What mechanism is there for participants to withdraw from the investigation and how is this communicated to the participants? |
| <i>Describe exactly how, and when, participants may withdraw if they change their minds about taking part including how participants know they have the right to withdraw.</i> |
| The participant can withdraw at any point in the study. Information about withdrawing from the study has been provided in the information sheet. |

| | | |
|---|----------------------------------|----------------------------------|
| <i>Briefly describe the main benefits and contribution of the study. Include any immediate benefits to participants as well as the overall contribution to knowledge or practice.</i> | | |
| There will be no direct benefit from participating in the study. However, if he/she is interested, a summary of findings can be provided. | | |
| 2.17 What arrangements are in place to ensure participants receive any information that becomes available during the course of the activity that may be relevant to their continued participation? | | |
| <i>Describe how participants will be made aware of relevant information that was not available when they started.</i> | | |
| Each case study is a one off assessment, therefore if something changed during the activity, participants will be informed and the appropriate action will be taken. | | |
| 2.18 Debriefing, Support and/or Feedback to participants | | |
| <i>Describe any debriefing, support or feedback that participants will received following the study and when.</i> | | |
| If the participant is interested a summary of the findings can be provided | | |
| 2.19 Adverse / Unexpected Outcomes | | |
| <i>Please describe what measures you have in place in the event of any unexpected outcomes or adverse effects to participants arising from their involvement in the project</i> | | |
| This is a low risk assessment. If an adverse event or unexpected outcome would occur, we will stop the assessment. Participants will be advised to discontinue use of the brace should any adverse affects occur and contact the research team. | | |
| 2.20 Will the activity involve access to confidential information about people without their permission? | | |
| <input type="radio"/> Yes <input type="radio"/> No | | |
| If yes, please explain and justify <i>State what information will be sought, from which organisations and the requirement for this information.</i> | | |
| 2.21 Does the activity involve medical research, human tissue, DNA samples or body fluids? | | |
| <input type="radio"/> Yes <input checked="" type="radio"/> No | | |
| If yes, please detail <i>Clearly state the source of the material and anonymisation protocols</i> | | |
| 2.22 Confidentiality/Anonymity - Will the activity involve: | | |
| | Yes | No |
| e. complete anonymity of participants is <u>not</u> possible (i.e. researchers may or will know the identity of participants and be able to return responses)? | <input checked="" type="radio"/> | <input type="radio"/> |
| f. anonymised samples or data (i.e. an irreversible process whereby identifiers are removed from samples/data and replaced by a code, with no record retained of how the code relates to the identifiers. It is then impossible to identify the individual to whom the sample or information relates)? | <input checked="" type="radio"/> | <input type="radio"/> |
| g. de-identified samples or data (i.e. a reversible process in which the identifiers are removed and replaced by a code. Those handling the data subsequently do so using the code. If necessary, it is possible to link the code to the original identifiers and identify the individual to whom the sample or information relates)? | <input type="radio"/> | <input checked="" type="radio"/> |
| h. participants having the option of being identified in any publication arising from the research? | <input type="radio"/> | <input checked="" type="radio"/> |
| i. participants being referred to by pseudonym in any publication arising from the research? | <input type="radio"/> | <input checked="" type="radio"/> |
| j. the use of personal data? | <input checked="" type="radio"/> | <input type="radio"/> |
| <i>If yes to any proceed to question below If no to all, please skip to question 2.24</i> | | |
| 2.23 Which of the following methods of assuring confidentiality of data will be implemented? (Please select all relevant options) | | |
| N.B. Attach DP Checklist (click here to see further DP advice) | | |
| <input checked="" type="checkbox"/> data and codes and all identifying information to be kept in separate locked filing cabinets | | |
| <input checked="" type="checkbox"/> access to computer files to be available by password only | | |
| <input type="checkbox"/> other | | |

| |
|---|
| If other, please describe method. |
| 2.24 Does the activity involve excavation and study of human remains? |
| <input type="radio"/> Yes <input checked="" type="radio"/> No |
| If yes, please give details <i>Discuss the provisions for examination of the remains and the management of any community/public concerns, legal requirement etc.</i> |
| |

Section 3: BIOLOGICAL ORGANISMS/ENVIRONMENT

| |
|--|
| 3.1 Does the activity involve micro-organisms, genetic modification or collection of rare plants? |
| <input type="radio"/> Yes <input checked="" type="radio"/> No |
| <i>If yes please provide further details below State the type and source of the samples to be used in the project and include compliance with relevant legislation. If no please continue <u>section 4</u></i> |
| |

