# SCIENTIFIC UNDERPINNINGS OF THE CLINICAL ASSESSMENT OF PATELLOFEMORAL ALIGNMENT

A Thesis Submitted for the Degree of Doctor of Philosophy By Kevin Daniel Campbell-Karn

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## Acknowledgements

"If you want to learn to swim, jump into the water. On dry land, no frame of mind is ever going to help you. The doubters said, 'Man cannot fly,' The doers said, 'Maybe, but we'll try,' And finally soared in the morning glow while non-believers watched from below."

"Empty your mind, be formless, shapeless, like water. You put water into a cup, it becomes the cup. You put water into a bottle, it becomes the bottle. You put it in a teapot, it becomes the teapot. Water can flow, or it can crash. Be water my friend." (Bruce Lee)

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#### Abstract

Patellofemoral pain is a common condition with multiple risk factors. A common consideration in the aetiology of patellofemoral pain is mal-alignment of the patellofemoral joint, which in itself, also has many causes. Clinical assessment of patients with patellofemoral pain requires a variety of tests to ascertain the underlying pathophysiology. Patellofemoral mal-alignment is, therefore, of clinical importance during physical assessments by clinicians. A common method of clinical assessment of patellofemoral mal-alignment is the McConnell assessment. At present, there is a lack of scientific evidence to support the clinical outcome measures from the McConnell assessment method for patellofemoral alignment. Whilst some authors have looked to modify this method to increase the objectivity of the outcome measures, there remain concerns about the reliability of the McConnell assessment method, whether modified or not, and how this may inform appropriate treatment, rehabilitation and onward referral. The McConnell assessment of patellofemoral alignment was developed to provide a rationale for McConnell taping to realign the joint. Realignment of abnormal joint position should, therefore, reduce pain and provide accelerated progression of therapeutic interventions and rehabilitation. At present, scientific evidence for the effectiveness of McConnell taping to reduce pain and realign the patellofemoral joint lacks agreement. Therefore, the purpose of this research was to examine the clinical assessment of patellofemoral alignment, as proposed by McConnell, in providing measurements of alignment compared to more detailed methods of assessment via magnetic resonance imaging (MRI), and to determine if McConnell taping would affect pain alongside any changes in patellofemoral alignment.

The first experimental chapter (3) explored the clinical and radiological assessment processes used by physiotherapists and sports therapists. The results revealed that 42% of physiotherapists and sports therapists used the McConnell assessment method, or a modified version by Herrington, during the clinical assessment to measure patellofemoral alignment. Experimental Chapter 4 tested a custom-made calliper designed to replicate and objectify the McConnell method of assessment. The calliper (named the Patellofemoral Calliper) was used to assess patellofemoral alignment in asymptomatic participants with the outcomes being compared to

recognised MRI methods of patellofemoral alignment assessment. The results revealed statistically significant intra-tester reliability for the calliper, however, lacked clinically relevant agreement with an MRI method that replicated the McConnell assessment on the MRI images. In addition, the calliper did not provide statistically significant correlation coefficients to values of patellofemoral alignment derived from MRI.

Experimental Chapter 5 explored osteoarthritic patellofemoral joints to determine if this population would have greater lateral alignment compared to participants from Chapter 4. The results highlighted increased lateral positioning in participants with osteoarthritis compared to an asymptomatic sample, confirmed via MRI. An observation from this study highlighted variability in the vertical axis of rotation of the femur during scanning that may have influenced the measurements that would be derived from clinical assessment. When the vertical axis of rotation was corrected to the posterior condylar line, the correlation between a clinical equivalent method of the McConnell method of assessment (derived from the scans to replicate the calliper used in Chapter 4) and the recognised alignment measures from MRI all improved. The result of the findings from Chapter 5 led to the experimental study in Chapter 6, whereby the Patellofemoral Calliper was tested on patients with patellofemoral pain and compared with MRI scans. However, during testing of the patellofemoral participants, the patient setup was given greater scrutiny, and the participant remained on the MRI scanner table for calliper testing. The results of this study saw improved agreement between the calliper and MRI derived measures, as well as improved correlation coefficients between the calliper and MRI alignment values.

The final experimental chapter (7) investigated the effect of McConnell medialisation taping, compared to a placebo tape application, in reducing pain and altering patellofemoral alignment in patients with patellofemoral pain. The results revealed that pain was reduced in both the McConnell medialisation taping and the placebo taping methods. Additionally, one MRI assessment method identified a difference in patellofemoral alignment following McConnell medialisation tape, but not for the

placebo taping. All other assessments for alignment were non-significant for McConnell medialisation tape and for the placebo tape.

The results of the experimental studies in this thesis demonstrate that clinical assessment of patellofemoral joint alignment requires development of the patient setup to ensure reliable values can be obtained. Specifically, vertical axis orientation of the femur requires control to enable meaningful data from clinical assessment. This may enable greater reliance on the clinical assessment methods available, including the McConnell assessment, especially when modified to provide objective outcome measures. McConnell medialisation taping of the patellofemoral joint in patients with patellofemoral pain is supported by this research in providing immediate pain reducing effects. However, changes in patellofemoral alignment following McConnell medialisation taping are not identified as a modifiable variable.

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# **Chapter 1 - Introduction**

Musculoskeletal complaints are among the most common cause of time off work in the UK (Office for National Statistics, 2017), with knee pain being the most commonly reported lower limb complaint in the primary care setting (Van Der Waal et al., 2006). An estimated 11-17% of all general practice visits for the lower limb are due to patellofemoral pain (van Middelkoop, van Linschoten, Berger, Koes, & Bierma-Zeinstra, 2008; Wood, Muller, & Peat, 2011). While there are a plethora of risk factors associated with this condition, there is a paucity of literature concerning cause and effect relationships in the development of patellofemoral pain (Lankhorst, Bierma-Zeinstra, & van Middelkoop, 2013).

Early identification of biomechanical issues is important to enable appropriate interventions aimed at reducing pain and lowering the risk for pathological progression (Crossley, 2014; Kalichman et al., 2007; Lack, Barton, Sohan, Crossley, & Morrissey, 2015). Conservative treatment of patellofemoral pain is both recommended and supported for the successful management of this condition (Barton, Lack, Hemmings, Tufail, & Morrissey, 2015; Lack et al., 2015; McCarthy & Strickland, 2013). Because of the multifactorial mechanisms that lead to patellofemoral pain, a comprehensive clinical history and examination is vital to identify potential risk factors and to tailor appropriate treatments (McCarthy & Strickland, 2013). One common cause of patellofemoral pain progression is malalignment of the patella within the trochlear groove (Hunter et al., 2007; Song, Lin, Jan, & Lin, 2011). Mal-alignment causes reduced contact area between the articulating facets of the patella and trochlea, leading to a proportional increase in peak joint pressures (Besier, Gold, Delp, Fredericson, & Beaupré, 2008; Powers, Ward, Chan, Chen, & Terk, 2004). Over time, the cumulative effect of increased articular load can induce pain in the subchondral bone (Besier et al., 2008; Collado & Fredericson, 2010). Due to the greater stresses on the chondral surface, this increased loading is a risk factor for premature 'wear and tear', and ultimately failure of the articular cartilage in the patellofemoral joint, with the eventual development of patellofemoral osteoarthritis (Crossley, 2014).

At present, there is lack of consensus on best practice for clinically assessing patellofemoral alignment (Crossley, Stefanik, et al., 2016; McCarthy & Strickland, 2013; Upadhyay, Wakeley, & Eldridge, 2010; Wilson, 2007). A clinical assessment and treatment approach for patellofemoral mal-alignment was proposed by McConnell (McConnell, 1986). This method remains under scrutiny for its reliability and validity (Herrington, 2002; McEwan, Herrington, & Thom, 2007; Mendonça et al., 2015; Wilson, 2007). The assumption of this approach is that the half-way distance between the medial and lateral femoral epicondyles, when compared to the half-way distance between the medial and lateral borders of the patella, can provide insight into the patellofemoral joint alignment. The offset between these two centres is thought to inform the clinician about pathological issues between the patella and the trochlear groove. This method faces criticisms for the subjective nature of the offset derivation (Wilson, 2007), with a wide range of reliability and validity coefficients reported (Herrington, 2002; McEwan et al., 2007; Mendonça et al., 2015; Watson et al., 1999; Wilson, 2007). At present, the most informative method of assessment is radiological review, however, this is not without its own methodological flaws (Wilson, 2007). X-ray, magnetic resonance imaging (MRI) and computed tomography (CT) scans all have merits in their ability to provide detailed, unrivalled information regarding structural derangements, including interaction between the articular surfaces and the osseous morphology (Smith, Davies, Toms, Hing, & Donell, 2011). Again, these methods are not without their own limitations. For example, cost implications (MRI and CT) as well as exposure risks from ionizing radiation (X-ray and CT) may limit their use. Additionally, MRI may be contraindicated due to claustrophobia or from metal within the body such as pacemakers or cochlear implants. It would therefore be of value if clinical assessment could provide the practitioner with reliable and valid methods of assessment for screening patients with patellofemoral pain.

Whilst the McConnell assessment method has mixed results for its validity and reliability (Herrington, 2002; McEwan et al., 2007; Mendonça et al., 2015; Wilson, 2007), the values improve when adapted with a more technically precise method, such as a clinical measurement tool (Herrington, 2002; McEwan et al., 2007;

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Mendonça et al., 2015; Sacco et al., 2010). If the McConnell assessment process can be honed to provide accurate outcome measures in the assessment of patellofemoral alignment, it may decrease the reliance on radiological investigations, thereby increasing cost effectiveness. Furthermore, improved validity from the McConnell assessment could help highlight those patients who are potentially in need of radiological assessment. There are added implications for those currently using the McConnell method of assessment, as improving the reliability and validity will lead to greater robustness in the clinical decisions for treatment and referral.

The McConnell assessment of alignment was originally developed to inform a specific treatment method, whereby tape is applied in a corrective manner. For example, if the patella is assessed as being lateralised, a medialisation tape is applied to 'pull' the patellar apex back towards a more favourable and anatomical position, thus improving articular congruency (McConnell, 1986). Improved congruency would optimise the load distribution over the articular surface and, therefore, reduce the pain stimulus in the sub-chondral bone. It is known that pain has deleterious effects on muscle activation (Bazett-Jones, Huddleston, Cobb, O'Connor, & Earl-Boehm, 2017) and leads to coping strategies to avoid painful motions (Neal, Barton, Gallie, O'Halloran, & Morrissey, 2016). The McConnell taping method has shown some effectiveness at reducing pain (Barton, Balachandar, Lack, & Morrissey, 2014; Edmonds, McConnell, Ebert, Ackland, & Donnelly, 2016), which should allow for improved function and the progression to rehabilitation exercises (McConnell, 1986). At present, the ability of tape to change patellofemoral alignment and reduce pain are contentious (Barton et al., 2014; Callaghan & Selfe, 2012; Edmonds et al., 2016; Ghourbanpour, Talebi, Hosseinzadeh, Janmohammadi, & Taghipour, 2017; Osorio et al., 2013). Clinical application of tape should follow an evidence-based underpinning for the effects of altering alignment and reducing pain.

For McConnell alignment assessment and taping to be recommended as an evidence-based approach to clinicians assessing and treating patellofemoral malalignment, it is important to evaluate the use of this approach within clinical environments. If there is widespread use of this assessment technique, the ability of this method to reliably extract superficial osseous landmarks for identifying potential pathology would benefit from further investigation. Further, the treatment of patellar taping to realign the joint and reduce pain warrants further investigation to ascertain its effectiveness in the management of patellofemoral pain.

The overall aim of this thesis was to investigate the clinical assessment of patellofemoral joint alignment and the response to realignment taping, with a view to informing evidence-based practice. It is acknowledged that patellofemoral pain is multifactorial, and so the approach used was to identify current practice and to focus on transverse alignment. Therefore, the following specific research questions were developed:

- 1. What clinical methods are used to assess patellofemoral pain in current clinical practice?
- 2. Is the McConnell method of transverse alignment assessment for the patellofemoral joint reliable and accurate?
- 3. What are the effects of McConnell medial correction taping on pain and alignment?

To address the overall aim of this research thesis, five experimental studies were conducted. The first experimental study (Chapter 3) used a questionnaire to explore the clinical and radiological assessment methods used by two groups of healthcare professionals (physiotherapists and sports therapists). This first study provided insight into the methods used to assess patients with patellofemoral pain in a clinical setting as well as establishing if patients are referred within this context for radiological assessment to confirm structural abnormalities. The experimental studies in Chapters 4, 5 and 6 investigated the McConnell method of alignment assessment, with specific emphasis on the reliability and validity of the measurements derived from superficial osseous landmarks. In Chapter 4, a custommade calliper (Figure 1.1) designed to replicate the McConnell method of assessment (named the Patellofemoral Calliper) with objective outcome values was investigated in an asymptomatic sample. This device was tested for intra-tester reliability and agreement with an MRI-derived replication of the McConnell alignment

methods of measuring alignment, to identify if the clinical device could infer malalignment that MRI-based assessments would derive.



*Figure 1.1.* The Patellofemoral Calliper measuring the offset between the patella centre and transepicondylar centre.

The aim of Chapter 5 was to investigate MRI derived measurements of patellofemoral alignment in an osteoarthritic sample and compare them to the asymptomatic data collected in Chapter 4. Within the experimental study of Chapter 5, it was considered appropriate to progress to patients with osteoarthritic patellofemoral joints, as these would provide more extreme measures to understand the relationship between osteoarthritic progression of patellofemoral alignment. Chapter 5 provided comparative data to inform the differences in patellofemoral alignments between a symptomatic and an asymptomatic group. An additional aim was to investigate the effects of vertical axis orientation of the femur in the McConnell method of assessment. The results of the vertical axis analysis of the femur informed the follow-up chapter (6) during which alignment was assessed in 5 patients with patellofemoral pain using the custom-made calliper and traditional MRI, with added controls for the positioning of the lower-limb.

The aim of the final experimental study (Chapter 7) was to investigate the effectiveness of McConnell medialisation taping to realign the patellofemoral joint and reduce pain. The realignment was tested using the calliper and MRI-derived measures, with pain deviations being assessed using patient-reported global rates of change during a single-leg squat manoeuvre. The aim of this final study was to apply the principles of the McConnell assessment method to a sample of patients with patellofemoral pain, to better understand the effects of taping on pain and alignment.

# **Chapter 2 - Literature Review**

#### Search strategy

Literature searches were conducted within electronic databases (BMJ Journals Collection, MEDLINE, PubMed, SAGE Journals, Scopus, SPORTDiscus, ScienceDirect) including search terms: Patella, patellofemoral, alignment, malalignment, tracking, mal-tracking, patellofemoral pain, patellofemoral pain syndrome, osteoarthritis, clinical assessment, physical assessment, radiological assessment, imaging, X-ray, MRI, McConnell tape, tape, brace, questionnaire. Inclusion criteria for articles were filtered based on age (within the last 10 years unless cited more than 5 times in recent articles), relevance, and citing within significant articles. The reference lists of utilised studies were reviewed for additional articles. Exclusions were made based on publication language other than English, animal studies, and studies that were not peer-reviewed.

### Context

The patellofemoral joint is a common cause of pain for the general public (van Middelkoop et al., 2008; Wood et al., 2011) and there are a range of risk factors associated with patellofemoral joint conditions (Lankhorst, Bierma-Zeinstra, & van Middelkoop, 2012). However, the biomechanical principles underlying the causes of pain and degeneration of this joint, are controversial (Crossley et al., 2016; Harbaugh, Wilson, & Sheehan, 2010; Lankhorst, Bierma-Zeinstra, & van Middelkoop, 2013; Wyndow, Collins, Vicenzino, Tucker, & Crossley, 2016). From a clinical perspective, it is important that the physical assessment of the knee provides a sound basis for clinical reasoning the pathophysiology (McCarthy & Strickland, 2013; Upadhyay et al., 2010), so that appropriate therapeutic interventions, exercise rehabilitation, diagnostic imaging, or onward referral to an orthopaedic surgeon, can be considered. Therefore, the principles of patellofemoral joint anatomy and biomechanics required in-depth review, to ascertain whether there may be causal influences in the development of joint pathologies and pain. It was found that malalignment within the joint is multifaceted in its aetiology, due to the coupled anatomical underpinnings of the knee joint. The current methods of assessing the

patellofemoral joint were, therefore, scrutinised for their potential to provide accurate, and reliable outcomes for a clinician to base their treatment and referral reasoning on. Additionally, radiological assessment can provide detailed information about joint tissues that may influence a treatment plan (Drew, Redmond, Smith, Penny, & Conaghan, 2016), and so, formed part of this review. Finally, a method of taping, currently adopted as a therapeutic intervention for mal-alignment and patellofemoral pain, was reviewed for its potential effectiveness in reducing pain and influencing the alignment of the patellofemoral joint.

#### Anatomy and biomechanics of the patellofemoral joint

The knee is a modified synovial hinge joint consisting of the tibia, femur and patella. This joint complex is the most intricate component of the lower limb kinetic chain (Zaffagnini, Dejour, et al., 2013). The distal femoral condyles articulate with the superior tibial plateau which, as the name suggests, consists of a largely flat surface of the tibia. The medial and lateral menisci deepen the concavity of the tibia to increase the congruency of the tibiofemoral joint whilst enabling important rotational movements (Rao et al., 2015). To enable this movement to occur, the menisci have a small degree of distortion available around the vertical axis. This motion is most prevalent in a flexed tibiofemoral joint where the knee can be actively rotated. The tibiofemoral joint has a typical sagittal range of movement from 0° extension to 140° flexion. In the transverse plane the tibiofemoral joint has a maximum rotation range of 31° at 30° of flexion, whilst at 0° of flexion only 8° of rotation is available (Nordin & Frankel, 2013). During terminal extension, the tibia rotates laterally to lock the knee, known as the screw-home mechanism. This motion is the normal anatomical path of the tibiofemoral joint at the end-range of extension (Nordin & Frankel, 2013). The screw-home mechanism locks the tibia into lateral rotation creating a closed pack position to allow reduced muscle activity and, therefore, preserve energy. The femoral condyles have an anterior junction, which forms the trochlear groove for the articulation of the sesamoid bone named the patella, forming the patellofemoral joint. The patella connects the quadriceps femoris muscle group to the tibial tuberosity, with concentric muscle activity providing tibio-femoral extension and eccentric contractions controlling flexion. The patella is the largest sesamoid bone in the human body and displaces the quadriceps tendon anteriorly to increase the leverage of the quadriceps femoris, thus increasing the mechanical efficiency (Loudon, 2016). The patella increases the quadriceps femoris lever arm by up to 10% in full flexion and up to 30% at 45° of extension (Nordin & Frankel, 2013). A second role of the patella is to dissipate the compressive load of the patella tendon over a larger surface in the trochlear groove. During flexion motion the patella tracks in a gentle 'C' shape (Yao et al., 2014) where it engages with the lateral facet initially, moves medially and then opens laterally. The loads placed upon the contact areas during knee flexion increase due to the quadriceps vector being at greater angles to the patellar tendon, thus causing increasing compressive joint loads (Nordin & Frankel, 2013). During static standing, the minimal quadriceps contraction required and the small quadriceps-to-patellar tendon angle means that very low patellofemoral compressive loads are present. As flexion increases during activities such as walking, the joint reaction forces rise to around one half of body mass. Activities including squatting or sitting, where knee flexion angles in the region of 90° are seen, cause joint reaction force increases of to up to 3 times body mass (Loudon, 2016). The surface contact area between the patella and trochlear groove increases at greater flexion angles to compensate for the increases in compressive load (Loudon, 2016; Salsich & Perman, 2007) and reduces again beyond approximately 90° as the patella drops deeper into the intercondylar groove and thereby reduces anterior displacement. In this sense, the specific surface contact area of the patellofemoral joint directly relates to the loads produced at any given angle. Subsequently, biomechanical abnormalities, whereby the contact area is altered or reduced, can cause a ramping of articular loads, thereby leading to pathology and degeneration over time (Erkocak et al., 2016; Tanamas et al., 2010; Van Haver et al., 2015). It is important, therefore, to understand the passive and active structures responsible for the orientation of the patellofemoral joint and how these may impact upon excessive joint loads.

#### Tissue restraints

The patellofemoral joint is surrounded by a cruciform arrangement of soft tissue structures that are influenced by a combination of active and passive tissues (Loudon, 2016). Superiorly, the patella attaches to the quadriceps femoris muscle 9

group which acts to apply force through the patella to the tibial tuberosity for sagittal plane movements. Medially, the patella is attached by the vastus medialis muscle. This muscle consist of two parts: the upper fibres, known as vastus medialis longus, and the lower fibres termed vastus medialis obliguus (Lieb & Perry, 1968). The vastus medialis longus muscle is orientated 15-18° to the vertical axis and therefore has a more vertical pull to the patella when compared to the vastus medialis obliguus which is orientated 50-55°, thereby causing a far greater medialisation of the patella by virtue of the line of pull. The vastus medialis obliguus has been identified as the main active restraint against lateralisation of the patella, and has been found to reduce the articular pressure if activated to optimal levels (Elias, Kilambi, Goerke, & Cosgarea, 2009). Literature has explored the strength, endurance, neuromuscular firing, and balance of the vastus medialis compared to the vastus lateralis (Elias et al., 2009; Gilleard, McConnell, & Parsons, 1998; Khoshkhoo, Killingback, Robertson, & Adds, 2016; Lankhorst et al., 2013; Miao, Xu, Pan, Liu, & Wang, 2015; Powers, 2000). The active stability that the vastus medialis obliguus muscle offers is considered to be of paramount importance to the functional stability of the patellofemoral joint (Balcarek, Oberthur, Frosch, Schuttrumpf, & Sturmer, 2014; Lin et al., 2008). Patellofemoral pain is linked to dysfunction of the vastus medialis obliguus muscle and the co-contraction of the vastus lateralis (Lin et al., 2010). Current recommendations of treatment focus on the retraining of the vastus medialis obliguus muscle to enhance strength, endurance and timing of contractions, leading to increased active stability of the patella during the initial phase of flexion as the patella engages with the trochlear groove (Elias et al., 2009; Lin et al., 2010; Miao et al., 2015; Rathleff et al., 2016). Concerns within these recommendations are seen in the sample sizes upon which they are based (Elias et al., 2009; Lin et al., 2010; Miao et al., 2015) as well as a lack of consideration for the impact of pain upon the muscle activation (Lin et al., 2010; Miao et al., 2015). The concerns are considered in recent research refuting the effectiveness of treatments that are aimed at enabling retraining of vastus medialis obliguus (Araújo, de Souza Guerino Macedo, Ferreira, Shigaki, & da Silva, 2016). Ribeiro, Grossi, Foerster, Candolo, & Monteiro-Pedro (2010) identified that a reduction in joint pain is essential due to the deleterious effect pain has on muscle firing patterns. In this context, it is unclear if pain has caused a deactivation of the correct motor pattern for movement, or if other biomechanical

issues have caused pain that has then led to a change in muscular activation. Prior to examination of potential pain-reducing treatments and mechanical corrections, consideration of the passive soft tissue restraints is warranted, as these will impact the muscular components, including the activation levels, due to the interactions of the active and passive tissues around the knee and lower limb.

Passive restraints of the patellofemoral joint for optimal articulation, include medial and lateral structures. Laterally, the anatomy consists of the superficial layer of the deep fascia. The intermediate layer consists of the components of the iliotibial band as well as the quadriceps aponeurosis and the deep layer of the joint capsule (Merican & Amis, 2008). Additionally, a lateral epicondylopatellar ligament has been identified (Fulkerson & Gossling, 1979). Medially, the intermediate layer consists of the medial patellofemoral ligament as well as the superficial component of the medial collateral ligament (Andrish, 2015). The deep layer is made up of the joint capsule and retinaculum, as well as their thickenings that form the medial patellofemoral ligament and the lateral patellofemoral ligament (Amis, Firer, Mountney, Senavongse, & Thomas, 2003; Zaffagnini, Dejour, et al., 2013). These passive structures all have recognised influences on patellar translation and tilt, which, when sub-optimal in their length, are understood to contribute towards patellofemoral malalignment and mal-tracking (Amis et al., 2003; Andrish, 2015). Importantly, the literature stresses that the most important passive restraining structure is the medial patellofemoral ligament (Amis et al., 2003; Bedi & Marzo, 2010; Philippot, Boyer, Testa, Farizon, & Moyen, 2012; Zaffagnini, Colle, et al., 2013; Zaffagnini, Dejour, et al., 2013). Where elongation or damage to this ligament occurs, the patella is permitted greater mobility towards lateralisation that may influence patellofemoral pain and/or instability (Zaffagnini, Dejour, et al., 2013). Laterally, the iliotibial band has the greatest influence in patellar translation (Zaffagnini, Dejour, et al., 2013). Due to its muscular attachments, the iliotibial band can have altered tension, and therefore, varied influence over the lateralisation of the patella during active flexion motion (Merican & Amis, 2009). This becomes particularly pertinent when the neuromuscular patterns of motion are considered alongside weaknesses or pain. Gait and functional load-bearing movements (such as sit-to-stand) can become compromised, leading to an over activation of the tensor-fascia lata muscle, which

attaches via the iliotibial band (Powers, 2010). Subsequently, greater lateral force vectors are observed during load-bearing activities (Weiss & Whatman, 2015), with possible pain inducing aggravation to the sub-chondral bone of the patellofemoral joint. However, it must be appreciated that the current literature is yet to establish if there are predetermined biomechanical errors that lead to patellofemoral dysfunction and pain. On-going research is required to understand what the process of cause and effect is. In the meantime, the objective physical assessment measurements are considered very important for aetiological clinical reasoning of existing patellofemoral pain.

### Patellar and trochlear facet considerations

The articular surface of the patella is divided into two distinct facets separated by the central ridge. The lateral facet typically has a larger surface area in conjunction with the greater load placed through it as it articulates with the lateral femoral condyle and facet of the trochlea (Andrish, 2015). The medial facet has a second ridge creating the *odd facet*. The facets consist of the thickest hyaline cartilage in the body, capable of withstanding large compressive forces with very low frictional properties (Andrish, 2015). The articular surface lacks a neural innervation and, therefore, is not pain sensitive; rather, the subchondral bone is believed to be the source of pain when joint surfaces are overloaded (Besier et al., 2015).

The lateral facet of the trochlear groove is typically larger than the medial, as would be expected due to the greater load being placed through this facet and the resultant forces it is required to dissipate (Iranpour, Merican, Dandachli, Amis, & Cobb, 2010). The lateral facet is also more anteriorly positioned at the ridge and begins more proximally where the patella initially engages on this side (Yao et al., 2014). As the knee moves into flexion the patella drops into the trochlear groove and tracks medially before then tilting outwards at full flexion, thus causing the medial facet to have the greater contact area and load at this range (Andrish, 2015). In this context, the different loads placed through the patellar facets and trochlear surfaces can help in the identification of pathology within the patellofemoral joint (Loudon, 2016). During the initial flexion phase of 0-30°, there is a greater load placed on the lateral facet as the patella initially drops into the trochlear groove and subsequently medialises before lateralising during deep flexion angles (Iranpour, Merican, Baena, Cobb, & Amis, 2010; Yao et al., 2014). When patients typically present with pain in the patellofemoral region during the initial flexion range of motion, the lateral facet, and more specifically the subchondral bone, is believed to be the pain-inducing structure (Besier et al., 2008; Collado & Fredericson, 2010). It is hypothesised that the pain is induced during the initial flexion phase due to the greater focal stress placed on the patellofemoral joint from kinematic errors, such as mal-tracking (Loudon, 2016; Sheehan, Derasari, Brindle, & Alter, 2009; Sheehan, Derasari, Fine, Brindle, & Alter, 2010). A change in the tracking of the patella will cause a reduced contact area and, therefore, create a greater specific load on the articular cartilage (Merican & Amis, 2009). Normally, as the knee flexes, the contact area increases to dissipate the increasing compressive loads (Freedman, Sheehan, & Lerner, 2015). There are current beliefs that the increased cartilage load and stress of patients with patellofemoral pain could be a key contributing factor to the production of pain, specifically through the lateral facet, as this is the most common area for patellofemoral joint pathology (Besier et al., 2008, 2015; Farrokhi, Keyak, & Powers, 2011). However, studies investigating the mechanical changes that affect the articular surfaces or joint kinematics are yet to establish robust results from their existing modelling techniques for the development of patellofemoral pathology (Besier et al., 2008, 2015; Sheehan et al., 2009, 2010). While an understanding of the changes in joint stresses are developed from a sound foundation of knowledge, the existing methodologies lack a fully comprehensive prediction model of the patellofemoral joint and how it is affected. Nonetheless, work continues to pursue greater detail and the existing knowledgebase provides some basis for components to consider in pathologic joints, with a level of clinical caution. From the current understanding, it is important to consider patellar tracking (transverse motion during flexion/extension) and alignment (static transverse positioning) measurements that may be measurable when patients seek medical advice due to pain in the patellofemoral joint. In this context, understanding patellofemoral pain and the assessment process of this condition is extremely important.

#### Patellofemoral pain

Pain around the anterior knee region can have many origins (Bumbaširevic, Lešic, & Bumbaširevic, 2010). There are umbrella terms (anterior knee pain, chondromalacia patella, patellofemoral pain syndrome, movie-goers knee) as well as potential causative diagnoses in the terminology used to identify the problem. At the recent International Patellofemoral Pain Research Retreat in Manchester (Crossley et al., 2016), 'patellofemoral pain' was defined as pain located around or behind the patella. Specifically, this pain must be elicited during one or more load-bearing movements where the knee is required to flex under load (e.g. squatting). This highlights the functional links between the elicitation of pain and the activity. The causes of pain can be multifactorial, however, the location of irritation is well defined. A statement was added at the 4<sup>th</sup> International Patellofemoral Pain Research Retreat that patients with prior dislocations or subluxations should be considered as an alternative sub-group, who may present differently and require alternative treatments (Crossley et al., 2016). Patellofemoral pain is a common condition among the general and sporting populations, mostly affecting those who are physically active and over the age of 40 (van Middelkoop et al., 2008; Wood et al., 2011). However, patellofemoral pain is also commonly seen in patients of all ages and activity levels (van Middelkoop et al., 2008; Wood et al., 2011), with raised incidence reported in females (Boling et al., 2010). As this condition progresses, it has a profound longterm impact on the ability to perform exercise and other physical activities of daily living (Collins et al., 2013; Lankhorst et al., 2015). Patellofemoral pain may also be a precursor to degenerative changes within the joint (Crossley et al., 2016; Hinman, Lentzos, Vicenzino, & Crossley, 2014). In this context, patellofemoral osteoarthritis is, therefore, an important consideration in the potential progression of patellofemoral pain.

### Osteoarthritis of the patellofemoral joint

Osteoarthritis is defined as a degenerative condition whereby the articular cartilage of the bones forming a joint is excessively loaded leading to structural failure of the tissue, with resultant irritation of the sub-chondral bone and the development of osteophytes on the articular surfaces (Glyn-Jones et al., 2015). Worldwide prevalence of symptomatic knee osteoarthritis is high in populations over 50 years of age (Busija et al., 2010) with men having a higher incidence than women in under 50 years of age and the reverse in over 60 years of age (Garstang & Stitik, 2006). Treatment is currently based on lifestyle management to reduce the loads, pain management to reduce symptoms, and therapeutic care to assist with return to activities of daily living (Bennell, Hunter, & Hinman, 2012; Glyn-Jones et al., 2015). End stage osteoarthritis is currently treated with surgical arthroplasty (Glyn-Jones et al., 2015).

The development of osteoarthritis is based on long-term overload of the articular surfaces that leads to degenerative changes with irritation of the sub-chondral bone (Glyn-Jones et al., 2015). There are anatomical risk factors that lead to this excessive loading (Garstang & Stitik, 2006). Specifically, dysplasia of joint surfaces causes a reduction in the contact area leading to focal overload of the articular surfaces (Glyn-Jones et al., 2015). Mechanical mal-alignment of the bone structures is also considered a risk factor due to the effects this will have on reducing the contact area of the articulating surfaces, which causes a subsequent proportional increase in load (Busija et al., 2010; Hunter et al., 2007). Whilst single incidents may be tolerated by the joint tissue, prolonged overload causes degeneration and, ultimately, osteoarthritis (Garstang & Stitik, 2006). The principle of overload underpins the link between mal-alignment of the patellofemoral joint and long-term changes that may lead to osteoarthritic development. However, medium term evaluation (5-8 y) has shown that those with patellofemoral pain continue to have chronic pain, not necessarily with osteoarthritic changes (Lankhorst et al., 2015). The methodological retrieval of osteoarthritic markers in this study was highlighted as a potential limitation by the authors (Lankhorst et al., 2015), meaning this may not be a true representation. Additionally, the medium-term prognosis of on-going and increasing symptoms within patients with patellofemoral pain, even without confirmed osteoarthritic changes, continues to be a concern for the potential longterm development of osteoarthritis (Macri, Stefanik, Khan, & Crossley, 2016). Research to support the mal-alignment outcomes of patients with osteoarthritis is warranted to help inform potential cause and effect relationships of patellofemoral osteoarthritis. Such data would enhance clinicians' understanding of the progression of osteoarthritis that may be due to mal-alignment of the patellofemoral joint.

Patellofemoral pain is a common and debilitating condition that may progress to degenerative osteoarthritis; therefore, the importance of appropriate assessment and effective treatment is unparalleled.

#### Assessment of patellofemoral pain

When assessing any joint, a thorough subjective history is recommended to inform the selection of clinical examination tests (Hengeveld, Banks, & Maitland, 2013). Because patellofemoral pain is multifactorial, there are a plethora of clinical assessments available that may contribute towards the patient's problem (Barton, Lack, Hemmings, Tufail, & Morrissey, 2015; Cook, Mabry, Reiman, & Hegedus, 2012; Näslund, Näslund, Odenbring, & Lundeberg, 2006). The clinical assessment of the patellofemoral joint includes a wide variety of tests aimed at understanding potential underlying pathologies. At present, however, patellofemoral pain and clinical assessment lacks clearly defined criteria and agreement about the principles of the physical examination that can lead to an appropriate and individualised diagnosis of the causes and pathology (Lankhorst et al., 2013; McCarthy & Strickland, 2013). One component of assessment that deals with the interaction between the articular surfaces of the patella and trochlea is measurement of alignment and tracking (Drew, Redmond, Smith, Penny, & Conaghan, 2016; Elias & White, 2004; Kujala et al., 1993; McConnell, 1986; Pal et al., 2013; Powers, 2003; Tomsich, Nitz, Threlkeld, & Shapiro, 1996; Wilson, 2007). Patellar mal-tracking is thought to relate to patellofemoral pain as a risk factor; however, current literature does not support the notion of a causal relationship (Song et al., 2011). Equally, static mal-alignment of the patella in the trochlear groove may provide insight into abnormal loading of the patellofemoral joint that increases the likelihood of patellofemoral pain (Song et al., 2011). A mal-aligned joint is considered to be the result of imbalances in the passive and active restraints of the patella that may cause loads which exceed the physiological thresholds of the articular tissues (Wyndow et al., 2016). Reliable and accurate identification of joint mal-alignment is, therefore, of paramount importance in the clinical identification of potential risk factors for injury, as well as a means of assessment in the outcomes of treatment success.