**Section 4
HAZARDOUS SUBSTANCES**

| |
|--|
| 4.1 Does the activity involve any hazardous substances? |
| <input type="radio"/> Yes <input checked="" type="radio"/> No |
| <i>If yes please continue If no please continue to <u>section 5</u></i> |
| |
| 4.2 Does the activity involve igniting, exploding, heating or freezing substances? |
| <input type="radio"/> Yes <input checked="" type="radio"/> No |
| 4.3 Does the activity involve substances injurious to human or animal health or to the environment? |
| <input type="radio"/> Yes <input checked="" type="radio"/> No |
| 4.4 Are you using hazardous chemicals? |
| <input type="radio"/> Yes <input checked="" type="radio"/> No |
| <i>If Yes to any please attach all relevant COSHH (<u>single substance OR multi/complex substance</u>) and/or <u>risk assessment forms</u> N.B. Please address issues of quantity involved, disposal and potential interactions as well as a thorough evaluation of minimisation of risk</i> |

**Section 5
OTHER HAZARDS**

| |
|---|
| 5.1 Does the activity relate to military equipment, weapons or the defence industry? |
| <input type="radio"/> Yes <input checked="" type="radio"/> No |
| <i>If yes please provide details and attach relevant permissions and risk assessments. Describe the hazard, clearly explaining the risks associated and specify how you will minimise these If no please continue</i> |
| |
| 5.2 Does the activity relate to the excavation of modern battlefields, military installations etc? |
| <input type="radio"/> Yes <input checked="" type="radio"/> No |

*If yes please provide details and attach relevant permissions and risk assessments. Discuss the provisions for examination and the management of any community/public concerns, legal requirement, associated risks, etc.
If no please continue*

Section 6: FIELDWORK/TRAVEL

6.1 Does the activity involve field work, lone working or travel to unfamiliar places?

Yes No

*If yes, answer the following questions
If no, go to Section 7*

6.2 Where will the activity be undertaken?

N.B. If your work involves field work or travel to unfamiliar places (e.g. outside the UK) please attach a risk assessment specific to that place
Give location(s) details (e.g. UCLan campus only)

6.3 Does the activity involve lone working?

Yes No

*If yes please provide further details below and attach a completed risk assessment form
Describe the lone working element, clearly explaining the risks associated and specify how you will minimise these*

6.4 Does the activity involve children visiting from schools?

Yes No

*If yes please provide further details below and attach a completed risk assessment form
Describe the nature of the visit, clearly explaining the risks associated and specify how you will minimise these*

Section 7: ETHICAL AND POLITICAL CONCERNS

7.1 Are you aware of any potential ethical and/or Political concerns that may arise from either the conduct or dissemination of this activity (e.g. results of research being used for political gain by others; potential for liability to the University from your research)?

Yes No

*If yes please provide details below
If no please continue*

7.2 Are you aware of any ethical concerns about collaborator company / organisation (e.g. its product has a harmful effect on humans, animals or the environment; it has a record of supporting repressive regimes; does it have ethical practices for its workers and for the safe disposal of products)?

Yes No

If yes please provide details below. If no please continue


7.3 Are there any other ethical issues which may arise with the proposed study and what steps will be taken to address these?

Yes No

*If yes please provide details below
If no please continue*

Section 8: DECLARATION

This section needs to be signed by the Principal Investigator (PI), and the student where the study relates to a student project (for research student projects PI is Director of Studies and for Taught or Undergrad project the PI is the Supervisor). Electronic submission of the form is required to roffice@uclan.ac.uk. Where available insert electronic signature, if not a signed version of the submitted application form should be retained by the Principal Investigator.

| | |
|--|---|
| Declaration of the: | |
| <input checked="" type="radio"/> Principal Investigator | |
| OR | |
| <input type="radio"/> Director of Studies/Supervisor and Student Investigators | |
| (please check as appropriate) | |
| <ul style="list-style-type: none"> The information in this form is accurate to the best of my knowledge and belief, and I take full responsibility for it. I have read and understand the University Ethical Principles for Teaching, Research, Knowledge Transfer, Consultancy and Related Activities. I undertake to abide by the ethical principles underlying the Declaration of Helsinki and the <u>University Code of Conduct for Research</u>, together with the codes of practice laid down by any relevant professional or learned society. If the activity is approved, I undertake to adhere to the study plan, the terms of the full application of which the Ethics Committee* has given a favourable opinion and any conditions of the Ethics Committee in giving its favourable opinion. I undertake to seek an ethical opinion from the Ethics Committee before implementing substantial amendments to the study plan or to the terms of the full application of which the Ethics Committee has given a favourable opinion. I understand that I am responsible for monitoring the research at all times. If there are any serious adverse events, I understand that I am responsible for immediately stopping the research and alerting the Ethics Committee within 24 hours of the occurrence, via roffice@uclan.ac.uk. I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to security and confidentiality of personal data. I understand that research records/data may be subject to inspection for audit purposes if required in future. I understand that personal data about me as a researcher in this application will be held by the University and that this will be managed according to the principles established in the Data Protection Act. I understand that the information contained in this application, any supporting documentation and all correspondence with the Research Ethics Committee relating to the application, will be subject to the provisions of the Freedom of Information Acts. The information may be disclosed in response to requests made under the Acts except where statutory exemptions apply. I understand that all conditions apply to any co-applicants and researchers involved in the study, and that it is my responsibility to ensure that they abide by them. For Supervisors/Director of Studies: I understand my responsibilities as Supervisor/Director of Studies, and will ensure, to the best of my abilities, that the student investigator abides by the University's Policy on Research Ethics at all times. For the Student Investigator: I understand my responsibilities to work within a set of safety, ethical and other guidelines as agreed in advance with my Supervisor/Director of Studies and understand that I must comply with the University's regulations and any other applicable code of ethics at all times. | |
| <input type="radio"/> Signature of Principal Investigator: or <input type="radio"/> Supervisor or Director of Studies: |  |
| Print Name: | Jim Richards |
| Date: | 26/01/2015 |
| Signature of Student Investigator: | |
| Print Name: | |
| Date: | Click here to enter a date. |
| Section 9: ACCOMPANYING DOCUMENTATION | |
| Please indicate here what documentation you have included with your application: | |
| <input checked="" type="checkbox"/> Proposal / protocol | |

* Ethics Committee refers to either BBAHSSS, PSYSOC or STEMH

- RDSC2 form – Application to Register for a Research Degree / Application for Research Programme Approval
- External ethics approval letter
- Letter of permission
- Participant consent form(s)
- Participant information sheet(s)
- Interview or observation schedule
- Questionnaire(s)
- Advert(s)
- Debrief sheet(s)
- DP checklist
- Risk Assessment
- COSHH
- Other

If 'Other' please list/describe

9.3 Consent Form:



CONSENT FORM

TITLE OF STUDY: Exploring the effects of a proprioceptive knee brace for osteoarthritis in healthy individuals.

RESEARCHERS: Dr Tariq Kwaees, Dr Ambreen Chohan, Professor Jim Richards, Mrs Gillian Rawlinson

The following test will require you to have various markers attached to your body in order to model the way in which you move. This will also prevent you from being identified in any report/publication. The procedure should cause you no discomfort, however, if you do feel some discomfort, attempts will be made to remedy the situation. You will be required to walk a predetermined distance of approximately 10 metres up to 20 times with and without a knee brace. Before any of the testing can take place we require informed written consent, please complete below if you agree to the terms of this research study.

PLEASE INITIAL BOX

1. I confirm that I have read and understand the information sheet version..... I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

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

3. I understand that once my data has been anonymised it will not be removed from the study

4. I understand the reasons why I am required to wear shorts for this study and agree to do so.

5. I agree to proceed with the testing.

| | | |
|---|-------|-----------|
| _____ | _____ | _____ |
| NAME OF PARTICIPANT | DATE | SIGNATURE |
| _____ | _____ | _____ |
| NAME OF PERSON TAKING CONSENT (IF DIFFERENT FROM RESEARCHER) | DATE | SIGNATURE |
| _____ | _____ | _____ |
| RESEARCHER | DATE | SIGNATURE |

9.4 Consent Form (Case Studies):



Clinical Case study

Please initial box

1. I confirm that I have read and understand the information sheet version.....
I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my legal rights being affected.
3. I understand that all data will be coded using my participant code and date of assessment
4. I understand that once my data has been anonymised it will not be removed from the study
5. I understand the reasons why I am required to wear shorts and/or a t-shirt for this study and agree to do so.
6. I agree to be contacted in order to complete a second assessment after testing the brace for 4 weeks, and understand I am free to withdraw from the intervention should I wish, or if I suffer an increase in symptoms.
7. I agree to proceed with the testing.