Clinical assessment of patellofemoral alignment and tracking can involve subjective observations and objective measurements. Subjective observation of the patella and its relationship to femoral osseous landmarks appears to have developed from the McConnell assessment (Figure 2.1), whereby the offset of the centre of the patella to the mid-femoral epicondyles is estimated (McConnell, 1986). The McConnell method reported a 96% success rate in the outcomes of taping and exercise that were based on the clinical assessment. However, the paper lacks control group scores as well as reliability and validity of the assessment and treatments proposed. Due to the subjective estimation within this process, critical review of the method has led to development of the assessment process. More recently, interpreting the position of the patella within the trochlear groove in static positions as well as during motion has been proposed to ascertain differences (Fulkerson, 2002; Witvrouw et al., 2005). However, there is little evidence to support the accuracy, reliability or validity of estimation methods (Powers, Mortenson, Nishimoto, & Simon, 1999; Watson, Leddy, Dynjan, & Parham, 2001; Wilson, 2007). Two articles (with shared authors) claim to find reliability and agreement in the clinical assessment process when compared to MRI (Herrington, 2002; McEwan et al., 2007). The Herrington (2002) paper compared twenty manual therapists for inter-tester reliability using the modified McConnell method of assessment with tape to establish the patellofemoral alignment. The methodology of this reliability study used only a single participant for measurement, therefore limiting the strength of the study. Whereas, the McEwan et al. (2007) study tested using the same methods but had a single tester assessing twenty-four participants, thereby not considering inter-tester reliability. Both of these papers reported excellent inter- and intra-tester reliability scores as well as good agreement to MRI based alignment assessment. The two papers were limited in their use of inter-class correlation coefficients as a measure of agreement and report that the mean clinical assessment score of therapists agreed with the MRI measurement. However, in one paper (Herrington, 2002) the mean was 1.4mm skewed from the MRI result and had a standard error of +/-3.9mm. In the second paper (McEwan et al., 2007), the clinical assessment mean was 3.1mm different to the MRI means. Whilst both papers conclude that there was good reliability, agreement, and validity for experienced manual therapists in clinically assessing patellofemoral alignment, the specific differences in millimetres between the methods would not be considered

acceptable in a clinical setting. The comparisons made between the clinical method and the MRI method are of interest to future research. Firstly, the methods of these two papers attempt to provide an objective outcome measure of patellofemoral alignment. Second, they compare the scores to a recognised MRI method in an attempt to identify agreement between radiological outcomes and the clinical assessment. A possible missing link here is that the MRI images could have been used to replicate the clinical method to establish if the clinical approach offered agreement with a more objective approach that was not limited by surface contact with the joint. Further consideration of such comparisons is warranted.

Within clinical assessment of patellofemoral alignment, the clinician estimates the interaction between the patella and the trochlear groove via palpation and observation of their relative positions. Limitations of these methods can be identified in the inter- and intra-rater reliability of an estimation (Fitzgerald & McClure, 1995; Herrington, 2002; Sacco et al., 2010; Tomsich et al., 1996; Watson et al., 1999), potential accuracy of the osseous landmark palpations (Herrington, 2002; Mendonça et al., 2015), and the setup of the patient for testing (Wilson, 2007). The patient setup during assessment appears vague, with methods requiring the patient to be positioned with the hip/femur/knee in an anatomical zero position so that the foot/knee/patella complex is facing forwards relative to the participant (Herrington, 2002; Mendonça et al., 2015; Ota, Ward, Chen, Tsai, & Powers, 2006; Sacco et al., 2010). Studies investigating clinical assessment all appear to contain similar methodological flaws in their lack of consistency in the setup and control of the patients' legs (Herrington, 2002; Mendonca et al., 2015; Ota, Ward, Chen, Tsai, & Powers, 2006; Sacco et al., 2010). This will likely affect the accuracy of the results and highlights a concern within a clinical environment. Additionally, inaccuracy may lead to misdiagnosis of patellofemoral mal-alignment that could affect patient care. The repeatability of patient setup, or the accuracy of using the surface anatomy to infer alignment of the limb, are yet to be investigated as a methodological concern. Conversely, with radiological assessment, the relative need for patient setup is removed due to the use of osseous landmarks, such as the femoral condyles, to act as a reference line (Endo, Stein, & Potter, 2011). In this way, radiological assessment is superior due to the ability for greater precision in the process of data

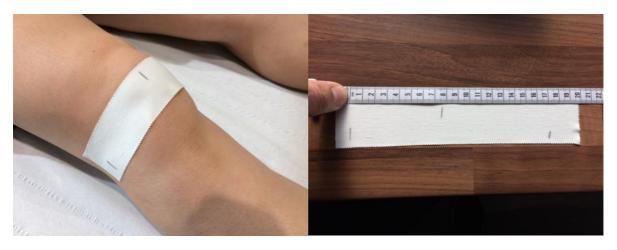
extraction. It must not be ignored, however, that the passive positioning of the lower limb within a radiological assessment may also impact upon the surrounding soft tissues that could affect patellofemoral alignment.



*Figure 2.1.* McConnell method of assessing patellofemoral alignment comparing the centres of the patella and transepicondylar axis.

Any form of estimation may lack reliability and validity and may be affected by the experience of the clinician (Herrington, 2002). Objective assessment should provide the clinician with greater reliability and validity when identifying measurements. In light of this, the McConnell method of assessing patellofemoral joint alignment has been modified to allow for objective outcome measures (Herrington, 2002; McEwan, Herrington, & Thom, 2007; Mendonça et al., 2015; Sacco et al., 2010). Specifically, tape placed over the knee is marked for osseous landmarks that can then be measured for the linear relationships between the epicondyles and the centre of the

patella (Figure 2.2) (Herrington, 2002; McEwan et al., 2007; Sacco et al., 2010). Using tape as a method of measurement has seen excellent inter- and intra-tester reliability, although lack reliability when tested between-days (Sacco et al., 2010). A potential methodological flaw with this measurement is the accuracy of identifying osseous landmarks for post hoc measurement. For instance, the clinician is required to locate the epicondyles, and must accurately identify and mark this osseous location. When methodologies are developed, they should be repeatable between testers. Whilst a clinician will have the ability to palpate the epicondyles and borders of the patella, the pinpoint accuracy of these landmarks may be affected by any tension or movement of the skin during palpation, as well as the ability to highlight a single location of what is a relatively broad anatomical process (e.g. the epicondyle). To date, the methodologies of clinical assessment have mostly lacked considerations of the pinpoint location repeatability of this approach. Additionally, when assessing using tape, it must be applied in a manner that does not cause any movement or stretching of the skin so as not to influence the measurement. Another potential flaw is that the application of tape over the knee has been identified as having an influence on the perception of pain (Barton et al., 2014), which may also impact muscle activation and, therefore, patellar alignment (Callaghan et al., 2012). The potential for a diagnostic yield from modified objective clinical assessment of patellofemoral alignment, warrant further investigation. It is unknown if these modifications or devices have been adopted by clinicians in practice; however, based on the limited research, it seems unlikely. Radiological assessment currently provides the clinician with objective measures of alignment to enable a diagnostic yield, and will be the subject of review.



*Figure 2.2.* Herrington modified McConnell assessment method for objective outcome measures.

#### **Radiological assessment**

Radiological assessment includes the use of X-ray, magnetic resonance imaging (MRI) and computed tomography (CT) (Smith et al., 2011). X-ray and CT use ionising radiation during the capture of images (Chun-Sing et al., 2011; Krille, Hammer, Merzenich, & Zeeb, 2010). Thus, there are risks associated with both methods (de González & Darby, 2004; Wall et al., 2011). CT and MRI also have cost implications that may reduce the likelihood of referral by a clinician. Standard X-ray images are limited in that they only image dense material such as bone (Li, Zhong, Connor, Mollenhauer, & Muehleman, 2009). This approach can be useful for some assessments (e.g. fracture identification), but lacks the ability to provide detailed images of soft tissue or articular cartilage imaging (Li et al., 2009). CT scans image soft-tissue as well as bone, thereby allowing for a three-dimensional cross-sectional view of the area scanned (Sanders, Loredo, & Grayson, 2001). MRI is based on magnetic fields that provide image slices of tissue, including bone, cartilage and other soft tissue structures, without radiation exposure and with superiority in evaluation of cartilage and ligamentous anatomy (Dejour et al., 2013).

There is no universal acceptance regarding the type of scan, setup of the patient, or data extraction method for diagnosing mal-alignment (Dei Giudici et al., 2015; Fulkerson, 2002; McCarthy & Strickland, 2013). This has caused difficulty in pooling data from clinical trials in patellofemoral joint abnormalities. Early studies into patellofemoral subluxation led Alan Merchant and colleagues (1974) to recommend the axial view of the patellofemoral joint, thus enabling the orthopaedic consultant to understand the interaction of the joint and to measure parameters that may help diagnose pathology. In this seminal work, the congruence angle was developed as a means of measuring the interaction between the central ridge of the patella, and the deepest point of the trochlear groove, to provide outcome measures for potential patellofemoral instability. Recommendations were made for abnormal congruence angles for laterally subluxing patellae (+16° or more) which has led many researchers to use these guidelines when researching mal-alignment (Ghourbanpour

et al., 2018; Ribeiro et al., 2010; Smith et al., 2011). However, within recent literature the basis of the Merchant et al. (1974) guidelines for identifying mal-alignment of the patellofemoral joint may not be appropriate for the associations made. In the context of measuring patellofemoral relationships, the congruence angle was originally developed to clinically identify minor subluxations (Merchant et al., 1974). The use of the congruence angle in recent literature has been as a means of identifying changes in the patellofemoral relationship between interventions (Ghourbanpour et al., 2018), understanding patellar tracking (Nha et al., 2008) as well as identifying participants with a pathologic patellofemoral joint for patellofemoral pain (Smith et al., 2011; Tan, Ibrahim, Lee, Chee, & Hui, 2017). The specific parameters for assessing the congruence angle appear to have moved away from those originally identified due to the need to restrict the number of radiological assessments made and to limit exposure to radiation. Any assessment of congruence angle not following the original methods would mean the ranges identified are no longer appropriate for comparison. Furthermore, it is unknown if the measurement of congruence angle, when taken out of the original context from the Merchant et al. (1974) study, can provide a useful means of reporting patellofemoral relationships. In a recent publication exploring the congruence angle as a patellofemoral alignment assessment method, Ghourbanpour et al., (2018) used the congruence angle in addition to pain scores, lateral patellofemoral angles and lateral patellofemoral displacement on patients with patellofemoral pain. The study had both intervention and control groups whereby routine physiotherapy was provided for all participants, however, the intervention group were also treated with patellofemoral taping. The study identified congruence angle as a measure of alignment, and yet, did not report the angle or setup of the participant in the scanner for the tests. Participant positioning could have impacted the results due to the potential effects of load, muscle contraction, and angle. The implications for these may be related to the findings of no change in alignment in contrast to the reductions in pain. The importance of reporting the angle as well as the load and contractile state of the participant needs to be considered in future studies. This is confirmed in the Tan et al., (2017) study where the link between instability and congruence angle was significantly correlated at 10° and 20° of knee flexion but not in extension. Concerns for the use of the congruence angle in clinical practice alongside other alignment measurements where radiological parameters

differ (e.g. flexion angle), mean that patients identified as having a patellar subluxation may be mis-diagnosed if the assessment did not follow the original guidelines. Continued exploration of the relationships between the bones and landmarks of the patellofemoral joint is needed to ascertain contemporary underpinnings of the results of any radiological assessment method. In this light, it should be questioned whether assessment methods such as the congruence angle should be renamed when used out of their original context.

The bisect offset was first described by Stanford et al., (1988) as a measurement obtained from the difference between a line drawn perpendicular to the posterior femoral condyles through the trochlear apex and the lateral border of the patella. The perpendicular distance between these lines is measured and is expressed as a percentage of the total patellar width. The bisect offset is orientated by the posterior femoral line, thereby providing a constant in the articular interaction between the tibiofemoral joint and the patellofemoral joint. By the expression of the measurement as a percentage of the total patellar width, the offset is directly related to the anatomical size of the patella. Measurements of bisect offset within the literature have identified excellent inter-rater reliability of .93 - .97 (Callaghan et al., 2016; Stefanik, Zumwalt, Segal, Lynch, & Powers, 2013) and .96 - .99 for and intra-rater reliability (Ho et al., 2017; Stefanik et al., 2013). Advantages of the bisect offset for reliability are identified in the markers used for measurement. Dei Giudici et al., (2015) concluded in their study that the bisect offset was the most reliable measurement for patellar alignment and that congruence angle showed the greatest variability when testing forty knees from twenty patients. When comparing these two methods, the accuracy of identifying the inferior pole of the patella for the congruence angle is seen as a major limitation. Whereas the bisect offset appears less sensitive to osseous markers. This reduced sensitivity is likely due to the need to identify border limits for the bisect offset, which may be easier to define on images than a single point on a peaked surface, such as the inferior patellar apex for measuring the congruence angle.

The bisect offset is used as a measure of patellar displacement (Macri et al., 2018) and extreme scores are associated with the risk of patellofemoral instability (Hunter

et al., 2007; Stefanik et al., 2013) and joint degeneration (Hunter et al., 2007). In the study by Hunter et al. (2007), 595 knees were assessed at 2 and 5 year follow ups to identify changes associated with joint degeneration. Whilst this study identified a strong link between bisect offset and degeneration advancement, it should be highlighted that the participants for the study were aged 70-79 years meaning that degeneration was more likely due to age as opposed to excessive load from malalignment. Additionally, whilst the study did utilise a weight-bearing scan with the knee flexed between 30° and 40°, the follow up assessments may have been affected by other controlling factors in the setup procedure. For instance, the angle of flexion is given a range as opposed to a specific angle which may have influenced the alignment scores. Additionally, the setup of the patient may have lacked control for orientation of the femur which may have impacted upon the patellofemoral alignment. In a similar study by Stefanik et al. (2013), 566 knees were assessed for alignment in patients with patellofemoral pain. The participants in this study were from a broader age range (50-79 years) but were all experiencing patellofemoral pain and degenerative changes. Whilst bisect offset was identified as a predictor of components associated with patellofemoral morphology, there were limitations in the methodological data gathering of the study. Specifically, the parameters for radiological assessment were non-weight-bearing and with the knee fully extended without any muscular activation. This may not be the most appropriate setup for understanding patellofemoral relationships.

When the bisect offset measurement was originally proposed, the images used were from CT (Stanford et al., 1988), whereas many studies reporting bisect offset base their measurements on X-ray or, mostly, MRI (Callaghan et al., 2016; Ho et al., 2017; Hunter et al., 2007; Stefanik et al., 2013; Xue et al., 2018). Many of the advances in scanning processes have been to add load to the joint during the assessment. Measurements of the bisect offset have shown variability in outcomes between loaded, weight-bearing, and non-weight-bearing methods (Drew et al., 2016), with differences exacerbated in those with excessive lateral patellar displacement (Draper et al., 2011; Souza, Draper, Fredericson, & Powers, 2010). The study by Draper et al. (2011) highlighted distinct increases in the lateralisation of the patella during supine initial flexion motion (0° to 5°) compared to upright weight-bearing flexion

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motion in patients without abnormal patellar translation. Conversely, the same study identified greater lateralisation in 25° to 30° of flexion in the weight bearing knees of participants with pre-existing excessive patellar translation. In the study by Souza et al. (2010), lateralisation was increased at a variety of flexion ranges in patients with patellofemoral pain, however, the authors also highlighted this may have been additionally influenced by femoral rotation. These changes identified in bisect offset measurement would be applicable to other radiological measurements for patellofemoral alignment due to the derivation of the landmarks. The Draper study is limited by the ability to perform the knee weight-bearing motion in an unrestricted pattern during the radiological assessment. Additionally, the sample size for both studies (Draper et al., 2011; Souza et al., 2010) were limited in participant size to 20 for Draper et al. (2011) and 30 for Souza et alc. (2010). The Souza study used 15 participants with patellofemoral pain and had matched participants who were pain free. Both studies failed to report any effect size calculations or justifications for the sample sizes used. The Souza et al. (2010) study appeared to allow a more functional motion due to the use of a single leg squat, which may also have exacerbated the femoral rotation and, therefore, could have impacted the results. Nonetheless, it appears that bisect offset, as well as other alignment measurement methods, may be influenced by the loading of the articular structures and it is recommended that imaging be conducted under load due to the potential influence of forces on the displacement of the patella. At present, guidelines are not clear about the influences of position or orientation of the knee during these loaded measurements.

Lateral patellar overhang (also termed lateral patellar displacement) measures the lateral trans-patellar overhang from a line drawn perpendicular to the anterior femoral condyles (Powers et al., 1999). Inconsistencies occur in the literature regarding the whether the perpendicular line is taken from the medial condyle or the lateral (Dei Giudici et al., 2015; Ghourbanpour et al., 2018; Herrington, 2002; Lan, Lin, Jiang, & Chiang, 2010; McEwan et al., 2007). It is unknown if the differences in condyle used have any impact upon the measurement of displacement. Additionally, the lateral patellar overhang appears to relate to the lateral patellar shift in the derivation of the measurements (Sasaki & Yagi, 1986). The lateral patellar shift is

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derived from a line drawn across the anterior femoral condyles with a perpendicular line drawn from the tip of the lateral condyle, through the patella. A line is drawn between the most medial and lateral edges of the patella and a measure is taken from the most lateral edge of the patella to where the perpendicular line from the femoral condyles intersects the patella. This measurement is reported as a percentage of the patella width (Sasaki & Yagi, 1986). The advantages of the lateral patellar overhang and lateral patellar shift are the relative ease with which the patella landmarks can be identified from the Merchant view. However, identifying the summit of the femoral condyle for the vertical line may cause some inaccuracies in displacement measurement. Additionally, when used on MRI outputs, the user is likely to need to superimpose the widest patella onto the appropriate condylar image. Recent literature recommends and primarily uses the bisect offset as a measurement of patellofemoral displacement instead of the lateral patellar overhang and lateral patellar shift (Callaghan et al., 2016; Dei Giudici et al., 2015; Drew et al., 2016; Ghourbanpour et al., 2018; Ho et al., 2017).

Axial views have been used as the basis for other measurement techniques to better understand the articulation of the patella in the trochlear groove (Endo et al., 2011). However, no studies have provided ranges for normal or abnormal outcomes to guide treatments. The methods developed focus on different osseous components to derive measurements. Some methods use the posterior femoral condyles as a reference line for orientation (bisect offset, lateral patellar displacement), while others use the anterior femoral condyles (lateral patellar shift, lateral patellar overhang, lateral patellar displacement). Furthermore, the setup of the patient in the imaging process have different parameters from which they can be obtained. Research has investigated the impact on alignment for contracted versus relaxed quadriceps femoris (Delgado-Martínez, Estrada, Rodríguez-Merchán, Atienza, & Ordóñez, 1996; Panni et al., 2011), load-bearing versus non-load bearing (Draper et al., 2011; Powers, Ward, Fredericson, Guillet, & Shellock, 2003), and wide ranges of static flexion angles (Drew et al., 2016; Salsich & Perman, 2013; Varadarajan, Gill, Freiberg, Rubash, & Li, 2010). Whilst there are rationales for each of these approaches, there is a lack of consensus as well as a varied approach to sampling and inclusion criteria which will likely account for some of the variability. Contraction

of the quadriceps femoris muscle group appears to have mixed effects in changing the position of the patella (Delgado-Martínez et al., 1996; Panni et al., 2011). Loadbearing measurements identify differences in tracking motions compared to supine (non-load bearing) motions (Draper et al., 2011; Powers et al., 2003). Furthermore, altering the flexion angle naturally influences the outcomes of patella position due to the relative congruence of the joint at different angles (Drew et al., 2016; Salsich & Perman, 2013; Varadarajan et al., 2010). Of relevance, when the patella engages with the trochlear groove (10-30° flexion), it can inform the clinician about the advancement of alignment progression (Elias & White, 2004) as this range is also where most patellofemoral pain sufferers report symptoms (Crossley et al., 2016). By 30° of flexion, the patella should have tracked medially (Elias & White, 2004; Kujala, Österman, Kormano, Komu, & Schlenzka, 1989). In this sense, a lack of medialisation, or clear lateralisation, should be more evident at 30° of flexion as a sign of patellofemoral mal-alignment. In osteoarthritic studies, where pathology causes changes to occur to the osseous and cartilaginous architecture, lateralisation has been more evident (Macri et al., 2016; Sharma et al., 2001). However, there is contention as some studies have highlighted little to no difference in alignment for osteoarthritic patellofemoral joints (Shawn Farrokhi et al., 2015; Kalichman et al., 2007). It is also unclear if there is a detectable crossover point where the patella begins to progress towards a mal-aligned position prior to developing osteoarthritic changes (Farrokhi et al., 2011; Hunter et al., 2007; Sharma et al., 2001), or if progression of this disease is measurable over time or preventable (Lankhorst et al., 2015; Macri et al., 2016). Research should continue to investigate the relationships between the articular surfaces during static and dynamic measurements to better understand what can be gleaned from radiological and clinical assessments of the patellofemoral joint. Where possible, studies would benefit from a standardised imaging and setup procedures as well as data extraction methods to enable future pooling of data. At present, no clear guidelines are available for this.

#### Influences of patellofemoral measurement in patient management

Patellofemoral alignment is measured via two methods: radiological and clinical assessment. Radiological assessment of the patellofemoral joint is recommended only for specialised investigations (X-ray) or if a clinician has identified cogent

reasons for aiding the investigations and management (MRI), however, in some cases these are deferred to ensure the problem will not self-resolve (Remedios, France, & Alexander, 2017). Conversely, clinical assessment of patellofemoral alignment is used to identify risk factors for the pain experienced by the patient and consider conservative interventions in their management (Cook, Hegedus, Hawkins, Scovell, & Wyland, 2010; McCarthy & Strickland, 2013; Post, Teitge, & Amis, 2002). Clinical assessment can, therefore, be considered a commonly conducted musculoskeletal process by appropriately trained professionals (e.g. physiotherapists), whereas radiological assessments will usually follow clinical assessment referral by physiotherapists, doctors and orthopaedic consultants.

The management of a patient with patellofemoral pain typically follows an evidencebased path and is treated conservatively in the first instance (Barton et al., 2015; McCarthy & Strickland, 2013). McConnell (1986) proposed a clinical assessment and taping treatment method to identify patellofemoral mal-alignment and provide pain relief to allow for advancement of therapeutic exercise interventions. It is unknown how much this method is in use at present, however, it is clear that there are no set guidelines for assessment of patellofemoral pain (Papadopoulos, Noves, Barnes, Jones, & Thom, 2012). Recent literature investigating the effectiveness of the taping technique does not appear to follow the McConnell assessment process prior to application (Araújo et al., 2016; Ghourbanpour et al., 2018; Ho et al., 2017). The lack of use of the McConnell method of assessment is likely due to the limited support for the validity and reliability of the method currently available (Sacco et al., 2010; Wilson, 2007). Where clinical reasoning identifies pathology and pain in the patellofemoral joint, it is recommended that a thorough physical examination be completed in the lower limbs. During this process, the clinician attempts to identify the structures responsible for eliciting pain (the symptom) as well as identifying probable causes and risk factors that may have led to the pain. Current literature identifies a plethora of structures and tests (Cook et al., 2010; McCarthy & Strickland, 2013; Smith et al., 2012) that are left to the interpretation of the clinician for devising a suitable treatment and rehabilitation plan for the patient. The most commonly identified tests for patellofemoral pain are Q-angle, J-sign, patellar apprehension test, Ober's test and Clarke's test (Cook et al., 2012; Papadopoulos et

al., 2012; Sheehan et al., 2010; Solinsky, Beaupre, & Fredericson, 2014). Additionally, the mobility and strength of the joints provides additional background to areas of concern. From a clinical perspective, aside from the McConnell method, there are no specific measurements of patellofemoral alignment. Therefore, the current treatment of patellofemoral pain and mal-alignment are reliant upon clinical interpretation and reasoning of selected assessments as well as a subjective consideration of the pain and mechanisms from the patient history. Treatment uncertainty has led to the 'best practice guide to conservative management of patellofemoral pain' published as a result of the patellofemoral pain research retreat review (Barton et al., 2015). The 'best practice guide' was based on level 1 evidence from systematic reviews in combination with semi-structured interview outcomes with patellofemoral experts. The recommendation was for a tailored multimodal approach based on supportive evidence of the interventions. However, this highlights that each patient requires an in-depth and unique approach of therapeutics interventions. It remains unclear what assessments will provide the requisite information to base the interventions on. Whilst a multimodal approach does offer the clinician guidance on the plethora of treatments that can be used, there remains a gap in the decisionmaking processes that start from the clinical assessment that should provide the basis for these interventions. The success of this management approach is based more simplistically on the pain reductions in the short and medium term that may provide a longer-term gain if continued.

### Bone formation risks for patellofemoral pathology

During growth and development, the osseous architecture of the lower limb can play a significant role in the risk of developing patellofemoral pathology (Garstang & Stitik, 2006; Hunter et al., 2007). Three secondary risk factors include femoral anteversion, external tibial torsion and morphology of the trochlea and patella (Erkocak et al., 2016; Tuna, Semiz-Oysu, Pekar, Bukte, & Hayirlioglu, 2014). The trochlea and patella are discussed elsewhere in this review; however, the orientation of the femur and tibia requires further discussion. Femoral anteversion is the associated rotational development of the femoral neck, whereby in acetabulo-femoral neutral, the lowerlimb and foot will appear to be facing inwards in a pigeon-toed stance. Due to this stance, a medialisation effect of the tibial tuberosity is seen and, therefore, an increased quadriceps torque vector as associated with an increased Q-angle. Femoral anteversion is often associated with external tibial torsion (Collado & Fredericson, 2010). Tibial torsion is defined as a rotational change in the orientation of the tibia that causes the foot to either turn inwards (internal tibial torsion) or outwards (external tibial torsion). External tibial torsion, along with femoral anteversion, create biomechanical risks for increased patellar stresses that may lead to patellofemoral pain (Dejour, Walch, Nove-Josserand, & Guier, 1994; Erkocak et al., 2016). This external tibial positioning causes an increase in the torque vector of the quadriceps muscle group that may lead to increased stresses, and therefore pain, in the subchondral bone of the lateral trochlear facet. A recent study (Erkocak et al., 2016) has highlighted the differences in both femoral anteversion and external tibial torsion between controls and patellofemoral pain sufferers, although, importantly, there were no differences between the symptomatic and contralateral pain-free knees, meaning that the morphology alone is not the sole cause of patellofemoral pain. The study by Erkocak and colleagues (2016) investigated participants with unilateral patellofemoral pain and compared measurements from the painful knee to the contralateral knee as well as a matched symptom free control group. However, the CT scans were performed with the participants laying supine with their leg muscles relaxed. For the patellofemoral measurements, relaxed quadriceps femoris muscles would mean the patella was positioned by the passive restraints of the local tissues as opposed to a contracted position, which may have influenced the amount of patellar displacement, Q-angle, and patellar tilt. Femoral anteversion and tibial torsion are important morphological considerations in lower limb biomechanical assessments for understanding potential influences on patellofemoral pain, although these factors are not considered singular in causing this condition (Dejour et al., 1994; Zaffagnini, Dejour, et al., 2013). It is, therefore, important to consider femoral vertical axis rotation and its effects on the patellofemoral joint.

### Causes of patellofemoral joint pain from lower limb mechanics

As medical professionals continue to ascertain causative factors in patellofemoral pain, the understanding of the contributing mechanisms in the patho-anatomy evolves alongside. While the study of the dynamic control and movement of the lower limb as an interconnection of active and passive tissues has enhanced this understanding (Crossley et al., 2016; Draper et al., 2011; Hunter et al., 2007), there is still a lack of consensus. Altered positioning of the lumbo-pelvic, acetabulofemoral, tibio-femoral, sub-talar and mid-foot to forefoot joints can all influence the passive and active restraints around the patellofemoral joint with consequent alterations in biomechanics (Barton, Levinger, Crossley, Webster, & Menz, 2012; Lack, Barton, Sohan, Crossley, & Morrissey, 2015; Matthews et al., 2017; Piva et al., 2006; Reiman, Bolgla, & Lorenz, 2009). Individual biomechanical effects are thought to involve all of the kinetic chain due to the interactive nature of the tissues. A common example that is measured clinically, as well as radiologically, is the Q-angle (de Oliveira Silva et al., 2015). The Q-angle is an angle formed from a line drawn from the anterior superior iliac spine down through the centre of the patella, and an intersecting line between the tibial tuberosity and the centre of the patella (Brattström, 1964). The Q-angle is important due to the resultant force vector produced in the line of pull of the quadriceps muscle group. A Q-angle greater than 20° is considered to be a risk factor for patellofemoral pain (Haim, Yaniv, Dekel, & Amir, 2006), however, the literature lacks definitive support of the Q-angle for the cause of patellofemoral pain (Duffey, Martin, Cannon, Craven, & Messier, 2000). Due to the multi-joint interaction of the lower-limb, changes in posture, muscular activation or osseous development can all influence the Q-angle and, thus, alter the lateralisation of the patellofemoral joint during active motion (de Oliveira Silva et al., 2015). Consequently, the influences of the Q-angle should be considered dynamically to fully understand the influences produced. Whilst the theory of a greater lateral pull has scientific merit, evidence suggests that a static measure of the Q-angle may not be an accurate predictor of increased valgus stresses (Freedman, Brindle, & Sheehan, 2014; Park & Stefanyshyn, 2011). Furthermore, the conditions under which the Q-angle are measured lack definitive consensus (Almeida et al., 2016) with many studies pursuing variations in Q-angle measurement processes (Almeida et al., 2016; de Oliveira Silva et al., 2015; Herrington & Nester, 2004; Sheehan et al., 2010) or lacking in detail about how conditions are controlled (Lee, Lee, & Lee, 2014; Park & Stefanyshyn, 2011). The lack of consensus, therefore, highlights the complexities of measurements of the

lower limb and a lack of clarity in methodologies upon which recommendations for patellofemoral pain measurements are made.

Powers, Ward, Fredericson, Guillet, & Shellock (2003) studied knee motion using dynamic MRI analysis in a single leg squat and concluded that the primary contributor to lateral tilt and lateralisation of the patella was due to medial femoral rotation. The influence of femoral rotation was more prominent at the first 10° of flexion, most likely due to the patellar engaging more with the trochlear groove as greater flexion angles were produced, thereby forced by the articular surfaces and force vectors of the active tissue restraints into a more centralised position (Salsich & Perman, 2013). As patellofemoral pain is synonymous with irritation during the first 20° of flexion (Amis et al., 2003), femoral rotation provides a factor to consider in the changes in lateral load during patellar engagement with the trochlear groove (Powers, 2003). A primary influence of femoral rotation (discounting femoral anteversion) is muscular activity. Lateral rotators of the femur include the piriformis, guadratus femoris, obturator internus, obturator externus, gemellus superior, gemellus inferior as well as additional lateral rotation inputs given by the lower fibres of gluteus maximus, gluteus medius and minimus (in hip extension) psoas major and minor and sartorius (Kendall, McCreary, Provance, Rodgers, & Romani, 2005). With such a vast array of muscles available for lateral rotation, each muscle will have individual influences in lateral stability and control as well as the motion of rotation. To this end, the functional control and stability of the femur in walking and greater flexion motions, such as stand-to-sit/sit-to-stand, are important to consider when medial rotation of the femur might cause an increased static or dynamic Q-angle (Aliberti, Costa, Passaro, Arnone, & Sacco, 2010). The concept that the femur moves under the patella, rather than the patella locating abnormally over the trochlea, adds justification to femoral rotation being influential in patellofemoral joint loads during dynamic functional movement.

The Q-angle is a static measurement process. At present, research questions the use of the Q-angle and other static measurements in a clinical setting for the identification of risk factors associated with patellofemoral pain (Cook et al., 2012; Freedman & Sheehan, 2013; Nunes, Stapait, Kirsten, de Noronha, & Santos, 2013).

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Dynamic observations of knee valgus during activities such as stair ascent may provide more meaningful results for correctional rehabilitation than static measures (de Oliveira Silva et al., 2015). Dynamic Q-angle assessment offers a functional method of assessment that appears to correspond with the biomechanical pathology of patellofemoral pain as opposed to a static, non-load bearing Q-angle assessment. When assessing the Q-angle dynamically, the 3D kinematics of functional motion that are common risk factors for patellofemoral pain (e.g. stair ascent) are tested (Aliberti et al., 2010). However, the Q-angle itself is not the only parameter that needs considering, as a change in knee valgus will also influence the measurement outcome. A lack of agreement between testers for Q-angle and other patellofemoral clinical assessment methods (Smith et al., 2012), can be explained by influences such as knee valgus stresses, and highlights the need for increased inter-rater reliability and more accurate assessment methods than are currently available or being used within research and clinical settings. Therefore, greater control of the lower limb setup is required due to the potential impacts on assessment outcomes (Powers, 2003; Reiman et al., 2009). Factors such as vertical axis orientation of the femur may be more influential on the joint alignment pathologies than is currently recognised, as is considered in total knee arthroplasty (Cherian et al., 2014; Iranpour, Merican, Baena, et al., 2010). Therefore, vertical axis orientation may be a co-component of the measurement process in understanding what needs to be corrected functionally. For example, a medially rotated femur during stair ascent will cause an increased lateralisation of the patella with subsequent increases in articular loads (Salsich & Perman, 2007). Over time, tissues adapt and respond to stress leading to permanent changes in their molecular structure (Khan & Scott, 2009). Neurological adaptations to the altered physiology of the tissues surrounding the joint inevitably leads to sub-optimal neuromuscular adaptations that may form part of the predisposition to joint damage (Lankhorst et al., 2013). As tissue damage occurs to the joint surfaces over time, pain may ensue which could add further to neuromuscular adaptations (Lankhorst et al., 2013; Powers, 2000; Toumi et al., 2013). Whilst assessment of the patellofemoral joint may highlight a lateralised patella, the literature lacks specific identification of vertical axis orientation of the femur during assessment in the pathological progression of patellofemoral pain (McCarthy & Strickland, 2013; Wilson, 2007).