| | | |
|---|-------|-----------|
| _____ | _____ | _____ |
| Name of Participant | Date | Signature |
| _____ | _____ | _____ |
| Name of Person taking consent (if different from researcher) | Date | Signature |
| _____ | _____ | _____ |
| Researcher | Date | Signature |

Who can I contact to discuss any issues or to make a complaint? Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. If you have any complaints about the study or how you have been treated in the study, please in the first instance contact the researchers, they will do their best to answer your questions.

Professor Jim Richards JRichards@uclan.ac.uk 01772 894575

Dr Ambreen Chohan AChohan@uclan.ac.uk 01772 892793

Failing this, you may contact the University Officer for Ethics:

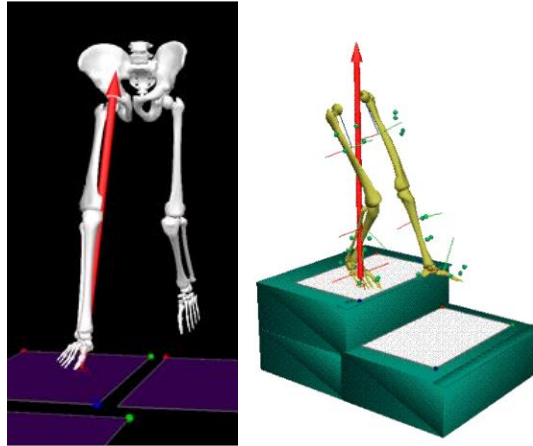
University Officer for Ethics OfficerforEthics@uclan.ac.uk

If you are interested in a summary of the findings please initial this box and provide your name and address underneath.

9.5 Advertisement Poster:



**Are you aged between 30 and 60?
Help us look at how a new design of knee brace helps people with Knee Osteoarthritis
We are currently recruiting Healthy individuals**



We want to establish how the knee mechanics during clinical assessment tasks changes when using a new knee brace in healthy people and people with knee osteoarthritis, which will help us with future designs of these devices. This work is taking place in the Movement Laboratory in Brook Building. You would need to attend just once for a maximum of 1 hour.

**For Further Information Contact
Dr Tariq Kwaees (Research Student): TAKwaees@UCLAN.ac.uk**

9.6 Participant Information Sheet:



PARTICIPANT INFORMATION SHEET

TITLE OF STUDY:

Exploring the effects of a proprioceptive knee brace for osteoarthritis in healthy individuals. You are invited to take part in a clinical case study. Before you decide whether to take part it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully, discuss it with friends, relatives or your doctor if you wish. Ask us if there is anything that is not clear or if you would like more information. Take your time to decide whether or not you wish to take part.

WHAT IS THE PURPOSE OF THIS STUDY?

Increases in the forces at the knee have been associated with increased load at the knee and progression of knee osteoarthritis. Osteoarthritis knee braces are common non-surgical approaches to reducing this loading. Recent advances in brace design have led to the development of a new proprioceptive brace which claims to produce a similar effect without realigning the ankle or knee joints. This first stage of the work aims to explore the movement and muscle activity in a group of healthy participants. This data will then help to decipher what potential effect the brace may have on an individual with medial compartment osteoarthritis. This study will investigate the effects of a new proprioceptive knee brace designed to offer a low profile conservative management tool for individuals with mild to moderate medial compartment OA, in health individuals.

AM I SUITABLE FOR THIS STUDY?

In order to participate in this study you should be aged between 30 and 60 and have no current musculoskeletal injuries or disorders, no history of surgery or traumatic injury to the lower extremities or lower back, no history of medical conditions that limit physical activity. There are no direct benefits to you in this initial study. However, if positive changes in joint loading are seen then there could be benefits to people with knee osteoarthritis.

DO I HAVE TO TAKE PART?

No. It is up to you to decide whether or not you take part. If you do wish to participate, you will be given this information sheet to keep and given the opportunity to ask the researchers any questions you have regarding the study. During the study, if there is any aspect you are unhappy with, you have the right to withdraw at any point without giving any reasons and without any negative consequences. Any anonymised data up to that point may not be removed.

WHAT WILL I HAVE TO DO IF I TAKE PART?

You will be required to attend the Allied Health Movement Lab (Brook Building - BB021, Figure 1) at the University of Central Lancashire for a single testing session on a mutually convenient date. The testing session should not exceed 1 hour. You will be asked to bring with you a pair of shorts or similar with some standard flat footwear (these may be supplied if you do not have these however).

Before the session begins, written informed consent will be taken. The data collection session should last no more than 60 minutes. We will begin by measuring your thigh circumference in order to select an appropriately sized brace.



Figure 1: Movement Laboratory, Brook Building BB021.

We will place small reflective markers on your pelvis and lower limbs. These points will allow us to model the data we obtain from you as a skeleton and facilitate analysis of joint movement. You will be filmed by 10 highly accurate infra-red cameras (Qualisys Oqus Cameras, SE) in conjunction with force platform analysis and electromyography (EMG) (Delsys). The footage from the movement analysis cameras will not look like normal video; the only visible information will be the small reflective markers appearing as white points on the screen (Figure 2). In order for EMG data to be recorded the skin will first be cleaned with an alcohol wipe. Then small discrete surface electrodes will be placed upon the skin over the appropriate muscles on the dominant leg to measure the muscle activity (Figure 3). Movement analysis will involve you walking several times and slowly stepping down from a 10 cm high step with and without the brace (OA Reaction Web, DJO Int.) several times.

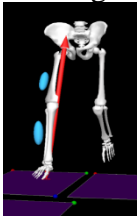


Figure 2: Model of foot, shank, thigh,



Figure 3: Delsys EMG

WILL MY PARTICIPATION IN THIS STUDY BE KEPT CONFIDENTIAL?

All data will be password protected and all associated documents and files will be stored in accordance with Data Protection guidelines. No identifiable personal information will be passed on to any 3rd parties. All data collected from you will be coded and no recognisable photographic or video image will be taken at any point. If we write about the results of the study your name and details will be removed completely.

WHAT WILL HAPPEN TO THE RESULTS OF THE RESEARCH STUDY?

You will not be contacted or required to complete any further assessments regarding this study. The findings of this study will form part of a postgraduate research degree (MSc by research), may be submitted for peer reviewed conferences and journals and may also be used to provide an independent report to the company who make the brace.

WHO HAS REVIEWED THIS STUDY?

The University of Central Lancashire STEMH Ethics committee have reviewed and approved this study.

WHO IS DOING THE RESEARCH?

The Allied Health Research Unit in the School of Sport Tourism and Outdoors at the University of Central Lancashire are organising the research. This study is funded by DJO inc. However, they have no involvement in the planning, data collection and analysis of the results associated with this study. Research Team Contact details:

| | | | |
|-------------------|------------------|--|-------------------|
| Dr Tariq Kwaees | Research Student | TAKwaees@UCLAN.ac.uk | |
| Dr Ambreen Chohan | Research Fellow | AChohan@UCLAN.ac.uk | Tel: 01772 892793 |

Please contact the research team should you wish to participate having read the information provided.

WHAT IF THERE IS A PROBLEM?

If you have any complaints about the study or how you have been treated in the study, please in the first instance contact the researchers using the details provided above, they will do their best to answer your questions. Failing this you may contact the University Officer for Ethics on Officerforethics@UCLAN.ac.uk.

THANK YOU FOR TAKING TIME TO READ ABOUT THIS STUDY, IF YOU HAVE ANY QUESTIONS PLEASE DO NOT HESITATE TO ASK.

9.7 Participant Information sheet (Case Studies):



Participant Information Sheet

Clinical Case Study

Title of study: Clinical case study – Qualisys Movement Analysis and EMG

You are invited to take part in a clinical case study. Before you decide whether to take part it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully, discuss it with friends, relatives or your doctor if you wish. Ask us if there is anything that is not clear or if you would like more information. Take your time to decide whether or not you wish to take part.

Why have I been chosen? You have been chosen because you are of 18 years or over and have come to the Allied Health Professions Research Unit at UCLan with a deviation in your movement.

Do I have to take part? No, you do not have to take part; it is up to you to decide. If you do decide to take part you will be given this Information Sheet to keep and be asked to sign a Consent Form. If you decide to take part, you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

Who is doing this research? The study is conducted by the University of Central Lancashire.