### Patellofemoral mal-alignment taping

The goal of any joint assessment is to determine the best treatment for the long-term management of a pain. Patellofemoral mal-alignment is multifactorial in its aetiology for the development of appropriate treatment and management (Barton, Lack, Hemmings, Tufail, & Morrissey, 2015; Cook, Mabry, Reiman, & Hegedus, 2012; Näslund, Näslund, Odenbring, & Lundeberg, 2006). Broadly, current treatments aim to reduce pain, reduce irritation of the joint structures, and correct biomechanical errors of the lower limb (Crossley et al., 2016; McCarthy & Strickland, 2013). Within this context, an approach that has been widely accepted by the musculoskeletal community is the McConnell taping technique that was originally developed alongside the McConnell assessment method (McConnell, 1986). This approach was proposed to reduce pain, realign the patella within the trochlear groove, and enable advancement of other therapeutic and rehabilitative exercises towards restoration of patient function. While the effects of McConnell patellar taping have been well studied, the effectiveness of this approach is unclear (Araújo, de Souza Guerino Macedo, Ferreira, Shigaki, & da Silva, 2016; Barton, Balachandar, Lack, & Morrissey, 2014; Callaghan & Selfe, 2012; Edmonds, McConnell, Ebert, Ackland, & Donnelly, 2016). Pain appears to be a modifier that literature broadly agrees is influenced in the short-term (Barton, Balachandar, Lack, & Morrissey, 2014; Edmonds, McConnell, Ebert, Ackland, & Donnelly, 2016). However, few studies have investigated longer-term effects of patellar taping (Aminaka & Gribble, 2008; Barton et al., 2014). The realignment effects of taping raise contention. Where taping was found to altered the alignment of the joint (Herrington, 2010; Pfeiffer, 2004), the measurements were performed in a relaxed state. During muscle contraction or dynamic motion, however, the influence of the soft-tissue structures will likely overcome a surface application of tape. In this sense, the ability of tape to move the patella is questionable, or may be overcome by motions of the joint (Herrington, 2010; Pfeiffer, 2004). Due to the patella being under the influence of contractile tissues, it is possible that the tape is affecting the neuromuscular patterns of these tissues that may influence dynamic motion of the patella to alter tracking and reduce pain (Aminaka & Gribble, 2008; Edmonds et al., 2016; Keet, Gray, Harley, & Lambert, 2007). At present, taping is still recommended as part of the multimodal

treatment approach for patients with patellofemoral pain (Barton et al., 2015; Crossley et al., 2016). Future studies are needed to better understand the alignment influences of taping on the joint.

### Development of the patellofemoral calliper

From the current clinical assessment methods, a need was established for a clinical device that could objectively assess patellofemoral alignment following the McConnell principle of alignment assessment (McConnell, 1986; Sacco et al., 2010; Smith et al., 2012). Previous devices and methods were considered (Herrington, 2002; Sacco et al., 2010; Shih, Bull, McGregor, & Amis, 2004; Tomsich et al., 1996) during the development of this device. Specifically, it was highlighted that the device should be handheld, provide millimetre increments of offset, be simple to set up and use, and require minimal interpretation. Two plausible methods were, therefore, explored. The first design used a central cog with two arms that were toothed at the proximal end of the measurement arms. These arms would rotate towards the epicondyles or patellar borders thus ensuring a consistent centre for measuring the offset. Two pairs of these mechanisms would be used to identify the offset for alignment measurement. The second method utilised a twin sliding calliper setup with frontal plane guide channels where a cog was located to ensure the two arms moved dependently. This latter method was pursued due to the ease of manufacture and simplistic calibration method.

An initial development of the calliper was designed and made using CNC milled polycarbonate, gears and toothed tracks, as well as a spirit level bubble for levelling. This prototype was used for initial pilot testing of the idea for potential clinical application. Following a successful Emerald grant funding application, a rapid prototype was developed, and made, by E.G. Technology using 3D printing with specific removal of ferrous metal to enable the calliper to safely enter an MRI scan room (Figure 2.3). This second prototype formed the basis of the forthcoming research chapters.



Figure 2.3. Patellofemoral calliper.

### Summary

Patellofemoral pain is a common complaint in the general population and in those participating in sport and exercise. At present, there is no clear consensus on what parameters should be assessed during the clinical presentation of a patient with patellofemoral pain. Many methods have been developed with the aim of providing the clinician with potentially meaningful data about pathology. Alignment continues to be a consideration for identifying a measurable component for patellofemoral pain as mal-alignment is linked to damage of the articular surfaces that can lead to pain, and, over time could be a risk factor for osteoarthritis. Current clinical methods for assessing alignment appear to lack reliability and validity. Equally, there are few data concerning how clinicians assess alignment in patients with patellofemoral pain. The pursuit of greater understanding about the clinical assessment method for patellofemoral alignment, as outlined by Jenny McConnell, is warranted to enhance the clinical processes available.

Clinic-based assessment methods of patellofemoral pain are undoubtedly part of the clinical reasoning used to inform treatment options for patients with patellofemoral pain. The taping technique proposed by Jenny McConnell in 1987 has been the source of research in the pursuit of understanding existing patellofemoral pain management methods. The evidence suggests that taping may elicit a short-term reduction in pain. However, the mechanisms by which this occurs remain unclear. Additionally, research that supports the use of this taping method has primarily shown changes in alignment during an optimal setup – specifically, during relaxed extension. Further investigations into whether taping can reduce pain during trochlear engagement of the patella, and if this reduction in pain is associated with a clinical or radiological change in alignment, would inform best practice management of patients with patellofemoral pain.

## Chapter 3 - Current clinical assessment of patellofemoral alignment in patients with anterior knee pain

### Introduction

Lower extremity complaints contribute a high number of GP consultations with incidence rates for new complaints of 6-10% of visits per year (Jordan et al., 2010; Van Der Waal et al., 2006). The knee is the most commonly recorded complaint at 10-30% of all lower extremity conditions during GP visits (Jordan et al., 2010; Van Der Waal et al., 2006). Thus, knee complaints are a major concern for the health sector with only a slightly lower incidence than back pain. Whilst knee pathology can develop from a plethora of origins, the most common knee complaints are thought to occur to from the patellofemoral joint (Callaghan & Selfe, 2007). The incidence of patellofemoral pain is not well understood, with reported prevalence of 3-40% and a general acceptance that it is likely to represent 11-17% of all knee complaints reported to GPs. In addition, the incidence of patellofemoral pain is higher in sporting populations at 25% (Callaghan & Selfe, 2007; Crossley, Bennell, Green, Cowan, & McConnell, 2002; Crossley, Stefanik, et al., 2016).

Patellofemoral pain is the term used to describe pain located in the sub-patella and surrounding area. The pain is most commonly felt during load-bearing during initial flexion from full extension or during the return to an extended position (Crossley, van Middelkoop, et al., 2016). The pain felt during a loaded activity is normally due to irritation of the subchondral bone (Kramer & Kocher, 2007) as the articular cartilage itself is non-pain sensing. A plausible biomechanical reason for this irritation is an increase in the load of the lateral facet of the trochlear groove due to a lateralisation of the patella from altered excitation of the of active restraints with a lengthening of the passive restraints (Lankhorst, Bierma-Zeinstra, & van Middelkoop, 2013; Panagiotopoulos, Strzelczyk, Herrmann, & Scuderi, 2006; Zaffagnini et al., 2013). Powers (2003) proposed the notion that the mal-alignment of the patellofemoral joint originates from the trochlear groove via the femoral vertical axis orientation rather than the patella misaligning within the trochlear groove. Both identify that the interaction of the patella and the trochlea is of paramount concern.

The potential origins of patellofemoral mal-alignment are multifactorial. Thus, there are no clear clinical or radiological guidelines for the diagnosis of patellofemoral malalignment other than the association of symptoms during activity (Crossley, Callaghan, & Van Linschoten, 2016), in combination with subjective pain responses and location of pain. At present, patellofemoral mal-alignment is not confirmed as a predisposing factor to patellofemoral osteoarthritis (Crossley, Stefanik, et al., 2016), and yet interventions designed around realignment continue to be considered in the management of patellofemoral pain (Crossley et al., 2016). Clinical assessment of the patellofemoral joint is considered the 'cornerstone of diagnosis' even though there are no accepted tests currently available (Nunes et al., 2013). A review of likely causes of patellofemoral pain and assessment methods highlights that, despite conflicting and limited evidence for some clinical assessment methods, patellar alignment is still assessed in a clinical environment or as the basis for radiological assessment (Collado & Fredericson, 2010; Powers, 2003; Smith et al., 2012; Upadhyay, Wakeley, & Eldridge, 2010; Waryasz & Mcdermott, 2008). Radiological assessments of the patellofemoral joint include methods designed to assess the relationship between the patella and femur (trochlea), including measures of alignment, to inform therapeutic or surgical interventions (Dei Giudici et al., 2015; Draper et al., 2011; Freedman et al., 2015; Pal et al., 2013; Tan et al., 2017). Referrals for radiological assessment include the use of X-ray, computed tomography (CT) and magnetic resonance imaging (MRI). The use of these radiological assessment methods depend on the requirements of the referral and the justification of exposure. During X-ray and CT, the patient is exposed to ionising radiation of varying degrees. CT has a much higher exposure level, with evidence of large variances between assessment centres for the same scans (Shrimpton, Hillier, Meeson, & Golding, 2011). The exposure levels for both X-ray and CT are lower for the peripheral limbs than when the torso is scanned, which is advantageous for the knee. However, there is still a risk of radiation-induced cancer (de González & Darby, 2004; Shrimpton, Hillier, Meeson, & Golding, 2011; Wall et al., 2011). MRI scans feature magnetic field forces which, if suitably screened prior to scanning, represent a much lower overall risk to the patient as there is no radiation present (Schenck, 2000).

Radiological assessment of the patellofemoral joint alignment can be measured via X-ray, CT or MRI. There are a variety of measurements of alignment that can be made from these outputs, including: bisect offset, congruence angle, lateral patellar overhang, patella-lateral condyle index, patellar lateralisation, lateral patellar displacement, and lateral patellar shift (Elias & White, 2004; McNally, 2001; Sasaki & Yagi, 1986; Song et al., 2011). The most recognised are the congruence angle and the bisect offset as these have been shown to be most associated with patellofemoral pain (Drew et al., 2016). The other methods are not as strongly associated with patellofemoral pain, although some literature has also noted limited evidence to support the use of all of these alignment measurements for patellofemoral pain (Song et al., 2011). These methods are overviewed in the 2<sup>nd</sup> experimental chapter on page 70.

In the United Kingdom, musculoskeletal medicine is studied by a range of first line professionals including physiotherapists, osteopaths, chiropractors, sports therapists, and sports rehabilitators. Physiotherapists assess and treat a broad array of injuries, illnesses and disabilities (Physiotherapy, 2017), including musculoskeletal injuries such as patellofemoral pain. At present, the Chartered Society of Physiotherapy has 57,000 members, covering 90% of registered physiotherapists (Physiotherapy, 2018). Osteopathy focuses on the diagnosis and treatment of medical conditions whereby the musculoskeletal system alongside the ligaments and connective tissues can function in a state of balance. The General Osteopathic Council stipulate that osteopaths are able to treat a vast array of postural problems as well as arthritis and minor sports injuries (GOsC, 2014). Due to the focus of osteopathy on manipulation and massage (GOsC, 2018), this profession will not be considered in the current study. Chiropractors focus the origin of injury on the spine (BCA, 2018), and so these professionals will also not be considered for this study. Sports therapists, in this context focusing on members of The Society of Sports Therapists, are trained to graduate-level in the prevention, assessment and treatment of musculoskeletal injuries, which will therefore include the patellofemoral joint (Society of Sports Therapy, 2013). The current practicing membership is 4,300 (C. Robertson, personal communication, April 24, 2018). Sports Rehabilitation, as overviewed by The British

Association of Sports Rehabilitators and Trainers, concerns the assessment and diagnosis of pain, injury or illness of the musculoskeletal system (British Association of Sports Rehabilitators and Trainers, 2018); the current graduate membership is ~700 (R. Gordon, personal communication, April 24, 2018) and therefore the profession was considered too small in the context of examining the patellofemoral assessment methods used.

At present, one questionnaire for patellofemoral clinical assessment is the only available evidence for the clinical assessment methods currently in use. The questionnaire focused on physiotherapists in North Wales (Papadopoulos, Noyes, Barnes, Jones, & Thom, 2012). That study's outcomes were that physiotherapists rely on the visual analogue scores of pain in the knee, and subjective perceptions of functional tasks rather than any depth of physical assessment. Other questionnaires focused on the treatments administered (Smith et al., 2017) or the outcomes from patients (Dey et al., 2016) rather than the assessment methodologies. Seminal work (McConnell, 1986) recommended the clinical assessment of the patellofemoral joint via its orientation in three planes. To measure for transverse plane positioning (medial/lateral alignment), the patient is positioned supine and the medial and lateral epicondyles are palpated so that the clinician can estimate the centre of these two landmarks. The patella is then then palpated for the medial and lateral borders and again the centre of these landmarks is located (Figure 3.1). The offset between the two centres is then estimated to identify whether the patella is positioned centrally, medially or laterally. The McConnell assessment informs a taping technique to correct the mal-alignment and reduce pain, to allow further physiotherapeutic treatment and an accelerated return to normal function. Taping of the patellofemoral joint is still in use by health and allied health professionals, as evidenced by the volume of studies continuing to investigate patellar taping (Callaghan et al., 2012; Chang, Chen, Lee, Lin, & Lai, 2015; Logan et al., 2017; Roy, Gaudreault, Tousignant, Vézina, & Boudreau, 2016). Therefore, the assessment method for this taping technique as described by McConnell (1986), is likely to form part of the diagnostic process; however, the use within clinical assessment is not known. The McConnell method has been modified to increase the objectivity of its assessment (Herrington, 2002; McEwan, Herrington, & Thom, 2007). Specifically, tape is placed

over the front of the knee to allow for the medial and lateral epicondyles to be marked as well as an estimated centre of the patella. These marks are then measured for the offset between the centre of the patella, to the medial and lateral epicondyles (Figure 3.2).



*Figure 3.1.* McConnell method of assessing patellofemoral alignment comparing the centres of the patella and transepicondylar axis.



*Figure 3.2.* Herrington modified McConnell assessment method for objective outcome measures.

The McConnell method of patellofemoral assessment is used for direct analysis of patellofemoral alignment. However, there are other methods in use in the clinical environment as part of the assessment of factors related to patellofemoral pain (Collado & Fredericson, 2010; McCarthy & Strickland, 2013). Clinical considerations centre on an in-depth clinical history of the production and development of pain, observational assessment of the patellar positioning and patellofemoral joint motion during lower limb range of movement testing (including active motion and loadbearing motion). Specific tests include the J-sign, Q-angle measurements, patellar apprehension test, Clarke's sign and Obers test (Collado & Fredericson, 2010; McCarthy & Strickland, 2013). The J-sign is an observational test, whereby the patient extends the non-load bearing knee. During the last 30° of extension, as the patella moves up from the trochlea, a sharp lateralisation is considered a positive Jsign meaning that there is an excessive pull towards the lateral position (Sheehan et al., 2010). The Q-angle is an angle formed by a line drawn from the anterior superior iliac spine down through the centre of the patella and an intersecting line between the tibial tuberosity and the centre of the patella (Brattström, 1964). Angles greater than 20° are considered to be a risk factor for patellofemoral pain due to the increased vector of lateralisation this angle creates as the quadriceps muscle group pulls the patella laterally (Haim et al., 2006). The patellar apprehension test involves a lateral glide performed to the patella at 30° of flexion to test for any apprehension, pain or involuntary protection processes, such as a quadriceps contraction or grabbing the knee. The knee is then flexed with the sustained glide and the same signs are assessed (Nijs, Van Geel, Van Der Auwera, & Van De Velde, 2006). Clarke's sign is a provocative test whereby the therapist holds the patella in its resting position with the use of the web of the hand while the patient then contracts their quadriceps (Doberstein, Romeyn, & Reineke, 2008). Pain or an inability to hold this contraction for more than two seconds is a positive sign of chondromalacia patellar (irritation and deterioration of the articular cartilage of the patella). Ober's test is a passive test for tightness and pain in the iliotibial band. The patient is side lying and extends their uppermost leg at the knee and hip with the leg passively lowered from abduction towards adduction. Positive results are indicated if the leg

cannot be adducted without pain or tightness (Waryasz & Mcdermott, 2008). Alternative clinical assessments involve examination of lower limb alignment, and hip and ankle positioning and motion (McCarthy & Strickland, 2013). It should be noted that all of the aforementioned clinical tests have reliability, sensitivity and validity concerns (Cook, Mabry, Reiman, & Hegedus, 2012; Crossley, Callaghan, et al., 2016; McCarthy & Strickland, 2013).

The use of clinical assessment of patellofemoral alignment in the development of treatment, rehabilitation and referral is unknown. Increasingly, patients are aware of the diagnostic value of X-ray, MRI and CT. These radiological assessment methods of the patellofemoral joint may provide greater accuracy than clinical assessment as to the true nature of any apparent patellofemoral mal-alignment (Draper et al., 2011; Freedman et al., 2015; Pal et al., 2013; Tan et al., 2017). The therapist responsible for the diagnosis and treatment of a patient presenting with patellofemoral pain may consider radiological assessment. At present, there are no studies outlining the prevalence of patients who are referred for radiological assessment as part of the diagnostic process of a physiotherapist or sports therapist. Thus, the primary aim of this study was to investigate the prevalence of McConnell's method of clinical assessment of patellofemoral pain. The second aim of this study was to quantify the percentage of patients who are referred for additional diagnostics via radiological assessments by therapists in these professions. The third aim was to determine the type of radiological analysis used when assessing images of the patellofemoral joint.

### Methods

### Participants

Ethical approval for this study was obtained from the Brunel University London Research Ethics Committee (Appendix I). Health and allied health professionals from physiotherapy and sports therapy were invited to respond to a questionnaire. Convenience sampling was utilised in the selection of participants to take part in this study. Participants were contacted via e-mails from professional links and professional bodies or where contacts within the physiotherapy and sports therapy communities were made at appropriate conferences. All participants provided on-line informed consent.

### Sample characteristics

The Society of Sports Therapists agreed to disseminate this questionnaire to 1/3 of its membership. Further attempts to recruit participants focused on disseminating the survey directly to practitioners and via conferences. The survey ran from 15<sup>th</sup> January 2014 until the 21<sup>st</sup> April 2018, at which point 131 responses had been received. However, due to the inclusion criteria, from the 61,300 members of the two professional bodies, 119 of respondents were deemed eligible, and agreed to participate.

### Procedure

SurveyMonkey was used to survey the participants. Closed questions were chosen due to their lack of ambiguity although consideration had to be made that the responders might wish to answer alternatively to the proposed answers, therefore, comments boxes were available in questions where it was deemed that practitioners might need to expand or offer alternative answers (Boynton & Greenhalgh, 1998). Three principle areas were highlighted as being of particular interest to the research. It was established that, at present, there was a lack of clarity about the use of clinical and radiological assessment of patellofemoral alignment. Therefore, three components were established for the questionnaire to ascertain. These were:

- Clinical assessment methods used in the diagnostic assessment of patellofemoral pain based on profession.
- Use of radiological assessment methods in the diagnostic assessment of patellofemoral alignment based on profession.
- Type of radiological assessment used in the diagnostic assessment of patellofemoral alignment based on profession.

Pilot studies were run with feedback sought from appropriate practitioners in the musculoskeletal injury assessment industry to remove potential ambiguity of questions. The questionnaire continued to develop based on the feedback of these

pilot studies until the researchers were satisfied that the questions would provide valuable information about the use of clinical and radiological assessment of patellofemoral alignment (Table 3.1).

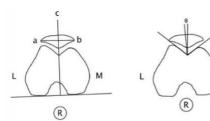
Question	Answer options
Which of the following professions are you	Physiotherapist
allied to?	Sports Physiotherapist
	Graduate Sports Therapist
	Sports Therapist
How many years have you been assessing	0-1 year
and treating injuries of the knee?	1-3 years
	3-5 years
	5-10 years
	10+ years
Approximately how many knees have you	0-25
needed to assess IN THE PAST YEAR that	25-50
have had pain in the patellofemoral joint?	50-100
	more than 100
Which of the following assessment methods	Clinical history
do you use for patellofemoral joint pain:	Observation of the patellar position in standing
	Observation of the patellar position in supine
	lying
	Observation of the patellar position during
	movement
	Observation of the patellar position during step
	up/step downs
	McConnell method
	Modified McConnell (Herrington method using
	tape and markers rather than just
	observation/estimation)
	J-sign
	Q-angle

*Table 3.1.* List of questions used for the questionnaire sent to physiotherapists and sports therapists.

	Patellar apprehension test Obers Other (please specify)
Do you ever refer patellofemoral joint pain for imaging assessment?	Yes No
Of the injuries that you assess as being due to the patellofemoral joint, approximately what percentage of these do you refer for radiological assessment?	0-10% 10-25% 25-50% 50-75% 75-100%
If you refer for radiological assessment, which type do you request?	X-ray MRI CT-scan None – I do not refer for radiological assessment Other (please specify)
If you refer for X-ray, what view(s) do you request?	Skyline Anterior/posterior Medial/lateral Other (please specify)
If you refer for X-ray, what angle of flexion do you request at the knee?	0 degrees 0-20 degrees 30-30 degrees 30-40 degrees >40 degrees I leave it up to the radiologist Other (please specify)
Following an X-ray, do you rely solely on the radiologist's report or do you prefer to interpret the scans yourself?	I rely on the radiologists assessment only I rely on my own observations I make a judgement based on the radiologist's and my observations Other (please specify)

When you refer for X-ray, do you ALSO refer for an MRI at the same time?	Yes always (100% of the time) Yes often (70-99% of the time) Yes sometimes (40-70% of the time) Not very often (1-40% of the time) Never Other (please specify)
Do you refer patellofemoral joint pain for MRI without X-ray?	Yes always Yes often Yes sometimes Not very often Never Other (please specify)
If you refer for MRI, what angle do you request the knee be flexed to during the scan?	0 degrees 0-20 degrees 30-30 degrees 30-40 degrees >40 degrees I leave it up to the radiologist Other (please specify)

During radiological assessment of the patellofemoral joint some clinicians will use one or more of the following methods.

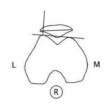


**Bisect Offset** 

Congruence Angle

Which of the above methods do you use when assessing alignment of the patellofemoral joint? Please expand if you use other methods. Lateral Patellar Overhang

Bisect offset Congruence angle Lateral patellar overhang Lateral patellar shift Other (please specify)



Lateral Patellar Shift

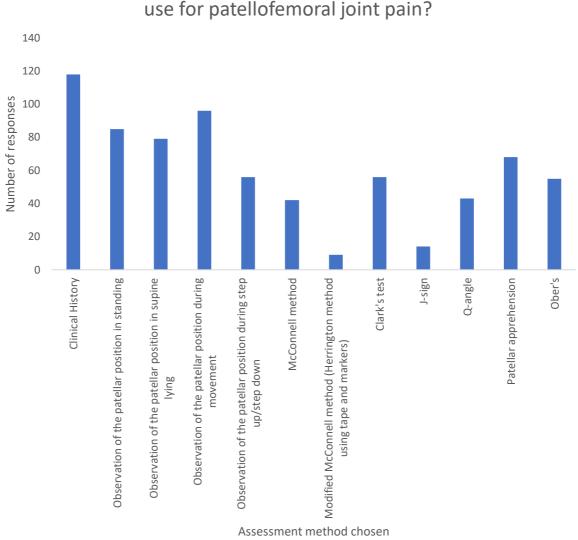
### Sample

Out of a population of 61,300 therapists (57,000 physiotherapists and 4,300 sports therapists), 119 responses were obtained with 73 physiotherapists and 46 sports therapists completing the questionnaire. Whilst this represented a small fraction of the available therapists within these professions, it was considered that not all of the 61,300 available practitioners would have had the musculoskeletal expertise or experience to take part in this study. Following contact with the Chartered Society of Physiotherapy (CSP Membership data, February 2019, unpublished), it was determined that approximately 64% of physiotherapists work in musculoskeletal care. Therefore, the total population was reduced to 40,800. Within sports therapy it was considered that all of the members would have the ability to assess patellofemoral pain as this profession specialises in musculoskeletal care. Due to the response rate of 119, there was a margin of error of +/-9% at a 95% confidence level.

### Results

As shown in Figure 3.3, the assessment method used most often for patellofemoral pain was clinical history, with a frequency of 116 (97%). The number of practitioners who used the McConnell method of assessment was 42 (35%), with 9 (8%) indicating that they used the modified McConnell method developed by Herrington (2002). The two McConnell methods were among the lowest used clinical methods of assessing patellofemoral pain used, alongside the J-sign (n = 14, 12%) and the Q-angle (n = 43, 36%). Other assessment methods rated highly were Ober's (n = 55, 46%), Clarke's sign (n = 56, 47%) and the patellar apprehension test (n = 68, 57%). The observation of the patellar position in standing (n = 85, 71%), lying supine (n = 79, 66%) and during movement (n = 96, 81%) were the next highest scoring methods for assessing patellofemoral pain. To determine whether there was any change in the methods used based on when the responders were trained, the responders were grouped by their years of experience. Analysis of the assessment method (defined by the number of years of experience) revealed that apart from those with 0-1 year of experience, experience did not affect the use of the McConnell

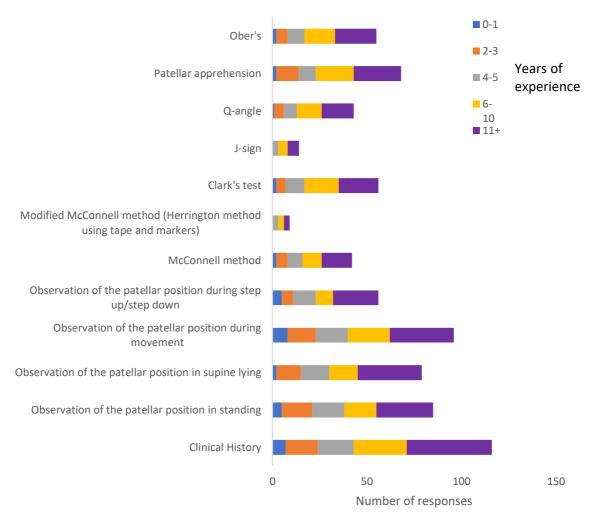
method (ranging from 33-44% for those with 2 or more years of experience). Clarke's sign, Q-angle and Ober's test had reduced use amongst more recently qualified therapists (see Figure 3.4).



Which of the following assessment methods do you use for patellofemoral joint pain?

Figure 3.3. Methods used for the assessment of patellofemoral joint pain.

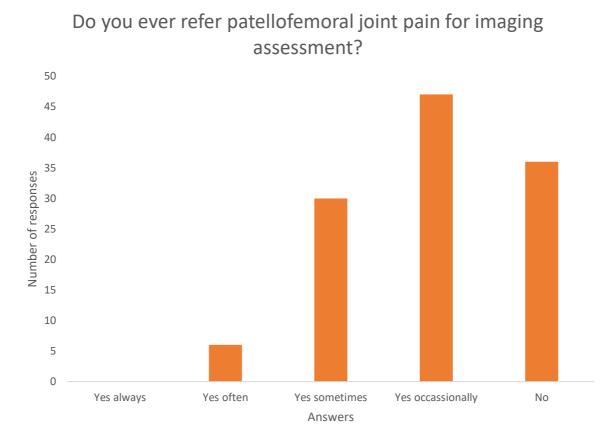
# Comparing number of years experience to the type of assessment method used for patellofemoral pain.



*Figure 3.4.* Number of years of experience versus the type of assessment method used to assess patellofemoral pain.

Imaging for patellofemoral pain was not used by 30% of therapists, with only 6 (5%) answering that they often referred for imaging and 30 (25%) stating they sometimes referred for imaging (Figure 3.5). If a therapist did refer for imaging, MRI was the most common selection (n = 63, 53%), with X-ray (n = 36, 30%) the second most popular choice (Figure 3.6). Some additional comments were noted, in that the therapist did not always have control of referral for imaging if the patients had to be referred through their GP. The diagnostic methods used or requested by therapists

for patients referred for radiological assessment was low (n = 64). Nonetheless, the use of diagnostic methods from the images were varied as displayed in Figure 3.7.



*Figure 3.5.* Number of responders who refer patellofemoral joint pain for imaging assessment.

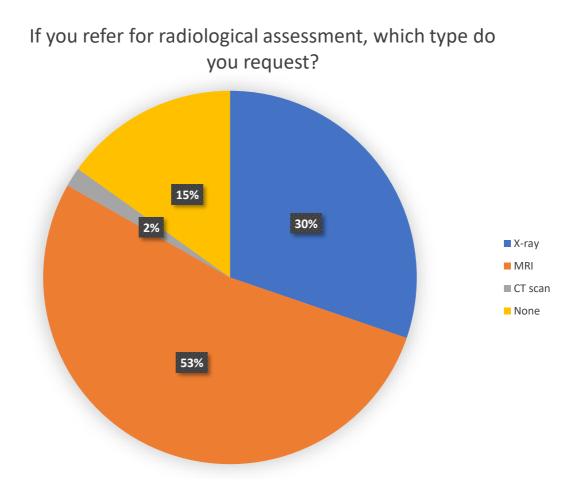


Figure 3.6. Type of radiological assessment chosen if the therapist referred.

# Which of the above methods do you use when assessing patellofemoral alignment?

Figure 3.7. Type of radiological data extraction method for patellofemoral alignment.

### Discussion

The first aim of the current study was to investigate the prevalence of McConnell's method of clinical assessment of patellofemoral pain. Whilst only 42 (35%) of the 119 responders used the McConnell's method, this method was still relatively well used by physiotherapists and sports therapists within the United Kingdom. Additionally, 9 (8%) responders used the Herrington modified method, whereby the method is measured objectively via the relative positions of the patella and femur using a tape and pen to locate the landmarks and measure the actual distances (see Figure 3.2). Only one responder used both the Herrington and the McConnell method. Therefore, the combined number of practitioners using either method was 50 (42%). Further, the length of time a practitioner had been practicing did not influence the use of the McConnell methods, highlighting that it is still widely used. Number of years of practice is an important consideration in the context of the current thesis as it suggests the McConnell assessment method has continued to be

used in recent years. Whilst the response frequency was higher for those with 6 or more years of experience (n = 73), the differences in years of experience did not impact the use of McConnell methods (see Figure 3.4). Consideration of the sampling is needed for the interpretation of these results. The proportion of the sample that were sports therapists was 39% (n = 46) leaving 61% (n = 73) of responses by physiotherapists. The participants were recruited via opportunity volunteer sampling methods, meaning that this may not be a true representation of the professional population. Additionally, the response rate for sports therapists with three or less years of experience was high at 48% of total answers (n = 22). It is plausible that this rate of inexperience leads to a reduced confidence in application of assessment techniques which has, therefore, reduced the response rate of physical assessments. The results of the methods used for assessing patellofemoral pain from the current study demonstrate that physiotherapists and sports therapists commonly evaluate patellofemoral alignment as part of the clinical assessment.

The most common method of assessing patellofemoral pain was clinical history, with 116 of 119 (97%) responders reporting use of this method in addition to physical examination. Clinical history is supported by recommendations for assessing patients with patellofemoral pain, as pain patterns are considered extremely important during diagnosis (Crossley, Stefanik, et al., 2016). The clinical history will support any working hypothesis the clinician may be considering; however, the scope of the questionnaire did not seek to obtain any specific information about what clinical history. Nevertheless, the questionnaire results indicate that clinical history is the most common method of assessing patellofemoral pain.

The assessment method with the next highest score was the observations of patellar position during lying supine (n = 79, 66%), standing (n = 85, 71%), and movement (n = 96, 81%). Thus, it appears there is a heavy reliance on clinical judgement of the position of the patella in relation to the femur via subjective impressions of the joint. The reliance on subjective impressions supports the notion that some of the inexperience of the participants may have influenced their use of such methods as opposed to more skilled execution of specific tests. Subjective clinical judgements follows recommendations within the literature (Draper et al., 2011; Upadhyay et al.,

2010), although it should be noted that inter-rater reliability of subjective assessments of patients is variable (Herrington, 2002; Sacco et al., 2010; Smith et al., 2012). Observation during movement elicited the highest score for the observation assessments (81%), although it was unclear which movements are observed by the therapists. The current recommendation of the Patellofemoral Pain Research Retreat group is that pain at the front of the knee produced during a squatting manoeuvre is the best available test for diagnosing patellofemoral pain (Crossley, Stefanik, et al., 2016). However, context is important, as the recommendation relates to the production of pain rather than the observation of the specific position of the patellar in the joint. Interestingly, pain during stepping only received 56 (47%) responses, raising the question of whether the observation of movement is during non-load bearing active range of movements rather than a load bearing activity such as squatting.

The Q-angle (n = 43, 36%), Ober's sign (n = 55, 46%), Clarke's sign (n = 56, 47%) and apprehension test (n = 68, 57%) were considered well used for the assessment of patients with patellofemoral pain. These physical assessments were selected by a high proportion of those with 4 or more years of experience and appeared to not feature often in the less experienced practitioners. By contrast, the J-sign had only a small use for assessing patients with patellofemoral pain (n = 14, 12%). The J-sign is a subjective observation of patellar motion during end of range extension. A large proportion of therapists appear to be observing the patella during movement (n = 96, 81%) with only a small number using the J-sign. Upon further analysis, 13 of the 14 practitioners who selected the J-sign highlighted that they also observed the patella during movement. Thus, within the professions of physiotherapy and sports therapy in the United Kingdom, the J-sign is not a commonly-used method of assessment for patients with patellofemoral pain. The current literature surrounding inclusion of the J-sign resides mostly within the orthopaedic community (Beckert, Albright, Zavala, Chang, & Albright, 2016; Tanaka, Elias, Williams, Demehri, & Cosgarea, 2016; Tanaka, Williams, Elias, Demehri, & Cosgarea, 2015; Xue et al., 2018), with researchers using the method as an inclusion criteria for studies with patellar maltracking groups (Sheehan, Derasari, Brindle, & Alter, 2009; Smith et al., 2012). The reason for the infrequent use of this test by therapists is unclear, especially in the

context of the high number of therapists using observation in motion as part of their assessment method. From the present study, observation appears to be valued for understanding patellar position in patients with patellofemoral pain. Therefore, measurable values obtained from clinical assessments would provide greater diagnostic yield in the development of treatment and referral plans. Additionally, the greater the experience of the practitioner, the greater the breadth of clinical assessment that may inform treatment and referral.