What will I have to do if I take part? What will I have to do if I take part? Prior to data collection you will be asked complete a questionnaire about your knee pain and function. We will then ask you to change into shorts and/ or a t-shirt (these can be provided by the movement analysis lab). In order to collect this information we will attach small reflective balls to your feet, legs, waist, shoulders and arms with double sided sticky tape. Data will be collected using a motion analysis system, this consists ten cameras, Figure 1. These cameras will not record any video footage which could be used to determine your identity and will only be displayed as an animated skeleton, Figure 2.

We also attach small devices (EMGs and dEMGs) to your skin that can record your muscle activity (Figure 3). In order to do this, a small alcohol wipe will be used to clean the area of the skin where the device will be attached. Afterwards the device will be attached to your skin with a specifically designed sticker, this is all non-invasive. You will then be asked to carry out several tests with and without a knee brace. These tests will all be activities of daily living, such as walking, stepping down from a step, and running. The testing will take no more than one hour to complete. Once the session is complete you will be asked to wear the brace during specific active periods. You will then be contacted after a period of 4 weeks to complete a follow up questionnaire on your knee pain and function. Should you experience any significant increase in pain or symptoms during brace use or other adverse reactions (eg. Rubbing, chafing), please discontinue use and contact the research team for further advice.



Figure 1: Movement Analysis Laboratory

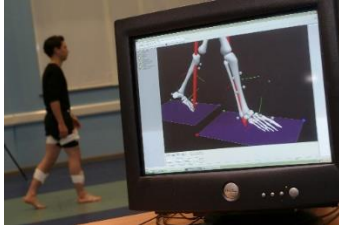


Figure 2: Generation of an animated skeleton

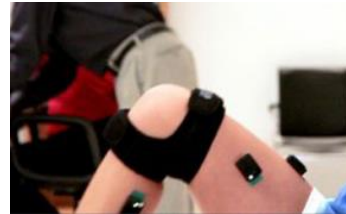


Figure 3: Delsys EMG

All data will be coded and no names will be able to be associated with any data recorded. All tests will not exceed either the range of movement or forces on the lower limb experienced in normal daily life. Data will be coded and stored independently from any other records which could be used to determine your identity. Questionnaires will always be stored coded and kept separately to any consent forms.

What will happen with my information? All data will be stored in line with UCLAN regulations and in accordance with the data protection act. Electronic data will be stored on a password protected PC, on the Allied Health Professions PC network. All consent forms and other documents will be stored so that no names can be associated with them in a locked filing cabinet. Electronic data and forms will be kept for 5 years following the end of the project, and then destroyed. The data we have collected may be used for teaching purposes and in some cases may be used as case studies in conference presentations, research degrees, and text books.

What will happen to the results of the research study? Results are intended to be published in scientific journals, may form part of a student's postgraduate research degree, or may be presented at conferences and to support getting research funding for future studies. If you would be interested in receiving a summary report of the findings at the end of the study period please indicate on the consent form in the box provided.

Who can I contact to discuss any issues or to make a complaint? Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. If you have any complaints about the study or how you have been treated in the study, please in the first instance contact the researchers, they will do their best to answer your questions.

Professor Jim Richards JRichards@uclan.ac.uk 01772 894575

Dr Ambreen Chohan AChohan@uclan.ac.uk 01772 892793

Failing this, you may contact the University Officer for the Ethics:

Officer for Ethics Officer for Ethics@uclan.ac.uk

Thank you for taking the time to read about the study, if you have any questions please do not hesitate to ask.

9.8 KOOS Questionnaire:

ID Number: _____.



Date: ____ / ____ / ____.

Please tick the appropriate box:

Pre
4 months post

| |
|--------------------------|
| <input type="checkbox"/> |
| <input type="checkbox"/> |

Instructions: Thank you for taking the time to complete this questionnaire.

- Please answer every question by circling the appropriate option
- Circle only one answer for each question.
- If you are unsure about how to answer a question, please give the best answer you can or ask the research team for help.

Mechanical Symptoms

Answer the following questions in relation to what you have experienced in the **last week**. (Stiffness is a sensation of restriction or slowness in the ease with which you move your knee).