Clinical assessment of the Q-angle has questionable reliability and validity in the true assessment of patellofemoral pain or mal-alignment (Smith et al., 2012), unless tested radiologically (Elias & White, 2004). Even then, there are a plethora of different methods adopted, with controversy in the literature about how best this can represent the nature of the altered positioning of the patellofemoral joint. There are also conflicting outcomes from research about the link between the Q-angle and patellofemoral pain (Lankhorst et al., 2013). The Q-angle does, however, provide the therapists with a numerical value that they can associate with a potential diagnosis and treatment pathway. Similarly, Ober's test scored highly even though there is conflicting evidence for directly linking results from Ober's test to patellofemoral kinematics (Herrington, Rivett, & Munro, 2006; Kang, Choung, Park, Jeon, & Kwon, 2014; Willett, Keim, Shostrom, & Lomneth, 2016). Clarke's sign and the apprehension test are more provocative tests of the patellofemoral joint. Clarke's sign lacks scientific support (Doberstein et al., 2008; Nijs et al., 2006), possibly due to the test irritating patellofemoral joints in asymptomatic participants from the nature of the test. Surprisingly, Clarke's sign was one of the highest scoring assessment methods; however, this could be due to an increased likelihood of the patient providing a positive test result to aid confirmation of a working hypothesis. It is of interest that the popularity of the Clarke's sign, Q-angle and Ober's tests was less in those who qualified in the last 3 years, which suggests that these tests are now in decline as clinical methods of assessment, which does agree with the literature guidelines.

The apprehension test was the highest scoring physical test, and appears to feature heavily in screening tests for patellofemoral joint instability (Sheehan et al., 2009;

Smith et al., 2012). The apprehension test has been shown to have some diagnostic value as a clinical test in patients with patellofemoral pain (Nijs et al., 2006), but with conflicting findings more recently highlighting a low sensitivity for the test (Nunes et al., 2013). The findings from this study demonstrate that clinical assessment of patellofemoral pain utilises a wide variety of different subjective and somewhat objective testing methods, including the use of the McConnell method of assessment. As previously outlined, limitations within sampling methods of this study restrict the interpretative value of the results presented. However, the margin of error was identified at 9% with a 95% confidence interval. Nonetheless, greater clarity of the use of clinical diagnostic methods of patellofemoral assessment are warranted. Additionally, research into the effectiveness of the McConnell method is necessary based on the continued use of the McConnell method by the physiotherapy and sports therapy professions in the United Kingdom, with a limited number of therapists opting to use a more objective method as described by Herrington (2002). If the method can be adapted to provide an objective measurement of medial-lateral displacement then this may provide a more reliable tool for the assessment of patients with patellofemoral pain.

To gain additional understanding of the use of radiological assessment for patellofemoral pain by the physiotherapy and sports therapy professions, the second aim of this study was to investigate the percentage of patients who are referred for additional diagnostics via radiological assessments in these professions. The results highlighted that 30% of all therapists in this study did not refer for radiological assessment at all, and only 5% highlighting that they would often refer for radiological assessment at all. 25% of this sample said they would sometimes refer for imaging. From the data provided, it is unclear how many of these therapists were working in private clinics with direct referral access to radiological assessments. Additionally, within the scope of practitioners used within this opportunistic voluntary sample, it is feasible that only a small proportion were working in an environment where they were primarily responsible for the onward referral for radiological assessment. This highlights a clear limitation to the sampling methods of this study and impacts the weight of interpretation of this component. The Patellofemoral Pain Consensus Statement of 2016 (Crossley, Stefanik, et al., 2016) highlighted the links

between potential osteoarthritic developments due to alignment and trochlear morphologies measured from radiological assessments. Indeed any true understanding of the osseous morphology of the patellofemoral joint is only assessable via radiological assessment or surgery (Endo et al., 2011). The low rate of referral from the responses within this study raises potential questions about the true understanding of these professional groups of the kinematics of the patellofemoral joint. Alternatively, it may be that most patellofemoral pain sufferers under their care are appropriately managed with multiple conservative treatments based on the results of the tests completed by the therapist. This does agree with the individualised multi-modal model proposed by Barton, Lack, Hemmings, Tufail, & Morrissey (2015) and the model is supported by the 2016 Patellofemoral Pain Consensus Statement Part 2 (Crossley et al., 2016), although the basis on which the therapist builds the treatment regime is unclear.

To understand the type of assessments requested, the methods of radiological assessment referred by therapists when investigating patellofemoral pain were investigated. MRI was the most popular at 85%, X-ray was the second most popular at 49%. Of additional interest were the comments from some therapists who highlighted that they had little control over the type of radiological assessment methods used, as they would need to refer to the patient's G.P. for onward diagnostics. The analysis method used for determining if a patient has a malalignment anomaly from the scans had a low response rate, at 64 of 119, possibly due to this not being a common factor of a therapists' role in combination with some therapists (n = 36) reporting they did not refer for radiological assessment at all. The most common method of radiological assessment was the bisect offset, at 32 (50%), with congruence angle (31, 48%) and lateral patellar shift (28, 44%) giving similar results. The least opted for was lateral patellar overhang (18, 28%). These results highlight that whilst only a little more than half of respondents gave specifics of which analysis they preferred to use for scans when assessing alignment, there was recognition that the interaction between the patella and the trochlear groove was of significance in the planning of future treatment or possibly referral. Some comments made included "I'm more interested in functional outcomes" and "I tend to look at the bigger picture" highlighting that therapists perhaps are not considering the

radiological outcomes due to their belief in the subjective interpretation they glean from their overall assessment without the need for more specific numerical evidence. Clinical judgement may offer some explanation as to the continued use of assessment methods such as the McConnell technique, and certainly clinical history during the assessment of patellofemoral pain. That there is still a reliance on the physical examination is no doubt in part due to the limitations of cost, the success of conservative management (Barton et al., 2015; Crossley, Callaghan, et al., 2016) and possibly a lack of awareness of the validity and reliability of the tests being used due to the conflicting results in the literature. Further investigation of the assessment of patellofemoral alignment is warranted if the clinical setting could offer therapists reliable and valid outcome measures without the need for radiological assessment.

The present study investigated the methods used when assessing patients with patellofemoral pain. Specifically, the clinical assessment and use of the McConnell method for assessing alignment of the patellofemoral joint was considered. The McConnell method guides the user towards potential taping interventions perceived to be effective at reducing pain to allow for advancement of therapeutic and exercise treatments for patellofemoral pain. The findings of this current study highlight that this method is still in use by a good proportion of physiotherapists and sports therapists in the United Kingdom, although the limitations of the sample may pose restrictions on some of the interpretations available. In addition, radiological assessment for this condition continues to be used by these professions. The results of this study demonstrate that a greater understanding of the validity and reliability of the McConnell method of assessment and its association with radiological techniques is warranted, which will be the subject of the following experimental chapters.

# Chapter 4 - Feasibility of using a custom-made patellofemoral calliper for the assessment of patellofemoral alignment in an asymptomatic sample

### Introduction

Knee problems are a common complaint among the general population (Wood et al., 2011) with 3% of all GP visits in the UK and 23 to 31% of all physical injuries being knee-related (Thomeé, Augustsson, & Karlsson, 1999). Wood, Muller, & Peat (2011) found that one in six knee-related injuries were coded as a 'patellofemoral condition'. One of these coded diagnoses was 'anterior knee pain'. However, anterior knee pain is not a diagnosis but rather a symptom that has a number of different potential causes (Bumbaširevic et al., 2010).

One common cause of anterior knee pain is mal-alignment of the patellofemoral joint (Lankhorst, Bierma-Zeinstra, & Middelkoop, 2012). The patellofemoral joint is a complex articulation between the retropatellar surface of the sesamoid patella and the trochlear groove of the femoral condyles. Patellofemoral mal-alignment is an abnormal static position of the patella within the trochlear groove (Song et al., 2011). Patellofemoral mal-tracking refers to an abnormal patellar movement within the trochlear groove during knee extension and flexion (Song et al., 2011). Both mal-alignment and mal-tracking can cause undue stresses to the joint and surrounding structures, with resultant damage and potential pathology (Sheehan et al., 2009).

Mal-alignment of the patella most commonly occurs with an increase in lateral positioning (Merican & Amis, 2009). Lateralisation causes patellar kinematic abnormalities in the trochlear groove, predominantly in the last 20° of knee extension (Amis et al., 2003), which is mainly due to a decreased congruency of the patellofemoral joint as the patella rises out of the trochlear groove. Decreased congruency can lead to increased retropatellar and trochlear surface stress, thus damaging the hyaline cartilage surfaces and potentially irritating underlying painsensitive structures (Witvrouw, Lysens, Bellemans, Cambier, & Vanderstraeten, 2000). The cartilage itself is not pain sensitive (Kramer & Kocher, 2007); therefore the pain is due to increased contact pressures that irritate other retropatellar 61

structures, such as the subchondral bone (Kettunen, Visuri, Harilainen, Sandelin, & Kujala, 2005). Full thickness chondral defects are more common in the patellofemoral joint than in the tibiofemoral compartments, with patellar defects being more common than trochlear defects (Flanigan, Harris, Trinh, Siston, & Brophy, 2010).

There are a number of different causative or contributory factors to patellofemoral mal-alignment, including excessive femoral anteversion; valgus knee; external rotation of the tibial tuberosity; external tibial torsion; tight iliotibial band; tight lateral retinaculum; weak vastus medialis obliquus muscle with greater activity in vastus lateralis; laxity or deficiency of the medial retinaculum and/or medial patellofemoral ligament; planovalgus of the foot; and poor neuromuscular control (Baker, Bennell, Stillman, Cowan, & Crossley, 2002; Besier et al., 2008; Garth, 2001; Lankhorst et al., 2013; Merican & Amis, 2009; Ribeiro et al., 2010; Wilson, 2007). Treatment of anterior knee pain due to patellar mal-alignment is highly dependent on the identification of the underlying causes. Within this context, the identification of pathological mal-alignment is important (Hunter et al., 2007; Sharma et al., 2001). At present, the diagnostic processes for identifying mal-alignment of the patellofemoral joint vary. Both clinical and radiological methods are used (Smith, Davies, Chester, Clark, & Donell, 2010). The method of choice is often dependent on training, accessibility and cost.

Clinical methods for assessing the patellofemoral joint include measurement of the Q-angle, functional testing and the so-called McConnell technique (Herrington, 2002; Herrington & Nester, 2004; Liebensteiner et al., 2008). The latter was developed by McConnell (McConnell, 1986) and has been broadly adopted by the physiotherapy community when assessing alignment of the patellofemoral joint (see Chapter 3). The aim of this method is to determine the centre of the patella in relation to the femoral epicondyles. As such, this assessment method is reliant on accurate localisation of the medial and lateral patellar borders and femoral epicondyles. The clinician then makes a visual judgement of the offset between the two centres (Figure 4.1). Whilst the McConnell technique may be useful within a clinical context, this subjective measurement is reported to have limited reliability (Cook et al., 2012;

Fitzgerald & McClure, 1995; Mendonça et al., 2015; Tomsich et al., 1996; Watson et al., 1999; Wilson, 2007). Herrington (Herrington, 2002) refined the method by using zinc oxide tape to mark the epicondyles and central patella and subsequently measured the offset between the two centre points (Figure 4.2). Whilst this refinement was a useful first step toward improved reliability of the McConnell technique, it is still reliant on an accurate location of the epicondyles as well as the subjectively perceived mid-point of the patella (Sacco et al., 2010).



*Figure 4.1.* McConnell method of assessing patellofemoral alignment comparing the centres of the patella and transepicondylar axis.



*Figure 4.2.* Herrington modified McConnell assessment method for objective outcome measures.

One method of assessing objectively the patellar position relative to the femur is via the use of magnetic resonance imaging (MRI) (Keller & Levine, 2007). However, MRI is expensive and not always available to the clinician (see Chapter 3). Additionally, MRI may be a contraindication for some patients due to metal implants, such as a pacemaker or cochlea implant, or due to claustrophobia. It is clear, therefore, that there is a need for clinicians to readily, objectively and reliably determine the position of the patella in relation to the femur. Thus, a calliper was developed that measured the medial-lateral offset of the middle of the patella with respect to the mid-point of the femoral epicondyles.

The first aim of this study was to determine the reliability of the measures obtained from a purpose-built patellofemoral calliper. The second aim was to compare the measurements obtained using the Patellofemoral Calliper against MRI data. The first two experimental hypotheses were:

H<sup>1</sup>:The patellofemoral calliper will provide reliable measures.

H<sup>2</sup>:The patellofemoral calliper measurements will agree with the MRI data.

When using the McConnell method, one assumes that the mid-patella point between the medial and lateral borders of the patella provides a suitable reference point for the peak formed where the medial and lateral facets meet (i.e. the apex). A second assumption is that the mid-point between the medial and lateral epicondyles of the femur aligns with the deepest part of the trochlear groove. The variations in osseous shapes and patellofemoral joint kinematics are important within the context of patellar mal-tracking (Harbaugh et al., 2010). Several measures have been established, which can only be obtained by means of radiological assessment (MRI, X-ray and CT). These measures include the bisect offset, congruence angle, lateral patellar overhang, lateral patellar shift, and lateral patellar displacement. All these measures quantify numerically the relationship between the patella and the trochlear groove by means of describing the relative orientation of specific osseous landmarks of these bones (see Table 4.1 for specific definitions). However, the landmarks used (and therefore the assumptions in relation to the patellofemoral alignment) differ across the various measures. The assessment of these radiological measures is expensive and requires expert knowledge. For the clinician, it would be beneficial if the superficial landmarks could predict the radiological measures. Therefore, the final aim of this study was to compare the calliper measurements against radiological measurements obtained from MRI images. Within this context, the different radiological measurements were compared against each other. The third hypothesis was:

H<sup>3</sup>: The patellofemoral calliper measurements of patellofemoral alignment would correlate significantly with the MRI results.

#### Methods

#### **Participants**

Ethical approval was obtained from the Brunel University Research Ethics Committee (see Appendix II). Thirty-seven healthy participants with no acute injuries to the knee were recruited via opportunistic voluntary sampling (12 males and 25 females, age 18 to 49 y). The sample size was established from availability of participants from within a university setting where participants were able to travel offsite to an MRI scanner located at Royal Holloway University. Additionally, limited funding was available for the MRI scans meaning that the sample size was related to the efficiency of testing procedure. None of the participants suffered from heat and/or swelling around the knee or experienced anterior knee symptoms such as pain or instability. All participants completed an MRI screening questionnaire and gave written informed consent.

# Instrumentation

The Patellofemoral Calliper was designed to quantify the location of the centre of the patella with respect to the femoral epicondyles. The Patellofemoral Calliper was used to locate the superficial landmarks of the femoral epicondyles and the medial and lateral borders of the patella via two callipers connected through guide channels. The central positions for each pair of calliper arms were determined and aligned by using a twin circular calibration device. The offset of the two centres was then measured in millimetre increments on a ruler screen adhered to the device during calibration. A single axis spirit level was built into the body of the Patellofemoral Calliper to ensure that the measurements were taken in the transverse plane (Figure 4.3).



*Figure 4.3.* The Patellofemoral Calliper measuring the offset between the patella centre and transepicondylar centre.

A 3-Tesla scanner was used for the MRI (Magnetom Trio syngo MR 2004A, Siemens, Erlangen, Germany). The MRI scanner settings were: pixel spacing 0.210 mm, slice thickness 4 mm, imaging plane transverse, TR 2300 ms and TE 95 ms, and an acquisition time of 2 min 40 s. Participants lay supine on the scanner table with a support cushion placed under the knee to produce 30° knee flexion (verified via a modified 360° plastic 12-inch goniometer). A spirit level was placed against the medial calcaneal border and the medial border of the first metatarsal head to give a reproducible vertical foot position. Vertical foot alignment gave reproducibility in the relative position of the osseous landmarks of the knee for the Patellofemoral Calliper measurement.

#### Procedure

During the MRI scan, participants were given instructions to contract their knee extensors at a low level. A contracted state ensured that the patella remained in a fixed and repeatable position for the Patellofemoral Calliper. A 3 kg sand-filled bag was placed over the anterior talocrural joint line to provide a resistance to leg extension so that the quadriceps femoris muscles could be activated during the scan. The leg was also strapped to the MRI table at the ankle to prevent vertical and rotational movement.

The Patellofemoral Calliper measurements were made after the MRI scan. For this purpose, the participant lay supine on a massage plinth. Knee and ankle position were adjusted and fixed as per the MRI procedure, with the knee at 30° flexion, and the participant was instructed to contract their knee extensors at a low level, as before. The callipers were used to locate the femoral epicondyles and the outer borders of the patella. The Patellofemoral Calliper was held parallel to the horizon, as verified using a spirit level bubble within the device. The offset describing the distance between the two calliper centre points was then recorded. To quantify intratest reliability, the measurement process was conducted three times and the callipers were re-set each time.

## Measurement of the medial-lateral patellar position on MRI images

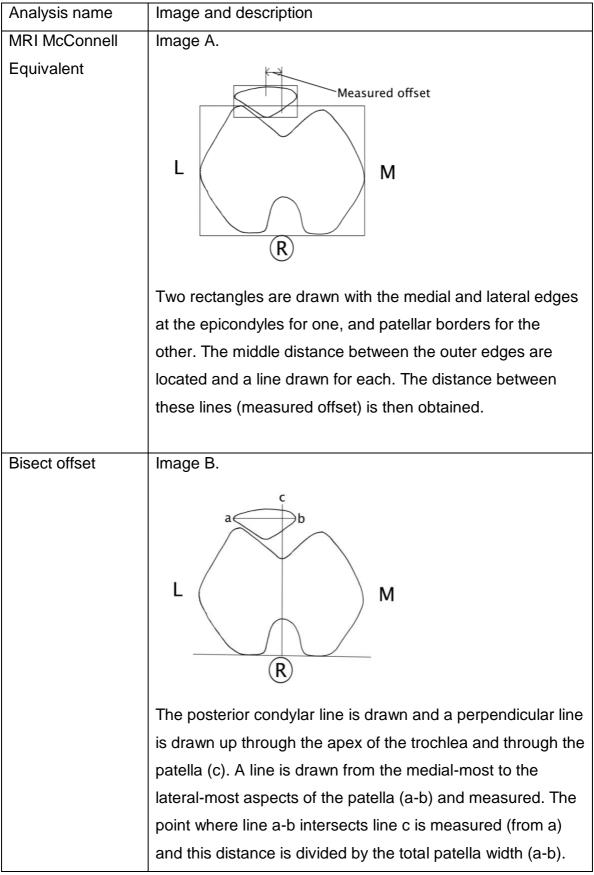
The MRI images were analysed using OsiriX, version 9 (Pixmeo SARL, Geneva, Switzerland). The slice with the widest femoral epicondylar distance was used for further analysis and the widest patellar markers were superimposed onto this image (Stefanik et al., 2013). The image was then used to determine the location of the patella with respect to the femoral epicondyles, applying the same principles as for the Patellofemoral Calliper measurement (subsequently referred to as "MRI McConnell equivalent"). This slice was also used to assess the bisect offset, congruence angle, lateral patellar overhang and lateral patellar shift (Song et al., 2011).

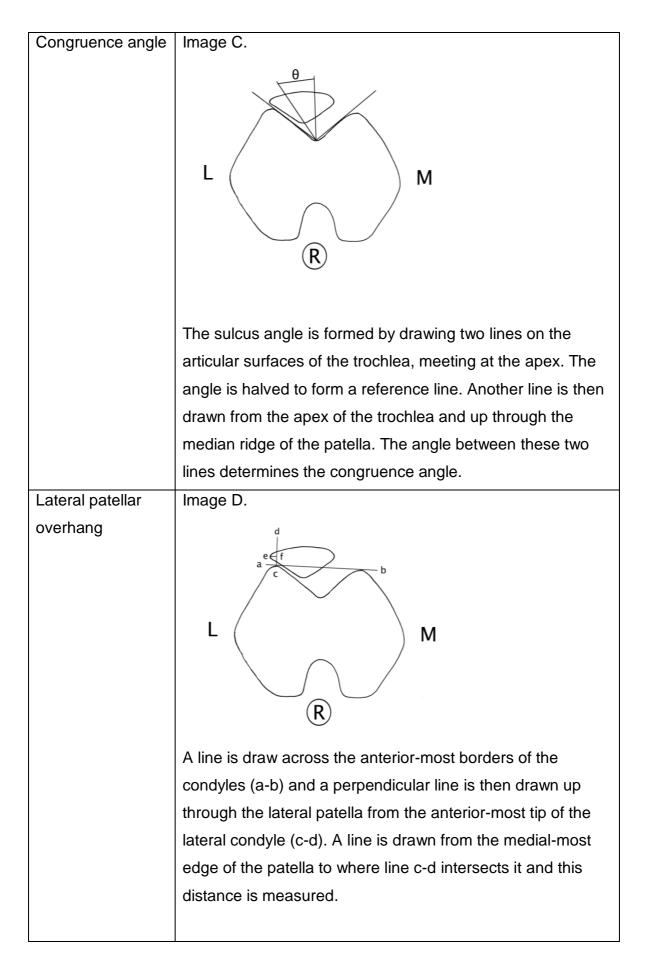
To measure the MRI McConnell equivalent, a rectangle was drawn around the medial and lateral epicondyles to ensure orientation was perpendicular to scanned image (Table 4.1, Image A). The mid-point between the medial and lateral patellar borders was then taken and a perpendicular line drawn through the patella. Another rectangle was located around the medial and lateral borders of the patella. Again, the mid-point was identified and a perpendicular line drawn. The MRI McConnell equivalent was then defined as the distance between the perpendicular lines of the patella and the epicondyles.

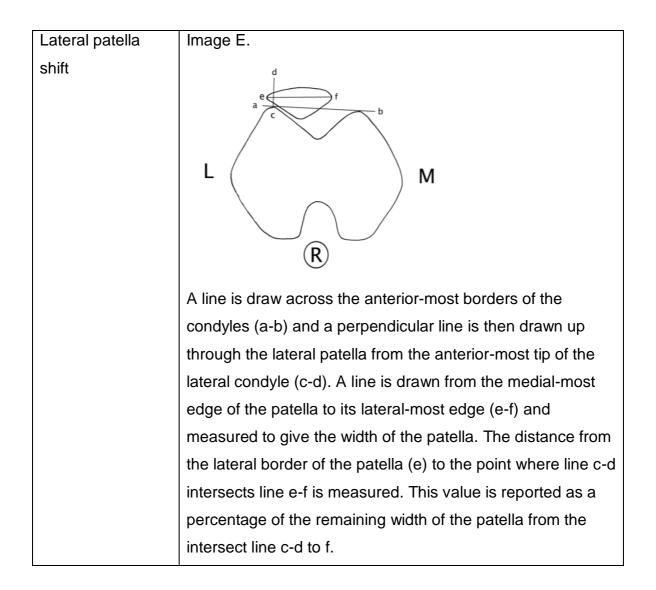
For the bisect offset, the posterior condylar line was identified as the line connecting the most posterior points of the medial and lateral condyles. A line was constructed that was perpendicular to the posterior condylar line and passed through the trochlear apex. The point between this line and the line that connects the most medial and lateral points of the patellar border was then identified. The bisect offset was defined as the distance between the lateral patellar border and this intersection point compared to the total patellar width, expressed as a percentage (Table 4.1, Image B). The congruence angle was identified as the angle enclosed by the line bisecting the sulcus angle and the line connecting the apex of the trochlea and the median ridge of the patella. The sulcus angle was measured as the angle formed by the lines connecting the deepest part of the trochlea and the most anterior points of the medial and lateral condyles, respectively (Table 4.1, Image C). For the lateral patellar overhang, a line was drawn between the most anterior points of the medial formed by the medial and lateral condyles, respectively (Table 4.1, Image C).

and lateral anterior condyles. A perpendicular line was then drawn passing through the most anterior point of the lateral condyle; the distance from where this line bisected the most lateral edge of the patella was measured (Table 4.1, Image D). Finally, the lateral patellar shift used the same landmarks and was calculated as the lateral patellar overhang distance as a percentage of the remaining width of the patella (Table 4.1, Image E). Table 4.1.

MRI analysis methods used to assess alignment of the patella.







# Statistical Analysis

Data were analysed using IBM SPSS statistics for Mac, version 23 (IBM Corp., Armonk, N.Y., USA). The critical  $\alpha$  level was set to p = .05. Where multiple correlation coefficients were conducted, the p value was adjusted using a Bonferroni correction to reduce the likelihood of a type I error (critical  $\alpha$  level was divided by the number of tests conducted). All data were tested for normality via Shapiro-Wilk test and all results were normally distributed (p = <.05). To quantify intra-tester reliability of the dependent variable Patellofemoral Calliper measurements, intra-class correlation coefficients were determined using three separate measurements made on each participant. One correlation coefficient was calculated for each pair of measurements (i.e., three in total). According to Cohen (1992), correlation values for *r* were determined based on <.10 trivial, .10 to .29 small, .30 to .49 medium, and >.50 large.

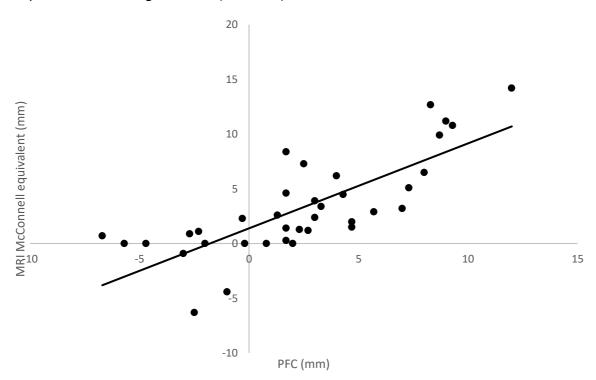
Agreement between the Patellofemoral Calliper and MRI McConnell equivalent measurements was assessed using the method described by Bland & Altman (1986). First, the Pearson product moment correlation coefficient was calculated, and the corresponding scatter plot with line of equality was produced. Second, the difference between the Patellofemoral Calliper and the MRI McConnell equivalent method (i.e., the bias) was calculated and plotted against the mean of the Patellofemoral Calliper and MRI McConnell equivalent values. The limits of agreement were estimated by multiplying the corresponding standard deviation by 1.96. The resulting values were then added and subtracted to and from the bias to yield the upper and lower limits of agreement with the number of cases that fell outside the limits of agreement obtained. The acceptable limit of agreement was established a priori as +/- 2 mm. Initially a calculation was made based on the proposed ranges of congruence angle range that are considered clinically relevant (Merchant et al., 1974). The angle was superimposed onto the MRI of this cohort and transposed into a horizontal measurement in line with the borders of the patella, which gave a potential range of +/- 4 mm. This range was not considered to be a clinically acceptable range. Halving this score to provide +/- 2 mm appeared to provide a more anecdotally relevant range. Additionally, research revealed measurements of patellar displacement equal to or greater than 4 mm were considered an appropriate cut-off point for evaluating clinically relevant patellar tracking measures (Heesterbeek, Beumers, Jacobs, Havinga, & Wymenga, 2007). It was, therefore, deemed that a difference greater than 2 mm would lead to clinically unacceptable results. The acceptable limits of agreement established a priori were compared to the upper and lower limits of agreement. The number of cases that fell outside the acceptable limits of agreement were obtained to decipher the acceptance of the agreement.

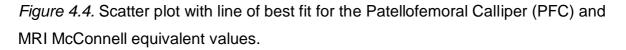
To quantify the relationships between the dependent variables of Patellofemoral Calliper measurements and the recognised radiological measurements, Pearson's product-moment correlation coefficient was calculated. Additionally, to quantify the relationships between the radiological measurements amongst each other, Pearson's product moment correlation coefficient was, again, calculated.

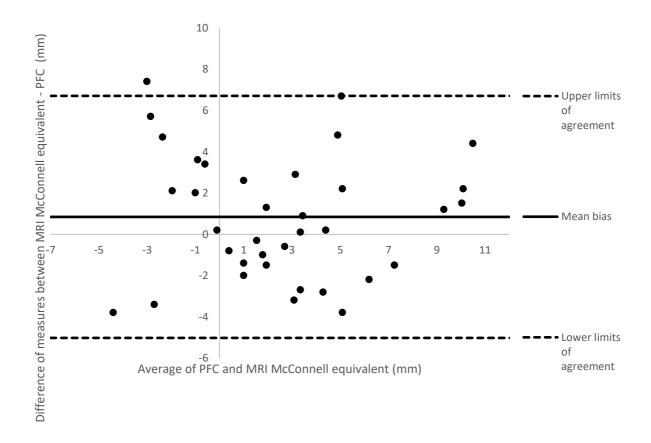
## Results

The intra-class correlation coefficients quantifying the intra-tester reliability of the Patellofemoral Calliper alignment measurements were r(35) = .99, P > .01.

The Pearson product-moment correlation coefficient describing the relationship between the Patellofemoral Calliper alignment measurements and the MRI McConnell equivalent alignment measurements (Figure 4.4) was r(35) = .78, p < .01. The Bland and Altman plot (Figure 4.5) revealed a systematic bias of the Patellofemoral Calliper values in the positive (i.e., lateral) direction with a mean bias of .9 mm. The lower and upper limits of agreement were calculated to be between -5mm and +6.7 mm, respectively, and 95% of the data points obtained from the Patellofemoral Calliper fell into these limits. Only 68% of the data points fell into the hypothetical confidence interval that was established based on the *a priori* acceptable limits of agreement (+/–2mm).







*Figure 4.5.* Bland and Altman plot displaying the limits of agreement for the Patellofemoral Calliper (PFC) and the MRI McConnell equivalent.

The correlation coefficients describing the relationship between the Patellofemoral Calliper measures and the radiological measures ranged between r(35) = -.47 and - .01 (see Table 4.2). A statistically significant correlation coefficient was identified between the Patellofemoral Calliper and the bisect offset r(35) = -.47, p < .005 with a medium effect size.

The correlation coefficients describing the relationships amongst the radiological measures ranged from r(35) = .101 to .981. The lateral patellar shift correlated significantly with lateral patellar overhang r(35) = .98, p < .005, large effect).

## Table 4.2.

	PFC	Bisect offset	СА	LP overhang	LP shift
PFC	1	47*	01	10	13
Bisect offset	47*	1	.33***	.36***	.41**
CA	01	.33***	1	.10	.10
LP overhang	10	.36***	.10	1	.98*
LP shift	13	.41**	.10	.98*	1

Pearson correlation coefficients for the Patellofemoral Calliper and radiological assessments of patellofemoral alignment.

\* Correlation is significant at the .005 level (2-tailed).

\*\* Correlation was significant prior to Bonferroni correction at the .01 level (2-tailed)
\*\*\* Correlation was significant prior to Bonferroni correction at the .05 level (2-tailed)
PFC: Patellofemoral Calliper

CA: Congruence angle

LP: Lateral patellar

# Discussion

The first aim of this study was to determine the reliability of the measurement of patellar alignment obtained from a custom-made calliper. The intra-class correlation coefficients quantifying the relationship between separate measures were equal to or greater than .99, which is markedly higher than intra-class correlations previously reported for clinical assessment of patellar alignment (Fitzgerald & McClure, 1995; Sacco et al., 2010; Tomsich et al., 1996; Watson et al., 1999) and similar to modified methods (Herrington, 2002; Mendonça et al., 2015). The poor reliability reported in some studies is likely to be due to the subjectivity of the methods, which is a limiting factor within the context of current clinical practice. The results of the current study demonstrate that where the reliable measurement of patellar alignment is required, the Patellofemoral Calliper provides is a useful, objective and reliable tool. However, limitations to the current study can be identified in the methods for intra-rater reliability. The methods used in this study meant that the researcher was not blind to the test-retest scores for the calliper. Even though the calliper was reset between

each test, the researcher would have knowledge of the previous scores which may have influenced the follow-up readings. This could be improved if an additional assessor were to extract the calliper measures. Due to the research team limitations for this study and the design of the callipers, this was not possible.

Despite the excellent reliability of the Patellofemoral Calliper, the measures did not agree with the MRI McConnell equivalent that was determined using MRI. With regards to the second aim of this study to compare the measurements obtained using the Patellofemoral Calliper against MRI data, the comparisons yielded a statistically significant correlation. However, further analysis via the Bland and Altman method for testing agreement produced relatively large lower and upper limits of agreement of -5 mm and +6.7 mm respectively. The limits of agreement were considerably larger than the *a priori* established acceptable limit of +/-2mm. The lack of agreement can be attributed to two reasons. First, whilst the calliper measured transepicondylar distance from the superficial layers of the soft tissue, the MRI McConnell equivalent was measured at the osseous surface. The fact that the soft tissue thickness of the medial side of the knee is greater than on the lateral side could result in minor differences in the estimation of the centre position of the femur. Second, whilst every effort was made to ensure reproducibility of position between the scanner and the therapeutic treatment couch, it is possible that differences may have occurred that would account for the lack of agreement. Both notions could therefore explain differences in Patellofemoral Calliper and MRI McConnell equivalent measures. This does reflect the nature of clinical assessment in that repeatability of patient setup is of paramount importance in the procedure for objective testing.

Despite the lack of agreement between the Patellofemoral Calliper and MRI McConnell equivalent, the calliper may provide useful information in relation to other clinical measures that have been associated with anterior knee pain. Within this context, assessments of alignment were identified from the MRI scans. The final aim of the current study was to compare the calliper measurements against previously established radiological measurements obtained from MRI. The results revealed weak to moderate correlations between the Patellofemoral Calliper and radiological measures. The strongest correlation for the calliper was observed for the bisect offset (-.47), whilst the weakest was with the congruence angle (-.01). When considering the methods adopted in these radiological methods, the bisect offset uses similar osseous landmarks to extract the information. Specifically, the patella is bisected by the apex of the trochlea, and the difference between the two halves is calculated. In principle, the Patellofemoral Calliper assumes that the mid points between the femoral epicondyles and the medial and lateral borders of the patella are directly related to the alignment of the patellofemoral joint. The calliper derivation of alignment has similarities to the calculation of bisect offset, which assumes that the relationship between the patella and the trochlea is linked by the apex of the trochlear and how this bisects the patella between its borders. The similarity in derivation of the Patellofemoral Calliper and bisect offset is a likely explanation for the highest correlation observed. Conversely, the congruence angle describes the relationship between the sulcus angle of the trochlea and the median ridge of the patella, which has no link to the osseous structures used in the derivation of the Patellofemoral Calliper measure, thus explaining the low correlation. Collectively, these results indicate that the relationship between the superficial osseous landmarks and the radiological measurement methods is limited. Therefore, it is not advisable to make inferences about any of the radiological measures based on superficial anatomy.