1. How severe is your knee stiffness after first wakening in the morning?

None Mild Moderate Severe Extreme

2. How severe is your knee stiffness after sitting, lying, or resting later in the day?

None Mild Moderate Severe Extreme

3. Do you have swelling in your knee?

Never Rarely Sometimes Often Always

4. Do you feel grinding, hear clicking or any other type of noise when your knee moves?

Never Rarely Sometimes Often Always

5. Does your knee catch or hang up when moving?

Never Rarely Sometimes Often Always

6. Can you straighten your knee fully?

Always Often Sometimes Rarely Never

7. Can you bend your knee fully?

Always Often Sometimes Rarely Never

Pain

1. How often is your knee painful?

Never Monthly Weekly Daily Always

What degree of pain have you experienced during the **last week** while:

2. Twisting/pivoting on your knee?

None Mild Moderate Severe Extreme

3. Straightening knee fully?

None Mild Moderate Severe Extreme

4. Bending knee fully?

None Mild Moderate Severe Extreme

5. Walking on flat surface?

None Mild Moderate Severe Extreme

6. Going up or down stairs?

None Mild Moderate Severe Extreme

| | | | | | |
|----------------------------------|------|------|----------|--------|---------|
| 7. At night while in bed? | None | Mild | Moderate | Severe | Extreme |
| 8. Sitting or lying? | None | Mild | Moderate | Severe | Extreme |
| 9. Standing upright? | None | Mild | Moderate | Severe | Extreme |

Activities of daily living

The following questions are regarding how your physical function has been affected by your knee (your ability to move around and take care of yourself).

During the **last week** what degree of difficulty have you experienced while:

| | | | | | |
|---|------|------|----------|--------|---------|
| 1. Descending stairs? | None | Mild | Moderate | Severe | Extreme |
| 2. Ascending stairs? | None | Mild | Moderate | Severe | Extreme |
| 3. Rising from sitting? | None | Mild | Moderate | Severe | Extreme |
| 4. Standing? | None | Mild | Moderate | Severe | Extreme |
| 5. Bending to floor/pick up an object? | None | Mild | Moderate | Severe | Extreme |
| 6. Walking on flat surface? | None | Mild | Moderate | Severe | Extreme |
| 7. Getting in/out of car? | None | Mild | Moderate | Severe | Extreme |
| 8. Going shopping? | None | Mild | Moderate | Severe | Extreme |
| 9. Putting on socks/stockings? | None | Mild | Moderate | Severe | Extreme |
| 10. Rising from bed? | None | Mild | Moderate | Severe | Extreme |
| 11. Taking off socks/stockings? | None | Mild | Moderate | Severe | Extreme |
| 12. Lying in bed (turning over, maintaining knee position)? | None | Mild | Moderate | Severe | Extreme |
| 13. Getting in/out of bath? | None | Mild | Moderate | Severe | Extreme |
| 14. Sitting? | None | Mild | Moderate | Severe | Extreme |
| 15. Getting on/off toilet? | None | Mild | Moderate | Severe | Extreme |
| 16. Heavy domestic duties (shovelling, scrubbing floors, etc)? | None | Mild | Moderate | Severe | Extreme |
| 17. Light domestic duties (cooking, dusting, etc)? | None | Mild | Moderate | Severe | Extreme |

Sport and recreation function

The following questions are regarding how your higher level physical function has been affected by your knee (e.g. your ability to exercise).

During the **last week** what degree of difficulty have you experienced while:

| | | | | | |
|----------------------|------|------|----------|--------|---------|
| 1. Squatting? | None | Mild | Moderate | Severe | Extreme |
| 2. Running? | | | | | |

| | | | | |
|--|------|----------|--------|---------|
| None | Mild | Moderate | Severe | Extreme |
| 3. Jumping? | | | | |
| None | Mild | Moderate | Severe | Extreme |
| 4. Turning/twisting on your injured knee? | | | | |
| None | Mild | Moderate | Severe | Extreme |
| 5. Kneeling? | | | | |
| None | Mild | Moderate | Severe | Extreme |

Knee-related quality of life

| | | | | |
|---|---------|------------|----------|-----------|
| 1. How often are you aware of your knee problems? | | | | |
| Never | Monthly | Weekly | Daily | Always |
| 2. Have you modified your lifestyle to avoid potentially damaging activities to your knee? | | | | |
| Not at all | Mildly | Moderately | Severely | Totally |
| 3. How troubled are you with lack of confidence in your knee? | | | | |
| Not at all | Mildly | Moderately | Severely | Extremely |
| 4. In general, how much difficulty do you have with your knee? | | | | |
| None | Mild | Moderate | Severe | Extreme |

Thank you for completing the questionnaire. Please give it back to a member of the research team. We will now assess you knee function in detail.