When the radiological measurements were compared to each other the highest correlation was noted (r(35) = .98, p < .001) between lateral patellar shift and lateral patellar overhang. This is to be expected since the derivation of these variables relies on similar landmarks. The lateral patellar shift and lateral patellar overhang both had low correlations with the bisect offset (r(35) = .36 and .41, respectively) however, following the Bonferroni correction these were non-significant. The correlations between the lateral patellar shift and lateral patellar overhang to the bisect offset are of interest, as they suggest that there may be a relationship between the different landmarks being assessed by these methods of alignment assessment. Overall, however, the correlation of the radiological measures amongst each other was low. This indicates a disparity between the relationships of different landmarks and the conclusions that they derive. A potential limitation to the data

collected within this study was identified in the use of multiple correlation coefficients. To adjust for this and reduce the risk of a type I error a Bonferroni correction was made to the *p* value. Following this adjustment, the significant correlations were only present for the bisect offset and patellofemoral calliper as well as the lateral patellar shift and lateral patellar overhang. The differences between the MRI outcomes surmises that different osseous landmarks may not have an interrelationship. Whilst some measurement methods do use the same landmarks (the patellar width), no measurement methods relate the landmarks to the transepicondylar midway point as used in the McConnell method (and Patellofemoral Calliper). Collectively, these findings suggest that the relationship between the superficial osseous landmarks and the radiological measurement methods is limited, meaning that clinical assessment of these superficial landmarks may not provide insightful information about patellofemoral alignment.

#### Conclusion

That the radiological measurements did not have strong correlation coefficients with each other suggests that a more complex approach may be needed to fully understand the relationship between the outcomes of the various measurements and clinical conditions. From a clinical perspective, however, it would be valuable if, when radiological measures are unavailable, inferences could be made based on superficial osseous measures. The results of the Patellofemoral Calliper compared to MRI measurements for patellofemoral alignment highlighted that, at present, greater understanding about the relationship between the superficial osseous landmarks and the other measurements derived from MRI is needed. Additionally, greater scrutiny is required for the patient setup during testing. Therefore, future research should investigate alignment measurements to identify potential relationships between alignment assessments from MRI. It may provide greater insight if these tests were conducted in symptomatic knees due to greater potential alignment variability.

# Chapter 5 - MRI alignment analysis of osteoarthritic patellofemoral joints

#### Introduction

The patellofemoral joint is lined by the thickest articular cartilage in the human body (Andrish, 2015; Brattström, 1964). This is necessitated by the extremely high loads and shear stresses observed during normal load-bearing motion with knee flexion and extension (Farrokhi, Keyak, & Powers, 2011). The patella is a sesamoid bone that develops within the quadriceps femoris tendon to transfer contractile forces from the muscle to the tibial tuberosity. The patella tracks within the groove of the trochlea throughout tibiofemoral flexion and extension, with varied distributions of loads onto the articulating facets (Andrish, 2015). During extension, the patella is less congruent with the trochlear and is elevated from the femur to affect leverage of the quadriceps femoris. The adjustment to a third-class lever provides greater distance from the fulcrum to enable an increased mechanical advantage, although this changes during flexion as the patella drops into the trochlear groove. The compressive loads within the patellofemoral joint can reach up to ten times body-mass during activities of daily living, and up to twenty times body-mass during sport (Andrish, 2015). Prolonged excessive loads due to movement error or abnormal joint contact pressure can lead to degenerative changes within the joint, and ultimately, cause pain (Sharma et al., 2001).

Osteoarthritis is a degenerative condition whereby the articular cartilage lining the joint degrades, leading to irritation of the underlying bone and osteophyte formation (Glyn-Jones et al., 2015). As the disease progresses, the articular cartilage degradation leads to a reduction in the normal joint space as seen on radiographs (Matos, Giordano, Cardoso, Farias, & e Albuquerque, 2015; Yamanaka, Takahashi, Ichikawa, & Yamamoto, 2003). Age is a recognised risk factor for osteoarthritis; however, trauma from long-term excessive loading to the articular surfaces is the underlying concern (Busija et al., 2010). Aside from systemic precursors, such as sex, genetics and ethnicity, the biomechanical and environmental factors under which the joint is exposed relate directly to the increased prevalence of this condition

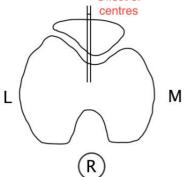
(Garstang & Stitik, 2006). Specifically, previous joint injury, obesity, occupational demands, physical activity, joint biomechanical incongruence, and muscle weakness are the recognised risk factors (Garstang & Stitik, 2006). These are interlinked, as they are affected by changes that occur from compressive loads in the joint leading to abnormal and excessive mechanical loading. It is excessive loading that causes articular damage (Farrokhi et al., 2011), and that ultimately may lead to osteoarthritis (Macri et al., 2016). For example, an increase in body mass will elicit a subsequent increase in load during occupational demands and physical activity (Macri et al., 2016). Joint mal-alignment is a biomechanical factor that is thought to contribute to excessive loads (Garstang & Stitik, 2006), although there are limited data to support this principle (Farrokhi et al., 2015). However, investigation of valgus and varus alignments of the tibiofemoral joint have been associated with advanced progression of osteoarthritis in the tibiofemoral joint (Sharma et al., 2001), therefore providing some support for this concept.

Osteoarthritis of the patellofemoral joint, whilst more common than tibiofemoral osteoarthritis (Hinman, Lentzos, Vicenzino, & Crossley, 2014), is less understood in the context of disease development and progression (Farrokhi et al., 2011; Hinman & Crossley, 2007; Hunter et al., 2007; Lankhorst et al., 2015; Utting, Davies, & Newman, 2005). In a recent study, 44% of adult patients with chronic knee pain had radiographic osteoarthritic changes of the patellofemoral and tibiofemoral joints combined, with 25% having only patellofemoral osteoarthritic changes (Hinman et al., 2014). This compares to only 1% of patients who had isolated tibiofemoral osteoarthritis. The prevalence of patellofemoral osteoarthritis is of significant interest when considering if mal-alignment may be linked to the onset and development of osteoarthritis. Theoretically, the increased contact pressure and reduced contact area from mal-alignment would provide sound justification for the development of excessive loads that might lead to osteoarthritic degenerative changes. The increased loads may cause progression of the patella into the region of increased load (e.g. towards the lateral trochlear facet), leading to greater measurements of patellofemoral mal-alignment (Table 5.1, image 2). However, if the loads were spread evenly across the two trochlear facets but only the compressive load was excessive, the patella would progress posteriorly and centrally into the apex of the

trochlea, and the alignment variance would not differ from asymptomatic groups (Table 5.1, image 3). The progression of the patella is supported by Hinman et al. (2014) who identified that for patients with isolated patellofemoral joint osteoarthritis, 44% had lateral facet osteoarthritis (meaning the patella would mal-align laterally), 44% had medial and lateral facet osteoarthritis (meaning the patellar would align centrally and progress posteriorly) and 12% had medial facet osteoarthritis (where the patella would mal-align medially). Table 5.1.

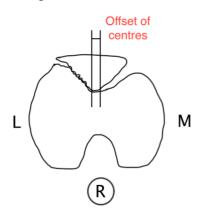
Examples of osteoarthritic degenerative change and the impact on patellofemoral alignment (right knees shown).

Image representing	Explanation of patellofemoral alignment and
patellofemoral offsets	progression
Image 1.	Normal Knee.
Offset of	Patellofemoral joint with normal joint space



and centrally located alignment.

Image 2.



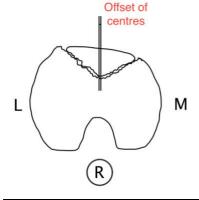
Lateral facet osteoarthritis.

Osteoarthritic degenerative changes to the lateral facet of the patella and trochlea causing lateral progression of the patella with resultant lateralisation of the centres (transepicondylar and patella).

Bilateral facet osteoarthritis.

Osteoarthritic degenerative changes to the lateral and medial facets with resultant joint space narrowing and progression of the patella centrally towards the trochlear apex.





L: Lateral M: Medial R: Right knee 83

In the initial management of patellofemoral joint complaints, conservative treatments are recommended (McCarthy & Strickland, 2013). If conservative treatment is unsuccessful, or if the joint stability is of concern, surgical intervention is normally considered (Barton et al., 2015; McCarthy & Strickland, 2013; Upadhyay et al., 2010). Onward referral should normally include radiological assessments, which may feature X-ray, MRI and CT scans (Endo et al., 2011). From these scans, a variety of measures should be made that may include: bisect offset, sulcus angle, congruence angle, lateral patellar overhang, lateral patellar shift, lateral patellar displacement, tibial tubercle-trochlear groove (TT-TG) distance, Insall-Salvati ratio, Blackburne Peel index, patellofemoral index, Dejour types and crossing signs, lateral patellofemoral angle, patellar tilt angle, and Merchant views of the articulations (Endo et al., 2011). For measuring transverse alignment of the patellofemoral joint, the bisect offset, congruence angle, lateral patellar overhang, and lateral patellar shift are recognised methods of analysis, providing specific measurements of articular interaction (Drew et al., 2016; Song et al., 2011). In a previous chapter (4), it was found that these MRI derived measurements, when obtained in asymptomatic participants, had poor correlation coefficients with each other. The poor correlation may have been due to a narrow range of alignment values. Individuals with osteoarthritis present with a wider range of alignment values due to biomechanical pathologies in the joint (Macri et al., 2016). Investigating an osteoarthritic population will, theoretically, provide a greater understanding about the potential differences between an asymptomatic patellofemoral joint alignment and that of an osteoarthritic knee. Therefore, the first aim of this study was to determine differences in bisect offset, congruence angle, lateral patellar overhang and lateral patellar shift identified from MRI scans between patellofemoral osteoarthritic knees and asymptomatic knees. The experimental hypothesis was:

H<sub>1</sub>: There are significant differences between patellofemoral alignment measurements obtained via MRI scans for bisect offset, lateral patellar overhang and lateral patellar shift between patellofemoral osteoarthritic knees and asymptomatic knees.

According to results presented in Chapter 3, radiological assessment of patients with patellofemoral pain is not a common process within the clinical setting for

physiotherapists or sports therapists. There appears to be a fundamental reliance on the clinical history as well as outcomes of a variety of clinical tests that contain subjective and objective observations; none of which have been shown to consistently provide reliable or valid data about the true nature of patellofemoral alignment (Beckert et al., 2016; Cook et al., 2012; Doberstein et al., 2008; Näslund et al., 2006). The second experimental study (Chapter 4) found that a custom-made calliper (the Patellofemoral Calliper) designed to provide an objective and reliable measurement of patellofemoral alignment by replicating the McConnell estimation method, correlated significantly with the bisect offset (r(35) = -.46, p = <.01). However, the calliper lacked clinically relevant agreement with MRI outputs in a sample of asymptomatic participants. Osteoarthritic changes of the patellofemoral joint may identify wider ranges of alignment than asymptomatic samples, due to the biomechanical abnormalities progressing the patellar towards the sub-chondral bone. It is unknown if the difference is a consequence of osteoarthritic changes. As noted in the first experimental study (Chapter 3), the McConnell method is still a popular choice during clinical assessment of patellofemoral pain, with 42% of physiotherapists and sports therapists adopting it. The McConnell method warrants further investigation to ascertain if alignment might be detectable clinically in assessing progression of change. Therefore, the second aim of this study was to compare the MRI McConnell equivalent method to the recognised MRI alignment measurements of bisect offset, congruence angle, lateral patellar overhang, and lateral patellar shift in a sample of patients with symptomatic patellofemoral osteoarthritis. The hypothesis was:

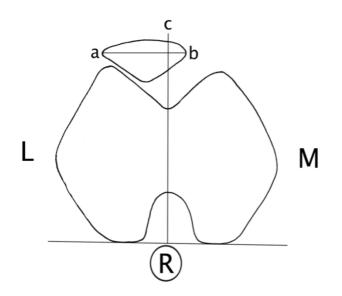
H<sub>2</sub>: The MRI McConnell equivalent measurements will significantly correlate with recognised MRI alignment measurements of bisect offset, congruence angle, lateral patellar overhang, and lateral patellar shift in a sample of patients with symptomatic patellofemoral osteoarthritis.

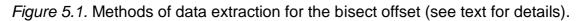
Biomechanical incongruence is recognised as being one of the causative factors predisposing to osteoarthritic changes in joints (Garstang & Stitik, 2006). Patellofemoral pain is commonly associated with many biomechanical abnormalities that lead to pathology of the joint (Powers, 2010). A current theory is that the patella may mal-align due to irregularities in the passive and active soft-tissue restraints that

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control the position of the patellar as it tracks within the trochlear groove during motion. However, the kinetic chain above and below the knee is thought to affect these stabilising mechanisms by altering the position of the underlying bone (the femur), leading to changes in the dynamic movement of the lower limb (Powers, 2010). Changes in positioning of the femur can impact the lower limb by altering neuromuscular timing, reducing strength and creating tightness that tends to rotate the femur medially (Souza et al., 2010). Medialisation of the trochlea occurs, with subsequent relative lateralising of the patella due to the pull of the quadriceps femoris origin. Over time, it is likely that this lateral force vector causes patellofemoral joint pathology and pain (Powers, 2010). The lateral force vector may also contribute to the development of osteoarthritis, due to excessive loading over a prolonged period of time (Busija et al., 2010). An observation from the second study (Chapter 4) was that some of the MRI images featured rotated femurs (around the vertical axis) even though the methods were designed to ensure that all participants were positioned the same. Any difference in vertical axis orientation could impact the measurement of patellofemoral alignment during a clinical assessment, as the derivation would lead to measurement errors. As rotation of the femur is a biomechanical consideration in the development of patellofemoral pain (Salsich & Perman, 2013), it is likely that a symptomatic sample would show greater femoral rotation, either as a contributory mechanism or as a consequence. Additionally, it is recognised from surgical interventions that femoral vertical axis orientation is a key component in the success of arthroplasty (Iranpour, Merican, Dandachli, et al., 2010). When assessing the alignment, it is of clinical importance that the femur is orientated so that the posterior femoral condules are parallel when the alignment measurement is obtained. During the recognised MRI assessment methods for assessing alignment, the measures are obtained by using osseous landmarks for orientation. An example is in the bisect offset (see Figure 5.1), whereby the line drawn through the apex of the trochlea (line C) is perpendicular to a line drawn on the surface of the posterior femoral condyles. To understand if the McConnell method of assessing alignment is affected by femoral vertical axis orientation, the measurement can be corrected to be perpendicular to the posterior femoral condyles, as it is with the bisect offset. The third aim, therefore, was to analyse the MRI scans using the MRI McConnell equivalent method with the femoral vertical axis orientation corrected to the posterior femoral condyles, and to compare these to the bisect offset, congruence angle, lateral patellar shift and lateral patellar overhang. The hypothesis was:

H<sub>3</sub>: The MRI McConnell equivalent method corrected to the posterior femoral condyles will have a higher correlation with the recognised MRI alignment measurements of bisect offset, congruence angle, lateral patellar overhang and lateral patellar shift in a symptomatic patellofemoral osteoarthritic sample.





## Methods

## **Participants**

Ethical approval for this study was obtained from the HRA NRES Research Ethics Committee in collaboration with Manchester Metropolitan University and in agreement with the Brunel University London Research Ethics Committee (see Appendix III). Thirty symptomatic participants aged 44 to 70 y (*M*59, *SD*8) took part in this study. The sample size was established based on MRI funding limitations as well as the opportunistic availability of participants from a previous knee study. This sample size was comparable with similar studies (Dei Giudici et al., 2015; Freedman & Sheehan, 2013; Salsich & Perman, 2013). Participants for the current study were recruited from a large research study conducted by Manchester Metropolitan 87 University (Research in OsteoArthritis Manchester – R.O.A.M.), where individuals had expressed an interest in being considered for future research studies. The previous research was for osteoarthritic knees and the disease was confirmed in all participants via radiographic examination (Felson et al., 2012). All participants had patellofemoral pain reproduced during stair climbing, kneeling or squatting, but not in standing or walking. Participants were excluded if they had a previous patellar fracture or if they had undergone previous patellar realignment surgery. The pain experienced must have emanated from the patellofemoral joint, and not predominantly from the tibiofemoral joint. Participants were also excluded if they had rheumatoid arthritis or any other inflammatory condition. Any recent (within 3 months) steroid injection into the affected knee would render the participant excluded from the study. To enable comparisons with asymptomatic participants, thirty-seven participants' data were used from the second experimental study (Chapter 4) with an age range of 18 to 49 y (*M* 26, *SD* 6). The asymptomatic participants were free from injury and pain to the right knee. All participants completed a screening guestionnaire prior to entering the MRI scanner.

## Instrumentation

MRI was conducted using an upright open 0.25 tesla scanner (G-scan, Easote Biomedica, Italy). The MRI scanner settings were: pixel spacing 0.4mm, slice thickness 2 mm, imaging plane transverse, TR 530 ms and TE 18 ms, with an acquisition time of 2 min 43 s. Participants lay supine on the scanner table with their knee extended and foot positioned against a foot plate.

## Procedure

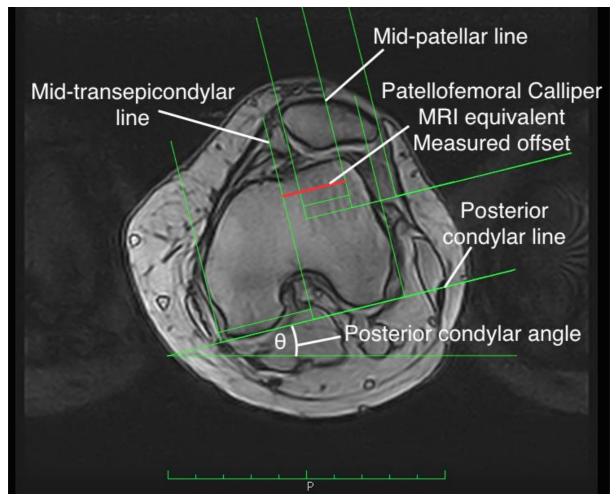
During the MRI scanning, participants lay supine in a relaxed state while the MRI scanner was set and scout scans were produced. Participants maintained their foot position on the foot plate but were otherwise not asked to contract during the scanning due to the potential pain it may cause. The foot position of each participant was controlled by aligning the first phalanx with a mark on the footplate to standardise the lower limb position of each patient, as it would be during a clinical 88

assessment. Thus, the participants position was replicable for comparisons of the scans.

#### **MRI** analysis

The MRI images were analysed using OsiriX, version 9 (Pixmeo SARL, Geneva, Switzerland). Images containing the widest patella and the widest epicondylar distance were compared with landmarks superimposed if the widest patella image was different to the femoral image. Initially, four recognised methods of assessment were used to determine the alignment parameters of the patellofemoral joints. These were: bisect offset, lateral patellar overhang, lateral patellar shift and congruence angle. The methods for data extraction are outlined in Chapter 4 (page 70). Further analysis included repeating the MRI McConnell equivalent method outlined in Chapter 4 (page 70) to investigate whether this symptomatic group correlate higher with the recognised alignment methods.

An observation noted from the MRI scans was that there appeared to be a wide range in the orientation of the femoral vertical axis of 35° (-23° to 12°). This observation was considered important due to notion that any femoral vertical axis orientation difference of the femur from zero could alter the relationship between the MRI McConnell equivalent method and any other alignment measurement. The MRI McConnell equivalent relies on the measurements being taken perpendicular to the scanner table, whereas the other MRI alignment analysis methods all orientate from femoral landmarks that are not affected by rotation (e.g. the femoral condyles). Thus, it was deemed appropriate to add a sixth analysis to investigate the MRI McConnell equivalent method corrected to the posterior femoral condyles. To this end, the line drawn across the posterior femoral condyles for the bisect offset was used to define the perpendicular line for measuring the centre of the transepicondylar line and the centre of the patella for the measured offset (see Figure 5.2).



*Figure 5.2.* MRI data extraction methods for MRI McConnell equivalent corrected to the posterior condylar angle.

# Statistical analysis

Data were analysed using IBM SPSS statistics for Mac, version 23 (IBM Corp., Armonk, N.Y., USA). The critical  $\alpha$  level was set to p = .05. Data that violated the Shapiro-Wilk test for normality were subsequently assessed using non-parametric equivalents (MRI McConnell equivalent and congruence angle from the previous study). To determine whether there were differences in bisect offset, congruence angle, lateral patellar overhang and lateral patellar shift identified from MRI scans between patellofemoral osteoarthritic knees and asymptomatic knees, independent samples t-tests were performed for non-equal variances due to the difference in sample sizes and non-significant results from Levene's test for equality of variances. The t-test was performed on the data retrieved from the MRI scans from the symptomatic osteoarthritic sample and the data already retrieved from the asymptomatic sample in Chapter 4.

To compare the MRI McConnell equivalent method to the recognised MRI alignment measurements of bisect offset, congruence angle, lateral patellar overhang and lateral patellar shift in a symptomatic patellofemoral osteoarthritic sample, Pearson's product-moment correlation coefficients were calculated for the MRI McConnell equivalent alignment measurements and the recognised MRI alignment analysis methods measurements. The correlation outputs provided insight into relationships between the recognised MRI analysis methods for alignment and the MRI McConnell equivalent method. Cohen's *r* value ranges were used for determining the correlation coefficient relationships between the dependent variables, where <.10 is trivial, .10 to .29 is small, .30 to .49 is medium, and >.50 is large (Cohen, 1992).

To analyse the MRI McConnell equivalent method with the femoral vertical axis orientation corrected to the posterior femoral condyles to the bisect offset, congruence angle, lateral patellar shift and lateral patellar overhang, Pearson's product-moment correlation coefficients were calculated. The outputs would provide insight into any improvements or otherwise in significant correlation values between the vertical axis orientated MRI McConnell equivalent and the standard MRI McConnell equivalent values.

## Results

For the first aim of investigating differences in bisect offset, congruence angle, lateral patellar overhang and lateral patellar shift between patellofemoral osteoarthritic knees and asymptomatic knees, significant differences were found between the two groups for all recognised alignment assessment methods (Table 5.2).

#### Table 5.2.

Mean, standard deviation and t-test values for MRI alignment measurements between the osteoarthritic symptomatic and asymptomatic groups.

	OA symptomatic	Asymptomatic	t-test values
Bisect offset	M = 69.0,	<i>M</i> = 56.1,	<i>t</i> (34.589) = -4.571,
	<i>SD</i> = 14.6	<i>SD</i> = 5.0	<i>p</i> < 0.001
Congruence	<i>M</i> = 15.9,	<i>M</i> = -3.5,	<i>t</i> (39.608) = -4.977,
Angle	<i>SD</i> = 19.6	<i>SD</i> = 9.4	<i>p</i> < 0.001
Lateral	M = 7.4,	<i>M</i> = 2.9,	t(39.589) = -5.037,
patellar			
overhang	SD = 4.5	<i>SD</i> = 2.1	<i>p</i> < 0.001
Lateral	M = 23.7,	<i>M</i> = 6.8,	<i>t</i> (32.382) = -4.764,
patellar shift	SD = 18.9	SD = 5.1	p < 0.001

OA - Osteoarthritic

Mean delta values for the symptomatic group were found to be more laterally orientated than in the asymptomatic group (bisect offset 12.8%, congruence angle 19.4°, lateral patellar overhang 4.5mm, and lateral patellar shift 16.9%).

The second aim was to compare the MRI McConnell equivalent method to the recognised MRI alignment measurements of bisect offset, congruence angle, lateral patellar overhang and lateral patellar shift in a symptomatic patellofemoral osteoarthritic sample. As shown in Table 5.3, the Pearson product-moment correlation coefficients describing the relationship between the MRI McConnell equivalent and the recognised alignment measures were all non-significant. The positive relationship between the recognised MRI methods was significant, highlighting that changes in alignment of the patellofemoral joint are common across these methods.

# Table 5.3.

Pearson product-moment correlation coefficients for extracted MRI alignments.

	MRI	MRI	Bisect	Congruence	Lateral	Lateral
	McConnell	McConnell	offset	angle	patellar	patellar
	equivalent	equivalent			overhang	shift
		corrected				
MRI						
McConnell	1	N/A	.23	.08	.32	.23
equivalent						
MRI						
McConnell	N/A	1	.90*	.61*	.88*	.80*
equivalent	1 <b>1</b> // 1	I	.00	.01	.00	.00
corrected						
Bisect offset	.24	.90*	1	.74*	.89*	.88*
Congruence	.08	.61*	.74*	1	.70*	.66*
angle						
Lateral						
patellar	.31	.88*	.89*	.70*	1	.94*
overhang						
Lateral	.23	.80*	.88*	.66*	.94*	1
patellar shift	.20					•

\* Correlation is significant at the .01 level (2-tailed).

For the third aim of comparing the MRI McConnell equivalent method with the femoral vertical axis orientation corrected to the posterior femoral condylar angle to the bisect offset, congruence angle, lateral patellar shift, and lateral patellar overhang, the results revealed significant positive correlation coefficients that were all higher than the MRI McConnell equivalent method (Table 5.2).

#### Discussion

The purpose of this study was to investigate patellofemoral alignment assessed using MRI analysis in osteoarthritic knees. The results identified that (1) osteoarthritic patellofemoral joints were more laterally orientated than asymptomatic knees; (2) the MRI McConnell equivalent did not correlate with any of the recognised MRI alignment methods; (3) when the MRI McConnell equivalent method was corrected to the posterior femoral condyle angle, this measurement correlated positively with all recognised MRI alignment methods. Overall, osteoarthritic patellofemoral joints provide wider ranges of alignment values, meaning lateral progression of the patella appears to be an outcome of this condition. Additionally, vertical axis orientation of the femur is an important consideration in the clinical assessment of patellofemoral alignment.

The first aim of this study was to identify differences in bisect offset, congruence angle, lateral patellar overhang and lateral patellar shift identified from MRI scans between patellofemoral osteoarthritic knees and asymptomatic knees. There were significant differences between the two groups for all recognised methods of measuring alignment. The research hypothesis 1 is therefore accepted; that is, there are significant differences between patellofemoral alignment measurements obtained via MRI scans for bisect offset, lateral patellar overhang and lateral patellar shift between patellofemoral osteoarthritic knees and asymptomatic knees. The symptomatic group data for alignment measurements were statistically different to the asymptomatic group, and were identified as being more laterally orientated than the asymptomatic group. This lateral orientation highlights that the values obtained via MRI for these two groups differed significantly and, therefore, form a justification for future research to investigate alignment measures between asymptomatic and symptomatic (in this case osteoarthritic) patellofemoral joints. These results also support the notion that the alignment measurements, as extracted from MRI outputs, offer tangible evidence of patellofemoral alignment differences when investigating potential causes of patellofemoral pain progression towards osteoarthritis (Petersen et al., 2014). Whilst some literature does not fully support a direct link between patellofemoral pain and mal-alignment or mal-tracking (Lankhorst et al., 2013; Song et al., 2011), or refute that these measures relate to patellofemoral pain (Dye, 2001;

Ota, Nakashima, Morisaka, Ida, & Kawamura, 2008; Wilson, 2007), the results support that mal-alignment could be a developmental consideration that may cause excessive joint forces prior to the onset of osteoarthritic damage (Macri et al., 2016; Utting et al., 2005).

Limitations of the current study can be identified in the difference in scanning protocols as well as the unmatched cohorts. The symptomatic group were positioned in extension and without muscle activation, due to their osteoarthritic pain, which may have meant a greater tendency towards mal-alignment as the patella is thought to be more mobile in this range (Amis, Senavongse, & Bull, 2006). Ideally, the two samples would have been assessed under identical conditions; unfortunately, however, this was not possible due to the protocol for the symptomatic participants being dictated by a larger data collection study. The participants were required to complete a high number of scans and movements that might have exacerbated their symptoms, meaning that the scan had to be completed in extension and relaxed. Of note was the wide range of values and differences between the groups. Whilst it would be thought that if the symptomatic sample were to be contracted and at 30° of flexion, their patellae would be more centralised, evidence does not suggest that this difference is always statistically significant (Wilson, 2007), and this can lead to greater lateralisation in a flexed position (Draper et al., 2011).

The unmatched cohorts of this study were a potential concern for the detected significant differences in the data. Previous studies have utilised a symptomatic and asymptomatic contralateral limb in order to provide case matching (Dejour et al., 1994; Erkocak et al., 2016; Tanaka et al., 2016) or have attempted to match participants based on age and gender (Aliberti et al., 2010; Ota et al., 2008; Piva, Goodnite, & Childs, 2013). It is identified that in patients with a symptomatic patellofemoral joint, the contralateral asymptomatic knee can have pathologic morphology that may lead to patellofemoral pain conditions (Erkocak et al., 2016; Post et al., 2002). Therefore, case matching would be better achieved through attempts to identify participants who were of a similar demographic to the symptomatic knees. Case matching recruitment of participants was also not possible

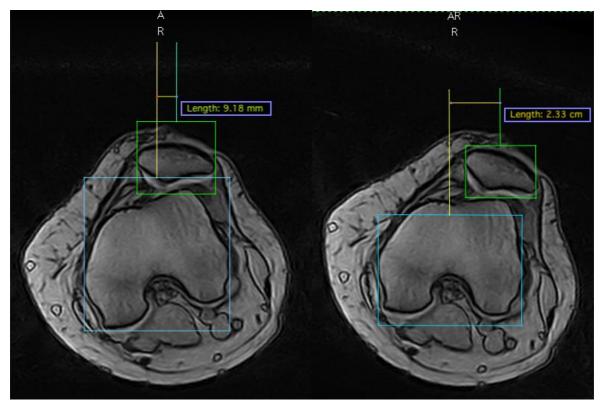
within this study as the data collected in Chapter 4 was already completed and there was a paucity of funding available to complete further MRI scans.

At present, the results of the current study indicate that there are detectable differences in patellofemoral alignment between asymptomatic samples and patellofemoral osteoarthritic samples. To further the understanding about the relationships between the osseous landmarks measured during alignment assessment, continued research into the clinical and radiological assessment of patients with patellofemoral pain is warranted. This would help develop greater understanding about the progression of patellar mal-alignment, as mal-alignment may be a precursor for patellofemoral osteoarthritis (Macri et al., 2016).

The second aim was to compare the MRI McConnell equivalent method to the recognised MRI alignment measurements of bisect offset, congruence angle, lateral patellar overhang and lateral patellar shift in a symptomatic patellofemoral osteoarthritic sample. Pearson product-moment correlation coefficients describing the relationship between the MRI McConnell equivalent and the recognised alignment measures were all non-significant. Therefore, the experimental hypothesis H<sub>2</sub> cannot be accepted. This highlights that the MRI McConnell equivalent method appears to not offer useable data about the relative position of the patella in the trochlea when compared to recognised alignment methods. It also raises concerns about the McConnell method when adopted in a clinical environment to infer malalignment conclusions that may inform treatments (McConnell, 1986). Of interest, the recognised alignment methods used on the MRI outputs all had positive correlation coefficients with each other with large effect sizes (ranging from r(28) = .94, p = .001to r(28) = .66, p = .001), highlighting that these methods all follow a similar pattern of output in relation to the changes in alignment for the symptomatic group. Similarities in MRI measures are to be expected due to the method of osseous marker comparisons between the recognised methods using related landmarks. For the bisect offset, the interaction between the deepest portion of the trochlear groove and the width of the patella must have a geometric relationship to the offset between the anterior lateral femoral condyle and the lateral border of the patella used in the lateral patellar overhang and lateral patellar shift. For the congruence angle, the

apex of the patella and how it articulates with the greatest depth of the trochlear groove can also be linked to the changes in position for the bisect offset, lateral patellar overhang and lateral patellar shift. Although the congruence angle appeared to offer lower correlation values, this may be due to the patellar apex remaining closer to the greatest depth of the trochlear groove whilst enabling a tilting of the patella. A tilt would provide greater offset measurements in all the other alignment assessment methods, as they are uniplanar in derivation.

The femoral vertical axis orientation during MRI data extraction exhibited a wide range of angles. The literature supports the finding that femoral rotation (usually medially) increases the lateral stresses of the patellofemoral joint (Powers et al., 2003) and that individuals with patellofemoral pain have altered femoral rotation when compared to healthy participants (Erkocak et al., 2016). Femoral rotation highlights a potential error that could develop when comparing the MRI McConnell equivalent values to any of the recognised alignment measures conducted, and may explain the weak correlation. Errors in alignment measures would originate from a different femoral vertical axis orientation causing a skewed offset to be taken by the MRI McConnell equivalent. As shown in Figure 5.3, the same image had an increase in lateral measurement of 14mm (from 9.2 mm to 23.3 mm) when the femur was corrected for rotation.



*Figure 5.3.* MRI McConnell equivalent data extractions on the same knee (osteoarthritic group) at two different femoral vertical axis orientations: left, as the participant was orientated naturally; right, the image corrected to be parallel with the posterior femoral condylar line.

The third aim of this study was to analyse the MRI scans using the MRI McConnell equivalent method with the femoral vertical axis orientation corrected to the posterior femoral condyles, and to compare these to the bisect offset, congruence angle, lateral patellar shift and lateral patellar overhang. Despite the previous lack of correlation between the MRI McConnell equivalent method and the recognised alignment measures, the differences in the femoral vertical axis orientation offered a potential explanation. Once the femoral vertical axis orientation was corrected, the results of the MRI McConnell equivalent corrected to the posterior femoral condyles provided very strong positive correlation coefficient values with the bisect offset, congruence angle, lateral patellar overhang and lateral patellar shift, in stark contrast to the MRI McConnell equivalent method corrected to the posterior femoral condyles will correlate with recognised MRI alignment measurements of bisect

offset, congruence angle, lateral patellar overhang and lateral patellar shift in a sample of people with symptomatic patellofemoral osteoarthritis.

The results from the current study raise new and important questions about how patellofemoral alignment is currently measured clinically. To-date, no investigations into the influence of femoral vertical axis orientation during the clinical measurement of patellofemoral alignment have been conducted. This may explain why previous have reported inconsistent findings when comparing clinical measures with radiological assessment values (Fitzgerald & McClure, 1995; Herrington, 2002; Lesher et al., 2006; McEwan et al., 2007; Ota et al., 2006; Tomsich et al., 1996). Whilst femoral rotation is recognised for its influence on the stresses that may cause patellofemoral pain and pathological progression (Powers et al., 2003), it appears to reside separately in the clinical diagnostic process (McCarthy & Strickland, 2013; Nunes et al., 2013) even though the link has been established during radiological assessments (Besier et al., 2008; Iranpour, Merican, Dandachli, et al., 2010; Wilson, 2007). Femoral vertical axis orientation is a consideration during knee replacement surgery (Iranpour, Merican, Dandachli, et al., 2010) and is linked to success or dysfunction following arthroplasty. Femoral vertical axis orientation, therefore, provides rationale for the need to ascertain this variable when alignment is measured clinically. From the results of this study, if clinical assessments currently adopted are to provide alignment values of the patellofemoral joint, control of the femoral vertical axis orientation is required due to its influence on the resultant alignment values. To this end, it is recommended that if mal-alignment is suspected, the patient should be considered for onward referral for radiological assessment to confirm the diagnosis, until such time that appropriate control measures can be established for femoral vertical axis orientation in a clinical environment.

Future research should continue to focus on the development of the clinical assessment process. Results from the current study offer insight into the effects of femoral vertical axis orientation during clinical assessment of patellofemoral alignment. Improved control of this orientation may increase the diagnostic yield of the clinical assessment process. Improved clinical assessments of patellofemoral alignment from femoral vertical axis orientation would enhance the clinical reasoning

for treatments, referral for radiological assessment, and for onwards referral to an orthopaedic surgeon.

# Chapter 6 - Technical note: validity and reliability of clinical assessment of patellofemoral alignment with a custommade calliper in patients with patellofemoral pain

## Introduction

Mal-alignment of the patellofemoral joint is abnormal static positioning of the patella within the trochlear groove (Song et al., 2011), and is considered a pivotal component in the potential development of degenerative changes and pain due to excessive articular loading (Hunter et al., 2007; Song et al., 2011). Treatments for patellofemoral pain are dependent upon identification of the underlying causes. Within this context, accurate measurement of patellofemoral alignment is important (Hunter et al., 2007; Sharma et al., 2001). Whilst radiological assessment can provide in-depth diagnostic value, the cost implications of magnetic resonance imaging (MRI) or computed tomography (CT), and the potential ionizing radiation exposure levels of X-ray and CT, limit their use (de González & Darby, 2004; Shrimpton, Hillier, Meeson, and Golding, 2011; Wall et al., 2011). Clinical assessment currently lacks support for diagnostic validity when measuring patellofemoral alignment (Cook et al., 2012; McEwan et al., 2007; Smith et al., 2012; Wilson, 2007). If clinical assessment validity could be improved, it would provide improved alignment information for the clinician about the need for interventions as well as potential measurable changes in joint positioning following treatment. To this end, the Patellofemoral Calliper was created as a means of providing a valid and objective measurement of patellofemoral alignment than current clinical assessment.

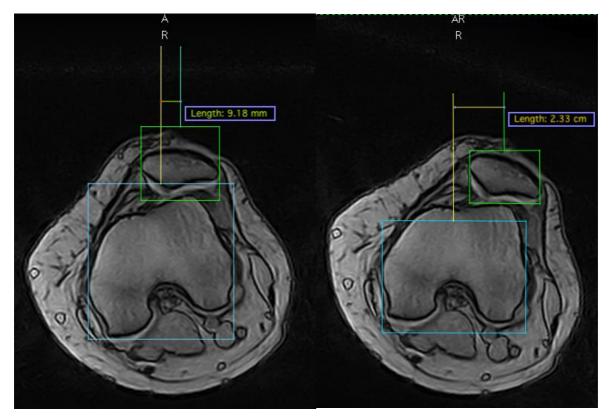
The Patellofemoral Calliper was tested for validity and reliability in a previous experimental study (Chapter 4), and the conceptual use of this measurement method was described in Chapter 5. The Patellofemoral Calliper was found to have excellent intra-tester reliability in asymptomatic participants, with intra-class correlation coefficients of .99 (p <.001). These values previously obtained in Chapter 4 differed with observational methods of assessing alignment in similar research studies where kappa coefficients for observations were between .006 and .57 (Tomsich et al., 1996; Watson et al., 1999; Wilson, 2007). The intra-class correlation coefficient 101

values of the Patellofemoral Calliper agreed with the modified McConnell assessment methods conducted by others with a range of correlation coefficient values of .85 to .94 (Herrington, 2002; McEwan et al., 2007; Mendonça et al., 2015). However, within the previous study (Chapter 4), when the Patellofemoral Calliper was compared to an MRI method that replicated the measurement (termed the MRI McConnell equivalent), the device was shown to not provide clinically relevant agreement with the MRI McConnell equivalent method. It was identified that the Patellofemoral Calliper had a systematic bias of .85 mm compared to the MRI McConnell equivalent method, and had upper and lower limits of agreement that were considered too broad to be clinically useful (+7 to -5 mm). Critical analysis of this study identified that there may have been methodological issues with the position of the participants between the MRI scanner table and the separate assessment table used for the Patellofemoral Calliper measurements. Additionally, the span of values obtained from the asymptomatic group was rather limited, meaning that the values were centring around the mid femur. Following this study, further investigations into the range of values in measurements for osteoarthritic patellofemoral joints (Chapter 5) were made.

The MRI McConnell equivalent measurement of alignment was replicated to compare it in this symptomatic group. Interestingly, the range of values was significantly different from the asymptomatic group, with greater lateralisation in all alignment measurements. The MRI McConnell equivalent values lacked association when compared to the recognised alignment methods applied to the scans. However, an observation was made that the scans from this sample appeared to have a greater rotation range of the femur on the scan images. Due to the MRI McConnell equivalent (and therefore the Patellofemoral Calliper) being measured perpendicular to the scan image, any difference in vertical axis orientation of the femur would impact upon the relationship between this method and the recognised alignment measurement methods due to the deviation of the axis (see Figure 6.1). Therefore, the scans were re-analysed with the measurement being orientated to the posterior femoral condyles. This analysis produced improved correlation coefficient values (.61 to .90, *p* <.001). It was therefore considered that the Patellofemoral vertical axis

orientation in the scanner or on the assessment table. Investigating this further would provide two key insights: 1) the validity of the Patellofemoral Calliper may improve, meaning the device may be usable in a clinical setting; 2) existing clinical assessment using the McConnell method does not currently control for the femoral vertical axis orientation, and so the current method risks errors in the derivation of the result. To address these concerns, the first aim of the current study was to investigate the agreement between the Patellofemoral Calliper values and the MRI McConnell equivalent in a patellofemoral pain sample with controlled femoral positioning. The hypothesis was:

H<sub>1</sub>: Patellofemoral Calliper values will have clinically relevant agreement with MRI McConnell equivalent results in patients with patellofemoral pain when the femoral rotation setup position is controlled.



*Figure 6.1.* MRI McConnell equivalent data extractions on the same knee at two different orientations of femoral rotation: left, as the participant was orientated naturally; right, the image corrected to be parallel with the horizontal plane.

Whilst agreement with the MRI McConnell equivalent is important for ensuring validity of the Patellofemoral Calliper, of additional importance is whether the values 103

obtained by this method have clinical relevance with established alignment methods. If a reliable clinical method of patellofemoral alignment were available, it could provide a rationale for therapeutic and rehabilitative interventions. The current alignment tests are not accurate or reliable enough to be recommended (Crossley, Stefanik, et al., 2016; Wilson, 2007). The previous study (Chapter 4) found limited association between the Patellofemoral Calliper and the recognised MRI alignment methods. However, it was subsequently highlighted that this may be due to the rotational orientation of the femur and potential differences in participant positioning between tests. If this could be controlled, the device, and therefore the clinical assessment process, may provide useful information about the estimated alignment of the patellofemoral joint. The second aim of this study was, therefore, to compare the Patellofemoral Calliper alignment values with the recognised MRI alignment methods of: bisects offset, congruence angle, lateral patellar overhang and lateral patellar shift. The second hypothesis was:

H<sub>2</sub>: The Patellofemoral Calliper values for patellar alignment in patients with patellofemoral pain will positively associate when compared to recognised MRI alignment methods: bisect offset, congruence angle, lateral patellar overhang and lateral patellar shift.

In line with the finding from Chapter 5 that the rotational orientation of the femur during assessment is of importance when assessing the patellofemoral joint, investigation of the vertical axis orientation warranted further analysis within this symptomatic sample. Whilst every effort was made to control the rotational position of the femur, it was deemed appropriate to assess the success of this by analysing the scans with the images corrected to the posterior femoral condylar angle as per Chapter 3. The final aim was to analyse the alignment values from the MRI McConnell equivalent corrected to the posterior condylar angle with the recognised alignment methods: bisect offset, congruence angle, lateral patellar overhang and lateral patellar shift. The hypothesis was:

H<sub>3</sub>: MRI McConnell equivalent values corrected to the posterior condylar angle will provide improved correlation values with the recognised MRI alignment assessment methods.

#### Methods

#### Participants

Ethical approval for this study was obtained from the HRA IRAS Research Ethics Committee and in agreement with Brunel University London Research Ethics Committee (see Appendix IV). Twenty participants (12 female, 8 male) aged 20 to 61 y (M = 36, SD = 13) took part in this study. The sample size for this study was limited due to MRI funding and availability of participants from a specific practice. This sample size was comparable with similar studies (Araújo et al., 2016; Ho et al., 2017; Osorio et al., 2013). Participants were recruited by an orthopaedic consultant and only included if they had patellofemoral pain pathology. The predominant symptom of patellofemoral pain is retropatellar pain, especially when performing movement on a flexed load-bearing knee (Crossley, Stefanik, et al., 2016), with mal-alignment a common underlying cause (Hunter et al., 2007; Song et al., 2011). Therefore, all participants were recruited if they experienced pain during such activities (e.g. squatting, stair ambulation, sit-to-stand). Pain was assessed on the day of testing via a single-leg squat, with the inclusion criteria being that the participant must have more than mild pain. Mild pain was rated as equal to or less than 2 out of 10 (Collins, Moore, & McQuay, 1997) on a visual analogue scale (see Appendix V). Participants were excluded if they had had previous corrective surgery for this condition, if they had a history of recurrent patellar dislocations, if they were being treated for osteoarthritis of the joint, or if they had any clinically significant knee joint effusion visible. All participants completed a screening questionnaire prior to recruitment.

## Instrumentation

The MRI were conducted using a 3-Telsa scanner (Magnetom Skyra, Siemens, Erlangen, Germany). The MRI scanner settings were: pixel spacing of 0.210 mm, slice thickness of 3 mm, imaging plane transverse, TR of 3500 ms, TE of 35 ms, and an acquisition time of 2 min and 10 s. Participants lay supine on the scanner table with their knees flexed to 30° of flexion (verified with a modified 360° plastic 12-inch goniometer) with supports placed under the knees to maintain this position. The feet were positioned together against a custom-made wooden footplate, fitted with an anti-slip surface, so that both feet were parallel and centred to the footplate to ensure 105

that all participants were positioned the same for each of the three scans. Participants were instructed to push on the footplate as if they were pushing away from the scanner. Straps were then applied above the knees as well as around the ankles to maintain the leg positioning. Specifically, the strap tension was only tightened to hold the leg in its contracted position and prevent the participant's legs rotating laterally prior to commencing the scan. An advantage of this scan not being load-bearing was that with a lower level of contraction the participant was less likely to fall into a valgus position from any inability to maintain lower limb alignment through muscular weakness or pain.

The Patellofemoral Calliper was previously designed by the researcher (K. Campbell-Karn) to replicate the McConnell clinical assessment method for measuring patellofemoral medial/lateral alignment. Details about this device are available in Chapter 4 (page 66).

# Asymptomatic inter-tester and intra-tester reliability testing of the Patellofemoral Calliper

Ethical approval was granted to carry out a reliability study for the Patellofemoral Calliper by the Brunel University London Research Ethics Committee. Thirty-three participants were recruited via convenience sampling from within a university setting. The participants had an age range of 18 to 25 y (M = 20, SD = 2) consisting of twenty female and thirteen male participants. Eligibility was based on the students not having any current knee injuries or complaints in the lower limb so that they could perform a quadriceps femoris muscle contraction without pain or discomfort. This opportunistic sample was chosen to enable a reasonable sample size for comparisons of intra-tester reliability for the Patellofemoral Calliper (Koo & Li, 2016) whilst enabling the tests to be completed at the same time on the participants to fix the participant positioning and remove this as a factor.

An inter-tester reliability study was conducted. Three testers with eight or more years of experience of assessing and treating musculoskeletal injuries were used for inter-tester reliability testing of the Patellofemoral Calliper. All testers were provided with a training day on how to use the calliper and given time to practice prior to

commencing the study. Participants were positioned by the lead researcher on a therapeutic treatment couch with their leg flexed to 30°, verified using a long arm plastic goniometer, and supported with wedges and cushions in this position. The ankle was strapped to the table using an adjustable length manual therapy belt. The participant was instructed to perform a low-level quadriceps femoris contraction aiming to extend their leg against the strap that had been applied and that they would need to hold this position while the three examiners took it in turn to measure the position of their patellofemoral joint. Each examiner recorded their measurement on a separate piece of paper. This sequence was repeated and recorded on a new sheet of paper to measure for intra-tester reliability of the three testers. Unfortunately, blinding of the testers was not possible, however blinding between the testers was achieved.

To test for inter-tester reliability, a two-way random effects intra-class correlation coefficient model ICC<sub>(2,3)</sub> for absolute agreement of values was performed (Shrout & Fleiss, 1979). The intra-class correlation coefficient results for the Patellofemoral Calliper between testers revealed a significant positive association of agreement (.96, p = <.001). For intra-tester reliability, a two-way random effects intra-class correlation coefficient model ICC<sub>(2,1)</sub> for absolute agreement for each of the testers was conducted (Shrout & Fleiss, 1979). All three testers revealed significant positive intra-tester reliability values (ICC<sub>(2,1)</sub> range .96 to .99, p = <.001).

#### Procedure

For the MRI testing, participants were instructed to lie supine in a fully relaxed state while the scanner was set up and the localiser scans were completed. During the transverse plane scanning, participants were instructed and briefed before entering the scanner on how to push against the footplate with a relatively low force, as if trying to push themselves along the scanner table. This force direction replicated the functional movement of squatting and ensured that the lower limb from the pelvis down was utilised to replicate a load-bearing squatting manoeuvre. The participants needed to maintain this contracted state for the duration of the scan as movement would cause blurring of the images.

The Patellofemoral Calliper measurements were obtained immediately after the completion of the MRI scan. The previous studies (Chapters 4 and 5) gave insight into the possible methodological issues of femoral positioning. To ensure that the scan image and Patellofemoral Calliper measurement were taken in the same position, the participant remained on the MRI scanner table and was asked to maintain the contraction from the scan while the table was removed from the scanner. The calliper was placed over the knee with the larger calliper arms locating around the femoral epicondyles (palpated by the tester for location) and the smaller calliper arms were placed around the medial and lateral borders of the patella.

#### MRI analysis

The MRI images were analysed using OsiriX, version 9 (Pixmeo SARL, Geneva, Switzerland). Images containing the widest patella and the widest epicondylar distance were compared with landmarks superimposed if the widest patella was from a different image slice for the femoral image. Six analysis methods were used for data comparisons of alignment from the MR images. These were: bisect offset, lateral patellar overhang, lateral patellar shift, congruence angle, MRI McConnell equivalent, and the MRI McConnell equivalent corrected to the posterior femoral condylar angle. For details about the specific process of measurement, refer to the methods used in Chapter 4 (page 70).

#### Statistical analysis

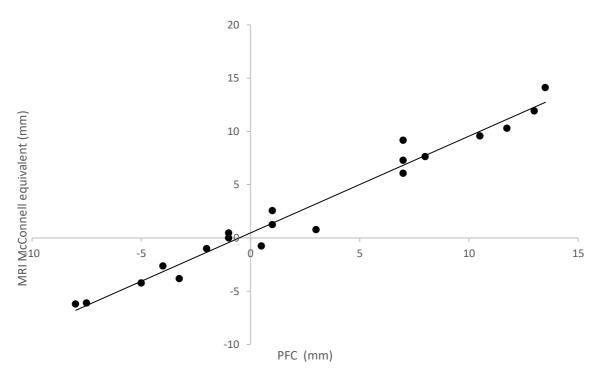
Data were analysed using IBM SPSS statistics for Mac, version 23 (IBM Corp., Armonk, N.Y., USA). The critical  $\alpha$  level was set to p = .05. All data were tested for normality via Shapiro-Wilk test and all results were normally distributed (p = <.05). There was one outlier for bisect offset, congruence angle, and MRI McConnell equivalent. However, upon investigation into this single participant, it was considered that their data were of interest as their knee represented the most extreme measurement of alignment of all participants. To determine the agreement between the Patellofemoral Calliper values and the MRI McConnell equivalent in a patellofemoral pain sample with controlled femoral positioning (Aim 1), agreement was tested using the method described by Bland & Altman (1986). The Pearson product-moment correlation coefficient was obtained and a scatter plot with line of equality was produced. The bias was calculated by identifying the difference between the alignment values measured by Patellofemoral Calliper and the alignment values derived from the Patellofemoral Calliper MRI equivalent method. The difference between the alignment values obtained was plotted against the mean of the Patellofemoral Calliper and the Patellofemoral Calliper MRI equivalent alignment values. The limits of agreement were estimated by multiplying the corresponding standard deviation by 1.96. The upper and lower limits of agreement were identified by adding and subtracting the limits of agreement to and from the bias. The clinically acceptable limits of agreement were established a priori as +/- 2 mm. This value was estimated to be of clinical relevance in the assessment of patellar position from data suggesting that a patellar displacement of equal to or more than 4 mm is of clinical significance for detecting mal-alignment (Giudici et al., 2015). It was, therefore, deemed that a difference greater than 2 mm would lead to clinical unacceptable results. The acceptable limits of agreement established a priori were compared to the upper and lower limits of agreement. The number of cases that fell outside the acceptable limits of agreement were obtained to decipher the acceptance of the agreement.

For the second aim of comparing the relationship between the Patellofemoral Calliper values with the recognised MRI alignment methods (bisects offset, congruence angle, lateral patellar overhang and lateral patellar shift), Pearson's product-moment correlation coefficients were used to determine the relationship between the Patellofemoral Calliper measurements of alignment and those obtained from the MRI images. Pearson's product-moment correlation coefficients were also conducted for the final aim of analysing the alignment values obtained from the MRI McConnell equivalent corrected to the posterior condylar angle with the recognised MRI alignment methods (bisect offset, congruence angle, lateral patellar overhang and lateral patellar shift). Cohen's *r* value ranges were used for the relationships

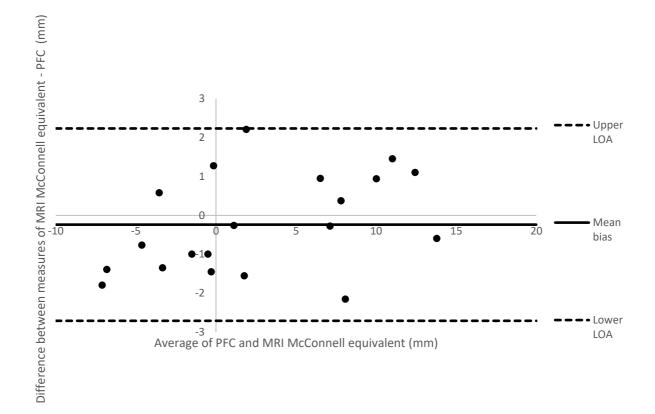
between the dependent variables, where <.10 is trivial, .10 to .29 is small, .30 to .49 is medium, and >.50 is large (Cohen, 1992).

#### Results

The Pearson product-moment correlation coefficient describing the relationship between the Patellofemoral Calliper and the MRI McConnell equivalent was r(18) =.99, p < .001 (Figure 6.2). The alignment obtained from the Patellofemoral Calliper had a systematic medial bias of -.24mm compared to the alignment from the MRI McConnell equivalent. The mean difference between the alignment values of the Patellofemoral Calliper and the MRI McConnell equivalent were plotted against the means (Figure 6.3). The lower and upper limits of agreement were calculated as – 2.7 mm to +2.2 mm and all values were within this range. The acceptable limits of agreement were set *a priori* as +/- 2 mm and 90% (18 cases) of the values were within these limits.



*Figure 6.2.* Scatterplot with line of best fit for patellofemoral alignment measured by the Patellofemoral Calliper and the MRI McConnell equivalent. PFC: Patellofemoral Calliper



*Figure 6.3.* Bland and Altman plot displaying the limits of agreement for the patellofemoral alignment measured by the Patellofemoral Calliper and the MRI McConnell equivalent.

PFC: Patellofemoral Calliper

LOA: Limits of agreement

Pearson product-moment correlation coefficients for investigating the relationship between the patellofemoral alignment measured by the Patellofemoral Calliper and the MRI (see Table 6.1), highlighted that there were significant positive associations for the lateral patellar overhang (r(18) = .63, p < .001), lateral patellar shift (r(18) =.62, p < .001) and congruence angle (r(18) = .64, p < .001). The bisect offset lacked significant association. For identifying association between the MRI McConnell equivalent corrected to the posterior femoral angle and the recognised MRI alignment methods, the Pearson product-moment correlation coefficients revealed significant positive values for all measures (Table 6.1) with only the congruence angle not achieving an improvement in correlation.

	PFC	MRI McConnell equiv.	Bisect offset	CA	LP Overhang	LP Shift	MRI McConnell equiv. corrected post. condyles
PFC	1	.99**	.27	.69**	.67**	.67**	.55*
MRI McConnell equiv.	.99**	1	.30	.76**	.71**	.71**	.58**
Bisect offset	.27	.30	1	.64**	.68**	.74**	.79**
CA	.69**	.76**	.64**	1	.72**	.74**	.75**
LP overhang	.67**	.72**	.69**	.72**	1	.98**	.77**
LP shift	.67**	.71**	.74**	.74**	.98**	1	.81**
MRI McConnell equiv. corrected post. condyles	.55*	.58**	.79**	.75**	.77**	.81**	1

*Table 6.1.* Pearson product-moment correlation coefficients for alignment measurements.

\*. Correlation is significant at the .05 level (2-tailed).

\*\*. Correlation is significant at the .01 level (2-tailed).

PFC: Patellofemoral Calliper

CA: Congruence angle

LA: Lateral patellar

#### Discussion

The first aim of the current study was to investigate the agreement between the Patellofemoral Calliper values and the MRI McConnell equivalent in a patellofemoral pain sample with controlled femoral positioning. The results highlighted that in this sample, controlling for participant positioning appeared to improve the validity of the device considerably. The Pearson product-moment correlation coefficient was .99 (p < .001) which was an improved association compared to the previous study of the calliper (Chapter 4) on an asymptomatic sample, where correlation was .78 (p <.001). The mean bias of the Patellofemoral Calliper in the current study was lower at -.24 mm compared to the previous result of .85 mm in Chapter 4. The limits of agreement highlighted a good agreement between the alignment values from the Patellofemoral Calliper and the MRI McConnell equivalent, as the plot reveals (Figure 6.3). The previous study (Chapter 4) saw a limits of agreement range of nearly 12 mm, whereas in the current study the range was reduced to 5 mm. The a priori limits of agreement set for clinical relevance was +/-2 mm, meaning the results exceed this level. Therefore, the null hypothesis cannot be rejected. The agreement results are, however, a significant step in the improving the control of the lower limb for clinical assessment of the patellofemoral joint. It is possible that previous research, where poor results have been found, have not had the same level of control of femoral vertical axis orientation (Cook et al., 2012; Wilson, 2007). Research currently lacks in-depth detail about the setup control mechanisms for femoral orientation. It is also plausible that when clinical assessment of patients with patellofemoral pain occurs, the control of the lower limb is insufficient to provide reliable and accurate results. Patient setup during clinical assessment may need greater development to enable more accurate outcome measures. Control of setup is also important for test-retest precision following any therapeutic interventions.

Whilst the limits of agreement range were 1 mm outside of the *a priori* acceptable range, the Patellofemoral Calliper alignment values did provide encouraging results for clinical assessment of patellofemoral alignment. Within this context, the second aim of this study was to compare the Patellofemoral Calliper alignment values with the recognised MRI alignment methods of: bisects offset, congruence angle, lateral patellar overhang and lateral patellar shift. The results revealed that the

Patellofemoral Calliper gave moderate positive associations (.67 to .69, p <.001) with the congruence angle, lateral patellar overhang and lateral patellar shift. This positive association indicates that the Patellofemoral Calliper offers clinicians a method of identifying patellofemoral alignment measurements that has moderate association with values of alignment obtained from three MRI methods of assessment. However, due to the lack of correlation with the bisect offset, it does not indicate how well the patella is centralising with the apex of the trochlear groove. The Patellofemoral Calliper comparison to MRI results provide a useful step towards improving the clinical assessment method that may improve validity of clinical measurements of patellofemoral alignment. However, further investigations are warranted into the setup protocols for measurements before clinical assessment of alignment is deemed valid.

For the final aim, the patellofemoral alignment values from the MRI McConnell equivalent corrected to the posterior condylar angle were compared to the values from the recognised MRI alignment methods (bisect offset, congruence angle, lateral patellar overhang and lateral patellar shift) to decipher if the vertical axis rotational orientation of the femur was affecting association. The results indicated that the rotational orientation was affecting the analysis as the MRI McConnell equivalent corrected to the posterior femoral condyles had improved associations with the bisect offset, congruence angle, lateral patellar overhang and lateral patellar shift (.75 to .81, p < .001). It is, therefore, thought that the orientation differences between the participants within this and the previous study (Chapter 4), continue to be a variable in need of greater control when setting up patients for clinical assessment. However, it is plausible that the differences are due to femoral anteversion or tibial torsion causing the vertical axis femoral orientation as these are risk factors for patellofemoral pain and, therefore, may affect the measurement values (Arendt & Dejour, 2013). This provides two considerations. Firstly, are the orientation differences causal in some of the cases of patellofemoral pain? Second, is it more appropriate to measure the patient in a plane that relates to the functional motion of the knee if it is reproducible, or to measure in relation to the condylar orientation as per radiological assessment? The Patellofemoral Calliper could provide

measurement of patellofemoral progression between treatments if the set-up of the patient is consistent.

A limitation of this study was the lack of assessor blinding. For both the reliability testing and the validity component of the Patellofemoral Calliper tests, assessor blinding would have reduced the risk of bias in the measurements which may have impacted the correlations and agreement scores. In addition, the use of blinding in the extraction of MRI data may have offered greater credibility to the results presented within this chapter. Whilst this was a consideration, the limitation of the research team training in the use of MRI software, time implications and specific review outcomes for the principle researcher meant that all tests were carried out by the principle researcher, thereby reducing the ability to blind the methods. In future research, the use of additional researchers to extract data from the Patellofemoral Calliper and from MRI would be recommended.

The overall purpose of the current study was to investigate the validity of the Patellofemoral Calliper compared to recognised outputs from MRI scans. When the femoral vertical axis orientation was controlled for in this study, the agreement of the alignment values from the Patellofemoral Calliper was improved over the previous study (Chapter 4). The improved agreement highlights an important step towards the developments needed in clinical assessment of patellofemoral joint alignment. The Patellofemoral Calliper was somewhat limited in its ability to predict recognised MRI alignment measurements. Therefore, if pathological mal-alignment is suspected, at present, the patient should be referred for radiological assessment.

The implications of the current study in clinical assessment have additional importance in the therapeutic interventions currently recommended for patellofemoral pain. A common treatment method believed to reduce pain and realign the joint is McConnell medialisation taping. In this context, the final chapter will examine the effects of McConnell medialisation taping on a patellofemoral pain sample for reducing pain and altering alignment.

# Chapter 7 - Effects of taping on patellofemoral alignment and pain in patients with patellofemoral pain

#### Introduction

Patellofemoral pain is a common lower limb complaint among the general population with an estimated 11-17% of all lower-limb related general practice visits due to this condition (van Middelkoop et al., 2008; Wood et al., 2011). Alignment is a mainstay in the assessment of patellofemoral pain (Hunter et al., 2007; Song et al., 2011). Thus, any mal-alignment between the femur and the patella, would be expected to reduce the contact surface area between the articulating facets of the patella and trochlea, with a proportional increase in joint load (Besier, Gold, Delp, Fredericson, & Beaupré, 2008; Powers, Ward, Chan, Chen, & Terk, 2004; Salsich & Perman, 2013) Over time, the increase in joint load may induce pain in the subchondral bone (Besier et al., 2008; Collado & Fredericson, 2010) and could lead to degeneration.

The presence of pain provides patients the impetuous to seek medical attention due to the deleterious effects on daily living. This pain can also be a limiting factor to the progression and development of the treatment and rehabilitation of the injury as pain itself alters human behaviour to movement (Apkarian, Baliki, & Geha, 2009). Thus, if pain can be reduced with immediate effect, the therapist will have the ability to implement interventions aimed at rehabilitating the deficits commonly associated with patellofemoral pain (Clifford & Harrington, 2013; Crossley et al., 2015; Crossley et al., 2016; Osorio et al., 2013). In 1986, McConnell published the seminal article investigating a method of assessing the patella's position relative to the femur, and offered a taping technique that would allow pain relief while other therapeutic and rehabilitative interventions could be performed to 'realign' the joint and return the patient to normal function (McConnell, 1986). One principle of the tape application is to correct excessive lateral alignment; therefore, the patella is taped with a medial glide directional pull. McConnell's taping method has some reported success in reducing pain to restore function (Barton, Balachandar, Lack, & Morrissey, 2014; Crossley et al., 2015; Edmonds, McConnell, Ebert, Ackland, & Donnelly, 2016). At present, research lacks clarity for the success of taping to alter patellofemoral

alignment (Ghourbanpour, Talebi, Hosseinzadeh, Janmohammadi, & Taghipour, 2018; Herrington, 2010; Pfeiffer, 2004). The short-term effects in reducing pain are well supported (Barton et al., 2014; Edmonds et al., 2016). However, mid- to longterm changes in pain and activities of daily living are not improved with McConnell taping (Barton et al., 2014; Crossley et al., 2015). Interestingly, a lack of improvement in mid- to long-term pain contrasts with the original intention of the taping. The original principle was to provide a short-term reduction in pain to allow for advancement of therapeutic and rehabilitative care that should therefore shorten the return to normal function (McConnell, 1986), although evidence in support of this notion is not currently available. In studies where mid- to long-term changes have been investigated (Barton et al., 2014; Callaghan & Selfe, 2012), the focus appears to have been based on taping as the treatment rather than how taping may impact the ability to include the other therapeutic and rehabilitative exercises earlier. In this sense, the immediate gains associated with patellofemoral taping are of greater importance as these may allow for targeted and permanent correctional therapy to reduce pain and improve function. This study should advance the knowledge of how a therapeutic intervention, in this instance McConnell medialisation taping, may or may not impact pain in patients with patellofemoral pain. This provides originality by applying the principles of taping to a specific cohort of participants who, in theory, should gain from its use. The first aim of this study, therefore, was to investigate the immediate effects of McConnell medial glide taping on reducing pain in patients with patellofemoral pain. The dependent variable was the pain located under the patella during a single leg squat. The experimental hypothesis was:

H<sub>1</sub>: Pain during a single leg squat will be reduced following McConnell medial glide taping.

The use of the McConnell method of alignment assessment, whereby the middistance between the epicondyles is compared as an offset between the middistance of the medial and lateral borders of the patella, has mixed advocacy (Herrington, 2002; McEwan, Herrington, & Thom, 2007; Mendonça et al., 2015; Tomsich, Nitz, Threlkeld, & Shapiro, 1996; Watson et al., 1999; Wilson, 2007). Due to the discrepancies between testers and the lack of agreement when compared to radiological images, some studies conclude that the McConnell method of alignment assessment should not form the basis of whether there is any patellofemoral malalignment (Sacco et al., 2010; Tomsich et al., 1996; Watson et al., 1999; Wilson, 2007). The results of Chapters 4, 5 and 6 of this thesis have shown that the McConnell method can provide some insight into the transverse alignment if femoral vertical axis orientation is controlled, although the clinical relevance of the values are currently questionable. It is unclear if this method of assessment, whilst limited in its clinical relevance for alignment values, can detect alignment change following medial glide taping. The principle behind patellar taping is that realignment occurs to the patellofemoral joint (McConnell, 1986). Evidence of alignment change is available when the patella position is measured with the quadriceps femoris muscle relaxed (Herrington, 2010; Pfeiffer, 2004). However, during open or closed kinetic chain activities the realignment that the tape aims to achieve is likely to be overcome by muscle contraction due to the force vectors of the quadriceps femoris on the patella (Elliott & Diduch, 2001). Balance of these force vectors is reliant upon correct timings and intensities of contractions by the individual muscles of the quadriceps femoris group. It is unclear if restoration of balance in muscular contraction is due to increased proprioceptive feedback (Callaghan, McKie, Richardson, & Oldham, 2012; MacGregor, Gerlach, Mellor, & Hodges, 2005), or if the muscular activation change is a by-product of the reduction in pain (Bazett-Jones et al., 2017). A change in balance of contractions could alter patellofemoral alignment. If proprioception or pain have an effect on muscular activity, the patellofemoral alignment may be altered following taping due to the same effects. For accurate understanding of the alignment of the patellofemoral joint, the most appropriate method of assessment at present is via radiological analysis. As was overviewed in Chapters 4 and 5, it was deemed most appropriate to utilise MRI assessment. However, the first study of this thesis (Chapter 3) highlighted that a proportion (42%) of healthcare and allied healthcare professionals were still using the McConnell assessment of alignment in the clinical assessment of patients with patellofemoral pain. Subsequent studies (Chapters 4, 5 and 6) found that clinical assessment of patellofemoral alignment was dependent upon control of femoral vertical axis orientation, and that the Patellofemoral Calliper offered reliable alignment values but with limited clinical relevance. This study, therefore, investigates whether any changes in patellofemoral alignment can be detected, as this is the basis upon which clinical application of

taping is made (McConnell, 1986). The outcomes of this study advance the previous investigations in Chapters 4, 5 and 6 by testing the detectability of change following a known intervention for patients with patellofemoral pain. Due to the high inter- and intra-tester reliability of this device, there is potential for it to detect change in patellofemoral position between interventions, which may provide the clinician with information about progression or regression from a baseline value. Any changes in patellofemoral alignment that may be detectable clinically would be of relevance to healthcare and allied healthcare professionals to help identify potential changes that may be associated with preventing patellofemoral mal-alignment worsening. If McConnell taping is successful in repositioning the patella within the trochlear groove, the identification of this change in a clinical environment is important as it could serve as an objective marker in patients with patellofemoral pain and patellar mal-alignment. The second aim of this study, therefore, was to investigate if McConnell medial glide taping changes patellofemoral alignment measured by MRI analysis and clinical assessment via the Patellofemoral Calliper. The experimental hypothesis was:

H<sub>2</sub>: Patellofemoral alignment, measured clinically and via MRI, will change following McConnell medialisation taping.

#### Methods

#### **Participants**

Ethical approval for this study was obtained from the HRA IRAS Research Ethics Committee and in agreement with the Brunel University London Research Ethics Committee and (see Appendix IV). Twenty participants (12 female, 8 male) aged 20 to 61 y (M = 36, SD = 13) took part in this study. The sample size for this study was limited due to MRI funding and availability of participants from a specific practice. This sample size was comparable with similar studies (Araújo et al., 2016; Ho et al., 2017; Osorio et al., 2013). Participants were recruited by an orthopaedic surgeon if the patient had retro-patellar pain instigated during flexed load-bearing knee motions. This pain marker was in-line with the identification of patellofemoral pain pathology (Crossley et al., 2016) and mal-alignment (Hunter et al., 2007; Song et al., 2011). Participants were assessed on the day of testing for pain during a single leg 119 squat with the criterion that they must have more than a mild pain, identified as 3/10 or more on a visual analogue scale (Collins et al., 1997). Participants were excluded if they had previous corrective surgery for this condition prior to recruitment and were screened prior to entering the MRI scanner room. No participants were excluded.

## Instrumentation

The MRI were conducted using a 3-Telsa scanner (Magnetom Skyra, Siemens, Erlangen, Germany). The MRI settings and participant setup procedures are described in Chapter 6 (page 107).

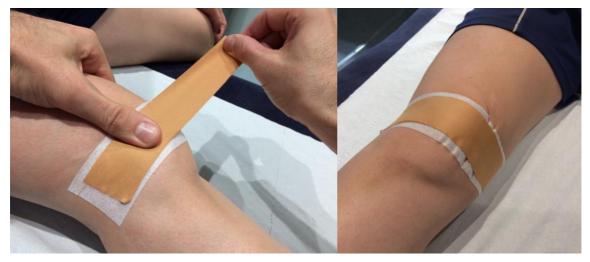
The Patellofemoral Calliper was designed to replicate the McConnell method of patellofemoral alignment assessment. Details about its construction and use are available in Chapter 4 (page 66).

An 11-point visual analogue scale was used for all participants to enable identification of pain levels during initial testing (see Appendix V). A 9-point global rate of change was used for assessing whether the application of tape caused any change in symptoms (see appendix VI). Global rate of change is recognised as providing a meaningful subjective report about changes in symptoms (Elfving, Lund, Lüning Bergsten, & Boström, 2016; Kamper, Maher, & Mackay, 2009). Typically, studies do not support long-term recall of symptom improvement using the global rate of change. However, the recall for short-term change in symptoms is considered excellent, which suited this study design (Kamper et al., 2009).

## Procedure

For collecting the MRI data, the methodology followed the same process and procedures outlined in Chapter 6 (page 107) for scanning as well as analysing the scans post-hoc. The Patellofemoral Calliper application and assessment also followed the same process (page 66). After the calliper reading, participants were invited to the rear of the scanner where they were asked to perform a single-leg squat on their painful side and indicate on the visual analogue scale their level of 120

pain. The participant was then placed back onto the MRI scanner table so that taping could be applied. For the intervention, the McConnell taping method for correcting mal-alignment (McConnell, 1986) was applied using a Leukotape P Combi Pack, whereby Hypafix was applied as a hypoallergenic base layer followed by Leukotape P to medialise the patella. As the Leukotape P was applied a medial glide of the patella was performed and tension was applied through the tape to pull the patella medially (Figure 7.1). The participant was then placed in the same position as before and the MRI scanning sequence was repeated. Following this scan, the Patellofemoral Calliper measurement for alignment was taken, then the participant was taken back to the rear of the scanner to repeat the single-leg squat. Due to limitations in the size of the research team, blinding of the extraction of Patellofemoral Calliper results was not possible. Lack of blinding may have had a negative effect on the bias of results gathering. Following the single-leg squat, the participant indicated on the 9-point global rate of change scale whether their pain had changed compared to before the tape was applied. The tape was then removed and the participant lay on the scanner table before the placebo taping was applied. For this, the same sequence was followed, however, when the Leukotape P was applied, no medialisation of the patella was performed and the tape was placed equally, without tension, over the front of the patella (Figure 7.2). The MRI sequence was again repeated, followed by the Patellofemoral Calliper alignment measurements. Finally, the participant was taken to the rear of the scanner to perform the last single-leg squat and to score the 9-point global rate of change compared to the first single-leg squat (Appendix VI). The order of tape application was counterbalanced such that ten participants received the McConnell tape first and ten received the placebo tape first. It is recognised, however, that true counterbalancing the order would have meant that the baseline measurements should have been randomised. This was not possible for this testing procedure due to the need for a visual analogue scale as a basis for the global rate of change score.



*Figure 7.1.* Application of McConnell medialisation tape with tension identified by skin ripples.



*Figure 7.2.* Application of placebo tape without tension (no skin rippling or medialising of the patella).

## MRI analysis

The MRI images were analysed for the bisect offset, congruence angle, lateral patellar overhang, and lateral patellar shift using the same software and analysis process as previously outlined in Chapter 4 (page 70).

## Statistical analysis

Data were analysed using IBM SPSS statistics for Mac, version 23 (IBM Corp., Armonk, N.Y., USA). The critical  $\alpha$  level was set to p = .05. All data were tested for normality via Shapiro-Wilk significance values and all results were normally distributed (p = < 0.05). For the first aim of investigating the immediate effects of McConnell medial glide taping on reducing pain in patients with patellofemoral pain, the global rate of change score was considered clinically relevant to the patient if the result was equal to or greater than 2 (Kamper et al., 2009). A score of between -1 and 1 would be considered no change and a score equal to or less than -2 was considered a clinically relevant worsening of pain. The global rate of change results were reported as mean (M) and standard deviation (SD). The percentage of participants who rated an improvement, no improvement or a worsening of pain was determined. Wilcoxon signed-rank tests were conducted to compare the effects of the independent variable (taping method: McConnell and placebo) on the dependent variable (global rate of change). The ranks were tested against a standardised zero score based on all participants rating a visual analogue scale pain of at least 3/10. This was to ensure the Wilcoxon signed-rank test was identifying positive, negative or no change, from each participant's pre-intervention pain score. Cohen's effect size for r was used for determining the effect size of the Wilcoxon signed-rank tests, where <.10 is trivial, .10 to .29 is small, .30 to .49 is medium, and >.50 is large (Cohen, 1992).

For the second aim of investigating if patellofemoral alignment was different following McConnell medial glide taping, each of the dependent variable of patellofemoral alignment was compared between the independent variables of no-taping, McConnell taping and placebo taping using repeated measures analysis of variance (ANOVA). For the repeated measures ANOVA, sphericity was assessed using Mauchly's test of sphericity, and where this test assumption was violated, the withinsubjects effects were analysed using Greenhouse-Geisser corrections. Where significance was detected following the repeated measures ANOVA, pairwise comparisons with Bonferroni adjustment were used for post-hoc analysis to detect the location of significant differences. Cohen's *d* was calculated to identify the effect size of the pairwise comparisons, and was rated <.20 for a trivial effect, .20 to .49 for a small effect, .50 to .80 for a medium effect, and >.80 a large effect (Cohen, 1992).

#### Results

The mean visual analogue scale for the baseline pain showed the participants had a moderate level of pain at the start of the experiment (M = 4.3, SD = 1.6). According to the global rate of change scores, the McConnell taping provided pain relief to eleven participants (55%), but increased pain in one participant (M = 1.6, SD = 1.4). For the placebo taping, twelve participants (60%) reported pain relief and none worsened (M = 1.7, SD = 1.2). The results of the pain scores and descriptive statistics are available in Table 7.1. The pairwise comparison results of the Wilcoxon signed-rank tests highlighted that both McConnell taping and placebo taping global rate of change scores were significantly improved from their pre-taping status, with a moderate effect size for McConnell taping (T = 1, p < .01, r = -.45) and a large effect for the placebo tape (T = 0, p < .01, r = -.50). There was non-significance between the McConnell and Placebo global rate of change scores after taping (T = 5, p = .69, r = -.06).

## Table 7.1.

Means, standard deviations, standard error, 95% confidence interval, and margin of error for all pain scores (visual analogue score and global rate of change) measurements in the baseline and taping interventions.

	VAS pre-	GRC post McConnell	GRC post	
Participant	intervention	taping	placebo taping	
1	3	2	3	
2	4	1	0	
3	4	2	0	
4	3	1	1	
5	3	2	2	
6	3	4	4	
7	4	1	0	
8	5	3	2	
9	6	3	3	
10	3	0	0	
11	7	3	1	
12	3	1	2	
13	7	1	3	
14	5	2	1	
15	5	0	1	
16	4	3	2	
17	3	0	3	
18	3	2	2	
19	8	3	2	
20	3	-2	2	
Mean	4.3	1.6	1.7	
Standard deviation	1.6	1.43	1.17	
Standard error	.4	.3	.3	
95% CI upper bound	3.6	.9	1.2	
95% CI lower bound	5	2.3	2.3	
Margin of error	.7	.7	.5	

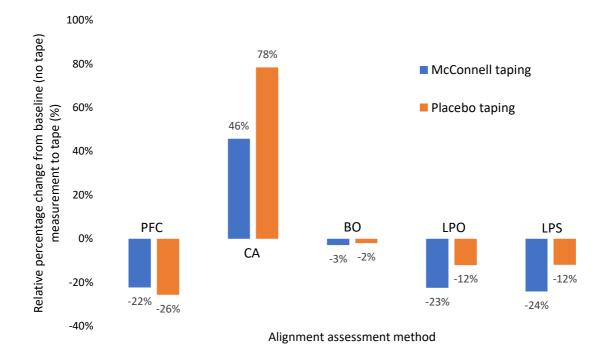
VAS: Visual analogue score.

GRC: Global rate of change score.

CI: Confidence interval

When analysing the ANOVA outputs, sphericity was tested and confirmed for all measurements except the congruence angle, where a Greenhouse-Geiser correction 125

was adopted. The repeated measures ANOVA showed an effect for taping on the lateral patellar shift ( $F_{1, 19} = 3.25$ , p = .05,  $\eta_p^2 = .146$ ), but no effects for taping on any of the other alignment measurement methods used: Patellofemoral Calliper,  $F_{1, 19} = 1.56$ , p = .223,  $\eta_p^2 = .076$ ; bisect offset,  $F_{1, 19} = 2.11$ , p = .136,  $\eta_p^2 = .100$ ; congruence angle,  $F_{1, 19} = 2.03$ , p = .161,  $\eta_p^2 = .096$ ; lateral patellar overhang,  $F_{1, 19} = 2.85$ , p = .07,  $\eta_p^2 = .131$ . Post-hoc analysis revealed that a significant difference in the lateral patellar shift was detected between the no tape and McConnell tape (p = .038) but not for between no tape and placebo (p = .765), or placebo and McConnell (p = .629). The Cohen's *d* effect size calculations (Table 7.2.) highlighted a small effect size (d = .27) for the pairwise comparisons between no tape and McConnell tape (d = .13).



*Figure 7.3.* Relative percentage change in alignment from MRI and clinical assessments following two taping methods.

PFC: Patellofemoral Calliper

CA: Congruence angle

**BO: Bisect offset** 

LPO: Lateral patellar overhang

LPS: Lateral patellar shift

## Table 7.2.

Means, standard deviations, and Cohen's <i>d</i> pairwise effect size calculations for all
alignment measurements in the baseline and taping interventions.

•						
	PFC (mm)	BO (%)	CA (θ°)	LPO (mm)	LPS (%)	
No tape <i>M</i> ( <i>SD</i> )	2.6 (6.8)	59.3 (6.5)	-6.1 (13.3)	3.0 (2.6)	8.2 (7.2)	
McConnell tape <i>M</i> ( <i>SD</i> )	2.0 (6.9)	57.5 (5.1)	-8.8 (12.8)	2.3 (2.7)	6.2 (7.3)	
Placebo tape <i>M</i> ( <i>SD</i> )	1.9 (7.1)	58.1 (5.8)	-10.7 (14.5)	2.7 (.91)	7.2 (7.7)	
ES No tape – McConnell tape	.08	.30	.21	.26	.27	
ES McConnell tape – Placebo tape	.01	.11	.14	.16	.13	
ES No tape – Placebo tape	.10	.19	.34	.19	.13	
PFC: Patellofemoral Calliper						
CA: Congruence angle						

BO: Bisect offset

LPO: Lateral patellar overhang

LPS: Lateral patellar shift

ES: Effect size (Cohen's *d*)

## Discussion

The overall aim of the current study was to investigate the pain and alignment changes in patients with patellofemoral pain using McConnell medial realignment taping. It was found that (1) both the McConnell and placebo tape had a reduction in pain but did not differ in their effect; (2) the McConnell taping identified a medial alignment difference in the lateral patellar shift, however, this was not identified in any other measurement method.

The first aim of this study was to investigate the immediate effects of McConnell medial glide taping on reducing pain in patients with patellofemoral pain. The results revealed similar reductions in pain for both independent variables (55% reporting pain reductions for McConnell taping and 60% for placebo taping). The results of the Wilcoxon signed-rank test confirmed that there was a significant improvement in pain from the baseline values with medium to large effect sizes according to Cohen's d, however, there was not a significant difference between the McConnell and Placebo taping interventions. This non-significant result is important in the context of 'corrective' medialisation McConnell taping. McConnell taping aims to reduce pain, thus enabling other therapeutic and rehabilitative interventions to occur (McConnell, 1986). In the current study, eight participants out of the eleven who felt pain relief from McConnell taping also had reduced pain from placebo taping. Therefore, 40% of the participants with knee pain felt improvement, regardless of whether the tape was applied with a medial glide (McConnell), or with no directional pull at all (placebo). In total, fifteen (75%) out of the twenty participants with patellofemoral pain had clinically relevant reductions in pain from either McConnell medialisation taping or placebo taping (or both). The results of the current study support recommendations that medial patellofemoral glide taping should be used to reduce pain in the short-term (Barton et al., 2014; Edmonds et al., 2016), however, a review by Barton and colleagues (2015) highlighted that medialisation taping was more effective than placebo taping, in contrast to the current study. Conversely, Callaghan & Selfe (2012) conclude that there is no statistical or clinical evidence for reduced pain between taping and non-taping groups. The placebo outcomes of this study raise the possibility that any tape applied to the knee may cause a reduction in pain for patients with patellofemoral pain. Within a clinical setting, applications of tape without due regard to methodology are of concern. A placebo treatment intervention poses an ethical issue due to the requirement of deception (Barnhill & Miller, 2015). As a healthcare practitioner, the therapists administering interventions are required to ensure that all treatments are agreed by the patient with informed consent. However, it is unclear if the application of tape currently administered by practitioners is effectively and reliably applied, meaning that the results of the placebo control suggest that any difference in application ability would not negatively impact reductions in pain. Research should continue to investigate the mechanisms of pain

reduction as well as the mid- to long-term effects that taping has on pain and function. The results of this study suggest that placebo tape offers some reduction in pain perception. One potential mechanism for the effect of placebo taping is the psychological benefit that the application of a modality may have on a patient in pain based on their experience (Liu, 2017). The basis of this centres around the links established between depression and pain followed by a stimulus (Bair, Robinson, Katon, & Kroenke, 2003; Phyomaung et al., 2014). The benefits of a placebo intervention are normally identified by the prior treatments of the patient (conditioning theory) or the expectations of the patient that a particular treatment may work (expectancy theory) (Koshi & Short, 2007). The research of this study did not investigate prior successful or unsuccessful treatments that the patients may have had. This may could have impacted the outcomes of the McConnell and placebo taping that should be considered in future research.

The mechanisms by which pain is reduced in patients with patellofemoral pain are yet to be fully understood. Theories have proposed that taping changes the alignment of the patellofemoral joint, thereby improving joint congruency and offload pressure on the irritated subchondral bone (Besier et al., 2008; Farrokhi et al., 2011). For a change in congruency to occur, patellofemoral alignment differences should be identifiable between pre- and post-taping interventions. In the current study, the placebo tape did not have a directional force, meaning the patellofemoral joint did not have a passive realignment applied that would offload the irritated subchondral bone. However, the placebo taping did reduce pain with a large effect size on the participants of this study. Alternative theories of the effects of taping have identified that patients with patellofemoral pain may have altered muscle activity around the joint that are affected by tape application (Lankhorst, Bierma-Zeinstra, & Middelkoop, 2012; Powers, 2000; Toumi et al., 2013). Specifically, changes in timing and duration of contractions of the vastus medialis obliquus muscle have been proposed as a mechanism to improve joint congruency. Kinaesthetic stimulation, such as that seen with taping, is thought to have some impact on both the perception of pain (Barton et al., 2014) and the activation of proprioceptors that enhance muscle activation (Callaghan et al., 2012), although some authors refute this (Leibbrandt & Louw, 2015). Future research would benefit from investigating the effects of kinaesthetic

stimulation on patellofemoral pain and neuromuscular patterns in the short- and long-term. Pain is thought to cause dysfunction to neuromuscular patterns of movement, therefore, reducing pain could enable the return of appropriate neuromuscular patterns of dysfunctional muscles. With increased stimulation of proprioceptors from tape also leading to a greater activation of motor neurones (Röijezon, Clark, & Treleaven, 2015), the combined effect should see an altered active alignment of the patellofemoral joint, as seen in increased extensor peaks in clinical trials (Osorio et al., 2013). From the results of the current study, it would be expected that altered patellofemoral alignment would occur in taping applications.

To test the second aim of whether McConnell medial glide taping changes patellofemoral alignment measured by MRI analysis and clinical assessment via the Patellofemoral Calliper, five alignment methods (four MRI and one clinical) were assessed following McConnell and placebo taping conditions. The results revealed that only the lateral patellar shift had a significant change in alignment, which was only evident in the McConnell taping intervention. There was a small effect size (identified by Cohen's d analysis) for the lateral patellar shift measurement between no tape and McConnell tape, meaning the results do not offer a strong rejection of the null hypothesis due to the minimal difference in standard deviations. The aim of McConnell medialisation taping was to change the alignment thereby improving symptoms of pain. It is unknown if the small effect size would be beneficial to the patients as there is no standardisation for how much alignment change causes favourable joint mechanics. For all other measurements of patellofemoral alignment (via MRI analysis and clinical assessment), no significant differences in either the McConnell taping or the placebo taping were identified. Additionally, the effect sizes of all of these tests were small at best, highlighting a lack of effect from the interventions. The change in alignment that would be considered clinically relevant, remains unknown. In the original research by Sasaki & Yagi (1986), post-operative improvements in patients with recurrent subluxations saw mean differences in lateral patellar shift values of 20.1% at full extension with the quadriceps femoris muscles contracted. This highlights the limited changes observed in the current study, however, the participants of the current study were assessed at 30° of flexion. This angle of flexion was chosen due to the engagement of the patella in the trochlear

groove. However, the patella is less mobile at this range, thereby reducing the likelihood of alignment change following taping. The current study represents a greater understanding of the likely alterations during load-bearing articulation through flexion, which is most relevant to the presentation of a patient with patellofemoral pain (Crossley et al., 2016), as opposed to an extended position as in the Sasaki & Yagi study (1986).

Overall, the clinical and radiological patellofemoral alignment identified a trend towards a medialisation of the patella for both the McConnell and placebo taping. However, the difference was non-significant and had trivial to small effect sizes. The lack of statistical significance may be influenced by the sample size of this study. The results presented mostly support literature highlighting no difference in patellofemoral alignment following realignment taping (Ghourbanpour et al., 2018; Lan et al., 2010). However, the results presented here contrast alignment studies where differences in pre- and post-taping alignment were identified, which may be explained due to their methods assessing participants in a relaxed and extended position (Herrington, 2010; Pfeiffer, 2004). The change in alignment identified in the lateral patellar shift for the McConnell taping suggests that McConnell medialisation taping may provide a measurable change in patellofemoral alignment in patients with patellofemoral pain during a contracted state at 30° flexion. The change in alignment identified in the lateral patellar shift is the first report of an alignment difference where the patella is under contractile force. It is unclear if the tape itself was able to directly influence the position of the patella, or if the force of the medial glide had added benefits of proprioceptive function that increased muscular output to promote medialisation. A limitation is identified from the low level of muscular contraction during the current study, meaning the contraction did not reflect the force vectors that would be seen during load-bearing at the same angle. Furthermore, nonrandomisation of the no tape condition was not deemed possible due to VAS forming the baseline data and, therefore, needing to be tested first. This lack of nonrandomisation may have induced a learning effect for symptom relief in the participants. Additionally, the lack of statistical significance in the four other alignment measurements raises concerns about the effect detected. Finally, a lack of assessor blinding to the data collection may have influenced the alignment measures from the clinical process and could have led to an inflated accuracy. A future study could investigate participants in an upright MRI scanner to measure if the effect of McConnell medial glide taping can be maintained and should utilise randomisation with assessor blinding.

While patellofemoral pain is one of the most common lower-limb complaints amongst the general population, the literature lacks definitive data for mal-alignment ranges (Wilson, 2007). In this sense, imaging analysis results are left to the interpretation of the healthcare practitioner to make an informed, and clinically reasoned judgement of therapeutic or surgical interventions. In the context of mal-alignment, the amount of change needed in the participants for the current study was unknown. It is plausible that the amount required to reduce pressure on the irritated subchondral bone was exceptionally small (Powers et al., 2004). A small change may not constitute 'correct alignment' for the individual, meaning that over time this minor correction may still lead to joint pain and pathology. However, a small alignment change may enable reduced pain in an acute context, as was the original goal of McConnell taping (McConnell, 1986). What is evident from the results of the current study, is that patients with patellofemoral pain have a small effect of altered lateral patellar shift following McConnell medial glide taping. However, no other alignment assessments reveal a difference following McConnell medialisation taping or placebo taping. Therefore, the research hypothesis H<sub>2</sub> is rejected: Patellofemoral alignment, measured clinically and via MRI, will differ following McConnell medialisation taping.

The results of the current study raise questions about the clinical implications of applying tape to a patient with patellofemoral pain. It appears that, for short-term reductions in pain in some patients, McConnell or placebo taping can reduce pain, although there is no clinically measurable difference in the alignment of the joint and no difference in three out of four radiological assessments of alignment. In line with the results of the current study, a recent study identified that patients with patellofemoral pain experienced no change in alignment of the patellofemoral joint after a four-week intervention with and without tape (Ghourbanpour et al., 2018). While taping has been shown to reduce pain in patients with patellofemoral pain (Crossley et al., 2015; Edmonds et al., 2016), aid muscular re-training (Osorio et al.,

2013), and alter patellofemoral alignment (Herrington, 2010; Pfeiffer, 2004), the results of the current study continue to raise concerns about the biomechanical effectiveness of patellofemoral taping. In conclusion, McConnell taping can reduce short-term pain in patients with patellofemoral pain; however, the clinical and radiological measurements do not corroborate with the underlying principle that malalignment *per se,* is altered.

## **Chapter 8 - Discussion**

Patellofemoral pain is a common and debilitating condition among both sedentary and active populations (Crossley et al., 2016; Wood, Muller, & Peat, 2011). The aetiology includes a plethora of systemic, biomechanical, and environmental factors that can contribute to the development and progression of this injury (Crossley et al., 2016; Garstang & Stitik, 2006; Lankhorst, Bierma-Zeinstra, & Middelkoop, 2012). Diagnosis of patellofemoral pain lacks clarity (Crossley et al., 2016), with research focusing on individual components of contributory risk factors in an attempt to aid overall understanding (Herrington, 2002; McCarthy & Strickland, 2013; Ota, Nakashima, Morisaka, Ida, & Kawamura, 2008). A common mechanism of biomechanical concern is patellofemoral mal-alignment (Crossley et al., 2016). Identification of incorrect positioning of the patella within the trochlear groove has been a source of research for the past thirty years since McConnell (McConnell, 1986) published the seminal article in clinical mal-alignment assessment, with proposed treatment parameters using taping. Unfortunately, research in this area is mostly conflicting with limited support for the clinical assessment method (Cook et al., 2012; Mendonca et al., 2015; Wilson, 2007) or the treatment of taping to 'correct' the mal-aligned joint (Barton et al., 2014; Leibbrandt & Louw, 2015). Imaging techniques for the assessment of the patellofemoral joint have advanced in recent years, and there are a variety of methods available for assessing the articular relationships and osseous shapes that may predispose patients to instability of the joint (Draper et al., 2011; Drew et al., 2016). However, onward imaging referral is typically reserved for diagnosing recalcitrant anterior knee pain. A therapy based, non-operative approach is used as the first line treatment for the majority of cases (Crossley et al., 2016; McCarthy & Strickland, 2013). Therefore, accurate clinical assessment of patellofemoral mal-alignment is essential in the management of patients with patellofemoral pain. Improved reliability and validity of patellofemoral alignment assessment in a clinical environment would enhance treatment planning and overall success of this condition. Furthermore, the McConnell assessment process previously discussed was proposed as a precursor to realignment taping (McConnell, 1986). The aim of the McConnell taping treatment is to realign the

patellofemoral joint, with subsequent reductions in pain. Therefore, the main purpose of this research thesis was to investigate clinical assessment of patellofemoral joint alignment and the response to realignment taping, with a view to informing evidencebased practice.

## Summary of findings

The first experimental study (Chapter 3) sought to ascertain the current assessment methods adopted by physiotherapists and sports therapists when assessing patellofemoral pain. A questionnaire was developed to examine how patellofemoral pain is currently assessed, including the onward referral for radiological analysis. The results highlighted that the McConnell method of assessment was used by 42% of practitioners who completed the questionnaire. Onward referral for radiological assessment of patients was common, with 70% stating they would refer. However, a very small proportion (5%) identified that imaging assessment was common practice. It was concluded that the McConnell assessment method was in use by a large proportion of the professions investigated. These therapists were seeking additional information regarding the patellofemoral joint morphology by referring for imaging assessment. This provided two considerations: 1) the McConnell method of assessment warranted further investigation as it was common in use for patients with patellofemoral pain, and 2) establishing the validity and reliability of clinically derived data, may lead to the more judicious, and therefore cost effective, use of the various imaging modalities.

Experimental Chapter 4 investigated validity and intra-tester reliability of a custommade calliper (the Patellofemoral Calliper) designed to provide an objective measurement tool in place of the McConnell transverse alignment estimation method. Previous research has found that validity and reliability improved when the McConnell assessment method was modified to provide an objective measurement (Herrington, 2002; Ota, Ward, Chen, Tsai, & Powers, 2006; Sacco et al., 2010). The Patellofemoral Calliper was first tested for reliability, and provided excellent intratester results; contrasting or improving upon findings of some studies (Fitzgerald & McClure, 1995; Lesher et al., 2006; Powers, Mortenson, Nishimoto, & Simon, 1999; Tomsich et al., 1996). The calliper measurements were then compared to MRI methods of assessing alignment, including a replication of the McConnell method on the MRI images for agreement testing. The agreement was not deemed acceptable for clinically relevant assessment of patellofemoral measurement. However, the calliper did correlate with the bisect offset, but not with any other methods. Whilst correlation coefficient results were unexpected and in contrast to similar studies (Herrington, 2002; Ota et al., 2006), the methodological parameters were considered a potential source of error. Methodological parameters raised concerns about the use of the McConnell method of clinical assessment, which was identified in Chapter 3 as being a common process. The patellofemoral calliper was designed to provide validity in the McConnell measurement method of patellofemoral alignment; yet the results of this study suggested that the process by which the calliper derived the measurements may not provide the clinician with meaningful data when compared to MRI. The use of asymptomatic participants was identified as a limitation, especially for the narrow range of alignment results achieved. The use of asymptomatic participants provided the rationale for investigating pathological (degenerative) patellofemoral joints to determine whether alignment differs in this population.

Experimental Chapter 5 investigated the assessment principle of the McConnell method, via MRI analysis, in an osteoarthritic sample. Patellofemoral osteoarthritis is a potential progression risk for patients with patellofemoral pain who have patellar mal-alignment (Crossley, 2014) due to the increased load on the articular surfaces. Within this study, an important discovery was made. The McConnell method of assessment, as replicated on the MRI images, poorly correlated with the recognised MRI alignment assessment methods, as would be expected following the results of Chapter 4. However, an observation was made that the vertical axis orientation of the femur within these images may be causing errors in the assessment process. Therefore, an analysis was added whereby the McConnell assessment method was applied perpendicular to the posterior femoral condyles. Altering the femoral vertical axis orientation improved the correlation values with the recognised MRI alignment assessment methods. The study in Chapter 4 was the first time the McConnell alignment assessment had been factored with the vertical axis of the femur. The correlation coefficient findings identified how important the vertical axis of the femur is to clinical assessment of the patellofemoral joint. It may also explain variations in

some of the previous literature for validity and reliability (Fitzgerald & McClure, 1995; Lesher et al., 2006; Powers et al., 1999; Tomsich et al., 1996). In conclusion, the results from Chapters 3 to 5 have highlighted that the McConnell assessment of patellofemoral joint alignment, which is in common use by physiotherapists and sports therapists, lacks validity when compared with objective measures obtained by MRI. This lack of validity is hypothesised to be due to the McConnell method not controlling for the vertical axis of rotation of the femur.

From the results in experimental Chapters 4 and 5, a follow up study was designed (Chapter 6) to investigate if the lower limb could be controlled sufficiently to improve the clinical assessment of patellofemoral alignment. Therefore, alignment values were compared from the Patellofemoral Calliper to MRI results in patients with patellofemoral pain. These results highlighted improved agreement for the calliper to an MRI derived McConnell equivalent, and had significant positive correlations to all alignment measurements obtained via MRI. From this study (Chapter 6), it was ascertained that with improved control of the femoral vertical axis, the clinical assessment of patellofemoral alignment may offer useful information for patellofemoral alignment measurement. It was accepted that continued development is still required to control this important parameter. The findings from Chapters 4, 5 and 6 do offer some explanations for the poor reliability and validity identified in the literature (Fitzgerald & McClure, 1995; Lesher et al., 2006; Powers et al., 1999; Tomsich et al., 1996). Where studies have statistically significant reliability and validity values (Herrington, 2002; Ota et al., 2006; Sacco et al., 2010), they have used adapted methods of the McConnell assessment that may lend these results to being, by default, less affected by femoral orientation. From the findings presented in Chapters 4, 5 and 6, the Patellofemoral Calliper produced significant inter- and intratester reliability that may provide the clinician with a device for inferring alignment values if the vertical axis of the femur could be controlled. Furthermore, due to patellofemoral pain being a condition that is thought to lead to progression of malalignment, especially in patients with osteoarthritis (Chapter 4), the Patellofemoral Calliper could provide clinical data about the progression, or regression, of malalignment. In this context, it was important to identify if realignment of the

patellofemoral joint, from McConnell medialisation taping, could be measured and would provide reductions in pain for the patient.

In the final experimental Chapter (7), the effects of McConnell medial realignment taping on pain and alignment were investigated. The taping aimed to provide a reduction in pain alongside a measurable change in the patellofemoral joint alignment that could be assessed using the Patellofemoral Calliper in a clinical setting; verified here by MRI. The results showed that whilst pain was reduced in most patients using the McConnell medialisation taping technique, a placebo tape had similar pain reducing effects. Upon analysis of the alignment, it was identified that one medialisation difference from McConnell taping was detected (lateral patellar shift), but with a small effect size. No other measures from the clinical (Patellofemoral Calliper) or MRI measurements identified a statistically significant alignment change due to taping. The lack of alignment medialisation contrasted with some studies (Herrington, 2010; Pfeiffer, 2004) and agreed with others (Ghourbanpour et al., 2018; Lan et al., 2010). One distinguishing parameter of the current study compared to others where a change in alignment was found was that the current study measured the participants in a contracted state at 30° of flexion. This contracted state meant that the patella was actively engaging with the trochlear groove and the quadriceps femoris muscle group was acting on the patellar alignment. The methods used aimed to ensure that the measurements obtained in this study represented the functional interaction between the patella and trochlear groove, alongside any effect of tape. Data observations identified a trend towards medialisation in the McConnell and placebo results when compared to the baseline, leading to the recommendation of a need for an increased sample size and identification of a clinically relevant change in patellar alignment. At present, there are no clear recommendations for 'normal' patellofemoral alignment. This final study culminates the research developed throughout this thesis to identify if the clinical data obtained from assessment can be used to infer treatment to correct alignment. At present, there is a need for a clinical assessment method to measure alignment to improve the diagnostic yield and inform treatments for reducing pain and correcting biomechanical abnormalities. The method proposed by McConnell can be adapted, via the use of a calliper, to provide statistically significant intra and inter-tester

reliability, however, the vertical axis of the femur is more important than previously identified in this assessment of patellofemoral alignment. Additionally, the treatment of corrective McConnell medialisation taping appears to reduce pain; however, placebo taping has similar effects. Patellofemoral alignment as measured by lateral patellar shift identified a small effect between pre- and post-McConnell tape, however, no other MRI analysis methods identified a statistically significant difference.

#### Implications

The results of this thesis add to the evidence of clinical assessment of patellofemoral joint alignment, as well as the outcomes of McConnell medialisation taping. The McConnell assessment of patellofemoral alignment was well used by physiotherapists and sports therapists in clinical assessment of patients with patellofemoral pain. The McConnell assessment process forms the basis of a vast array of interventions for patellofemoral pain, principally taping. The findings of this thesis conclude that in the context of the McConnell alignment assessment, the use of the Patellofemoral Calliper can provide statistically significant inter- and intratester reliability of measurements, although the validity of the resultant values is dependent upon the control of femoral orientation and requires further investigation. The current oversight of femoral vertical axis orientation during clinical assessment is a fundamental and significant finding of this research that may help towards improving the clinical assessment of patellofemoral alignment.

In a broader context, the lack of clinical utility of patellofemoral alignment testing may require greater understanding by the practitioners who are conservatively managing patellofemoral pain. Whilst a biomechanical (radiological) diagnosis and operative treatment of patellofemoral mal-alignment is of use when conservative management has been unsuccessful (McCarthy & Strickland, 2013; Vora, Curry, Chipman, Matzkin, & Li, 2017), the lack of validity in clinical alignment testing would suggest that clinical practitioners would be better placed to treat the common musculoskeletal causes of patellofemoral pain in the first instance. As has been shown in recent research, a multi-modal approach to this common injury appears to offer good short-to-medium term reductions in pain and an increase in return to daily activities (Barton

et al., 2015; Crossley et al., 2016). It is plausible that practitioners who are currently relying on the clinical utility of patellofemoral alignment testing may be narrowing their treatment options due to an inaccurate assessment. Until a valid clinical assessment method is found, practitioners should manage patients with patellofemoral pain via a multi-modal treatment approach.

The results of McConnell and placebo taping for patients with patellofemoral pain has added to existing knowledge (Crossley et al., 2015; Edmonds, McConnell, Ebert, Ackland, & Donnelly, 2016). Specifically, McConnell medialisation taping can have positive impacts on pain. However, the same effects can be achieved via placebo taping, implying that much of the pain reductions observed by patients may be based on kinaesthetic stimulation; the effects of which are unknown. Following McConnell medialisation taping, one statistically significant difference was detected in alignment measured using the lateral patellar shift. The remaining results lacked statistically significant differences in alignment following McConnell and placebo taping; therefore, taping does not change alignment in patients with patellofemoral pain when the thigh muscles are contracted and the limb is at 30° flexion.

Collectively, the results from this thesis demonstrate that components of clinical assessment and treatment of patellofemoral pain should not form the basis of assumption that mal-alignment can be measured or affected. For the development of improved clinical assessment of patellofemoral alignment, femoral vertical axis orientation requires improved control so that the validity of measures can also be improved. Taping can provide reductions in pain which may not require specific applications to be effective. To this end, any taping that produces a reduction in pain from the patient should be deemed successful. However, it should not be assumed that taping is correcting alignment abnormalities.

The clinical assessment procedure for alignment measurement should continue to be investigated to ascertain if a common process can be developed to clinically control for, or measure, the vertical axis of the femur. The vertical axis component may be crucial in the advancement of reliability and validity of clinical assessment. With greater understanding about the patellofemoral alignment abnormalities for each patient, the treatment, rehabilitation and onward referral process may be improved to reduce the progression of patellofemoral pathology. To improve the validity of clinical measurements, continued research into the objective measurement of patellofemoral alignment, either with the use of the Patellofemoral Calliper or other such methods, is warranted to ensure that the clinician is making treatment decisions based on the best available data. Finally, patellar taping should continue to be investigated to improve knowledge in the positive impacts taping has on the patient and their return to normal function.

#### Limitations

The main limitation to the aforementioned studies is relatively small sample size. During development, it was identified that clinical assessment may lack reliability and validity in assessing the alignment of the patellofemoral joint (Fitzgerald & McClure, 1995; Lesher et al., 2006; Powers et al., 1999; Tomsich et al., 1996). Therefore, in the investigation of the clinical method, it was necessary to compare these findings to a recognised reliable method of imaging; in this case MRI. Due to the use of MRI, there were cost and time implications in the collection of data for comparison. The number of participants in these studies (Chapters 4 to 7) were deemed sufficient when compared to similar studies (Edmonds et al., 2016; Ota et al., 2006; Pal et al., 2013; Sacco et al., 2010), however, due to the limited number of participants, statistical analyses were susceptible to extreme values of individual patients.

The testing protocols in which the participants were tested for alignment is also considered a limitation to the aforementioned studies. At present, there is no clear consensus about the ideal angle, position or activation levels that provide the most informative data about patellofemoral alignment. During the development of the experimental studies, two different angles of knee flexion were used, and different contraction protocols were set for the muscles acting across the knee. Specifically, experimental studies in Chapters 4, 6 and 7 had the knee set to 30° flexion while Chapter 5 was at 0°. At 30° flexion the patella is said to be engaged with the trochlear groove and any alignment abnormalities that occur in this range should be considered important in how they will impact contact pressures on the articular surfaces (Zaffagnini, Dejour, et al., 2013). The engagement region formed the basis

of using 30° flexion during the majority of experimental studies in this thesis. In terms of muscle contraction protocols, Chapter 4 utilised only the quadriceps for a knee extension hold whereas Chapters 6 and 7 saw participants co-contracting muscles across the knee in a leg press activity. Chapter 5, however, did not have any muscle contraction due to the pain from the osteoarthritic participants of the study. Testing procedures in the literature are varied for these parameters (Draper et al., 2011; Ota et al., 2006; Wilson, 2007) with some studies assessing in load-bearing, where appropriate scanners are available (Pal et al., 2013; Teng, Chen, & Powers, 2014; Varadarajan et al., 2010). It was unclear from the literature which of these setups was best for measuring patellofemoral alignment, however, all had their merits and limitations in the context of data gathering for this thesis.

The main limitations to the studies within this thesis are the small sample sizes, sample selection processes, the lack of unmatched cohorts, limited patellofemoral pain sufferers, differences in testing protocols for MRIs, and lack of blinding of assessors. Future research into this common, complex and multi-dimensional injury should focus on reducing the limitations in the studies presented here in order to continue to develop the knowledge and understanding about patellofemoral alignment and pain.

Finally, patellofemoral pain is a common patient complaint that is known to be multifactorial in its aetiology. Due to the plethora of risk factors and associated biomechanical considerations, research investigations into individual components of these factors will inevitably not reach definitive conclusions. It is impossible to develop a research project that can investigate all known components of this complex condition. This thesis provides contributes to the evidence-base for clinical assessment and taping treatment of patellofemoral pain.

### **Future research**

Due to the multifactorial nature of patellofemoral mal-alignment and pain, it is recommended that research focuses on stratifying the underlying pathologies related to patellofemoral symptoms and provide longitudinal studies to understand the pathological progressions in-line with clinical and radiological outcomes measures.

From this, a greater understanding of possible sub-groups of patellofemoral pain may be identified and recommendations can be made to streamline the clinical assessment process to, therefore, reduce the treatment and interventions required to aid the return to pain-free joint articulation.

# Conclusions

The main findings from the experimental Chapters (3-7) provide important evidence for the clinical assessment process, and subsequent taping treatment for patellofemoral pain. Improved control of vertical axis femoral orientation is required to improve the McConnell clinical assessment process currently in use, and until this is achieved, clinical assessment of alignment is not recommended. Additionally, taping to alter patellofemoral alignment does not change the patella position, but can reduce pain during aggravating movements. The patellofemoral assessment results of this thesis advance the knowledge of clinical assessment methods and provide improved understanding about the interpretation of 'measured' biomechanical parameters. Treatment via corrective realignment taping should continue to be used as a pain management intervention, but should not be considered a realignment procedure. Whilst there is evidence to support reductions in pain, the joint alignment appears unaffected, meaning that the clinician must use pain suppression as a window of opportunity to correct more global errors that may be reinforced by the presence of pain. Future research should focus on increasing the effectiveness of clinical assessment, and on measuring the effects of pain reductions from taping that accelerates corrective therapy in the mid- to long-term patient.

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## **Appendices**

#### Appendix I

#### Ethical approval for experimental Chapter 3

Head of School of Sport & Education Professor Susan Capel

Mr Kevin Campbell-Karn 452 West Wycombe Road High Wycombe Bucks HP12 4AH



Heinz Wolff Building, Brunel University, Uxbridge, Middlesex, U88 3PH, UK Tel +44 (0)1895 266494 Fax +44 (0)1895 269769 www.brunel.ac.uk

23<sup>rd</sup> July 2013

Dear Kevin

RE32-12 Accuracy and reliability of clinical assessment methods for measuring patellofemoral alignment

I am writing to confirm the Research Ethics Committee of the School of Sport and Education received your application connected to the above mentioned research study. Your application has been independently reviewed to ensure it complies with the University/School Research Ethics requirements and guidelines.

The Chair, acting under delegated authority, is satisfied with the decision reached by the <sup>10</sup> independent reviewers and is pleased to confirm there is no objection on ethical grounds to grant ethics approval to the proposed study.

Any changes to the protocol contained within your application and any unforeseen ethical issues which arise during the conduct of your study must be notified to the Research Ethics Committee for review.

On behalf of the Research Ethics Committee for the School of Sport and Education, I wish you every success with your study.

Yours sincerely

Bruddan.

P Dr Richard J Godfrey Chair of Research Ethics Committee School Of Sport and Education

Brunel is proud to host





#### **Appendix II**

#### Ethical approval for experimental Chapter 4

Head of School of Sport & Education Professor Susan Capel

Mr K Campbell 452 West Wycombe Road High Wycombe Bucks HP12 4AH



Heinz Wolff Building, Brunel University, Uxbridge, Middlesex, UB8 3PH, UK Telephone +44 (0)1895 266494 Fax +44 (0)1895 269769 Web www.brunel.ac.uk

29th February 2008

Dear Kevin

RE58-07 - Accuracy and reliability testing a transverse plane patellofemoral tracking calliper

I am writing to confirm the Research Ethics Committee of the School of Sport and Education received your application connected to the above project. Your application has been independently reviewed and I am pleased to confirm your application complies with the research ethics guidelines issued by the University.

On behalf of the Research Ethics Committee, I wish you every success with your study.

Yours sincerely

Dr Simon Bradford Chair of Research Ethics Committee

#### Ethical approval for experimental Chapter 5



#### NRES Committee North West - Cheshire

Research Ethics Office Barlow House 3rd Floor 4 Minshull Street Manchester M1 3DZ

Telephone: 0161 625 7821 Facsimile: 0161 625 7299

10 January 2012

Dr Michael Callaghan Post Doctoral Research Associate University of Manchester Arthritis Research UK Stopford Building Oxford Rd, Manchester M13 9PT

Dear Dr Callaghan

Study title:	The effects of a patellofemoral brace and patellar taping
	on knee movement, muscle activity and patellar position
	in patients with patellofemoral osteoarthritis (PFOA)
REC reference:	11/NW/0851

Thank you for your letter of 22 December 2011, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information was considered in correspondence by a sub-committee of the REC at a meeting held on 8 January 2012. A list of the sub-committee members is attached.

#### Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, <u>subject to the conditions specified below</u>.

#### Ethical review of research sites

#### NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

#### Non-NHS sites

The Committee has not yet been notified of the outcome of any site-specific assessment (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. We will write to you again as soon as one Research Ethics Committee has notified the outcome of a SSA. In the meantime no study procedures should be initiated at non-NHS sites.

A Research Ethics Committee established by the Health Research Authority

# Health Research Authority

**NRES Committee North West - Cheshire** 

Research Ethics Office Barlow House 3rd Floor 4 Minshull Street Manchester M1 3DZ

Telephone: 0161 625 7821 Facsimile: 0161 625 7299

11 January 2012

Dr Michael Callaghan Post Doctoral Research Associate University of Manchester Arthritis Research UK Stopford Building Oxford Rd, Manchester M13 9PT

Dear Dr Callaghan

Full title of study:	The effects of a patellofemoral brace and patellar taping
	on knee movement, muscle activity and patellar position
	in patients with patellofemoral osteoarthritis (PFOA)
REC reference number:	11/NW/0851

Thank you for your email of 10 January 2012. I can confirm the REC has received the documents listed below as evidence of compliance with the approval conditions detailed in our letter dated 10 January 2012. Please note these documents are for information only and have not been reviewed by the committee.

I can now confirm that the additional conditions have been met.

#### Documents received

The documents received were as follows:

Document	Version	Date
Participant Information Sheet	3	10 January 2012

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

11/NW/0851

Please quote this number on all correspondence

Yours sincerely

Miss Shehnaz Ishaq Committee Co-ordinator

A Research Ethics Committee established by the Health Research Authority

#### **Appendix IV**

#### Ethical approval for experimental Chapters 6 and 7



16 October 2017

LETTER OF APPROVAL

Applicant Mr Kevin Campbell-Kam

Project Title: Effect of taping on patellar map-alignment 001

Reference: 5476-A-Oct/2017-8452-2

#### Dear Mr Kevin Campbell-Kam,

The Research Ethics Committee has considered the above amendment application recently submitted by you.

The Chair, acting under delegated authority has agreed that there is no objection on ethical grounds to the proposed study. Approval is given on the understanding that the conditions of approval set out below are followed:

- Please amend "Brunei University" In the revised poster (check all your documents) to "Brunei University London" which has been our legal name since 2014.
- The agreed protocol must be followed. Any changes to the protocol will require prior approval from the Committee by way of an application for an
  amendment.

#### Please note that

- Research Participant Information Sheets and (where relevant) flyers, posters, and consent forms should include a clear statement that research ethics approval has been obtained from the relevant Research Ethics Committee.
- The Research Participant information Sheets should include a clear statement that queries should be directed, in the first instance, to the Supervisor (where relevant), or the researcher. Complaints, on the other hand, should be directed, in the first instance, to the Chair of the relevant Research Ethics Committee.
- Approval to proceed with the study is granted subject to receipt by the Committee of satisfactory responses to any conditions that may appear above, in addition to any subsequent changes to the protocol.
- · The Research Ethics Committee reserves the right to sample and review documentation, including raw data, relevant to the study.
- You may not undertake any research activity if you are not a registered student of Brunel University or if you cease to become registered, including
  abeyance or temporary withdrawai. As a deregistered student you would not be insured to undertake research activity. Research activity includes the
  recruitment of participants, undertaking consent procedures and collection of data. Breach of this requirement constitutes research misconduct and
  is a disciplinary offence.

Kind regards,

Poter OHten

Professor Peter Hobson

Chair, University Research Ethics Committee

Brunel University London

Kingston Lane Uxbridge UBB 3PH United Kingdom

University Research Ethics Committee Brunel University London

www.brunel.ac.uk

Health Research Authority South Central - Berkshire Research Ethics Committee Bristol REC Centre Whitefrans Level 3, Block B Lewins Mead Bristol BS1 2NT

Telephone: 0117 342 1389

<u>Please note</u>: This is an acknowledgement letter from the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

25 August 2016

Mr Kevin Campbell-Karn Senior Lecturer Bucks New University Queen Alexandra Road High Wycombe Bucks HP11 2JZ

Dear Mr Campbell-Karn

Study title:

REC reference: Protocol number: IRAS project ID: Effect of taping on patellar mal-alignment and subjective perception of pain in patients with patellofemoral pain 16/SC/0327 N/A 192566

Thank you for your letter of 25 August 2016. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 04 July 2016

Documents received

The documents received were as follows:

A Research Ethics Committee established by the Health Research Authority

Document	Version	Date
IRAS Checklist XML [Checklist_25082016]		25 August 2016
Participant consent form [Participant Consent form]	2	11 July 2016
Participant Information sheet (PIS)	2	11 July 2016
Research protocol or project proposal	2	18 July 2016

Approved documents

The final list of approved documentation for the study is therefore as follows:

Document	Version	Date
Covering letter on headed paper [Cover letter]	1	25 April 2016
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only)	1	14 March 2016
IRAS Checklist XML [Checklist_25082016]		25 August 2016
Letters of invitation to participant	1	29 March 2016
Other [2nd Supervisor CV]	1	05 February 2016
Other [MRI consent form]	1	05 February 2016
Other [Safety Screening questionnaire for MRI]	1	05 February 2016
Participant consent form [Participant Consent form]	2	11 July 2016
Participant Information sheet (PIS)	2	11 July 2016
REC Application Form [REC_Form_25042016]		25 April 2016
Research protocol or project proposal	2	18 July 2016
Summary CV for Chief Investigator (CI)	1	05 February 2016
Summary CV for supervisor (student research)	1	05 February 2016

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

16/SC/0327

Please quote this number on all correspondence

Yours sincerely

Stephan Ramey REC Assistant

Copy to: Dr Thomas Korff, Brunel University

A Research Ethics Committee established by the Health Research Authority



#### South Central - Berkshire Research Ethics Committee

Bristol REC Centre Whitefriars Level 3, Block B Lewins Mead Bristol BS1 2NT

07 July 2017

Mr Kevin Campbell-Karn Senior Lecturer Bucks New University High Wycombe Campus Queen Alexandra Road High Wycombe, Bucks HP11 2JZ

Dear Mr Campbell-Karn

Study title:

REC reference number:
SSA reference number:
Protocol number:
IRAS project ID:

Effect of taping on patellar mal-alignment and subjective perception of pain in patients with patellofemoral pain 16/SC/0327 16/SC/0580 N/A 192566

The REC gave a favourable ethical opinion to this study on 04 July 2016.

Following site-specific assessment by the Committee, I am pleased to confirm the extension of the favourable opinion to the new site(s) and investigator(s) listed below:

Research site	Principal Investigator / Local Collaborator
London Sports Orthopaedics C/O HCA London Bridge Hospital	Mr Kevin Campbell-Karn

The favourable opinion is subject to management permission or approval being obtained from the host organisation prior to the start of the study at the site concerned.

#### Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

16/SC/0327

Yours sincerely

(baun

Mrs Siobhan Bawn REC Manager

Email: nrescommittee.southcentral-berkshire@nhs.net

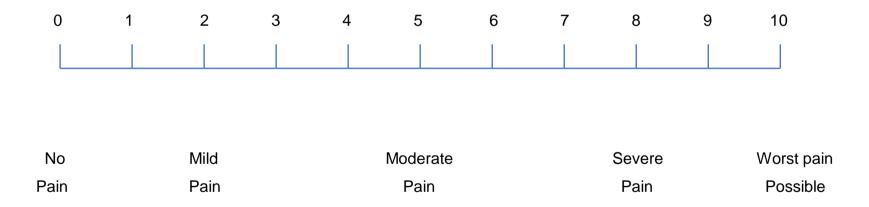
Copy to:

Dr Thomas Korff, Brunel University

## Appendix V

#### Visual analogue scale used during Chapter 7 data collection

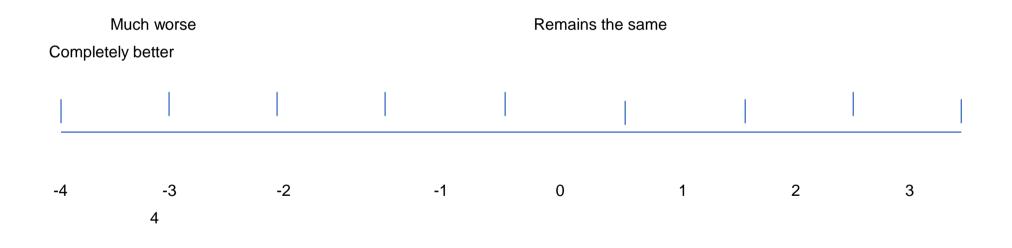
During the exercise/movement you have just performed, how would you rate the pain at the front of your knee?



## Appendix VI

Global rate of change scale used during Chapter 7 data collection

With respect to the pain at the front of your knee, how would you describe it now compared to when we first tested you today?



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## **Appendix VII**

## Participant information and consent forms

Experimental Chapter 4:

Participant Information Sheet

Title of study: Accuracy and reliability testing a transverse plane patellofemoral tracking calliper Name of researcher: **Kevin Campbell** Contact details: <u>k.campbell@londonmet.ac.uk</u> **Tel: 07976 292942** 

You are invited to participate in a study that is investigating a new design of calliper for measuring the movement of the knee cap from side to side in the knee. The new design, which has been named a Patellofemoral tracking calliper, will be assessed and validated against a known gold standard of magnetic resonance imaging (MRI). The aim of the study is to validate the Patellofemoral tracking callipers so that they can be used in clinical and further research settings.

For the study you will be required to have an MRI taken of your knee in a fixed position whilst you are contracting your thigh muscles (quadriceps) followed by a test in the same position with Kevin Campbell using the Patellofemoral tracking callipers. An MRI scanner uses a highly powerful magnet to create an image of your knee and can produce an image of the tissues within the knee. There are no side effects from having an MRI scan and you are not being exposed to radiation. Due to the powerful magnet you will be required to remove any metal, (e.g., jewellery), and you will have to complete a health questionnaire to ensure that you can proceed with the study.

Involvement within the study requires that you contract your thigh at a low level against a known torque/weight so that the thigh muscles are contracting. This is due to these muscles and their control of the knee cap's positioning. Only one appointment is required for the purposes of this study and it is anticipated that you

will be required for an hour. The testing will occur at the Royal Holloway MRI scanner in Egham.

Ethical consideration for this study has been sought and approved via the Brunel University Ethics committee. There is very little risk in any injury occurring from this study as you will be performing a low level muscle contraction for approximately 4 minutes while the scan is taken. There is a small possibility that this may cause a cramp; in which case the test will be stopped (at the participant's choice) and the tester will help to relieve the problem. During the time in the scanner you will have a safety button that you can use at any time to stop the test. In the unlikely event of injury, we will provide you with basic first aid and you would be encouraged to visit your GP.

Your involvement in this study is voluntary and if at any time during the testing procedure you feel you wish to withdraw from the study then you can do by notifying the researcher Kevin Campbell.

Please note that any personal information disclosed during the study will be held in the strictest confidentiality and will only be used with participants' permission. The information provided will not identify any of the participants outside of the study.

If you have any further questions, please feel free to ask or to contact my supervisor Dr Thomas Korff, Brunel University, Uxbridge Middlesex UB8 3PH. <u>thomas.korff@brunel.ac.uk</u>

## Consent:

I understand that in case of injury, if I have questions about my rights as a participant in this research, or if I feel I have been placed at risk, I can contact the Chair of the Human Subjects Research Review Committee.

I have read and understood the information provided. The nature, demands, risks and also the benefits of the study have been fully explained to me. I knowingly assume the risks involved and understand that I have the right to withdraw my



Participant's Name :\_\_\_\_

Central Manchester University Hospitals NHS

consent and discontinue participation from the study at any time without penalty or

loss of benefit. In signing the consent form, I am not waiving any legal claims, rights,

NHS Foundation Trust

Signature:

Date:

I certify that I have explained to the above individual the nature and purpose, potential benefits, and possible risks associated with participation in this study, have answered any questions that have been raised, and have witnessed the above signature.

I have provided the participant a copy of this signed consent form.

or remedies. A copy of this consent form will be given to me.

Investigator's Name	:
Date:	

Signature:

Experimental Chapter 5:

PARTICIPANT INFORMATION SHEET

Study Title: Effects of patellofemoral brace and taping on muscle and knee dynamics. The BRACE-TWO study

Please read carefully and feel free to ask for more information or an explanation of something you do not understand.

Introduction

We are conducting a study into knee bracing and knee-cap taping. Both are inexpensive, simple and risk free ways to ease knee-cap pain caused by arthritis. We are interested to see what effect a knee brace or knee-cap taping has on the

position of the knee cap and the knee. We understand that you have arthritis behind your knee-cap and wore a knee brace as part of our previous study. We would now like to know if the brace or tape change the position of the knee-cap or change the way the calf, thigh and hip muscles work.

#### What do I have to do?

There will be several tests done at Manchester Metropolitan University Institute for Biomedical Research. You will only need to have one visit. The tests will take about 3 and a half hours in total to complete. These tests will be:

**1.** An MRI scan of your knee when you are lying down *and* standing up. You will NOT need an injection. The scanner is smaller than the usual MRI scan you have been in before, and you won't be enclosed or have to lie in a tunnel; it is also less noisy.

2. We would like to look at how you walk up and down stairs. During these tests you will have several sticky markers placed on the skin of your feet, knees, thighs and hips and you will then be asked to walk up and down a short set of stairs several times. The sticky markers will help send out information to computers in the lab that will give us the information we need for the study about how your knee moves. We also would like to see how the muscles contract so we will put some small sticky pads on your calf, thigh and hip muscles which will send information to our computers to tell us which muscles are working, when they are working and by how much. All this information will help us calculate the amount of stress in the knee and behind the knee-cap. Because we are using skin markers, you will need to wear loose fitting shorts. Please bring you own if you like, but we can provide some for you.

We would also like to measure the position of the knee-cap when you are standing and compare it to the position of your knee-cap from the standing MRI scan.
 We will also do an ultrasound scan of your knee to help us calculate the stress in front and behind the knee-cap. This is much simpler and quicker than an MRI and will involve lying down on a couch in a normal room in the lab. Some gel will be applied to your knee to help make the images easier to see on the screen. This will take about 10 minutes.

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**5.** We will ask you to complete two short questionnaires about your knee-cap and hip which are the same ones you completed when we saw you for the previous brace trial. Each will take 5 minutes to complete. We also ask you about your usual level of pain using a simple scale from 0 -10.

6. Finally, we will take about 10 minutes to measure of the position of your knee-cap when standing with a specially made plastic device, which we will compare to your knee-cap position from the MRI scanner. This new device will be positioned over your knee-cap by one of the researchers.

#### Risks and burdens

There are no known risks to having and MRI scan or an ultrasound scan. These procedures are well established and known to be safe. The stair tests will be done using the usual height for domestic stairs and there will be bannisters on both sides. These will be done at your own pace in your usual way and will not be timed to see how fast you do them.

Before having your MRI scan you will be asked if you have any contraindications to entering the scanner. These will include any cochlear implants; any metal objects in the body including joint replacements; cardiac or neural pacemakers; hydrocephalus shunts; intrauterine contraceptive device or coil; any risk of having metal due to working with metal or an accident involving metal.

## The Brace and Tape

The brace is the one with which you are familiar as part of our previous trial. We will supply you with a new one which you can keep. The tape we will use is a single piece of adhesive medical tape commonly used in the treatment of knee-cap pain; this will be simply placed over the knee-cap for the MRI scan and the walking tests. There are no known risks or burdens from using the knee-cap tape, apart from any allergic reaction to the adhesive on the tape. If you think you have an allergy to adhesive tape then please let us know.

The walking tests and MRI scans will be done under 3 different situations for the knee: a) with the brace, b) with the tape and c) with nothing at all. The tape will be placed across the knee-cap with no force or pressure; this is a very common way for

physiotherapists to treat knee-cap pain due to arthritis. The brace will be exactly the same as the one you wore for our previous study; we will be able to give you a new brace if you find that helpful.

The tests will take approximately 3 and a half hours on one visit, but the majority of this time will be spent putting the sticky markers and pads on your skin and will not involve long periods standing in the MRI scanner or walking, or repeated stair ascending or descending.

## Respect of confidentiality

Any information and opinions you give us will be kept confidential. Our records will refer to you as a number rather than your name. Anything you tell us will be treated with the strictest confidence.

## Do I have to take part?

No you do not have to take part. The decision to take part in this study is voluntary and you can change your mind about taking part at any time without giving a reason. This will not affect your standard of care. We are also happy to discuss any queries at any stage of the study.

## Will I get paid for my participation?

Yes. You will receive reimbursement of £30 for your participation. This will be paid into your bank account after your visit to the Institute for Biomedical Research at MMU. It will be divided into £20 for taking part and £10 for travel fees.

## What if there is a problem?

In the event that something goes wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against the University of Manchester or Manchester Metropolitan University but you may have to pay your legal costs. The normal NHS complaints mechanisms will still be available to you if appropriate. If you have a concern about

## Central Manchester University Hospitals

any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. If they are unable to resolve your concern or you wish to make a complaint regarding the study, please contact a University Research Practice and Governance Co-ordinator on 0161 2757583 or 0161 2758093 or by email to research-governance@manchester.ac.uk.

What happens when the research study stops? When you have completed the study, you will still be under the care of the orthopaedic surgeon, physiotherapist, GP or any other clinician looking after you.

Who is organising and funding the research? The research is organised by The University of Manchester

Who has reviewed the study?

The study has been reviewed and approved by the NRES Committee North West Cheshire (No: 11/NW/0851)

## What do I do now?

If you are willing to take part in this study, the research team will contact you to arrange the appointment time for the tests. Then there will be further opportunity to ask questions about the study.

If you need any further information about this study please contact Dr. Michael Callaghan Ph.D. M.Phil. MCSP The Chief Investigator and Post Doctoral Research Physiotherapist Arthritis Research UK University of Manchester Tel: 0161-306-0542

Study Code: \_\_\_\_\_

190

Subject Number: \_\_\_\_\_

INFORMED CONSENT FORM

STUDY TITLE: Effects of patellofemoral brace and taping on muscle and knee dynamics. The BRACE-TWO study

Principal Investigator: Dr. M.J. CALLAGHAN

- I confirm that I have read and understand the information sheet dated\_\_\_\_\_\_ (version\_\_\_\_) for the above study. I have had the opportunity to 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 and without my medical care or legal rights being affected.
- 3. I understand that relevant sections of my medical notes and data collected during this study may be looked at by individuals from the University of Manchester, and Manchester Metropolitan University, from regulatory bodies, or from the NHS trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.
- 4. I will be having an MRI scan of my knee in lying and standing. I confirm that I do not have any contraindications or reasons described in the patient information sheet dated (version) preventing me from undergoing this examination and will complete a separate MR scan patient safety declaration to this effect.

5. I agree to take part in the above study.

6. I agree to my General Practitioner being notified of my participation in this study

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Participant Information Sheet

Lay study title: Effect of taping on kneecap position and experience of pain in patients with knee pain in the front of their knee.

You are being invited to take part in a research study. Before you decide whether to take part or not, 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

and discuss it with others if you wish. Ask me/us if there is anything that is not clear or if you would like more information.

## Study introduction

This study has been designed by Kevin Campbell-Karn (PhD student at Brunel University and Senior Lecturer at Bucks New University), Dr Thomas Korff (Senior Lecturer at Brunel University and lead supervisor) and Mr Ian McDermott (Consultant Orthopaedic Surgeon at London Sports Orthopaedics, Honorary Professor Associate at Brunel University and second supervisor). We are conducting this study into the measurement of the position of the kneecap in people with pain in the front of their knee before and after tape is applied. Taping has been recognised as a method by which some patients can have pain relief, however the means by which this happens is still under debate. If you have had an X-ray completed on your knee in the past, we will also compare this to the MRI scans that we will be conducting in this study. We would therefore like to ask you to take part in our study to see what changes happen when we tape your knee.

## Why have I been chosen?

You have been selected by Mr Ian McDermott as being an appropriate patient with problems in the front of your knee that we are looking to investigate further. It is the problem that you have that is of interest to us in order to have a greater understanding and be able to inform the scientific community about possible methods to better investigate this injury and how to treat it.

## Do I have to take part?

As participation is entirely voluntary, it is up to you to decide whether or not to take part. 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. By choosing not to take part (now or at any time) will not affect your current or future care.

What do I have to do to take part in the study?

We will be testing at the London Sports Orthopaedics practice in the MRI scanner at 31 Old Broad Street where you were first identified as a potential participant for this study by Mr Ian McDermott. This study has been designed as a crossover trial. This means that we expose you to all treatments that we are looking at rather than just one. We do this to reduce the need for lots of participants and also because your knee is unique to you and if we see a change between the different treatments then we can identify which one had the effect. You will only need to make one visit to take part in this study and it is expected that the visit will take up to an hour. During this visit we will test the following:

- 1. Measurement of your knee with a specially designed caliper
- 2. Squatting/stepping exercises performed with you rating your pain during the movement
- 3. MRI scan of your knee in a fixed position
- 4. Tape will then be applied to your knee and the above will all be repeated

5. Another tape is applied to your knee and the previous tests will be repeated There will be no other requirements for attending any further testing. If you have previously had an X-ray of your knee for this condition we would like to compare the X-ray to the MRI images for which we ask your consent to have access to these records so that we can make comparisons using your previous medical scans. Unfortunately we cannot pay your travel costs due to limitations in funding.

#### What are the risks?

The risks for all procedures are minimal. The only risks identified are from nondisclosure of metal objects when entering the MRI scanner. You will be screened for any such objects before entering the scanner which will include any cochlear implants; any metal objects in the body including joint replacements; cardiac or neural pacemakers; hydrocephalus shunts; intrauterine contraceptive device or coil; any risk of having metal due to working with metal or an accident involving metal. Otherwise, there are no known risks to having an MRI scan. The device can leave non-permanent marks on your knee from where it presses against your skin. The tape may also leave marks once it is removed, we will be using a hypoallergenic layer and so you should not experience any reactions from the tape.

#### What are the benefits?

By participating in the study, you will help increase our understanding of the kneecap and its measurement positions before and after taping. This may benefit other patients who may have the same condition. We will also share the information we obtain from the taping with Mr Ian McDermott for helping advise how this may or may not benefit the symptoms you are suffering from.

## What if something goes wrong?

If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for it. For complaints, please contact Professor Peter Hobson <u>peter.hobson@brunel.ac.uk</u>.

## Will my taking part be kept confidential?

All information that is collected about you during the course of the research will be kept strictly confidential. Any information about you that leaves the University/hospital premises will have your name and address removed so that you cannot be identified from it. In order to compare any previous scans on your knee to others we would also like to gain access to these scans that may have already been conducted. You do not have to give consent to the research team to see these previous scans to take part and it will not affect you in any way if you do or do not provide access.

## What will happen to the results of the research study?

The results of this study will aim to be published in scientific peer reviewed journals and be presented at international conferences. At no time during this process will any information that leads back to you or your participation in this study be released.

## Who has reviewed the study?

This study has been granted ethical approval by Berkshire NHS Research Ethics Committee.

## Research integrity

Brunel University is committed to compliance with the Universities UK <u>Research</u> <u>Integrity Concordat</u>. You are entitled to expect the highest level of integrity from our researchers during the course of their research.

#### What do I do now?

If you are willing to take part in this study, the chief investigator will contact you via the details you can provide on the information letter you have been given by Mr Ian McDermott. He will seek to arrange a mutually acceptable appointment date for taking part in the testing and you will be able to ask questions about the study both before and on the day of the testing.

For further information please contact Mr Kevin Campbell-Karn Human Performance, Exercise and Wellbeing Centre Bucks New University Queen Alexandra Road High Wycombe Bucks HP11 2JZ <u>kevin.campbell-karn@bucks.ac.uk</u> 01494 522141 x3265

Dr Thomas Korff Brunel University Kingston Lane Heinz Wolff Building HW200 Uxbridge UB8 3PH thomas.korff@brunel.ac.uk 01895 266477



Informed consent form

Lay study title: Effect of taping on kneecap position and experience of pain in patients with knee pain in the front of their knee.

Chief Investigator: Mr Kevin Campbell-Karn

Please initial each box

- 1. I confirm that I have read and understand the participant information sheet for the above study. I have had the opportunity to ask questions and have these answered satisfactorily.
- I understand that my participation is voluntary and that I am free to withdra any time, without giving any reason and without my medical care or legal ribeing affected.
- 3. I understand that relevant sections of my medical notes, previous scans of my knees and data collected during this study may be viewed by researchers f Bucks New University and Brunel University involved in this study where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.
- 4. I will be having an MRI scan of my knee. I confirm that I do not have any contraindications or reasons preventing me from undergoing this examination as described in the London Bridge Hospital contrast questionnaire sheet.

5. I agree to previous X-ray scans or MRI research team and compared to the MR		
6. I agree to take part in the above study.		
NAME of PARTICIPANT in CAPITALS		-
Signed	Date	_
NAME of PERSON TAKING CONSENT		_
Signed	Date	_